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# COMMENT

## MOBILE METHADONE CLINICS: A NECESSARY STEP IN FIGHTING THE OPIOID EPIDEMIC

*Laurel E. Via* \*

### INTRODUCTION

In the 1990s, healthcare providers began prescribing opioid<sup>1</sup> pain relievers at greater rates in reliance on pharmaceutical companies' claims that the drugs would not cause addiction.<sup>2</sup> However, that turned out not to be the case. Due to the highly addictive nature of opioid pain relievers and the frequency with which they were prescribed, individual addiction rates substantially increased.<sup>3</sup> Since then, opioid addiction has spiraled out of control with prescription and illicit opioid usage continuing to rise.

Prescription drugs are only part of the problem. While prescription opiates caused a wave of deaths starting in the 1990s, there have been two subsequent death waves related to opioid abuse.<sup>4</sup> In 2010, the second wave began with an increase in the number of

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1. The term "opioid" will be used throughout this Article to refer to both opioids and opiates. "In current usage, the term 'opioids' refers to all drugs derived from the opium poppy or emulating the effects of opium-derived drugs. Technically, the term 'opiates' refers to natural compounds found in the opium poppy, and 'opioids' refers to synthetic compounds that emulate the effects of opiates." LISA N. SACCO & ERIN BAGALMAN, CONG. RESEARCH SERV., R44987, *THE OPIOID EPIDEMIC AND FEDERAL EFFORTS TO ADDRESS IT: FREQUENTLY ASKED QUESTIONS 1* (2017).

2. *What Is the U.S. Opioid Epidemic?*, U.S. DEPT HEALTH & HUM. SERVS. (Sept. 4, 2019), <https://www.hhs.gov/opioids/about-the-epidemic/index.html> [<https://perma.cc/4WEN-EG4L>].

3. *Id.*

4. *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 19, 2020), <https://www.cdc.gov/drugoverdose/epidemic/index.html> [<https://perma.cc/V7KP-2KTD>].

heroin overdose-related deaths.<sup>5</sup> The third wave began in 2013 with increases in overdose deaths caused by synthetic opioids, including fentanyl and other illicit drugs laced with fentanyl.<sup>6</sup>

“[N]early 68,000 Americans died from fatal drug overdoses in 2018, with over 47,000 deaths directly attributable to opioid overdose. . . . [M]ore than two million Americans suffer from opioid use disorder, but fewer than one in five get the treatment they need.”<sup>7</sup> These numbers do not, however, account for the individuals who die indirectly from drug use each year.<sup>8</sup> “Additional mortality arises indirectly from drug use, including blood-borne infections, accidents and violence, and chronic underlying pulmonary, hepatic, and/or cardiovascular conditions.”<sup>9</sup> Accordingly, the current estimates are likely to be far lower than the actual number of drug-related deaths.

A number of treatment options have been tried in response to what has now been titled the “Opioid Epidemic.”<sup>10</sup> The most effective treatment for opioid dependence is methadone maintenance, which has been shown to reduce the number of opioid-related deaths and the spread of infectious disease.<sup>11</sup> However, many individuals who would benefit from methadone maintenance treatment are unable to access treatment.<sup>12</sup> This is due to a variety of factors, such as inadequate funding, restrictive zoning regulations, and waitlists at fixed-site clinics.<sup>13</sup> Additionally, methadone can only be dispensed by a federally licensed opioid treatment program

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5. *Id.*

6. *Id.*

7. Letter from Patty Murray, U.S. Sen., Elizabeth Warren, U.S. Sen. & Ann McLane Kuster, Member of Cong. to Uttam Dhillon, Acting Adm’r, U.S. Drug Enf’t Admin. (Jan. 17, 2020) [hereinafter Dhillon Letter], <https://www.help.senate.gov/imo/media/doc/01172020%20DEA%20Letter%20final%20PDF.pdf> [<https://perma.cc/74F4-6M36>].

8. Hannu Alho, Maunce Dematteis, Danilo Lembo, Icro Maremmanni, Carlos Rancero & Lorenzo Somaini, *Opioid Related Deaths in Europe: Strategies for a Comprehensive Approach to Address a Major Public Health Concern*, 76 INT’L J. DRUG POL’Y 1, 2 (2020).

9. *Id.*

10. In 2017, the Department of Health and Human Services (“HHS”) declared a public health emergency to address the national opioid crisis. *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, U.S. DEP’T HEALTH & HUM. SERVS. (Oct. 26, 2017), <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html> [<https://perma.cc/L5DY-L7UJ>].

11. Stacy C. Sigmon, *Access to Treatment for Opioid Dependence in Rural America*, 71 J. AM. MED. ASS’N PSYCHIATRY 359, 359 (2014).

12. *Id.*

13. *Id.*

(“OTP”), also known as a “methadone clinic.”<sup>14</sup> When unable to access treatment, opioid-dependent individuals are “at substantial risk for illicit drug use, criminal activity, infectious disease, overdose, and mortality.”<sup>15</sup> However, when they have access to appropriate treatment, patients begin to recover in all areas of life—housing, health, employment, and education.<sup>16</sup> When this treatment is combined with behavioral treatment, patients experience even better outcomes.<sup>17</sup>

While individuals throughout the country lack access to methadone maintenance treatment, the issue has been extensively studied in rural communities. Individuals living in rural communities, such as southwestern Virginia and West Virginia, have higher instances of opioid addiction but fewer treatment options.<sup>18</sup> Not only are rural areas experiencing a shortage of treatment facilities, but there are additional barriers to treatment in those localities that have at least one facility, such as waitlists, drive times, and transportation costs.<sup>19</sup> Mobile methadone clinics have been proposed by numerous organizations and individuals—ranging from the Substance Abuse and Mental Health Services Administration

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14. Jim Anderson, *How Restrictions on Methadone Can Result in Patient Harm*, CLINICAL ADVISOR (Oct. 11, 2019), <https://www.clinicaladvisor.com/home/the-waiting-room/how-restrictions-on-methadone-can-result-in-patient-harm/> [https://perma.cc/QRG8-6CDB]; JOHNATHAN H. DUFF, CONG. RESEARCH SERV., R45782, LOCATION OF MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION: IN BRIEF 2–3 (2019).

15. Sigmon, *supra* note 11, at 359.

16. Joycelyn Sue Woods & Herman Joseph, *From Narcotic to Normalizer: The Misperception of Methadone Treatment and the Persistence of Prejudice and Bias*, 53 SUBSTANCE USE & MISUSE 323, 323 (2018).

17. *Opioid Addiction*, NAT'L INST. ON DRUG ABUSE (Jan. 2018), <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/pharmacotherapies> [https://perma.cc/BMB4-4VYX].

18. See Sigmon, *supra* note 11, at 359; Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,012 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304) (“As of 2016, over 90% of NTPs were located in urban areas, forcing rural patients to travel great distances to receive their doses of medication.”); *Data Show Southwest Virginia Hard Hit by Opioid Crisis*, VA. HOSP. & HEALTHCARE ASS'N (Jan. 29, 2016), <https://www.vhha.com/research/2016/01/29/data-show-southwest-virginia-hard-hit-by-opioid-crisis/> [https://perma.cc/K3UJ-GXTJ]; *Rural Communities in Crisis*, BLOOMBERG AM. HEALTH INITIATIVE, <https://americanhealth.jhu.edu/RuralOpioidsCount> [https://perma.cc/TL4L-QXK2].

19. Paul J. Joudrey, E. Jennifer Edelman & Emily Wang, *Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 U.S. States*, 322 J. AM. MED. ASS'N 1310, 1310 (2019); Sigmon, *supra* note 11, at 359.

(“SAMHSA”)<sup>20</sup> to United States Senators and Representatives<sup>21</sup> to state and local addiction agencies<sup>22</sup>—as the solution to the problem of access to treatment. The facility shortage could be fixed by simply implementing the mobile clinics. More facilities would in turn reduce the number of individuals on waitlists. Drive times and transportation costs would also be significantly reduced or abolished altogether with the implementation of mobile clinics.

As with fixed-site methadone clinics, mobile methadone clinics must be accredited and certified by SAMHSA and licensed with the Drug Enforcement Agency (“DEA”).<sup>23</sup> However, in 2007, the DEA refused to issue any additional licenses for mobile methadone clinics, fearing the methadone would be diverted, or sold illegally, and believing they were not complying with their own regulations.<sup>24</sup> For years, professionals including SAMHSA, United States Senators and Representatives, and state and local addiction agencies have urged the DEA to lift the moratorium on issuing licenses for mobile methadone clinics. On February 26, 2020, the DEA finally issued a Notice of Proposed Rulemaking (“NPRM”) regarding the registration requirements for narcotic treatment programs (“NTPs”) with mobile components.<sup>25</sup> This would effectively lift the ban on mobile methadone clinics, as existing clinics could add a mobile component and new clinics could come online with a mobile program. In the NPRM, the DEA “proposes to revise the existing regulations for narcotic treatment programs (NTPs) to allow a mobile component associated with the registered program to be considered a coincident activity.”<sup>26</sup> Under the proposed rule, NTPs would not be required to obtain a separate registration for a mobile component.<sup>27</sup>

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

21. Dhillon Letter, *supra* note 7.

22. Vestal, *Federal Ban*, *supra* note 20.

23. JOHNATHAN H. DUFF, CONG. RESEARCH SERV., IF10219, OPIOID TREATMENT PROGRAM AND RELATED FEDERAL REGULATIONS (2019).

24. Vestal, *Federal Ban*, *supra* note 20; *DEA Proposal for Mobile Methadone Finally Released*, ALCOHOLISM & DRUG ABUSE WKLY., Mar. 9, 2020, at 3–4.

25. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

26. *Id.*

27. *Id.*

Part I of this Article will discuss the rise in opioid use disorder, the need for effective treatment, and the utility of methadone maintenance treatment options, as well as the history of the ban on mobile clinics. Part II will discuss the NPRM issued by the DEA on February 26, 2020, and explain the likely impact of the rule. Part III will provide an overview of the NPRM in its current form, explain its likely impact as written and show that mobile clinics are effective treatment options, and then argue that while a great start, the NPRM should be amended to require that mobile clinics offer a behavioral treatment component to maximize the chances of success.

## I. BACKGROUND

### A. *Overview of Opioids and Opioid Use Disorder*

The term “opioid” is defined in the Controlled Substances Act (“CSA”) as “any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.”<sup>28</sup> Opioids “include the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, such as oxycodone . . . , hydrocodone . . . , codeine, morphine, and many others.”<sup>29</sup> These drugs are highly addictive because they activate the “reward centers” of the brain.<sup>30</sup> Specifically, “[o]pioids trigger the release of endorphins, . . . [which] muffle [an individual’s] perception of pain and boost feelings of pleasure, . . . . When an opioid wears off, [the individual] may find [himself] wanting those good feelings back, as soon as possible,”<sup>31</sup> which leads to addiction.<sup>32</sup>

An individual who is addicted to opioids is said to suffer from Opioid Use Disorder (“OUD”). OUD is defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (“DSM-5”) as “a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two out

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28. 21 U.S.C. § 802(18).

29. *What Are Opioids?*, U.S. DEP’T HEALTH & HUM. SERVS. (May 15, 2018), <https://www.hhs.gov/opioids/prevention/index.html> [<https://perma.cc/MNX6-JXLV>].

30. *How Opioid Addiction Occurs*, MAYO CLINIC (Feb. 16, 2018), <https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-opioid-addiction-occurs/art-20360372> [<https://perma.cc/E8AC-KD9H>].

31. *Id.*

32. *Id.*

of 11 specific DSM-5 criteria within a 12-month period.”<sup>33</sup> OUD is classified as a chronic disease.<sup>34</sup> Consequently, individuals who suffer from OUD often experience episodes of relapse and remission and “may require long-term or even life-long treatment.”<sup>35</sup>

In 2017, the Department of Health and Human Services (“HHS”) declared a public health emergency to address the national opioid crisis.<sup>36</sup> “Opioids are the main cause of drug overdose deaths.”<sup>37</sup> In 2015, the Centers for Disease Control and Prevention (“CDC”) estimated that approximately 140 Americans died each day from drug overdoses.<sup>38</sup> Of those 140 deaths, around 90 were due to opioids.<sup>39</sup> By 2018, only three years later, 192 individuals per day died as a result of drug overdoses.<sup>40</sup> Of those deaths, an average of 128 were related to opioids.<sup>41</sup> However, these statistics only capture deaths and fail to account for the millions of Americans who suffer non-fatally from OUD. The CDC estimates 1.7 million Americans suffer from OUD related to prescription opioids and another 652,000 from OUD related to heroin use.<sup>42</sup> Of those nearly two million Americans suffering from OUD, only one in five receives treatment.<sup>43</sup> Those suffering from OUD experience a myriad of other problems. Non-fatal OUD has been associated with criminal activity, unemployment, and intravenous diseases.<sup>44</sup>

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33. Alho et al., *supra* note 8, at 2.

34. *Id.*

35. *Id.*

36. *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, *supra* note 10.

37. SACCO & BAGALMAN, *supra* note 1, at 8.

38. *See id.* at 2.

39. *Id.*

40. *See Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 19, 2020), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> [<https://perma.cc/S8MA-ZK2Q>].

41. *Understanding the Epidemic*, *supra* note 4. These numbers do not include those individuals who die indirectly from their drug use. Alho et al., *supra* note 8, at 2.

42. *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (May 27, 2020), <https://www.drugabuse.gov/drug-topics/opioid-overdose-crisis> [<https://perma.cc/QKK3-GA4T>].

43. JONAKI BOSE, SARRA L. HEDDEN, RACHEL N. LIPARI & EUNICE PARK-LEE, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2017 NATIONAL SURVEY ON DRUG USE AND HEALTH 48 (2018), <https://samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHFFR2017/NSDUHFFR2017.pdf> [<https://perma.cc/5XWK-RTH8>].

44. Sigmon, *supra* note 11, at 359.

## B. *Treatment of Opioid Use Disorder*

Starting in the late 1990s, government agencies attempted to reduce opioid use by cracking down on legal prescribing behaviors. The DEA, for example, “pushed for surveillance of prescription records and electronic communication, doubled down on prosecuting prescribers and helped to tighten the screws on patients seeking pain relief.”<sup>45</sup> While this attempt to curb the use of opioids by limiting prescription refills and issuance of prescriptions reduced the number of opioid prescriptions in the United States, it was ultimately unsuccessful due to the creation of synthetic opioids and the availability of opioids on the black market, which in turn led to two subsequent waves of opioid addiction.<sup>46</sup> As the rate of addiction continued to increase, experts realized limiting access to legal prescriptions would not be enough to address the growing epidemic. Instead, they needed to replace the synthetic and non-prescription opioids with accessible legal treatment options.

### 1. Treatment Options for OUD<sup>47</sup>

There are three types of treatments available for OUD—abstinence-based treatments, maintenance treatment programs, and medication-assisted treatment programs. All three types use medication to some extent but vary in the way they employ the medications. The medications approved by the Food and Drug Administration (“FDA”) for treatment of OUD include methadone, buprenorphine, and naltrexone.<sup>48</sup> These medications vary in the impact they have on the brain and will be discussed in greater detail below.

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45. Leo Beletsky & Jeremiah Goulka, *The Federal Agency That Fuels the Opioid Crisis*, N.Y. TIMES (Sept. 17, 2018), <https://www.nytimes.com/2018/09/17/opinion/drugs-dea-defund-heroin.html> [<https://perma.cc/HQJ3-4CVL>]. During this time, individuals were obtaining prescription drugs through “doctor shopping,” bad-acting physicians, pill mills, the Internet, pharmaceutical theft, prescription fraud, and family and friends.” SACCO & BAGALMAN, *supra* note 1, at 5–6.

46. See MAYO CLINIC, *supra* note 30; see also Mark R. Jones, Omar Viswanath, Jacquelin Peck, Alan D. Kaye, Jatinder S. Gill & Thomas T. Simopoulos, *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN & THERAPY 13, 14 (2018).

47. While there are several types of medications used to treat OUD, this Article will focus on methadone. This section will provide a brief overview of the other treatment options.

48. CATHIE E. ALDERKS, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE CBHSQ REPORT: TRENDS IN THE USE OF METHADONE, BUPRENORPHINE, AND EXTENDED-RELEASE NALTREXONE AT SUBSTANCE ABUSE TREATMENT FACILITIES: 2003–2015 (UPDATE) (2017), [https://www.samhsa.gov/data/sites/default/files/report\\_3192/ShortReport-3192.pdf](https://www.samhsa.gov/data/sites/default/files/report_3192/ShortReport-3192.pdf)

As the name suggests, the goal of abstinence-based treatments is long-term abstinence from all opioids.<sup>49</sup> Abstinence-based treatments have two phases: detoxification and relapse prevention.<sup>50</sup> Detoxification refers to the process of “dispensing an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state.”<sup>51</sup> Under this treatment plan, opioid use is reduced and then discontinued entirely.<sup>52</sup> During the detoxification phase, opioid agonists,<sup>53</sup> partial opioid agonists,<sup>54</sup> opioid antagonists,<sup>55</sup> and alpha-2 adrenergic agonists<sup>56</sup> can be used to manage withdrawal symptoms, avoid unnecessary suffering, and help prevent any medical complications.<sup>57</sup> Methadone, the most common opioid agonist, can be one of the substances used during the detoxification phase, but unlike with traditional methadone-based treatment, the methadone is tapered and ultimately discontinued.<sup>58</sup> The second phase, relapse prevention, is done at a long-term or short-term inpatient treatment facility.<sup>59</sup> Outcomes in abstinence-based programs are poor,

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[<https://perma.cc/3YJB-5T6E>].

49. Wim van den Brink & Christian Haasen, *Evidence-Based Treatment of Opioid-Dependent Patients*, 51 CAN. J. PSYCHIATRY 635, 637 (2006).

50. *Id.*

51. 42 C.F.R. § 8.2 (2007).

52. Van den Brink & Haasen, *supra* note 49, at 637.

53. An opioid agonist is a substance that “eliminates withdrawal symptoms and relieves drug cravings by acting on opioid receptors in the brain—the same receptors that other opioids . . . activate.” *Medications to Treat Opioid Use Disorder: How Do Medications to Treat Opioid Use Disorder Work?*, NAT’L INST. ON DRUG ABUSE (June 2018) [hereinafter *How Medications to Treat OUD Work*], <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work> [<https://perma.cc/F4Y3-4UTM>].

54. A partial opioid agonist, such as buprenorphine, binds to the same opioid receptors that a full opioid agonist does “but activates them less strongly than full agonists do.” *Id.*

55. Opioid antagonists “work[] by blocking the activation of opioid receptors. Instead of controlling withdrawal and cravings, [they] treat[] opioid use disorder by preventing any opioid drug from producing rewarding effects such as euphoria.” *Id.* Naltrexone is an opioid antagonist. *Id.*

56. Alpha-2 adrenergic agonists, such as clonidine or lofexidine, are used to manage opioid withdrawal symptoms. Linda R. Gowing, Michael Farrell, Robert L. Ali & Jason M. White, *Alpha-2 Adrenergic Agonists in Opioid Withdrawal*, 97 ADDICTION 49, 49 (2002).

57. Van den Brink & Haasen, *supra* note 49, at 637.

58. *Id.* Buprenorphine can also be used to treat the symptoms of opioid withdrawal under an abstinence-based treatment. As with methadone, buprenorphine will also be tapered and ultimately discontinued. *Id.*

59. *Id.* at 639.

as participants in long-term and short-term programs are quick to return to old habits upon release.<sup>60</sup>

Given the high rate of relapse associated with abstinence-based programs, maintenance treatment programs are used at a higher frequency than abstinence-based ones and, when properly implemented, have better results.<sup>61</sup> Maintenance treatment programs aim to reduce cravings, minimize withdrawal symptoms, and block the euphoric effects of future opioid use by providing patients with a controlled dose of an FDA-approved opioid.<sup>62</sup> “At the doses prescribed, and as a result of their *pharmacodynamic* and *pharmacokinetic* properties (the way they act at opioid receptor sites and their slower metabolism in the body), these medications do not produce a euphoric high [in individuals addicted to opioids] but instead minimize withdrawal symptoms and cravings.”<sup>63</sup> The aim is to wean the opioid-dependent person off of the medication; however, that is not always possible and some may need to take the medication indefinitely.<sup>64</sup>

Medication-assisted treatment (“MAT”) programs, the third treatment option, focus on total recovery.<sup>65</sup> MAT programs provide an opioid-dependent individual with a “comprehensive, individually tailored program of medication and behavioral therapy.”<sup>66</sup> Individuals enrolled in MAT programs receive the same medication and dosage as those enrolled in maintenance treatment programs.<sup>67</sup> Unlike patients enrolled in traditional maintenance treat-

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60. *Id.* at 637, 639. A study that looked at the rate of relapse over a 3-month follow-up period found that of 242 opioid-dependent patients in residential treatment, “34% of the patients relapsed to heroin use within 3 days, 45% within 7 days, 50% within 14 days, and 60% within 90 days.” *Id.* at 639.

61. *Id.* at 640.

62. Jennifer C. Veilleux, Peter J. Colvin, Jennifer Anderson, Catherine York & Adrienne J. Heinz, *A Review of Opioid Dependence Treatment: Pharmacological and Psychosocial Interventions to Treat Opioid Addiction*, 30 CLINICAL PSYCHOL. REV. 155, 160 (2010); *Medications to Treat Opioid Use Disorder: What Are Misconceptions About Maintenance Treatment?*, NAT’L INST. ON DRUG ABUSE (June 2018) [hereinafter *Maintenance Treatment Misconceptions*], <https://www.drugabuse.gov/publications/medications-to-treat-opioid-addiction/what-are-misconceptions-about-maintenance-treatment> [https://perma.cc/ES6V-TBYZ]. The FDA-approved opioids prescribed in maintenance treatment programs do cause euphoria, but only in people who have not built up a tolerance for opioids. *Id.*

63. *Id.*

64. *Id.*

65. *Medication-Assisted Treatment (MAT)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Sept. 1, 2020), <https://www.samhsa.gov/medication-assisted-treatment/> [https://perma.cc/SWY8-G7TL].

66. *Id.*

67. *See id.*

ment programs, MAT patients also receive medical, counseling, vocational, education, and other assessment and treatment services.<sup>68</sup> MAT programs have a high rate of success.<sup>69</sup> “Such a treatment approach has been shown to lead to positive clinical and social outcomes, including improved treatment retention and quality of life, and reductions in opioid misuse, criminality, drug-related harms including infections and infectious disease, and mortality.”<sup>70</sup> MAT is also associated with a patient’s ability to gain and maintain employment.<sup>71</sup>

The comprehensive care model found in MAT programs focuses on a “three-pronged effort to rehabilitate clients: (a) methadone to reduce the side effects of withdrawal and to stabilize the client, (b) counseling to address the underlying psychosocial problem(s) of addiction, and (c) supportive services to address logistical problems, such as employment, transportation, childcare, and medical care.”<sup>72</sup> The Federal Opioid Treatment Standards only require that OTPs provide comprehensive care at the primary facility or refer clients to other providers to meet their comprehensive needs.<sup>73</sup> Referring a client to these services suffices to meet the OTPs’ duty to comply with the federal standards, even if the client never actually receives those services.<sup>74</sup> What is even more troublesome is that many programs fail to keep records of referrals or to follow up with service providers.<sup>75</sup> To meet the requirement, OTPs simply must provide “adequate and reasonably accessible community resources.”<sup>76</sup> The benefits of comprehensive care are not achieved by

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68. *MAT Medications, Counseling, and Related Conditions*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions> [<https://perma.cc/ZY7P-7H6Q>].

69. *Medication-Assisted Treatment (MAT)*, *supra* note 65.

70. Alho et al., *supra* note 8, at 2; *see also* Catherine Anne Fullerton, Richard H. Dougherty, Meelee Kim, Allen S. Daniels, Cindy Parks Thomas, Sushmita Shoma Ghose, D. Russell Lyman, Miriam E. Delphin-Rittmon & Leslie B. Montejano, *Medication-Assisted Treatment with Methadone: Assessing the Evidence*, 65 PSYCHIATRIC SERVS. 146, 147 (2014).

71. *Medication-Assisted Treatment (MAT)*, *supra* note 65.

72. Michael L. Dennis, Georgia T. Karuntzos, Gail L. McDougal, Michael T. French & Robert L. Hubbard, *Developing Training and Employment Programs to Meet the Needs of Methadone Treatment Clients*, 16 EVALUATION & PROGRAM PLAN. 73, 74 (1993).

73. 42 C.F.R. § 8.12(f)(1) (2019); SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS 28 (2015) (“Any assessments or treatments not directly provided at the facility must be assured via a formal documented agreement with the appropriate community providers.”).

74. Dennis et al., *supra* note 72, at 74.

75. *Id.*

76. 42 C.F.R. § 8.12(f)(5)(iii) (2019).

simply referring an opioid-dependent individual to such a program—the opioid-dependent individual must actually receive those services to benefit.

Comprehensive care programs have been shown to result in the best treatment outcomes.<sup>77</sup> The types of programs comprehensive care offers vary, but they typically focus on counseling and mental health services, employment services, medical services, and other general services the client may need.<sup>78</sup> “The nature of the services provided is determined by the person’s current status or needs.”<sup>79</sup>

One study that examined twenty-one methadone programs found that comprehensive programs, including mental health, employment, and general services, were correlated with lower relapse rates among clients.<sup>80</sup> Another compared outcomes from three different treatment programs in terms of illegal drug use, alcohol use, legal issues, family, employment, and psychiatric problems.<sup>81</sup> The “Minimum Methadone Services” (“MMS”) group received the “lowest level of supervised care possible under current [FDA] standards. Methadone . . . was the only therapeutic component provided on a regular basis.”<sup>82</sup> Counseling, additional medications, or any other necessary services were provided only in the case of emergencies.<sup>83</sup> Individuals in the MMS group could be “protectively” transferred to another group.<sup>84</sup> There were two situations deemed serious enough to warrant a transfer: “(1) unremitting drug use as defined by eight consecutive opioid- or cocaine-positive urine samples during the course of the 24-week intervention, or (2) three

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77. Nat Wright, Oscar D’Agnone, Peter Krajci, Richard Littlewood, Hannu Alho, Jens Reimer, Carlos Roncero, Lorenzo Somaini & Icro Maremmani, *Addressing Misuse and Diversion of Opioid Substitution Medication: Guidance Based on Systematic Evidence Review and Real-World Experience*, 38 J. PUB. HEALTH e368, e368–69 (2015); Fullerton et al., *supra* note 70, at 146, 156; Michael Gossop, Duncan Stewart & John Marsden, *Treatment Process Components and Heroin Use Outcome Among Methadone Patients*, 71 DRUG & ALCOHOL DEPENDENCE 93, 97 (2003).

78. *Medication-Assisted Treatment (MAT)*, *supra* note 65.

79. Fullerton et al., *supra* note 70, at 147.

80. Rose M. Etheridge, S. Gail Craddock, George H. Dunteman & Robert L. Hubbard, *Treatment Services in Two National Studies of Community-Based Drug Abuse Treatment Programs*, 7 J. SUBSTANCE ABUSE 9, 10 (1995).

81. A. Thomas McLellan, Isabelle O. Amat, David S. Metzger, George E. Woody & Charles P. O’Brien, *The Effects of Psychosocial Services in Substance Abuse Treatment*, 5 ADDICTIONS NURSING NETWORK 38, 38 (1993).

82. *Id.* at 40.

83. *Id.*

84. *Id.*

emergency situations requiring immediate health care.”<sup>85</sup> Individuals in the “Standard Methadone Services” (“SMS”) group received regular counseling sessions in addition to methadone treatment.<sup>86</sup> Finally, individuals in the “Enhanced Methadone Services” (“EMS”) group received methadone, counseling, on-site employment and family services.<sup>87</sup> Patients who received SMS services “showed more, faster, and greater improvements than did the MMS patients.”<sup>88</sup> EMS patients showed even more improvements than SMS patients in terms of employment, alcohol use, criminal activity, and psychological well-being.<sup>89</sup>

“An interesting additional finding was that those MMS patients who were protectively transferred to [the SMS group] showed significant reductions in opiate and cocaine use within 4 weeks after the transfer, and at approximately the same dose of methadone.”<sup>90</sup> The researchers concluded this evidence, along with other studies they looked at, indicate that the psychosocial services offered by methadone clinics should be enhanced to improve the outcomes of methadone treatment.<sup>91</sup> Despite the requirement that OTPs offer this service and the obvious benefits from implementing such programs, the number of OTPs that actually offer these services has declined.<sup>92</sup>

Research shows that regular and frequent counseling is associated with higher rates of treatment success.<sup>93</sup> Frequency of counseling is associated with higher levels of treatment effectiveness, which in turn is associated with client retention.<sup>94</sup> Treatment programs that retain clients for longer periods produce better treatment outcomes overall.<sup>95</sup> Counseling frequency is not “an artifact of retention in the program, and it is [not] program retention ra-

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85. *Id.*

86. *Id.*

87. *Id.* at 41.

88. *Id.* at 46.

89. *Id.*

90. *Id.*

91. *Id.*

92. Peter D. Friedmann, Stephanie C. Lemon, Elizabeth M. Durkin & Thomas A. D'Aunno, *Trends in Comprehensive Service Availability in Outpatient Drug Abuse Treatment*, 24 J. SUBSTANCE ABUSE TREATMENT 81, 85 (2003); Dennis et al., *supra* note 72, at 74.

93. Robert Fiorentine & M. Douglas Anglin, *More Is Better: Counseling Participation and the Effectiveness of Outpatient Drug Treatment*, 13 J. SUBSTANCE ABUSE TREATMENT 341, 346 (1996).

94. *Id.* at 344.

95. *Id.* at 342.

ther than counseling frequency that predominately explains treatment effectiveness. . . . Rather, counseling frequency improves the prediction of relapse above that which is predicted by treatment retention.”<sup>96</sup> In fact, one study found that “counseling frequency significantly predicts a lower probability of relapse in the 6 months . . . and 30 days . . . prior to the [study’s] follow-up interview.”<sup>97</sup> The association between frequency of counseling and treatment effectiveness holds even for those who complete the treatment program.<sup>98</sup> Accordingly, researchers have reached the conclusion that frequency of counseling and treatment effectiveness have a causal relationship rather than a merely correlated one.<sup>99</sup> Research has also shown that individual and group counseling sessions are more effective treatment options than family counseling or participation in a twelve-step program.<sup>100</sup>

Employment services are another important component of the comprehensive care approach.<sup>101</sup> “[E]mployment rates of the population with substance abuse problems before admission or at admission to treatment have remained at relatively stable, low levels since 1970, ranging from 15 to 30 percent.”<sup>102</sup> However, these resources have been significantly underutilized.<sup>103</sup>

In 1989, the National Institute on Drug Abuse (“NIDA”) provided a research program with a grant to “develop and evaluate a training, public service, and/or employment program for methadone treatment clients.”<sup>104</sup> What was termed the Training and Employment Program (“TEP”) Study examined the effectiveness of employment services when offered to 249 clients from three methadone programs.<sup>105</sup> At each methadone program, the researchers

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96. *Id.* at 344.

97. *Id.* Another study also found a “direct inverse relationship . . . between treatment services and heroin use outcome at 6 months follow-up.” Gossop et al., *supra* note 77, at 97.

98. Fiorentine & Anglin, *supra* note 93, at 346.

99. *Id.* at 344.

100. *Id.* at 345.

101. Richard S. Schottenfeld, Richard Pascale & Sharon Sokolowski, *Matching Services to Needs: Vocational Services for Substance Abusers*, 9 J. SUBSTANCE ABUSE TREATMENT 3, 3 (1992).

102. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., INTEGRATING SUBSTANCE ABUSE TREATMENT AND VOCATIONAL SERVICES, at xv (2000), <https://store.samhsa.gov/sites/default/files/d7/priv/sma12-4216.pdf> [<https://perma.cc/MU5Z-3T3R>].

103. Schottenfeld et al., *supra* note 101, at 3. “Fewer than one in five programs could identify a vocational rehabilitation specialist, job counselor, or job developer on staff, yet programs rarely referred patients to vocational services.” *Id.*

104. Dennis et al., *supra* note 72, at 74.

105. *Id.*

implemented the following components: (1) a vocational needs assessment, (2) a vocational treatment plan, (3) development of a resource document of existing programs that could be utilized by methadone clients, (4) employment of an on-site vocational specialist, (5) job readiness and motivation workshops, and (6) budgeting for the program.<sup>106</sup> Across all three programs, a variety of employment services were offered to the clients: referrals to educational programs or job training centers, job skill services, assistance looking for a job, and job support services.<sup>107</sup> The study found that clients who received employment services showed reduced rates of unemployment.<sup>108</sup> After six to twelve months, “the TEP protocol significantly reduced unemployment in Pittsburgh (69.4% vs. 36.1%) and had a positive trend across sites.”<sup>109</sup> The percentage of TEP clients employed increased by over twenty percent.<sup>110</sup> Clients who receive employment services are more likely to obtain employment than clients who do not receive such services.<sup>111</sup>

In another study, 223 clients received vocational services.<sup>112</sup> All 223 clients received vocational assessments<sup>113</sup> and job counseling. Vocational assessments are important to match the clients with appropriate services.<sup>114</sup> The success of the services depends on matching the clients with the appropriate services.<sup>115</sup>

132 clients were referred for education or skills training. 139 clients received job-seeking skill training<sup>116</sup> and job development<sup>117</sup> services;

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106. *Id.* at 78–79.

107. *Id.* at 79, 81.

108. *Id.* at 82. Reduced unemployment was found across all three methadone programs. *Id.*

109. *Id.*

110. *Id.*

111. Sharon Reif, Constance M. Horgan, Grant A. Ritter & Christopher P. Tompkins, *The Impact of Employment Counseling on Substance User Treatment Participation and Outcomes*, 39 J. SUBSTANCE USE & MISUSE 2391, 2406–07 (2004).

112. Schottenfeld et al., *supra* note 101, at 6. One hundred eleven of the 223 clients were enrolled in methadone maintenance programs. *Id.*

113. *Id.* A vocational assessment involves evaluating

(a) the client’s abilities, skills, and successes in school, training, or work, (b) the client’s interests and vocational goals, (c) the client’s prior vocational and educational difficulties and failures, (d) the client’s current motivation and interest in finding employment, and (e) the client’s current problems gaining or maintaining employment or any barriers to employment.

*Id.* at 5.

114. *Id.* at 7.

115. *Id.*

116. “Job-seeking skills is a cognitive and behaviorally based intervention designed to enhance interview and job-seeking skills.” *Id.* at 5.

117. “Job development activities include developing a ‘job bank’ or general listing of jobs

120 of the 172 initially unemployed clients were successfully placed in either full-time or part-time employment; 38 clients left the program without gaining employment, and 106 of the 223 clients continued to be active in the vocational program.<sup>118</sup>

It is also important that there is close coordination between the vocational and the substance abuse services.<sup>119</sup> Finally, another study looked at the effects of methadone clinics hiring a full-time vocational counselor for placement in training and employment.<sup>120</sup> Thirty percent of the clients who were previously “not vocationally involved” were employed or enrolled in an educational or training program at the end of the 16-month program.<sup>121</sup>

## 2. The Role of Methadone in Opioid Treatment

Methadone is an opioid agonist, which means it binds to opioid receptors and produces similar effects as endorphins.<sup>122</sup> By binding to the opioid receptors and blocking them, methadone will decrease the effect of any subsequent opioid use.<sup>123</sup> Methadone also prevents the opioid-dependent individual from experiencing symptoms associated with withdrawal from opioids.<sup>124</sup> Methadone is a long-acting opioid and is used to replace shorter-acting opioids to which opioid-dependent individuals are addicted.<sup>125</sup> “Long-acting means that the drug acts more slowly in the body, for a longer period of time. By acting slowly, it prevents withdrawal for 24 to 36 hours without causing a person to get high.”<sup>126</sup> Preventing withdrawal symptoms is an important part of the treatment plan because the withdrawal symptoms are generally so intense that the opioid-dependent individual will continue to use opioids in increasing doses to avoid the withdrawal symptoms.<sup>127</sup> “Withdrawal symptoms may begin within 4 to 6 hours of the last [opioid] usage and may last for

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suitable for clients, locating specific employment opportunities for clients, and encouraging community employers to hire substance abusers referred from the program.” *Id.*

118. *Id.* at 6.

119. *Id.*

120. P.W. Appel, R. Smith, J.B. Schmeidler & J. Randell, *Impact of Vocational Counselor on Employment-Related Outcomes Among Methadone Patients*, 23 EVALUATION & PROGRAM PLAN. 437, 437–38 (2000).

121. *Id.* at 442.

122. Veilleux et al., *supra* note 62, at 157.

123. *Id.*

124. *Id.* at 159.

125. CTR. FOR ADDICTION & MENTAL HEALTH, OPIOID AGONIST THERAPY 1 (2016), <https://www.camh.ca/-/media/files/oat-info-for-clients.pdf> [<https://perma.cc/WLC3-9TUN>].

126. *Id.*

127. ALDERKS, *supra* note 48, at 1.

up to several months.”<sup>128</sup> Once the individual begins to receive an adequate dose of methadone, they no longer experience the highs and lows of the shorter-acting opioids.<sup>129</sup> Methadone “also helps to reduce or eliminate cravings for [illegal] opioids.”<sup>130</sup> For many opioid-dependent individuals, methadone is the only medication that will curb drug cravings.<sup>131</sup> This is especially true for individuals who have been abusing high doses of heroin or synthetic opioids, like fentanyl, over a prolonged period of time.<sup>132</sup>

Methadone is the best studied and most effective option for achieving the goals of maintenance treatment programs.<sup>133</sup> Methadone can be used in abstinence-based treatment, maintenance treatment programs, and medication-assisted treatment programs.<sup>134</sup> Unlike the methadone prescribed in abstinence-based treatment, methadone prescribed in maintenance treatment or medication-assisted treatment programs can be used indefinitely.<sup>135</sup> The individual will likely remain dependent on methadone to prevent him from using illegal opioids or misusing prescription opiates.<sup>136</sup> The majority of opioid-dependent individuals remain in methadone maintenance treatment for at least one year and show a decline in not only opioid use but also the use of other drugs, such as cocaine and alcohol.<sup>137</sup>

### 3. Other Medications Used in OUD Treatment Programs

In addition to methadone, the two medications prescribed in maintenance treatment programs are buprenorphine and naltrexone. Approved by the FDA since 2002, buprenorphine is a partial opioid agonist that can be prescribed by medical providers and

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128. *Id.*

129. Woods & Joseph, *supra* note 16, at 323; CTR. FOR ADDICTION & MENTAL HEALTH, *supra* note 125, at 1.

130. Woods & Joseph, *supra* note 16, at 323; CTR. FOR ADDICTION & MENTAL HEALTH, *supra* note 125, at 1.

131. Christine Vestal, *Some States Add More Methadone Clinics to Fight Opioid Epidemic*, WASH. POST (Nov. 12, 2018, 8:00 AM) [hereinafter Vestal, *More Methadone Clinics*], [https://www.washingtonpost.com/national/health-science/some-states-add-more-methadone-clinics-to-fight-opioid-epidemic/2018/11/09/8cace992-e133-11e8-b759-3d88a5ce9e19\\_story.html](https://www.washingtonpost.com/national/health-science/some-states-add-more-methadone-clinics-to-fight-opioid-epidemic/2018/11/09/8cace992-e133-11e8-b759-3d88a5ce9e19_story.html) [https://perma.cc/8W3X-HYMC].

132. *Id.*

133. Van den Brink & Haasen, *supra* note 49, at 640; *see also* Fullerton et al., *supra* note 70, at 156.

134. DUFF, *supra* note 14, at 1.

135. Fullerton et al., *supra* note 70, at 147.

136. *Id.*

137. McLellan et al., *supra* note 81, at 38.

taken at home.<sup>138</sup> While this approach eliminates the need to visit specialized treatment clinics, there are restrictions on the number of patients medical providers can treat.<sup>139</sup> After taking an eight-hour training course, physicians can apply for a waiver which enables them to treat 30 patients per year and, after one year, apply to treat up to 100 patients.<sup>140</sup> Physicians who hold certain board certifications can begin by treating up to 100 patients per year and, after one year, can apply to treat 275 patients.<sup>141</sup> The qualifications are stricter for nurse practitioners, physician assistants, certified nurse specialists (“CNSs”), certified registered nurse anesthetists (“CRNAs”), and certified nurse midwives (“CNMs”), who must complete 24 hours of training and comply with a number of other requirements.<sup>142</sup> They may apply for a waiver to treat 30 patients and some may meet the requirements to begin treating 100 patients.<sup>143</sup> Studies have shown that individuals who take buprenorphine show rates of retention between 70 percent and 80 percent and have opiate-free urine screens 43 percent to 64 percent of the time.<sup>144</sup>

One of the main problems with buprenorphine is that it comes in an sublingual<sup>145</sup> (“SL”) tablet.<sup>146</sup> The water-soluble nature of the SL tablet allows it to be dissolved and then injected.<sup>147</sup> Since it has the potential for abuse, buprenorphine is often diverted and sold on the black market.<sup>148</sup> Additional barriers to treatment with buprenorphine exist, including provider availability, limited insurance coverage, and cost.<sup>149</sup>

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138. *How Medications to Treat OUD Work*, *supra* note 53.

139. Anderson, *supra* note 14.

140. *Buprenorphine Waiver Management*, AM. SOC’Y ADDICTION MED., <https://www.asam.org/advocacy/practice-resources/buprenorphine-waiver-management> [<https://perma.cc/YL55-AY4Q>].

141. *Id.*

142. *Id.*

143. *Id.*

144. Van den Brink & Haasen, *supra* note 49, at 641.

145. “Sublingual” refers to a form of medication that is placed under the patient’s tongue. *Buprenorphine Hcl Tablet, Sublingual*, WEBMD, <https://www.webmd.com/drugs/2/drug-64748/buprenorphine-hcl-sublingual/details> [<https://perma.cc/L7KT-2LRP>].

146. Van den Brink & Haasen, *supra* note 49, at 641.

147. *Id.*

148. Christine Vestal, *Long Stigmatized, Methadone Clinics Multiply in Some States*, PEW (Oct. 31, 2018) [hereinafter Vestal, *Long Stigmatized*], <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/10/31/long-stigmatized-methadone-clinics-multiply-in-some-states> [<https://perma.cc/99KY-CJE6>].

149. Christopher M. Jones, Melinda Campopiano, Grant Baldwin & Elinore McCance-

Naltrexone, an third opioid agonist, “works by blocking the activation of opioid receptors.”<sup>150</sup> Naltrexone does not control withdrawal and cravings; rather, by blocking the activation of opioid receptors, the medication prevents any subsequent opioid use from producing any euphoric feelings.<sup>151</sup> Because it prevents the user from experiencing any feelings of euphoria, it has no abuse or diversion potential.<sup>152</sup> Vivitrol, a long-acting injectable form of Naltrexone, is not a narcotic and was approved by the FDA in 2010.<sup>153</sup> Vivitrol helps opioid-dependent individuals adhere to their treatment program.<sup>154</sup> It can be prescribed and administered by physicians without a special license.<sup>155</sup> However, naltrexone is only effective for certain people.<sup>156</sup> The use of naltrexone “for ongoing opioid use disorder treatment has been somewhat limited because of poor adherence and tolerability by patients.”<sup>157</sup> Another issue with naltrexone is that it is associated with a high risk of mortality.<sup>158</sup> If an individual relapses and stops taking naltrexone, he may have a reduced tolerance to opioids.<sup>159</sup> Accordingly, that individual may overdose on an opioid dosage that would have previously not caused him to overdose.<sup>160</sup>

The type of medication used in the treatment program dictates where it can be offered. “[S]ubstances are placed into one of five schedules based on their medical use, potential for abuse, and safety or dependence liability.”<sup>161</sup> While schedule I substances have no accepted medical use, schedule II–V substances do.<sup>162</sup> All providers distributing controlled substances must register with the

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Katz, *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, 105 AM. J. PUB. HEALTH e55, e55 (2015).

150. *How Medications to Treat OUD Work*, *supra* note 53.

151. *Id.*

152. *Naltrexone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone> [https://perma.cc/VYQ9-QH ZJ].

153. *How Medications to Treat OUD Work*, *supra* note 53.

154. *Id.*

155. *Id.*; *Naltrexone*, *supra* note 152.

156. Vestal, *More Methadone Clinics*, *supra* note 131.

157. *How Medications to Treat OUD Work*, *supra* note 53.

158. Hilary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARV. REV. PSYCHIATRY 63, 64 (2015).

159. *Naltrexone*, *supra* note 152.

160. *Id.*

161. AGATA DABORWSKA, VICTORIA R. GREEN, LISA N. SACCO & BRIAN T. YEH, CONG. RESEARCH SERV., R45405, THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT (P.L. 115-271): FOOD AND DRUG ADMINISTRATION AND CONTROLLED SUBSTANCE PROVISIONS 12 (2018).

162. *Id.*

DEA unless exempt. If the provider distributes a schedule III–V controlled substance, the provider can apply for a waiver under the Drug Abuse Treatment Act of 2000 (“DATA waiver”).<sup>163</sup> A provider distributing buprenorphine, a schedule III substance, is eligible for a waiver;<sup>164</sup> naltrexone is not a controlled substance, so no waiver is required. Buprenorphine<sup>165</sup> and naltrexone can be prescribed by one’s primary care physician and taken at home.<sup>166</sup> Methadone, however, cannot be prescribed by a physician in his or her office as it is a schedule II controlled substance.<sup>167</sup> Rather, the Federal Narcotic Treatment Act of 1974 “mandates that methadone can only be ordered and dispensed at federally licensed opioid treatment programs, often referred to as ‘methadone clinics.’”<sup>168</sup>

### C. Methadone Clinics and Their Mobile Components

Also known as an Opioid Treatment Program (“OTP”), “[a] methadone clinic is a place where a person who is addicted to opioid-based drugs, such as heroin or prescription painkillers, can receive medication-based therapy.”<sup>169</sup> All methadone clinics are regulated by state and federal laws.<sup>170</sup> Each clinic must apply for a state license and find a location that complies with local zoning regulations.<sup>171</sup> Methadone clinics also must comply with federal guidelines issued by the Federal Food, Drug, and Cosmetic Act (“FFDCA”)<sup>172</sup> and the Controlled Substances Act (“CSA”).<sup>173</sup> Under

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163. *Id.* at 12–13.

164. *Id.* at 13.

165. The Drug Addiction Treatment Act of 2000 permits certain Schedule III–IV drugs to be prescribed by physicians. Jones et al., *supra* note 149, at e55.

166. Vestal, *Federal Ban*, *supra* note 20.

167. Anderson, *supra* note 14; DABORWSKA ET AL., *supra* note 161, at 12.

168. Anderson, *supra* note 14.

169. Scot Thomas, *How Does an Opioid Rehabilitation Clinic Work with Methadone*, AM. ADDICTION CTRS. (Mar. 3, 2020), <https://americanaddictioncenters.org/methadone-addiction/clinic-facts> [<https://perma.cc/F7BG-YENP>].

170. *Id.*

171. Vestal, *Long Stigmatized*, *supra* note 148; Alaina McBournie, Alexandra Duncan, Elizabeth Connolly & Josh Rising, *Methadone Barriers Persist, Despite Decades of Evidence*, HEALTH AFFAIRS (Sept. 23, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190920.981503/full/> [<https://perma.cc/F4PV-3QRA>].

172. Buprenorphine and naltrexone are also subject to the FFDCA. DUFF, *supra* note 23, at 1.

173. Buprenorphine is also controlled under the CSA because it is a controlled substance. *Id.* Naltrexone carries no risk of abuse, so it is not controlled under the CSA. *Id.* These regulations would apply equally to mobile clinics. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,009 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

the CSA, both the DEA and the SAMHSA are charged with the regulation of methadone clinics.<sup>174</sup> All methadone clinics must obtain “accreditation from a SAMHSA-approved accreditor, certification from SAMHSA, and registration from DEA.”<sup>175</sup> To receive accreditation, the clinic undergoes a peer review process in which the SAMHSA-approved organization evaluates the clinic.<sup>176</sup> The accrediting organization will then visit the site and “review[] [the clinic’s] policies, procedures, and practices.”<sup>177</sup>

The DEA requires each person<sup>178</sup> and each “principal place of business or professional practice”<sup>179</sup> that dispenses opioids to register.<sup>180</sup> The CSA provides 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 the applicant manufactures, distributes, or dispenses controlled substances . . . .”<sup>181</sup> The CSA does not define “principal place of business or professional practice.” In *United States v. Clinical Leasing*, the Fifth Circuit looked to 21 C.F.R. § 1301.12(b)(3) in determining what the term “principal place of business or professional practice” means.<sup>182</sup> The court focused on “whether the practitioner ‘regularly engaged in the dispensing or administering of controlled substances’ at a particular location as determinative of whether a separate registration is required at such location.”<sup>183</sup> The court stated that “[i]f a physician intends to dispense controlled substances from a particular location several times a week or month he must first [obtain] a separate registration for the location.”<sup>184</sup>

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174. See DUFF, *supra* note 23, at 1.

175. *Id.*

176. *Id.*

177. *Id.*

178. 21 U.S.C. § 822(a)(1).

179. 21 U.S.C. § 822(e)(1).

180. See DUFF, *supra* note 23, at 2. “Through this registration mechanism, the CSA creates a ‘closed system’ of distribution in which distribution may lawfully occur among registered handlers of controlled substances.” BRIAN T. YEH, CONG. RESEARCH SERV., R45164, LEGAL AUTHORITIES UNDER THE CONTROLLED SUBSTANCES ACT TO COMBAT THE OPIOID CRISIS 1 (2018).

181. 21 U.S.C. § 822(e)(1).

182. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,009 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304) (citing *United States v. Clinical Leasing*, 930 F.3d 394, 395–96 (5th Cir. 1991)).

183. *Id.*

184. *Id.*

The CSA also requires registrants to keep complete records of controlled-substances inventories and distributions and to implement certain security measures.<sup>185</sup> There are no federal limits on the number of patients a methadone clinic can treat.<sup>186</sup> “However, in 2016 HHS determined—through SAMHSA survey data—that an OTP could manage, on average, 262 to 334 patients at any given time.”<sup>187</sup>

## 1. How Methadone Clinics Work

During a patient’s first visit to a methadone clinic, he is screened by the clinic’s staff.<sup>188</sup> “Drug use history, co-occurring disorders, and the impact of substance abuse on life are assessed via a clinical evaluation, while a medical evaluation reviews health history, current health, present medication requirements, and overall condition in regard to being given methadone.”<sup>189</sup> They also undergo blood or urinalysis tests and are told about the treatment program and what is required of them.<sup>190</sup> Often, patients do not receive medication on their first visit.<sup>191</sup> When patients do receive medication, whether during the first visit or a subsequent visit, they are not given any medication to take home.<sup>192</sup> Treatment protocols require the patient to take the medication at the clinic.<sup>193</sup> 42 C.F.R. § 8.12(i) imposes limitations on who is eligible for take-home doses in an effort to limit the potential for diversion.<sup>194</sup> Patients may receive take-home doses for those days when the clinic is closed.<sup>195</sup> “[I]ndividuals may become eligible for take-home doses on the basis of appropriate clinic attendance, absence of behavioral problems at the clinic or recent drug abuse, lack of known criminal activity, . . . evidence of a stable home with the ability to store methadone safely,”<sup>196</sup> length of time in treatment, and “[w]hether the rehabilitative benefit the patient derived from decreasing the frequency of clinical attendance outweighs the potential risks of

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185. YEH, *supra* note 180, at 5.

186. DUFF, *supra* note 14, at 3.

187. *Id.*

188. Thomas, *supra* note 169.

189. *Id.*

190. *Id.*

191. *Id.*

192. ALDERKS, *supra* note 48.

193. *Id.*

194. 42 C.F.R. § 8.12(i) (2019).

195. *Id.* § 8.12(i)(1).

196. Fullerton et al., *supra* note 70, at 147; 42 C.F.R. § 8.12(i)(2) (2019).

diversion.”<sup>197</sup> That means the majority of patients who receive daily doses are required to come to the clinic daily for their medication.<sup>198</sup>

## 2. Issues with Fixed-Site Methadone Clinics and the Solutions Provided by Mobile Clinics

Many patients are required to come to methadone clinics daily for their treatment.<sup>199</sup> Given this treatment necessity, the current system of a limited number of fixed-site clinics is a major barrier to adequate treatment. “Research has demonstrated significant access barriers to methadone, including waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the OTP daily.”<sup>200</sup> Financial factors, including low income and unemployment, also contribute to the lack of access to methadone clinics.<sup>201</sup> These issues impact the client’s ability to receive adequate and regular doses.<sup>202</sup>

Mobile methadone clinics are able to overcome many of the barriers posed by fixed-site methadone clinics.<sup>203</sup> Those mobile methadone clinics currently in use have been able to reach a greater number of patients than fixed-site outpatient methadone programs.<sup>204</sup> Mobile clinics also provide patients with more convenient and less costly treatment. These clinics “have been especially successful in addressing the geographical extremes of both rural and urban poor, where accessibility to fixed healthcare is limited due to the dearth of facilities and meager financial resources.”<sup>205</sup> The programs “that offer community-based, walk-in services at little or

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197. 42 C.F.R. § 8.12(i)(2) (2019).

198. ALDERKS, *supra* note 48.

199. Vestal, *Federal Ban*, *supra* note 20.

200. Jones et al., *supra* note 149, at e55.

201. Gerod Hall, Charles J. Neighbors, Jude Iheoma, Sarah Dauber, MerriBeth Adams, Robert Culleton, Fred Muench, Suzanne Borys, Rebecca McDonald & Jon Morgenstern, *Mobile Opioid Agonist Treatment and Public Funding Expands Treatment for Disenfranchised Opioid-Dependent Individuals*, 46 J. SUBSTANCE ABUSE TREATMENT 511, 511 (2014).

202. Britton A. Gibson, Debarchana Ghosh, Jamie P. Morano & Frederick L. Altice, *Accessibility and Utilization Patterns of a Mobile Medical Clinic Among Vulnerable Populations*, 28 HEALTH & PLACE 153, 153 (2014); *see also* NAT’L INST. ON DRUG ABUSE INT’L PROGRAM, PART B: 20 QUESTIONS AND ANSWERS REGARDING METHADONE MAINTENANCE TREATMENT RESEARCH 9 [hereinafter METHADONE QUESTIONS AND ANSWERS].

203. Gibson et al., *supra* note 202, at 153.

204. *See id.*

205. *Id.*

no charge are an effective means to reach underserved groups.”<sup>206</sup> Travel reports completed by patients who received treatment from both fixed-site methadone clinics and mobile clinics reported consistent reductions in both travel time and transportation costs when using mobile clinics.<sup>207</sup>

Mobile clinics ensure that individuals enrolled in a methadone maintenance program or a medication-assisted treatment program are able to receive adequate and regular doses of methadone.<sup>208</sup> By ensuring that opioid-dependent individuals have access to adequate and regular doses of methadone, mobile clinic programs also ensure the individual does not experience withdrawal symptoms, as such symptoms often lead to the individuals reverting back to opioid usage.<sup>209</sup> The programs cannot simply provide clients with take-home doses, because treatment protocols require the methadone to be provided daily at the prescribing clinic.<sup>210</sup>

Individuals who face transportation or financial barriers may be unwilling or unable to go to the clinic daily to receive their required doses. Unlike with fixed-site methadone clinics, mobile methadone clinics reduce the prohibitive burdens associated with treatment, such as monetary cost, substantial travel time, and potential impact on their employment from traveling six to seven times per week to the clinic.<sup>211</sup> The longer an opioid-dependent individual is enrolled in a treatment program, the more improvements she shows, which in turn makes it more likely she will successfully complete the treatment program.<sup>212</sup> “A key factor that appears to affect the length of stay in methadone maintenance treatment is ‘program accessibility.’”<sup>213</sup> Individuals enrolled in a mobile methadone treatment program are significantly more likely to remain in

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206. Hall et al., *supra* note 201, at 512.

207. Lawrence Greenfield, Joseph V. Brady, Karst J. Besterman & Aaron De Smet, *Patient Retention in Mobile and Fixed-Site Methadone Maintenance Treatment*, 42 *DRUG & ALCOHOL DEPENDENCE* 125, 126 (1996).

208. Gibson et al., *supra* note 202, at 153; *see also* METHADONE QUESTIONS AND ANSWERS, *supra* note 202, at 9.

209. *Opioid Agonist Therapy*, *supra* note 125.

210. ALDERKS, *supra* note 48, at 1.

211. Greenfield et al., *supra* note 207, at 126; Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11, 008, 11,009, 11,012, 11,015 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

212. METHADONE QUESTIONS AND ANSWERS, *supra* note 202, at 1 (citing S.B. SELLS & D.D. SIMPSON, NAT'L INST. ON DRUG ABUSE, *THE EFFECTIVENESS OF DRUG ABUSE TREATMENT* 10 (1976)).

213. Greenfield et al., *supra* note 207, at 126.

said program over a two-year period than clients enrolled in a fixed-site methadone treatment program.<sup>214</sup>

### 3. DEA Moratorium on Mobile Methadone Clinics

Given all this data, why are more individuals not enrolled in mobile methadone treatment programs? This is likely because in 2007, the DEA placed a moratorium on granting licenses to new mobile methadone treatment programs.<sup>215</sup> There does not appear to be any official guidance on the moratorium. However, the agency stopped issuing licenses for mobile units due to diversion concerns<sup>216</sup> and some indication that the DEA had not previously followed its own mobile unit licensure protocols in the past.<sup>217</sup>

The DEA had previously been issuing licenses on an ad hoc basis.<sup>218</sup> However, the moratorium resulted in a gradual decline in the number of mobile methadone treatment programs.<sup>219</sup> The mobile methadone clinics with grandfathered agreements and ones that dispense medications other than methadone were able to stay in business.<sup>220</sup> During the past five years, nineteen NTPs have operated a mobile component that offer a variety of medications.<sup>221</sup> “Currently, eight NTPs operate mobile [methadone] units under those [grandfathered] agreements.”<sup>222</sup> The programs are in six states<sup>223</sup> and Puerto Rico.<sup>224</sup> But other states, including Connecticut and New York, have expressed interest in having mobile methadone clinics or expanding their programs.<sup>225</sup> Limits were initially

214. *Id.* at 129.

215. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009.

216. Diversion refers to “the intentional transfer of a controlled drug from legitimate distribution and dispensing into illegal channels.” Wright et al., *supra* note 77, at e369.

217. *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 3–4; Vestal, *Federal Ban*, *supra* note 20.

218. *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 3–4.

219. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009.

220. *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 4.

221. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009; *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 4.

222. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009; *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 3–4.

223. Those six states are: California, Illinois, Massachusetts, Maryland, New Jersey, and Washington. Vestal, *Federal Ban*, *supra* note 20.

224. McBournie et al., *supra* note 171.

225. Vestal, *Federal Ban*, *supra* note 20.

placed on the mobile clinics because the DEA was concerned with diversion of the medications used in the treatment programs and with the cost of running the programs.<sup>226</sup> However, the DEA recently issued an NPRM that would no longer require methadone clinics to request a separate registration for mobile clinics from the DEA, which would effectively lift the moratorium.<sup>227</sup>

## II. ANALYSIS AND ARGUMENT

### A. *February 26 Notice of Proposed Rulemaking*

On February, 26, 2020, the DEA issued a notice of proposed rulemaking (“NPRM”) addressing the DEA’s 2007 moratorium on the licensing of mobile methadone clinics.<sup>228</sup> The DEA noted the moratorium resulted in a gradual decline in the number of clinics in operation.<sup>229</sup> The proposed rule is necessary because the DEA is currently not registering any new mobile clinics and, even if it were, without the new rule methadone clinics would have to register each mobile unit they dispatch.<sup>230</sup> The CSA provides 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.”<sup>231</sup> This means a physician must register every location from which she distributes or dispenses medication regularly.<sup>232</sup> The NPRM noted there are times when a mobile methadone clinic would operate in such a way that it would be considered a “principal place of business or professional practice,” and therefore, would require a separate registration.<sup>233</sup>

The DEA is authorized under the CSA to waive the registration requirement for certain cases when it is consistent with public health and safety.<sup>234</sup> The current NPRM is proposing to waive the

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226. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009–10; *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 3–4.

227. See Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009.

228. *Id.* at 11,008–09.

229. *Id.* at 11,009.

230. *Id.* at 11,009–10.

231. *Id.* at 11,008 (quoting 21 U.S.C. § 822(e)(1)).

232. 21 U.S.C. § 822(e)(1).

233. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,009.

234. 21 U.S.C. § 822(d); Registration Requirements for Narcotic Treatment Programs

registration requirement for mobile units.<sup>235</sup> Under the proposed rule, distributing methadone from a mobile unit would be considered a coincident activity to the operation of the fixed-site methadone clinic, and therefore would not require an additional registration for mobile clinics operated in the same state.<sup>236</sup> By waiving the registration requirement for any mobile clinics associated with a fixed-site methadone clinic and not placing any limitations on the number of mobile units, the DEA in effect lifts the moratorium on the licensing restriction. Since the NPRM was issued on February 26, 2020, neither the DEA nor any other agency has issued another NPRM addressing mobile methadone clinics. Comments about the NPRM were due to the DEA on April 27, 2020.<sup>237</sup>

### *B. Mobile Methadone Clinics Will Positively Impact Treatment Outcomes and Options*

Promulgating the NPRM would be an excellent first step in ensuring these treatment outcomes and options are possible, as the NPRM is “aimed at helping to alleviate the opioid crisis in the United States by formalizing the requirements for operating a mobile NTP and thereby allowing for greater access to OUD treatment while maintaining appropriate controls to reduce the likelihood of diversion.”<sup>238</sup> Proponents include SAMHSA itself, United States Senators and Representatives, and state and local addiction agencies who have been advocating for the DEA to promulgate such a regulation and lift the ban on mobile methadone clinics.<sup>239</sup> It seems their wishes have finally been granted.

“The consequences of opioid abuse and dependence include emergency department visits, premature death, HIV, hepatitis, criminal activity, lost workdays, and economic costs that in the United States exceed \$56 billion annually.”<sup>240</sup> However, when opioid-dependent individuals receive adequate and consistent doses of methadone and comprehensive services, they begin to lead socially

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with Mobile Components, 85 Fed. Reg. at 11,010.

235. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,008–09.

236. *Id.* at 11,009.

237. *Id.* at 11,008.

238. *Id.* at 11,009.

239. See Vestal, *Federal Ban*, *supra* note 20; Dhillon Letter, *supra* note 7.

240. Sigmon, *supra* note 11, at 359 (citing Howard G. Birnbaum, Alan G. White, Matt Schiller, Tracy Waldman, Jody M. Cleveland & Carl L. Roland, *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 PAIN MED. 657 (2011)).

and economically productive lives within months.<sup>241</sup> Methadone treatment programs are associated with higher retention, longer abstinence, and decreased economic costs.<sup>242</sup> Methadone clinic patients “find housing, improve their health, obtain employment, [and] many improve their education.”<sup>243</sup> Although many opioid-dependent individuals enrolled in methadone maintenance treatments remain reliant on methadone, enrollment in such a program is associated with “decreased time spent on drug-related activities and may allow dependent individuals to transition into abstinence-based programs.”<sup>244</sup>

Although the United States has seen a dramatic increase in OUD and therefore an increase in the need for treatment, there has been a decline in availability of treatment options and decreases in the length of stay in treatment.<sup>245</sup> By expanding access to mobile methadone clinics and thereby making treatment more readily available, opioid-dependent individuals will have consistent access to treatment, which will, in turn, help individuals comply with their treatment programs. Individuals who are able to stay in treatment show a decrease in drug use and improved outcomes overall.<sup>246</sup> By bringing the treatment programs to the clients, clients will not be forced to choose between receiving their daily dose of methadone and going to work that day.<sup>247</sup> The key factor to ensuring individuals stay in treatment longer is program accessibility.<sup>248</sup>

For many, methadone treatment remains inaccessible. Methadone is a schedule II substance that is heavily regulated by the DEA.<sup>249</sup> Unlike other treatment options, opioid-dependent individuals enrolled in methadone maintenance or medication-assisted treatment programs must travel to a methadone clinic each day to receive their medication. They are unable to receive the medication

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241. Woods & Joseph, *supra* note 16, at 323.

242. See Veilleux et al., *supra* note 62, at 156.

243. Woods & Joseph, *supra* note 16, at 323.

244. Veilleux et al., *supra* note 62, at 160.

245. See Etheridge et al., *supra* note 80, at 10.

246. Gossop et al., *supra* note 77, at 98 (citing D.D. Wayne Simpson, George W. Joc, Grace Rowan-Szal & Jack Greener, *Client Engagement and Change During Drug Abuse Treatment*, 7 J. SUBSTANCE ABUSE 117 (1995)); Greenfield et al., *supra* note 207, at 125–26.

247. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,012 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

248. Greenfield et al., *supra* note 207, at 126.

249. *Drug Scheduling*, DRUG ENFORCEMENT AGENCY, <https://www.dea.gov/drug-scheduling> [<https://perma.cc/ERG4-BXAC>].

from other physicians or clinics. This creates a number of barriers—waitlists, costs, and travel time, to name a few. Mobile methadone clinics can break down the barriers that prevent opioid-dependent individuals from accessing treatment. Methadone clinics would be able to set up in neighborhoods and provide medication from a mobile treatment unit.

When an individual is ready to receive treatment, he may not be able to begin immediately. Due to the limited number of methadone programs, many individuals will remain on a waitlist for months or even years.<sup>250</sup> One treatment program in Vermont, a state with one of the highest rates of OUD, reported a waitlist of 946 people.<sup>251</sup> This means individuals were forced to wait approximately two years to receive treatment.<sup>252</sup> A methadone clinic in Lexington, Kentucky also had a two-year wait.<sup>253</sup> Mobile clinics will allow providers to treat more individuals. Even when an individual is able to enroll in a treatment program, he may face additional challenges that interfere with the ability to receive care.

Travel is one of the major costs associated with treatment.<sup>254</sup> At the aforementioned clinic in Vermont, “[p]atients reported spending \$48.84 per week on transportation-related costs to attend the clinic.”<sup>255</sup> In addition to travel costs, individuals often must drive long distances to obtain treatment. Individuals have reported traveling up to two hours to receive treatment.<sup>256</sup> Once the individual arrives at the clinic, they may not be treated right away; additional time is spent waiting at the clinic.<sup>257</sup> These extensive travel and wait times mean that individuals are forced to choose between treatment and other aspects of life. “Employment, child care, unexpected emergencies and other life events have to be oriented around the clinic. On the street, methadone is sometimes referred to as the ‘liquid handcuffs.’”<sup>258</sup> When forced to choose between their

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250. Sigmon, *supra* note 11, at 359.

251. *Id.*

252. *Id.*

253. *Id.*

254. *Id.*

255. *Id.*

256. See, e.g., Jose A. Del Real, *Opioid Addiction Knows No Color, but Its Treatment Does*, N.Y. TIMES (Jan. 12, 2018), <https://www.nytimes.com/2018/01/12/nyregion/opioid-addiction-knows-no-color-but-its-treatment-does.html> [<https://perma.cc/C22Q-5THQ>] (reporting some individuals have to travel up to two hours to receive treatment); Sigmon, *supra* note 11 (reporting individuals who receive treatment from the clinic in Vermont traveled sixty minutes on average to receive treatment).

257. Del Real, *supra* note 256.

258. *Id.*

treatment and their jobs or their children, many do not have the luxury of putting their treatment first. “Some rural patients report that the burden of traveling daily to receive their medication effectively prevents them from working, further increasing the risk that they will discontinue treatment.”<sup>259</sup>

New Jersey is one the states that has a grandfathered agreement with the DEA that permits the state to operate mobile methadone clinics.<sup>260</sup> The New Jersey Medication Assisted Treatment Initiative (“NJ-MATI”) “provides outreach via fully equipped and staffed opioid medication vans that targeted traditionally hard-to-reach groups, such as injection drug users (IDUs), homeless persons, and the uninsured.”<sup>261</sup> The program offers medication (buprenorphine and methadone), mental health services, case management, employment and educational counseling, and other psychosocial services.<sup>262</sup> The goal of the program is to reduce common barriers, including lack of transportation and health insurance, to increase accessibility to treatment.<sup>263</sup> The program has succeeded in providing accessible treatment to groups of people who historically do not enroll in traditional methadone programs.<sup>264</sup> The program “had a higher proportion of African-American, homeless, and uninsured individuals than traditional methadone programs. This suggests that socially disenfranchised individuals were more likely to have access to [non-methadone] treatment options.”<sup>265</sup> As with the NJ-MATI, similar mobile treatment programs in Amsterdam and Baltimore, Maryland, were able to reach a greater number of minority clients than their fixed-site counterparts.<sup>266</sup>

In Baltimore, a mobile methadone clinic provided drug abuse treatment and psychosocial services to 399 clients over a three-year period.<sup>267</sup> “Travel reports completed by those patients who had previously participated in fixed-site outpatient drug abuse treatment programs showed consistent reductions in both travel

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259. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,012 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304) (citing Sigmon, *supra* note 11, at 359–60).

260. Vestal, *Federal Ban*, *supra* note 20.

261. Hall et al., *supra* note 201, at 512.

262. *Id.*

263. *Id.*

264. *Id.* at 514.

265. *Id.*

266. *Id.* at 512.

267. Greenfield et al., *supra* note 207, at 126.

time and transportation costs required to access the MHS treatment. Urinalysis data reflected a marked decline in opiate use by patients.”<sup>268</sup> A subsequent study compared the retention of clients enrolled in the mobile program with those enrolled in the fixed-site program. The results showed that “the chances of remaining in methadone maintenance drug abuse treatment over a two year period are significantly greater for those [clients] enrolled in the Baltimore mobile treatment program than in a selected group of fixed-site methadone maintenance programs from the same municipal setting.”<sup>269</sup> Clients enrolled in treatment with the mobile methadone clinic remained in treatment for a median 15.3 months.<sup>270</sup> Individuals who were enrolled in a fixed-site program in the same zip code where the mobile clinic operated remained enrolled for a median 3.9 months; individuals enrolled in a fixed-site program in a different zip code remained for a median of 6.27 months.<sup>271</sup> “The differences in retention between the mobile and fixed-site programs may be accounted for by several program level factors.”<sup>272</sup> The mobile clinic provided clients with an option that reduced both travel time and transportation costs compared with visiting a fixed-site clinic.<sup>273</sup> Longer retention, as discussed above, has been associated with better treatment outcomes.<sup>274</sup>

### C. *Concerns with Mobile Units*

The two primary concerns with mobile methadone clinics are the risks of diversion and the cost of the programs. The NPRM from February 26, 2020, addressed both of these concerns in great detail. The NPRM reached the conclusion that diversion and cost of the program are not significant enough concerns to continue the moratorium on the creation of new mobile methadone clinics. The NPRM noted that mobile clinics are able to put procedures and equipment in place to lower the risk of diversion significantly, and

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268. *Id.* (citation omitted).

269. *Id.* at 129.

270. *Id.*

271. *Id.*

272. *Id.* at 130.

273. *Id.*

274. *Id.*; see also Fiorentine & Anglin, *supra* note 93, at 342.

based on examination of the mobile clinics currently operation, diversion does not occur as often as the DEA once believed.<sup>275</sup> Additionally, when compared to the current operating system, the cost of starting and operating new mobile clinics is significantly less.<sup>276</sup>

### 1. Diversion Through Theft from Mobile Units

The NPRM issued on February 26, 2020, addressed many of the concerns regarding diversion of methadone. “Diversion is defined as the intentional transfer of a controlled drug from legitimate distribution and dispensing into illegal channels.”<sup>277</sup> Diversion negatively impacts methadone clinic clients and the community as a whole.<sup>278</sup> Diversion has negative implications for clients who divert their medication, as they then experience poor adherence to their treatment protocol.<sup>279</sup> Diversion is also detrimental to the larger community because diverted opioids result in increased costs associated with medical treatment of overdoses, illnesses, death, and crime, particularly theft.<sup>280</sup>

The CSA already imposes strict requirements on fixed-site methadone clinics to minimize the risk of diversion, and those requirements, in addition to others, would be applicable to the mobile units.<sup>281</sup>

Evaluation of the mobile units currently in existence shows that diversion is not as prevalent as the DEA seemed to fear when it adopted the moratorium.<sup>282</sup> A review of theft and loss reports from the mobile units that are currently in operation showed only one theft or loss since 2005.<sup>283</sup> Any methadone clinic that experiences loss or theft of controlled substances must notify the DEA within

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275. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,010–11 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

276. *Id.* at 11,012–14.

277. Wright et al., *supra* note 77, at e369.

278. See *DEA Proposal for Mobile Methadone Finally Released*, *supra* note 24, at 3–4; Vestal, *Federal Ban*, *supra* note 20.

279. Wright et al., *supra* note 77, at e369–70 (2015).

280. *Id.*

281. YEH, *supra* note 180, at 2; Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,010.

282. See Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,010–11.

283. *Id.* at 11,010.

one business day of the discovery of said theft or loss.<sup>284</sup> The registrant must detail the type and actual quantity of the lost or stolen controlled substance.<sup>285</sup> The registrant should also consider whether the loss or theft can be associated with specific individuals or a specific activity, whether such loss or theft is random or part of a larger pattern, and whether the controlled substance is likely to be diverted.<sup>286</sup> Even when no theft or loss has been reported, DEA has the authority to inspect any mobile methadone clinic and ensure compliance with the CSA and related regulations.<sup>287</sup>

Any controlled substances in the mobile unit must be kept in a safe that is not accessible from outside the unit.<sup>288</sup> The safe must also be bolted to the wall or floor so that it cannot be removed.<sup>289</sup> The safe must be designed to prevent forced entry, lock manipulation, and radiological attacks.<sup>290</sup> The DEA suggests 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.”<sup>291</sup> Individuals receiving treatment are required to wait somewhere physically separated from where the controlled substances are kept and dispensed.<sup>292</sup>

Further, “to minimize theft and diversion and to help the DEA monitor the flow of controlled substances in the United States, the CSA and its implementing regulations subject registrants to strict requirements regarding recordkeeping, maintaining the security of their controlled substance inventories, and reporting certain information to the DEA.”<sup>293</sup> Referred to as a “closed system’ of distribution,” this system helps ensure that controlled substances held by the methadone clinic are always accounted for.<sup>294</sup>

At the end of each day, the mobile unit would be returned to the fixed-site methadone clinic and all controlled substances would be

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284. 21 C.F.R. § 1301.74(c) (2020).

285. *Id.*

286. *Id.*

287. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,011.

288. *Id.*

289. *Id.*

290. *Id.*

291. *Id.*

292. *Id.*

293. YEH, *supra* note 180, at 2.

294. *Id.*

removed from the mobile unit.<sup>295</sup> If the mobile unit breaks down or is disabled for any other reason, the registrant would be required to ensure that all controlled substances in the unit are secure and accounted for.<sup>296</sup> If the mobile unit is taken somewhere for maintenance, all controlled substances would need to be removed from the unit and returned to the fixed-site methadone clinic.<sup>297</sup>

The federal regulations applicable to fixed-site methadone clinics also require practices to help prevent diversion and these practices would be required of mobile units. Each methadone clinic is required to have a Diversion Control Plan (“DCP”), which documents the clinic’s plan to reduce the possibility of diversion and assigns specific responsibilities to each staff member to carry out that plan.<sup>298</sup> The Federal Guidelines for Opioid Treatment Programs issued by SAMHSA states that “DCPs should address at least four general areas of concern: program environment, dosing and take-home medication . . . , prevention of multiple program enrollment, and prescription medication misuse.”<sup>299</sup>

## 2. Diversion of Properly Prescribed Medication

There are limitations on who is eligible to receive take-home doses of methadone.<sup>300</sup> A methadone clinic is only permitted to provide clients with take-home doses when the clinic is closed or the medical director determines the client presents a low risk of diversion.<sup>301</sup> For methadone, the client is required to be in treatment for a significant period of time.<sup>302</sup> The clinic should also perform random “call backs” to inventory a patient’s take-home doses and random drug testing on clients with take-home doses.<sup>303</sup> Other practices that should be in a clinic’s DCP include supervised

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295. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,011.

296. *Id.*

297. *Id.*

298. 42 C.F.R. § 8.12(c)(2) (2020); *see also* Wright et al., *supra* note 77, at e370.

299. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 73, at 18. Misuse refers to “the use of a medication other than as directed or as indicated, whether wilful or unintentional, and whether resulting in harm or not.” Wright et al., *supra* note 77, at e369.

300. 42 C.F.R. § 8.12(i) (2020).

301. *Id.* There are a number of criteria the medical director should consider in determining whether a client is “responsible in handling opioid drugs for unsupervised use.” *Id.* These include (1) absence of recent drug abuse; (2) regularity of clinic attendance; (3) stability of client’s home environment; and (4) length of time in treatment, among others. *Id.*

302. ALDERKS, *supra* note 48, at 1.

303. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 73, at 18.

consumption, client education on diversion, and monitoring and surveillance of the treatment area.<sup>304</sup> Mobile methadone clinics would follow the same protocols employed by fixed-site methadone clinics.

### 3. Cost

The cost of operating the mobile units would be less than the current system and less than opening an additional fixed-site methadone clinic. In the proposed rule, the DEA compared the costs of delivering MAT treatment without permitting new mobile clinics to permitting clinics to operate new mobile clinics as a coincident activity.<sup>305</sup> The DEA concluded that the cost of permitting new mobile units would be less than the current fixed-site only system in the form of reduced startup, labor, and operating costs.

To open a new fixed-site methadone clinic, registrants would be required to pay for a new registration fee, rent, any other registration or accreditation fees, and staffing and facility costs.<sup>306</sup> The registration fee would be \$244 per year per fixed-site facility.<sup>307</sup> Over a five-year period, registrants would pay between \$1000.45 and \$1117.45 in registration costs.<sup>308</sup> A new fixed-site methadone clinic would also have an increase in labor costs.<sup>309</sup> A fixed-site methadone clinic would need to employ a medical assistant to manage records and billing.<sup>310</sup> The DEA estimates that the cost of employing a medical assistant is \$48,994 annually.<sup>311</sup> Registrants must also pay any costs associated with renting an office space.<sup>312</sup> The DEA estimated that an NTP would require 1000 square feet of office space and that such space would cost, based on a “conservative” estimate, an average of \$46,000 annually.<sup>313</sup> If operated over a five-year period, the total cost of a new fixed-site methadone clinic would range from \$188,609.88 to \$210,666.53.<sup>314</sup> “The many fixed

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304. *Id.*; see also Wright et al., *supra* note 77, at e369, e371.

305. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,012 (proposed Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304).

306. *Id.*

307. *Id.*

308. *Id.* at 11,013.

309. *Id.*

310. *Id.*

311. *Id.*

312. *Id.*

313. *Id.*

314. *Id.*

capital and operating expenses associated with the startup and ongoing operation of a new facility discourage providers from doing this.”<sup>315</sup>

Under the NPRM, if the registrant operated a mobile methadone clinic, it would be seen as a coincident activity by the DEA and would not require additional registration.<sup>316</sup> Further, a provider could also open a new fixed-site methadone clinic and deploy additional mobile clinics, which would reduce registration costs and increase access.<sup>317</sup> The DEA estimates that labor costs for both fixed-site and mobile clinics would be the same in terms of personnel required to dispense methadone.<sup>318</sup> While a fixed-site methadone clinic would need to employ a medical assistant to manage records and billing, a mobile clinic would be able to outsource to a fixed-site clinic to handle those needs.<sup>319</sup>

The main cost would be the vehicle to serve as the clinic.<sup>320</sup> The NPRM noted that the capital expenses associated with purchasing a vehicle for the clinic would likely be less than the expenses associated with a fixed-site methadone clinic, specifically the monthly rent.<sup>321</sup> The DEA estimated that a vehicle suitable for operation as a mobile methadone clinic would cost between \$30,000 and \$40,000.<sup>322</sup>

The DEA recognized that there are certain costs unique to operating a mobile unit. First, the mobile unit would require a safe, and due to the confined space of the vehicle, the safe would likely need to be customized.<sup>323</sup> In their estimates, the DEA took the highest quoted price of the customized safe and doubled it.<sup>324</sup> Unlike the fixed-site clinic, the mobile clinic would incur “maintenance and transportation expenses such as fuel, repair, insurance, permits, licenses, tires, tolls, and driver wages and benefits.”<sup>325</sup> The average cost of operating a straight truck, the type of vehicle that would be

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315. *Id.* at 11,012.

316. *Id.* at 11,008–09.

317. *Id.* at 11,009.

318. *Id.* at 11,013.

319. *Id.*

320. *Id.* at 11,012.

321. *Id.*

322. *Id.* at 11,013.

323. *Id.*

324. *Id.*

325. *Id.*

used for this purpose, was \$1.63 per mile in 2016.<sup>326</sup> Based on data from currently operational mobile units, the DEA estimates the mobile clinic will travel no more than 5000 miles per year.<sup>327</sup> Accordingly, the DEA estimates the annual transportation and maintenance costs associated with a mobile unit to be \$8150 per year.<sup>328</sup> When the cost of operating a mobile methadone clinic over a five-year period is compared with the cost associated with operating a fixed-site methadone clinic over the same period, the cost of operating the mobile clinic yields a savings between \$318,855 and \$359,131.<sup>329</sup>

There are currently 1605 NTP registrations in the DEA database.<sup>330</sup> As of 2016, ninety percent of those clinics were located in urban areas.<sup>331</sup> The number of facilities offering detoxification or methadone treatment programs “declines among large, medium, and small non-adjacent rural areas.”<sup>332</sup> The fixed-site methadone clinics are “more limited in the geographic area they can reasonably serve than are mobile units.”<sup>333</sup> The DEA acknowledged that it cannot estimate the total benefit because there is no data on the number of clients currently treated by mobile units annually,<sup>334</sup> and there is no data on the number of “registrants that are currently deterred or prevented from opening additional [fixed-site methadone clinics] due to costs [that] might take advantage of this enabling rule to begin operating a mobile [methadone clinic].”<sup>335</sup> However, the DEA has estimated the minimum number of mobile clinics that will become operational after the rule is promulgated.<sup>336</sup> Based on the number of NTPs that operated a mobile unit

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326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.* “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.” *Id.* at 11,012–13.

330. *Id.* at 11,016. Other sources estimate approximately 1500 methadone clinics in operation. Vestal, *Federal Ban*, *supra* note 20.

331. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,012.

332. JENNIFER LENARDSON & JOHN A. GALE, ME. RURAL HEALTH RESEARCH CTR., DISTRIBUTION OF SUBSTANCE ABUSE TREATMENT FACILITIES ACROSS THE RURAL-URBAN CONTINUUM 2 (2008), <http://muskie.usm.maine.edu/Publications/rural/pb35bSubstAbuseTreatmentFacilities.pdf> [<https://perma.cc/DZ96-QCYC>].

333. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,014.

334. *Id.* at 11,012.

335. *Id.* at 11,014.

336. *Id.*

at some point in the past five years, the DEA estimates at least eleven mobile methadone clinics will be in operation plus the eight that are currently in use under the grandfathered agreements.<sup>337</sup> Based on the current number of fixed-site clinics, the minimum number of OTP entities that could operate mobile methadone clinics, however, is 851.<sup>338</sup> There are many states that are ready to roll out mobile units and many more that are interested.<sup>339</sup> Because the NPRM is an enabling rule, the OTPs would not be *required* to operate mobile units.<sup>340</sup> Further, existing fixed-site clinics could establish multiple mobile clinics, or new fixed-site clinics could be opened, which could then establish their own mobile clinics. Accordingly, the exact number is difficult to estimate.<sup>341</sup>

#### D. *The Regulation Should Include a Comprehensive Care Approach*

While the NPRM is a great first step in the right direction in providing opioid-dependent individuals with access to medications they need to live an opioid-free life, the medications offered by the mobile clinics will be more effective if adequate comprehensive services are also provided by the mobile clinics. Studies have shown that “expansion of methadone availability may be a necessary but not a sufficient medical response to the multiple problems of opiate dependence.”<sup>342</sup> To ensure that individuals receiving methadone treatment from a mobile unit are receiving the full range of MAT services, the DEA should implement the regulations in the proposed rule, but the final regulations should also require mobile units to provide comprehensive care to their clients.

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337. *Id.* There have been nineteen NTPs operating mobile units over the past five years, including the eight mobile units that have been dispensing methadone under the grandfathered agreements. *Id.* The operation of mobile units “yields a total cost savings for all [nineteen in total] over a five-year period of \$3,507,405 (at a 7% discount rate) to \$3,950,441 (at a 3% discount rate).” *Id.*

338. *Id.* at 11,016. The DEA noted that there is a difference between the number of NTP registrations and the number of NTP entities because an entity may operate more than one “principal place of business” and therefore may hold multiple registrations. *Id.* at 11,015. The DEA calculated that each entity operated fewer than two establishments. *Id.* at 11,016. Based on 1605 NTP registrations in the DEA database, the DEA calculated there are 851 NTP entities. *Id.*

339. Vestal, *Federal Ban*, *supra* note 20.

340. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,016.

341. *See id.*

342. MARK W. PARRINO, CTR. FOR SUBSTANCE ABUSE TREATMENT, U.S. DEPT OF HEALTH AND HUMAN SERVS., STATE METHADONE TREATMENT GUIDELINES 7 (1993).

Providing comprehensive care from the methadone clinic is feasible. The vehicle that houses the mobile methadone clinics can be designed with designated spaces to issue medication and to provide counseling and other services.<sup>343</sup> Mobile treatment programs providing MAT with buprenorphine<sup>344</sup> have been successfully implemented across the country.<sup>345</sup> Additionally, telehealth can be utilized to ensure patients receive complete wrap-around services.<sup>346</sup> A multidisciplinary staff, including counselors, physicians, and job placement specialists, would need to be hired to meet all of the clients' needs.

While one potential issue with this proposal is cost, the federal government provides grants to methadone clinics to fund treatment. SAMHSA provides grants to programs making methadone and medication-assisted treatment more available to opioid-addicted individuals.<sup>347</sup> "SAMHSA grants support programs designed to prevent and treat mental and/or substance use disorders. They also aim to improve access and reduce barriers to high-quality health care for individuals who experience or are at risk for these disorders, as well as for their families and communities."<sup>348</sup> For example, SAMHSA gave a \$524,000 grant to Mending Hearts, Inc. to provide medication-assisted treatment to homeless and low-income women in Tennessee.<sup>349</sup> The services provided by Mending Hearts, and funded by the grant, include medication, counseling, behavioral services, employment services, and recovery support services.<sup>350</sup> Another organization that has benefited from SAMHSA's grants is Project H.O.M.E. in Philadelphia, Pennsylva-

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343. Vestal, *Federal Ban*, *supra* note 20.

344. The DEA has not banned licensed prescribers of buprenorphine from utilizing mobile clinics. *Id.*

345. See, e.g., *id.*; Eric Wicklund, *Colorado to Use Mobile Health Units to Extend Reach of MAT Therapy*, HEALTH INTELLIGENCE (July 16, 2019), <https://mhealthintelligence.com/news/colorado-to-use-mobile-health-units-to-extend-reach-of-mat-therapy> [<https://perma.cc/B4R6-PWLF>]; Paul Gaita, *Mobile Treatment Vans Show Promise in Fighting Opioid Epidemic*, THE FIX (June 6, 2018), <https://www.thefix.com/mobile-treatment-vans-show-promise-fighting-opioid-epidemic> [<https://perma.cc/8B9J-D9HW>]; *Mobile Services Unit*, JEFFERSON CTR., <https://www.jcmh.org/mobileservices/> [<https://perma.cc/8N27-JPYD>].

346. *Mobile Services Unit*, *supra* note 345.

347. Vestal, *Federal Ban*, *supra* note 20.

348. *Funding Opportunities*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/tloa/tap-development-resources/funding-opportunities> [<https://perma.cc/S4PH-J7DY>].

349. *TI-18-009 Individual Grant Awards*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., [https://www.samhsa.gov/grants/awards/2018/ti-18-009?combine=&items\\_per\\_page=50&order=field\\_grantee\\_state&sort=asc&page=2](https://www.samhsa.gov/grants/awards/2018/ti-18-009?combine=&items_per_page=50&order=field_grantee_state&sort=asc&page=2) [<https://perma.cc/LT86-CV7V>].

350. *Id.*

nia. Project H.O.M.E. received a \$510,000 grant to provide medication-assisted treatment to opioid-dependent individuals.<sup>351</sup> Project H.O.M.E. planned to use the grant money to provide psychosocial services, peer support, and adult education and employment services.<sup>352</sup> In Seattle, Washington, federal grant money from SAMHSA has already been set aside to provide mobile methadone services once the ban has been lifted.<sup>353</sup> SAMHSA provides links to other agencies and organizations that offer grants that would cover the costs of the mobile clinics offering a variety of services on-site.<sup>354</sup>

Additionally, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the “Support Act”) provides grants for comprehensive opioid treatment programs.<sup>355</sup> These programs can be a single entity or an integrated delivery network.<sup>356</sup> The Support Act requires no fewer than ten competitive grants be awarded.<sup>357</sup> The Support Act also requires a program to offer certain services to be eligible for a grant.<sup>358</sup> These services include:

- (1) all FDA approved MAT; (2) withdrawal management; (3) counseling by a licensed provider; (4) testing for infections commonly associated with drug use; (5) treatment for co-occurring substance use and mental disorders; (6) residential rehabilitation; (7) outpatient programs; (8) recovery housing; (9) peer recovery support services; and (10) job training and placement assistance.<sup>359</sup>

The Support Act has authorized \$10 million to be appropriated for 2019–2023 for funding these programs.<sup>360</sup>

The 21st Century Cures Act (the “Cures Act”) established an opioid grant program titled the Opioid State Targeted Response (“STR”).<sup>361</sup> Over a two-year period from May 2017 through April

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351. *Id.*

352. *Id.*

353. Vestal, *Federal Ban*, *supra* note 20.

354. *Funding Opportunities*, *supra* note 348.

355. ELAYNE J. HEISLER & JOHNATHAN H. DUFF, CONG. RESEARCH SERV., R45423, PUBLIC HEALTH AND OTHER RELATED PROVISIONS IN P.L. 115-271, THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT 27 (2018).

356. *Id.*

357. *Id.*

358. *Id.* at 27–28.

359. *Id.* at 28.

360. *Id.*

361. HHS, *SAMHSA to Maintain Funding Formula for \$1B Opioid Grant Program*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Oct. 30, 2017), <https://www.samhsa.gov/newsroom/press-announcements/201710300530> [<https://perma.cc/R2CG-FEV6>].

2019, SAMHSA allocated \$1 billion in grants for state programs.<sup>362</sup> The grants were aimed at “expand[ing] access to evidence-based prevention, treatment, and recovery support services, reduc[ing] unmet treatment needs, and help[ing] to prevent opioid overdose deaths.”<sup>363</sup> States with a higher prevalence of OUD were given preference for the grants.<sup>364</sup> The grants covered costs associated with implementing prevention activities, supporting access to services provided by OTPs, and “[o]ther public health-related activities, as the State determines appropriate, related to addressing the opioid abuse crisis within the State.”<sup>365</sup> States were also eligible to receive grants for improving their prescription drug monitoring programs and covering the costs of training for practitioners.<sup>366</sup> However, at the end of the two-year period more than \$300 million dollars remained unspent.<sup>367</sup> States can request a non-cost extension to use the funds.<sup>368</sup> In March 2020, the Office of the Inspector General recommended SAMHSA work with states to establish MAT programs with the remaining grant money.<sup>369</sup>

In addition to grants, services can be paid for by public assistance programs and private health insurance. Medicaid reimbursement is available in thirty-seven states and Washington, D.C. for methadone treatment.<sup>370</sup> Medicare Part B covers the cost of services provided by OTPs.<sup>371</sup> Private health insurance coverage will vary based on state and organizational limitations.<sup>372</sup>

There are several studies that show individuals who receive MAT are more likely to live an opioid-free life and become a more

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362. SUZANNE MURRIN, OFFICE OF INSPECTOR GEN., STATES’ USE OF GRANT FUNDING FOR A TARGETED RESPONSE TO THE OPIOID CRISIS 1 (2020), <https://oig.hhs.gov/oei/reports/oei-BL-18-00460.pdf> [<https://perma.cc/6S7T-N5BZ>].

363. HHS, *SAMHSA to Maintain Funding Formula for \$1B Opioid Grant Program*, *supra* note 361.

364. 21st Century Cures Act, Pub. L. No. 114-255, § 1003(c), 130 Stat. 1033, 1045 (2016) (codified as amended at 42 U.S.C. § 290ee-3 note).

365. *Id.*

366. *Id.*

367. MURRIN, *supra* note 362, at 1.

368. *Id.* at 4.

369. *Id.* at 1.

370. Vestal, *Long Stigmatized*, *supra* note 148.

371. *Opioid Use Disorder Treatment Services*, MEDICARE.GOV, <https://www.medicare.gov/coverage/opioid-use-disorder-treatment-services> [<https://perma.cc/G6AM-BYW5>].

372. Vestal, *Federal Ban*, *supra* note 20.

productive member of society. Unfortunately, “90 percent of conventional drug treatment facilities do not offer [MAT].”<sup>373</sup> Requiring mobile methadone clinics to provide MAT services will ensure that more individuals are able to receive the treatment they need. Further, the design of the vehicles used to house mobile methadone clinics and the availability of grants will make it more feasible for mobile units to provide MAT directly to clients seeking treatment from the mobile unit.

### CONCLUSION

More than two million Americans suffer from OUD and thousands of opioid users die each year, yet only one in five opioid-dependent individuals receives the treatment they desperately need. Why? The treatment option that has been shown to be the most effective is medication-assisted treatment (“MAT”) with methadone. MAT provides individuals with OUD medication, namely methadone, to treat withdrawal and craving symptoms, as well as various behavioral treatment and psychosocial services to help the individual get their life back on track. However, not every treatment provider offers MAT with methadone and not every opioid-dependent individual has access to this treatment option due to barriers in place in the current system. Any treatment that involves methadone must be provided by a certified clinic, access to which is greatly limited. Waitlists, drive times, and general availability prevent many from having access to MAT with methadone. Additionally, the few OTPs that provide MAT are not required to offer the services on-site or to follow up with referrals. Mobile methadone clinics correct those issues, and the DEA’s NPRM is a necessary first step in instituting new mobile methadone clinics.

The DEA has not issued a license for a mobile unit since 2007. Multiple organizations and individuals have encouraged the agency to lift its moratorium. On February 26, 2020, the DEA responded by issuing an NPRM that would not require mobile units to receive a separate registration. This would effectively lift the ban on mobile units. Multiple studies have shown that comprehensive care is associated with more positive outcomes. As with those receiving treatment from a fixed-site methadone clinic, individuals

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373. MURRIN, *supra* note 362, at 1.

receiving medication from a mobile unit should also receive comprehensive care. Accordingly, in the final regulation the DEA should include a comprehensive care requirement.