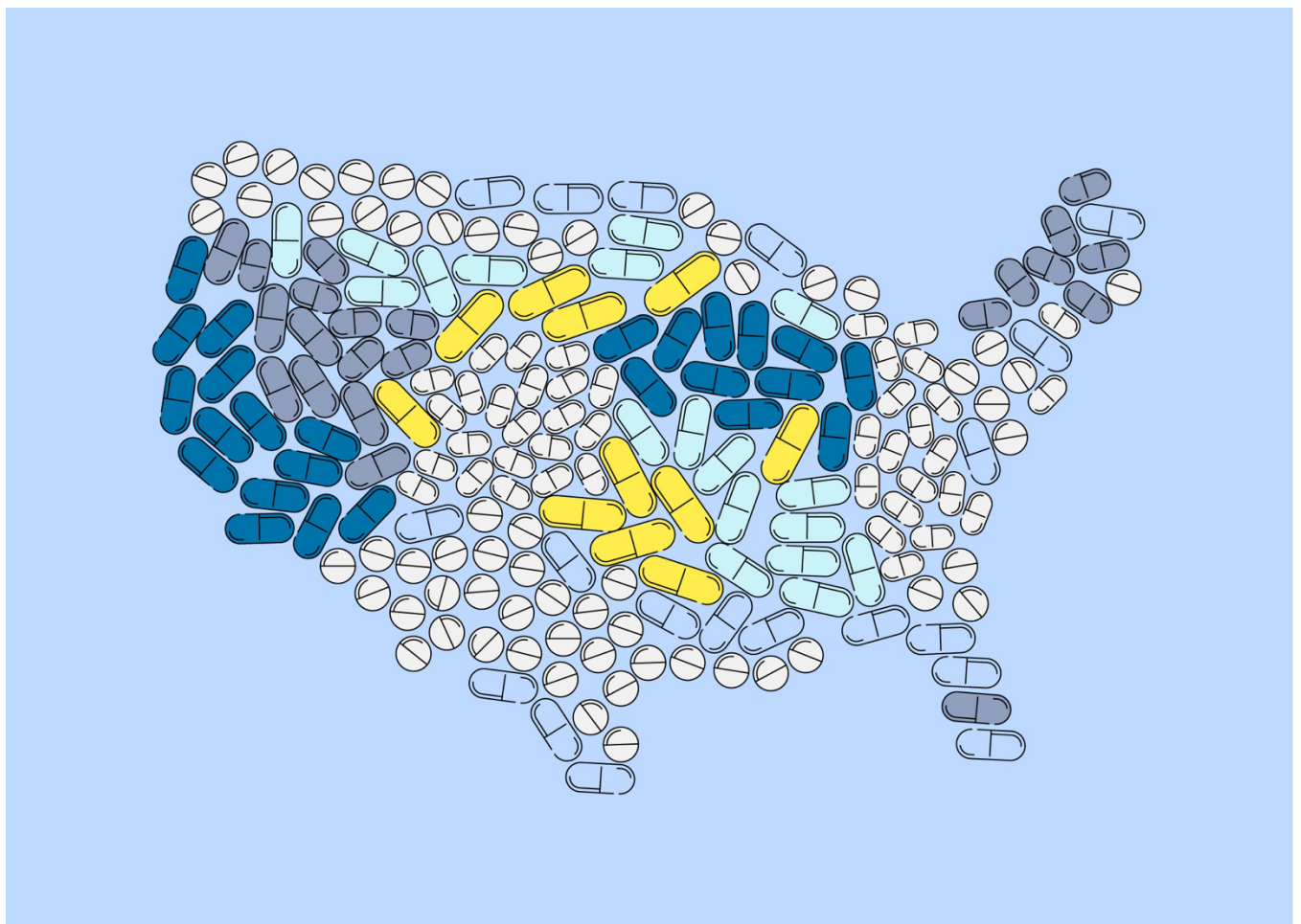


A Vast and Discretionary Regime

Federal Regulation of Methadone as a Treatment for Opioid Use Disorder



Bridget C.E. Dooling & Laura E. Stanley | August 11, 2022

Regulatory
Studies Center

THE GEORGE WASHINGTON UNIVERSITY

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Executive Summary

Methadone is an effective treatment for opioid use disorder, which makes it a key tool to address the opioid crisis. Paradoxically, regulations—particularly at the federal level, which is the focus of this report—greatly limit access to methadone when it is used to treat opioid use disorder. As policymakers consider what they can do to make it easier for people to begin and continue treatment, it is important to understand which changes regulators can make on their own by drawing upon existing statutory authority, and which changes would require an act of Congress.

This report analyzes four groups of regulations that are barriers to treatment for opioid use disorder with methadone. First, methadone-only patient care regulations limit who may provide treatment, who may receive it, how much medicine patients may take home, and more. Second, the prohibition on prescribing methadone—as opposed to dispensing it directly—requires patients to travel to their opioid treatment program to collect their medicine rather than collecting it from a pharmacy. Third, methadone’s categorization as a Schedule II controlled substance limits it further. Fourth, the cumulative effect of various entry barriers and operating costs depresses the available supply of treatment providers.

Working through each group of regulations, this report explains the rules and how they function as barriers. Then, the report finds that in almost every instance, federal regulators have clear statutory authority to amend or remove these regulatory barriers to treatment. It also explains the legal steps that agencies can take to make changes. This report is limited to questions of legal authority, to clarify whether the agencies possess discretion to pursue policy changes. An important next step will be to determine which changes to make, a complex decision that should draw upon the best available evidence. This report clarifies that federal agencies have discretion to lower barriers and improve access to methadone treatment for opioid use disorder. How will they use it?

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I. Introduction

Americans died of drug overdoses in record numbers in the 12-month period leading up to April 2021.¹ There were over 75,000 opioid overdose deaths in the United States, up 26% from the roughly 56,000 deaths in the previous year.² Methadone, which is approved by the Food & Drug Administration (FDA) as a treatment for opioid use disorder, as well as for pain, is one of the best tools available to reduce illicit opioid use and prevent overdose deaths.³ Over 400,000 people receive methadone from opioid treatment programs in the

¹ Press Release, Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 Annually (Nov. 17, 2021), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.

² *Id.*

³ See NAT’L ACADS. OF SCIS., ENG’G, AND MED., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES (2019).

United States, but with estimates of people suffering from opioid use disorder in the millions, the need for treatment is much greater than is currently being met.⁴

Federal regulations limit the way providers can give patients access to methadone.⁵ Methadone, when used for treatment for opioid use disorder, has more stringent restrictions than most other FDA-approved medications, even those that are also controlled substances. For example, other opioids used to treat pain, such as oxycodone and hydrocodone, can be prescribed by practitioners who are registered with the Drug Enforcement Administration (DEA) to dispense controlled substances, such as those in a primary care facility or hospital. By contrast, methadone for opioid use disorder can only be dispensed at “opioid treatment programs,” special facilities—sometimes referred to as “methadone clinics”—subject to different requirements than other types of healthcare facilities. Healthcare practitioners working in these facilities are subject to a host of requirements that shape how they deliver care. Once certified and accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with DEA, opioid treatment programs must follow strict federal requirements on how to treat patients, in addition to any other state or local requirements. The requirements restrain the supply of treatment at a time when the gap between the number of people with opioid use disorder and the number in treatment is large.⁶

Patients face regulatory barriers as well. The rules require patients to go to an opioid treatment program almost every day to receive their dose of methadone. Given how few opioid treatment programs are available to serve patients, rules that require an almost-daily roundtrip can involve traveling long distances that interfere with patients’ lives and their ability to work, be caregivers, and more.⁷ Over 90 percent of opioid treatment programs are in urban areas, which means rural patients must drive long distances to receive their daily dose of methadone.⁸ One study evaluated patient drive times to opioid treatment programs, finding that people living in counties with the highest rates of mortality due to opioid-related overdoses faced longer drive times (37.3 minutes) than those seeking recurring services for different chronic conditions requiring dialysis (15.1 minutes), with the widest gulf for rural

⁴ Noa Krawczyk, Bianca D. Rivera, Victoria Jent, Katherine M. Keyes, Christopher M. Jones & Magdalena Cerdá, *Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019*, INTL J. DRUG POL’Y (in press, available online Aug. 4, 2022).

⁵ This report focuses on federal regulation of methadone as a treatment for opioid use disorder, but states and local governments can and do implement more stringent requirements than the federal government. *See generally* Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1 (2017) (providing concise overviews of the legal and policy landscape for opioids, including methadone). *See also* Nick Werle & Ernesto Zedillo, *We Can’t Go Cold Turkey: Why Suppressing Drug Markets Endangers Society*, 46 J.L. MED. & ETHICS 325, 327-28 (2018) (summarizing the federal approach to regulating methadone).

⁶ Noa Krawczyk, Bianca D. Rivera, Victoria Jent, Katherine M. Keyes, Christopher M. Jones & Magdalena Cerdá, *Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019*, INTL J. DRUG POL’Y (in press, available online Aug. 4, 2022).

⁷ As of August 2022, there were only 1,948 opioid treatment programs in the United States. Substance Abuse and Mental Health Services Administration, “Opioid Treatment Program Directory,” accessed Aug. 7, 2022, <https://dpt2.samhsa.gov/treatment/directory.aspx>.

⁸ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008, 11,012 (Feb. 26, 2020).

patients (49.1 minutes compared to 22.6 minutes, respectively).⁹ Such travel-to-treatment distances make it harder for patients to initiate treatment and follow through on care, especially when they have to make the trip almost daily. Studies have found that the longer patients had to travel to obtain their daily dose of methadone, the less likely they were to complete treatment.¹⁰ One study found that patients who had to travel more than a mile to a treatment program were about half as likely to complete treatment as patients who traveled less than a mile.¹¹ DEA has acknowledged this issue, pointing out that “in rural and other underserved communities, the distance to the nearest [opioid treatment program] or the lack of consistent access to transportation may prevent or substantially impede access to these critical services.”¹²

Together, the requirements discussed in this report form a thicket of particularized regulatory requirements that healthcare practitioners and patients must endure to provide or receive treatment. As the opioid crisis continues to ravage the United States, policies that constrain access to methadone treatment should be examined to ensure that the restrictions adequately balance competing risks and are grounded in the best evidence. President Biden has indicated that he supports “eliminating outdated rules that place unnecessary administrative burdens on providers, discouraging them from prescribing effective treatments for addiction.”¹³ As the federal government considers how to achieve this objective, a related question is whether these various access restrictions are required by statute or whether the federal agencies can change them without needing to go back to Congress.¹⁴

To that end, this report evaluates which regulatory barriers to accessing methadone can be removed or amended by executive branch agencies and which are mandated by statute and therefore require Congress to make a legislative change to remove or otherwise adjust the

⁹ Paul J. Joudrey, E. Jennifer Edelman & Emily A. Wang, *Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States*, 322 JAMA 1310 (Oct. 1, 2019). Another study found that the patients had to drive 15 miles, on average, to get to their opioid treatment program. Andrew Rosenblum, Charles Cleland, Chunki Fong, Deborah Kayman, Barbara Tempalski & Mark Parrino, *Distance Traveled and Cross-State Commuting to Opioid Treatment Programs in the United States*, 2011 J. ENVTL. PUB. HEALTH 1 (2011).

¹⁰ Kyle Beardsley, Eric D. Wish, Dawn Bonanno Fitzelle, Kevin O’Grady & Amelia M. Arria, *Distance traveled to outpatient drug treatment and client retention*, 25 J. SUBSTANCE ABUSE TREATMENT 279 (2003); Susan K. Schmitt, Ciaran S. Phibbs, and John D. Piette, *The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment*, 28 ADDICTIVE BEHAV. 1183 (2003); Solmaz Amiri, Robert Lutz, M. Eugenia Sodas, Michael McDonnell, John Roll & Ofer Amram, *Increased distance was associated with lower daily attendance to an opioid treatment program in Spokane County Washington*, 93 J. SUBSTANCE ABUSE TREATMENT 26 (2018).

¹¹ Beardsley et al., *supra* note 10, at 283.

¹² Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,009 (Feb. 26, 2020).

¹³ White House Fact Sheet, Addressing Addiction and the Overdose Epidemic, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-addressing-addiction-and-the-overdose-epidemic/> (Mar. 1, 2022).

¹⁴ Even when statutes provide adequate authority for agencies to act, there can be reasons to return to Congress for more specific authority and direction. *See, e.g., West Virginia v. Environmental Protection Agency*, 597 U.S. ____ (2022) (finding that certain kinds of agency action require a “dear delegation” from Congress). In this report, we limit ourselves to the question of whether the existing statutes are sufficient for the agencies to make changes, but the agencies discussed below could certainly seek additional, specific statutory authority for the kinds of regulatory changes contemplated below.

barrier. This report focuses on regulations promulgated by SAMHSA and DEA. Although there are other regulatory regimes that intersect with methadone treatment,¹⁵ the SAMHSA and DEA regulations are the core.

The report identifies four groups of SAMHSA and DEA regulations that are designed or otherwise likely to limit access to methadone treatment. First, it assesses SAMHSA's patient care regulations for opioid treatment programs. Second, it considers the DEA regulations that effectively require patients to collect their medication on-site at their opioid treatment program. These regulations prohibit practitioners from prescribing methadone and instead require them to administer methadone directly to patients. Third, it assesses the DEA regulations that designate methadone as a Schedule II controlled substance. Finally, it considers the cumulative effect of other entry barriers and operating costs that apply to opioid treatment programs.

For each of these areas of regulation that impact methadone treatment, the report describes the regulations, explains their relationship to patient access, and provides an assessment of whether the agencies have the legal authority to adjust or remove these barriers without additional authorization from Congress. The report concludes that SAMHSA and DEA have significant discretion to remove or alter these regulatory barriers to methadone treatment, many of which have been in place since the 1970s. Ultimately, this demonstrates the wide latitude that federal agencies have to follow through on President Biden's direction and improve access to treatment for opioid use disorder.

II. Patient Care Regulations

SAMHSA oversees extensive regulations that govern patient care at opioid treatment programs. To obtain a registration from DEA to operate as a narcotic treatment program, opioid treatment programs must obtain certification from SAMHSA. As part of that certification, SAMHSA requires applicants to follow its patient care regulations.

¹⁵ For example, state and local restrictions can also create conditions that make it difficult to establish and run opioid treatment programs. *See, e.g.*, Frances McGaffey, State regulation of opioid treatment programs: Key findings, Presentation at National Academies of Sciences, Engineering, and Medicine, Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws - A Workshop (Mar. 3, 2022), <https://www.nationalacademies.org/event/03-03-2022/docs/D92D0EC4AFB42F571B6D825308C6FF0826CCC4C360F4> (describing state and local barriers such as moratoria and zoning restrictions). In addition, failure to align reimbursement policies can put treatment out of reach. *See, e.g.*, Matthew B. Lawrence, Federal Administrative Pathways to Promote Access to Quality Methadone Treatment 4-7, Commissioned Paper, National Academies of Sciences, Engineering, and Medicine, Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws - A Workshop, <https://www.nationalacademies.org/event/03-03-2022/docs/D978F464CB989FCBAB7E51F33345AB6F7FBEC4DC333D> (Feb. 21, 2022) (discussing options to better align payment systems with access to methadone). Both federal and state laws place extra requirements on patient confidentiality associated with their treatment for substance use disorder. Scott Stiefel, *The Chatbot Will See You Now: Protecting Mental Health Confidentiality in Software Applications*, 20 COLUM. SCI. & TECH. L. REV. 333, 361-67 (2019) (describing the federal and state laws regarding patient confidentiality for treatment of alcohol and substance use disorder). SAMHSA's Part 2 confidentiality regulations go beyond the HIPAA Privacy Rule to apply special protections for records that identify patients with substance use disorder. 42 C.F.R. Part 2.

A. SAMHSA Patient Care Regulations

SAMHSA promulgates the patient care regulations that opioid treatment programs must follow at 42 C.F.R. § 8.12. These include restrictions on the type of patient that opioid treatment programs may admit, the ancillary services that these programs must provide, limits on the number of doses a patient can take home, and restrictions on providing interim treatment.

Admission Criteria. SAMHSA restricts who opioid treatment programs may admit for maintenance treatment, defined as treatment at a stable dose for more than 21 days.¹⁶ A patient must have a one-year history of “addiction” to an opioid to be admitted to a program.¹⁷ Practitioners must use medical criteria to assess if a patient is “addicted,” such as the criteria in the Diagnostic and Statistical Manual for Mental Disorders.¹⁸ A program physician can waive this 1-year requirement for patients who were recently released from penal institutions, who are pregnant, or who were previous patients discharged within the last 2 years.¹⁹ Patients under the age of 18 must document that they made two unsuccessful attempts at short-term detoxification treatment or drug-free treatment in the previous 12-month period and obtain consent from a parent or legal guardian.²⁰ Patients must receive a physical evaluation before admission, and a full medical examination, including blood tests, must be completed within 14 days of admission.²¹

Ancillary Services. Although SAMHSA’s regulations imply that opioid treatment programs must also provide a host of services beyond treatment with medication, which we refer to here as ancillary services, the regulations are somewhat ambiguous regarding which services the opioid treatment programs must actually provide. The regulations first state that opioid treatment programs must provide patients with adequate counseling, vocational, and educational services.²² Programs can provide these services at the facility, or they can enter into an agreement with an outside provider to provide the services.²³ Each patient must have a treatment plan that includes the patient’s short-term goals and “education, vocational rehabilitation, and employment” as well as “the medical, psychosocial, economic, legal, or other supportive services that a patient needs.”²⁴ Later in the regulations, SAMHSA requires that programs provide each patient with substance abuse counseling and HIV transmission counseling.²⁵

¹⁶ 42 C.F.R. § 8.2.

¹⁷ 42 C.F.R. § 8.12(e)(1).

¹⁸ *Id.*

¹⁹ 42 C.F.R. § 8.12(e)(3).

²⁰ 42 C.F.R. § 8.12(e)(2).

²¹ 42 C.F.R. § 8.12(f)(2).

²² 42 C.F.R. § 8.12(f)(1).

²³ *Id.*

²⁴ 42 C.F.R. § 8.12(f)(4).

²⁵ 42 C.F.R. § 8.12(f)(5).

However, the regulations also state that programs only need to provide vocational and educational services for patients who request them or have a specific need for those services.²⁶ This provision appears to limit opioid treatment programs' requirement to provide these additional services. SAMHSA's guidance for opioid treatment programs lends support to this conclusion, as it includes a detailed discussion of the substance abuse and HIV counseling that opioid treatment programs must provide, but it excludes any discussion of the other types of services.²⁷

Toxicological Screening. Opioid treatment programs must also test patients for “drug abuse” by conducting eight or more random drug tests per year, per patient in maintenance treatment.²⁸ Patients entering detoxification treatment must receive an initial drug test, and if they move to long-term detoxification treatment, they must receive a monthly drug test.²⁹

Mode of Administration. Opioid treatment programs may only administer or dispense methadone in oral form, and they may only provide patients with take-home doses of methadone under a narrow set of circumstances.³⁰ The regulations allow for a single take-home dose for a day when the opioid treatment program will be closed, such as Sundays, as well as for state and federal holidays.³¹ Practitioners at opioid treatment programs must take into consideration eight criteria when determining if a patient is “responsible” enough to have a take-home supply of medication:

- i. Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
- ii. Regularity of clinic attendance;
- iii. Absence of serious behavioral problems at the clinic;
- iv. Absence of known recent criminal activity, e.g., drug dealing;
- v. Stability of the patient's home environment and social relationships;
- vi. Length of time in comprehensive maintenance treatment;
- vii. Assurance that take-home medication can be safely stored within the patient's home; and

²⁶ *Id.*

²⁷ SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS (Jan. 2015) <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>. This is also one area where state and local requirements sometimes add specificity underneath the federal regulatory requirements. *See* Prescription Drug Abuse Policy System, Medication-Assisted Treatment with Methadone (MAT) Laws, <https://pdaps.org/datasets/medication-assisted-treatment-with-methadone-mat-laws>.

²⁸ 42 C.F.R. § 8.12(f)(6).

²⁹ *Id.*

³⁰ 42 C.F.R. §§ 8.12(h)(3), 8.12(i).

³¹ 42 C.F.R. § 8.12(i)(1). SAMHSA requires opioid treatment programs to request an exception before they can provide unsupervised doses for other days, such as days surrounding holidays. *See, e.g.,* Dear Colleague Letter from Yngvild K. Olsen, Federal Holiday Guidance for Opioid Treatment Programs (Dec 14, 2021), <https://www.samhsa.gov/sites/default/files/colleague-letter-holiday-guidance-2021.pdf>.

- viii. Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risk of diversion.³²

If a practitioner determines that a patient is sufficiently responsible to receive a take-home supply of methadone using those eight criteria, there are time-in-treatment requirements that a patient must meet before they can take home additional doses of methadone beyond those provided for days when the clinic is closed. During the first 90 days of treatment, patients may take home one additional dose per week of methadone.³³ In the second 90 days of treatment, a patient may take home two additional doses per week.³⁴ After a year of continuous treatment, a patient may take home a 2-week supply.³⁵ After 2 years of continuous treatment, a patient may take home a one-month supply, which is the maximum amount of methadone a patient could take home.³⁶

Limits on Interim Maintenance Treatment. Finally, the regulations allow for interim maintenance treatment when an individual is eligible for admission to an opioid treatment program but cannot be placed in one in a reasonable geographic area within 14 days of seeking admission.³⁷ These patients can only be treated for 120 days, and the opioid treatment program must notify the relevant state health officer when a patient begins or leaves interim maintenance treatment.³⁸ The other standards are also adjusted for interim maintenance treatment. For example, take-home dosing is not allowed, but programs do not need to assign a counselor to the patient or provide other treatment services.³⁹

B. Impact on Access to Treatment

Many of SAMHSA's patient care regulations clearly impede patient access to methadone, while others deserve additional study.

Admission Criteria. The requirement that patients be addicted to an opioid for at least one year prior to admission creates a time delay to accessing treatment. This is not aligned with the American Psychiatric Association's diagnostic guidelines for opioid use disorder, which do not refer to a specific, minimum amount of time required before a patient can be diagnosed

³² 42 C.F.R. § 8.12(i)(2).

³³ 42 C.F.R. § 8.12(i)(3).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* For other controlled substances on Schedule II, refills are prohibited, but providers may issue multiple prescriptions that patients would fill over time for a maximum of 90 days of supply. 21 C.F.R. § 1306.12. As discussed in Section III, methadone, when used to treat opioid use disorder, may not be prescribed.

³⁷ 42 C.F.R. § 8.12(j). SAMHSA does not describe what is considered a "reasonable geographic area" in its regulations. In its guidance for opioid treatment programs, it describes a "reasonable geographic area" as 100 miles when describing requirements that are unrelated to interim treatment. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS at 48 (Jan. 2015), <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>.

³⁸ 42 C.F.R. § 8.12(j).

³⁹ *Id.*

with the condition.⁴⁰ SAMHSA regulations anticipate that some patient populations might not be able to show one year of “addiction” prior to needing treatment. The admission criteria can be waived for special populations, including patients recently released from penal institutions, pregnant patients, and prior patients.⁴¹ However, SAMHSA does not provide opioid treatment programs with the discretion to admit other types of patients to maintenance treatment who may benefit from the treatment. Given that the diagnostic criteria do not specifically reference one year, some people who might be diagnosed with opioid use disorder would nevertheless be ineligible for methadone treatment under SAMHSA’s regulations.

Ancillary Services. The relationship between ancillary services and patient access is less clear. On the one hand, increasing the number of services that opioid treatment programs must provide in addition to medication-based treatment increases the cost of running an opioid treatment program.⁴² On the other hand, ancillary services may help improve patient outcomes.⁴³ More research is needed to determine whether a requirement to provide ancillary services—as a group of services, or with regard to each type of service—is appropriately conceived of as a barrier to treatment.⁴⁴ We include ancillary services here as a potential barrier for purposes of completeness, and because it may be a fruitful area to explore in the future.

Toxicological Screening. Drug testing requirements are associated with direct costs, too, and get cited as one of the reasons why more practitioners do not treat patients with opioid use disorder. In one study, a research subject commented: “I think I would have to hire a nurse practitioner [who] would do nothing but . . . get urine screenings.”⁴⁵ Cost, and associated

⁴⁰ Centers for Disease Control, Assessing and Addressing Opioid Use Disorder, <https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html> (last accessed May 2022) (noting the criteria in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)).

⁴¹ 42 C.F.R. § 8.12(e)(3).

⁴² See Section V for discussion of how regulatory operating costs can reduce the supply of providers and therefore constrain access.

⁴³ E.g., Laura J. Dunlap, Gary A. Zarkin, Stephen Orme, Angelica Meinhofer, Sharon M. Kelly, Kevin E. O’Grady, Jan Gryczynski, Shannon G. Mitchell & Robert P. Schwartz, *Re-engineering methadone—Cost-effectiveness analysis of a patient-centered approach to methadone treatment*, 94 J. SUBSTANCE ABUSE TREATMENT 81 (2018) (evaluating, *inter alia*, different methods of delivering counseling services).

⁴⁴ See, e.g., Karen Dugosh, Amanda Abraham, Brittany Seymour, Keli McLoyd, Mady Chalk & David Festinger, *A Systematic Review on the Use of Psychosocial Interventions in Conjunction With Medications for the Treatment of Opioid Addiction*, 10 J. ADDICTION MED. 93 (2016) (surveying the available literature); Laura Amato, Silvia Minozzi, Marina Davoli & Simona Vecchi, *Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence*, 10 COCHRANE DATABASE OF SYSTEMATIC REV. Article No. CD004147 (2011) (finding that “adding any psychosocial support to maintenance treatments do not add additional benefits”); Robert P. Schwartz, Sharon M. Kelly, Kevin E. O’Grady, Devang Gandhi & Jerome H. Jaffe, *Randomized Trial of Standard Methadone Treatment Compared to Initiating Methadone without Counseling: 12-month Findings*, 107 ADDICTION 943 (2011) (concluding that “limited availability of scheduled drug counseling services should not be a barrier to providing supervised methadone to those dependent on heroin—at least for the first 4 months”).

⁴⁵ Suzanne McMurphy, Judy Shea, Julia Switzer & Barbara Turner, *Clinic-based Treatment for Opioid Dependence: A Qualitative Inquiry*, 30 AM. J. HEALTH BEHAV. 544, 547 (2006). It does not appear to be the case that opioid treatment programs must employ nurse practitioners for this task. The comment does, however, suggest that confusion and risk-aversion about regulatory requirements can serve as a barrier in and of themselves.

billing practices and incentives, have been described as “[p]erhaps the most under-addressed problem with urine testing.”⁴⁶ Evidence is lacking on whether this view is widely held. In addition to the financial costs, however, patients and advocates point out that some providers require a long history of negative drug tests before allowing take-home doses, and that a positive drug test can be used as a rationale to limit access to take-home doses.⁴⁷ Importantly, the take-home criteria listed above do not list a positive toxicology test as a reason to deny a take-home supply. Instead, the criteria refer to the “[a]bsence of recent abuse of drugs (opioid or nonnarcotic), including alcohol.”⁴⁸ Different opioid treatment programs may have different understandings of whether a positive test counts as “abuse” for purposes of determining whether a patient may receive a take-home supply. The ambiguity in the regulations can contribute, therefore, to limited access from the provider side. From the patient side, the indignity and inconvenience of ongoing urine testing may contribute to less adherence to treatment over time.⁴⁹

Mode of Administration. Patients who do not meet the take-home criteria or who have not been in treatment long enough to satisfy the time-in-treatment requirements must make almost daily visits to an opioid treatment program.⁵⁰ This restriction, likened to “liquid handcuffs,” creates a barrier to accessing treatment, and it has been studied extensively.⁵¹ Practitioners and researchers have documented in many studies that limiting take-home medication impedes patient access to methadone.⁵² In one study that relied on interviews with 85 patients, the patients specifically pointed to the take-home restrictions as one of the main barriers to treatment.⁵³ Another study found that the earlier patients are allowed to take home additional doses of methadone, the higher the likelihood that patients will stay in treatment.⁵⁴ SAMHSA has agreed that unsupervised use of methadone is critical for patient retention. In its 2015 guidance for opioid treatment programs, the agency explained that

⁴⁶ Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1, 67-68 (2016).

⁴⁷ Urban Survivor’s Union, *Methadone Manifesto*, https://sway.office.com/UjvQx4ZNnXAYxhe7?ref=Link&mc_cid=9754583648&mc_cid=51fa67f051 (accessed May 2022).

⁴⁸ 42 C.F.R. § 8.12(i)(2) (emphasis added).

⁴⁹ See Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1, 65 (2016) (quoting a patient on the “insulting” nature on ongoing testing after years of negative results). See also Utsha G. Khatri & Shoshana V. Aronowitz, *Considering the harms of our habits: The reflexive urine drug screen in opioid use disorder*, 123 J. SUBSTANCE ABUSE TREATMENT Article No. 108258 (2021) (noting erosion of trust between provider and patient related to drug testing, among other negative consequences).

⁵⁰ We note but set aside the question of whether the requirement for methadone to be administered orally is an access barrier. In theory, other forms of administration that are easier to administer could facilitate take-home doses.

⁵¹ David Frank, Pedro Mateu-Gelabert, David C. Perlman, Suzan M. Walters, Laura Curran & Honoria Guarino, *‘It’s like ‘liquid handcuffs’: The effects of take-home dosing policies on Methadone Maintenance Treatment (MMT) patients’ lives*, 18.1 HARM REDUCTION J. 1, 3 (2021).

⁵² Daryle E.A. Deering, Janie Sheridan, J. Douglas Sellman, Simon J. Adamson, Sheridan Pooley, Rhonda Robertson & Charles Henderson, *Consumer and Treatment Provider Perspectives on Reducing Barriers to Opioid Substitution Treatment and Improving Treatment Attractiveness*, 36 ADDICTIVE BEHAVIORS 636 (2011); Georgios Kourounis, Brian David Wensley Richards, Evdokia Kyprianou, Eva Symenidou, Minerva-Melpomeni Malliori & Lampros Samartzis, *Opioid Substitution Therapy: Lowering the Treatment Thresholds*, 161 DRUG & ALCOHOL DEPENDENCE 1 (2016).

⁵³ Deering et al., *supra* note 51, at 638

⁵⁴ Kourounis et al., *supra* note 51, at 5.

“policies that do not permit take-homes for any patients are unacceptable because these policies preclude individualized patient care. Take-home medication often is a critical issue for patients who are deciding whether to enter into and remain in treatment.”⁵⁵

At the beginning of the COVID-19 public health emergency, SAMHSA issued a more flexible policy for take-home medication to support patient access during the pandemic.⁵⁶ After learning that the take-home flexibilities increased patient engagement and led to few instances of diversion, SAMHSA issued a guidance document that pre-emptively extends the take-home flexibilities beyond the expiration of the declared COVID-19 public health emergency.⁵⁷ Additionally, SAMHSA announced that a rule is forthcoming that will make take-home flexibilities part of its regulations along with a definition of “stable” and “less stable.”⁵⁸ These policy moves demonstrate that SAMHSA views take-home policy as relevant to patient access and continuity of care.

Limits on Interim Maintenance Treatment. The interim treatment requirements seem to be intended to allow a patient to begin treatment with an opioid treatment program even if the opioid treatment program cannot accommodate them for long. Understanding whether these requirements function as an on-ramp to treatment, or whether they ultimately discourage treatment, is a topic that merits additional study. We include these requirements here because it is at least plausible that drawing the regulatory lines differently on the interim treatment requirements, such as adjusting the number of days that a patient can be considered “interim” or streamlining the associated paperwork requirements, could have an influence on access.

C. Removing or Amending Patient Care Regulations

This section finds that SAMHSA has ample statutory authority to remove or amend its patient care regulations. First, SAMHSA could remove or amend any of the patient care regulations through the rulemaking process. Second, SAMHSA could remove or amend its patient care regulations through guidance.

⁵⁵ SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS (Jan. 2015), <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>.

⁵⁶ SAMHSA released a guidance document that allows “stable” patients to take home a 28-day supply of medication and “less stable” patients to take home 14-day supply of medication if their state requests a blanket exception from the take-home regulations. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., OPIOID TREATMENT PROGRAM GUIDANCE (Mar. 19, 2020), <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. “Stable” and “less stable” were not defined in the guidance. *Id.* It also did not refer to the existing take-home criteria in the regulations. *Id.* See also Bridget C.E. Dooling & Laura Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Authorities and Methods*, 106 MINN. L. REV. HEADNOTES 74 (2021) (discussing this guidance).

⁵⁷ SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., METHADONE TAKE-HOME FLEXIBILITIES EXTENSION GUIDANCE (Nov. 18, 2021), <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance>.

⁵⁸ OFFICE OF INFO. & REGULATORY AFFAIRS, FALL 2021 REGULATORY PLAN AND THE UNIFIED AGENDA OF FEDERAL REGULATORY AND DEREGULATORY ACTIONS (Dec. 2021), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0930-AA39>.

i. SAMHSA Removes/Amends Patient Care Regulations through Rulemaking

On May 14, 1974, President Richard Nixon signed the Narcotic Addict Treatment Act (NATA), which amended the Controlled Substances Act (CSA) and directed the Secretary of Health & Human Services (HHS) to determine which practitioners were qualified to provide treatment for opioid use disorder.⁵⁹ The statute says:

The Attorney General shall register a [practitioner] to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both) . . . if the applicant is a practitioner who is determined by the Secretary [of HHS] to be qualified (*under standards established by the Secretary*) to engage in the treatment with respect to which registration is sought.⁶⁰

This language indirectly gives HHS authority to determine the content and extent of the standards, including its patient care requirements at 42 C.F.R. § 8.12.⁶¹ The statute merely states that HHS must establish standards, but does not dictate what those standards must contain. This leaves the Secretary with a wide range of discretion to structure the standards. While FDA and the National Institute on Drug Abuse (NIDA) wrote the original regulations to implement NATA, the Secretary of HHS has since given SAMHSA responsibility for administering and overseeing this program.⁶²

As a result, and for example, SAMHSA—through HHS—has the statutory authority to remove or alter the requirement that a patient must have a one-year history of “addiction” to an opioid in order to be admitted to a program. SAMHSA also has the statutory authority to remove or alter the requirements to provide a host of ancillary services. For example, rather than requiring opioid treatment programs to provide each patient with counseling, SAMHSA could eliminate that provision or require opioid treatment programs to provide counseling upon request. SAMHSA also has flexibility to remove or amend the eight take-home criteria from its regulations and allow the healthcare providers working in opioid treatment programs to have more discretion to determine if a patient in their care should have a take-home supply of methadone.

⁵⁹ See Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g) (2018). This statute was enacted shortly after the more general Comprehensive Drug Abuse Prevention and Control Act of 1970, which established that the Secretary of Health, Education, and Welfare (the precursor to the Secretary of Health & Human Services)—in consultation with the Attorney General and “national organizations representative of persons with knowledge about and experience in the treatment of narcotic addicts”—“shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts.” Comprehensive Drug Abuse Prevention and Control Act of 1970 § 4, Pub. L. No. 91-513, 84 Stat. 1236 (codified at 42 U.S.C. § 257a (2018)).

⁶⁰ Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g)(1) (2018) (emphasis added).

⁶¹ SAMHSA cited both 42 U.S.C. 823 and 42 U.S.C. 257a in its 2001 final rule transferring the regulations from FDA to SAMHSA. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076, 4090 (Jan. 17, 2001).

⁶² Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076 (Jan. 17, 2001). For more discussion of this history, see Section V(c)(ii).

SAMHSA's regulations that provide for interim maintenance treatment derive their statutory authority from the Public Health Service Act (PHSA) rather than the CSA. The PHSA directs HHS to allow patients to begin interim treatment if, "as a result of the limited capacity of programs, [they] will not gain such admission until 14 or more days after seeking admission to the programs."⁶³ It also authorizes HHS "to provide only minimum ancillary services" to these patients instead of the full set of services that are normally required.⁶⁴ This language indirectly establishes SAMHSA's authority to set the conditions for treatment programs to obtain authorization for interim treatment.

If SAMHSA amended its patient care standards through rulemaking, it would need to build an administrative record to support the changes, including evidence to support its rationale. The agency would also need to consult with the Attorney General before issuing new rules.⁶⁵

ii. SAMHSA Waives Patient Care Regulations

In its regulations, SAMHSA created a pathway to provide exemptions from its regulations upon request. The regulation states that "[a]n [opioid treatment program] may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the [opioid treatment program] regulatory requirements. . . . SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate."⁶⁶ The regulations allow opioid treatment programs to request exemptions from the certification requirements in 42 C.F.R. § 8.11 and from the patient care regulations in 42 C.F.R. § 8.12.⁶⁷

This regulatory authority gives SAMHSA the authority to consider exemption requests from opioid treatment programs on a case-by-case basis. SAMHSA used this regulatory authority to permit states to request exemptions related to the COVID-19 public health emergency.⁶⁸ SAMHSA could adopt this same approach to remove or relax the patient care regulations by issuing a guidance document that invites exemption requests from states. Although these policy changes would be less permanent than removing or relaxing the patient care

⁶³ 42 U.S.C. § 300y-11 (2018).

⁶⁴ *Id.*

⁶⁵ 21 U.S.C. § 823(g) (2018). The Attorney General has delegated Controlled Substances Act functions to the DEA. Redefinition of Functions; Delegation of Authority to Drug Enforcement Administration Official, 75 Fed. Reg. 4982 (Feb. 1, 2010). To demonstrate compliance with the consultation requirement, SAMHSA could document in its administrative record that it consulted with DEA.

⁶⁶ 42 C.F.R. § 8.11(h).

⁶⁷ *Id.*

⁶⁸ SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., OPIOID TREATMENT PROGRAM (OTP) GUIDANCE (Mar. 19, 2020), <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>; SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., FAQs: PROVISION OF METHADONE AND BUPRENORPHINE FOR THE TREATMENT OF OPIOID USE DISORDER IN THE COVID-19 EMERGENCY (Apr. 21, 2020). *See also* Bridget C.E. Dooling & Laura Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Authorities and Methods*, 106 MINN. L. REV. HEADNOTES 74 (2021) (discussing this guidance and its underlying authority).

regulations through rulemaking, SAMHSA could issue a guidance document relatively quickly.⁶⁹

Table 1. SAMHSA Patient Care Regulations (42 C.F.R. § 8.12)

Requirements	Access Issues	Options
Admission Criteria	Constrains who may be admitted to opioid treatment program	SAMHSA removes or amends patient care regulations through regulation or guidance
Ancillary Services	Unclear – provider costs; negative patient experience	
Toxicological Testing	Provider costs; negative patient experience	
Mode of Administration	Limits to take-home supplies	
Interim Maintenance Treatment	Unclear – may discourage treatment	

III. Prohibition on Prescribing Methadone

Federal regulations prohibit prescribing methadone to treat opioid use disorder outside of opioid treatment programs.⁷⁰ While both SAMHSA and DEA regulations apply, this section focuses on DEA regulations, which prohibit opioid treatment programs from prescribing methadone for pickup at a pharmacy or other facility.⁷¹ Practitioners at opioid treatment programs are only permitted to administer methadone directly to patients.⁷² This section describes these regulations and their impact on access to methadone treatment and assesses

⁶⁹ For the full flexibility of any regulatory changes to be felt on the ground, it is likely that states would need to embrace the changes. Also, policy changes that begin as guidance documents can grow into more permanent policies through regulation.

⁷⁰ NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, METHADONE TREATMENT FOR OPIOID USE DISORDER: IMPROVING ACCESS THROUGH REGULATORY AND LEGAL CHANGE: PROCEEDINGS OF A WORKSHOP 49 (2022) (summarizing remarks of Dr. Robert Brooner). To study how pharmacies could be part of the delivery system for methadone, researchers first needed to obtain exceptions from DEA and a waiver from SAMHSA. Robert K. Brooner, Kenneth B. Stoller, Punam Patel, Li-Tzy Wu, Haijuan Yan & Michael Kidorf, *Opioid treatment program prescribing of methadone with community pharmacy dispensing: Pilot study of feasibility and acceptability*, 3 DRUG & ALCOHOL DEPENDENCY REP. Article No. 100067, p.2 (2022) (“DEA exceptions (Title 21 CFR 1306 and 1307) were required for each of the three prescribers and the two pharmacy locations, one in Baltimore MD and the other in Rosedale MD, along with a waiver of federal regulation (42 CFR 8.11 [&] 8.12) from SAMHSA, all were granted for a 2-year period and required extensions to complete the evaluation.”).

⁷¹ 21 C.F.R. § 1306.07(a). As discussed in Section II, SAMHSA has broad authority to amend its regulations, including making changes to its regulations to include a “pharmacy track” within its definitions of opioid treatment program. This could, for example, exclude a number of the patient care requirements such as counseling, etc.

⁷² 21 C.F.R. § 1306.07(a).

DEA's legal authority to relax this restriction, ultimately finding that DEA is not obliged by statute to prohibit prescription methadone.

A. DEA Prohibition on Prescribing Methadone

Although narcotic treatment programs may administer methadone directly to patients, they are not permitted to prescribe methadone for pharmacy pick up. DEA regulations state that practitioners in narcotic treatment programs “may administer or dispense directly (but not prescribe)” methadone and other scheduled narcotic drugs.⁷³ DEA defines a “prescription” as an “order for medication which is dispensed to . . . an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user.”⁷⁴ This limits opioid treatment programs to dispensing methadone on site rather than prescribing methadone for pickup at a pharmacy.

This goes well beyond the restrictions for other controlled substances, which can be prescribed by individual practitioners for pickup at pharmacies registered with DEA to dispense controlled substances.⁷⁵

B. Impact on Access to Treatment

This regulatory approach limits patient access to methadone because it requires patients to travel to their opioid treatment programs almost daily. This geographic and logistical constraint is often cited as a reason why more people are not in treatment. Patients and advocates have called for federal policy to support pharmacy access to methadone.⁷⁶ In addition to limiting the way patients may receive their medication, the regulation also may depress the supply of providers who treat this patient population. To wit, the inability of providers to prescribe the drug, and the related requirement to have on-site dispensing, has been cited by some providers as a reason why they do not treat this patient population.⁷⁷

Providing an option for pharmacy access methadone would take advantage of the relative abundance of pharmacies compared to the limited number of opioid treatment programs.

⁷³ *Id.* DEA refers to the programs as “narcotic treatment programs” while SAMHSA refers to them as “opioid treatment programs.” This report uses the term “opioid treatment program” unless specifically referring to DEA requirements.

⁷⁴ 21 C.F.R. § 1300.01.

⁷⁵ See e.g., 21 U.S.C. § 1301.13 (2018); *infra* Section IV.

⁷⁶ Caty Simon, Louise Vincent, Abby Coulter, Zach Salazar, Nick Voyles, Lindsay Roberts, David Frank & Sarah Brothers, *The Methadone Manifesto: Treatment Experiences and Policy Recommendations From Methadone Patient Activists*, 112 AM. J. PUB. HEALTH S.117 (Apr. 2022).

⁷⁷ Suzanne McMurphy, Judy Shea, Julia Switzer & Barbara Turner, *Clinic-based Treatment for Opioid Dependence: A Qualitative Inquiry*, 30 AM. J. HEALTH BEHAVIOR 544, 547-48 (2006). The idea of pharmacy prescribing does not enjoy unanimous support. The association that represents opioid treatment programs, for example, does not support a general switch to prescribing, but has acknowledged that prescribing may be appropriate for “stable” patients who retain a relationship with their opioid treatment program. American Association for the Treatment of Opioid Dependence, Regulatory Reform and Policy Initiatives for OTPs in a Post Covid-19 World (Mar. 2, 2022), <http://www.aatod.org/wp-content/uploads/2022/03/Regulatory-Reform-and-Policy-Initiatives-for-OTPs-in-a-Post-COVID-19-World-09302021.pdf>. The larger question of whether methadone treatment for opioid use disorder should be limited to those providers working with opioid treatment programs is beyond the scope of this report.

Combined with a more permissive approach to take-home supplies, leveraging pharmacy access to methadone would potentially alleviate a major hurdle to treatment access.

C. Removing Prescribing Prohibition

This section finds that DEA could issue a rule to remove the restriction on prescribing methadone without additional authorization from Congress.

NATA does not expressly prohibit providers from prescribing methadone or prohibit pharmacies in filling prescriptions. Instead, NATA states that “practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose.”⁷⁸ This effectively limits who may dispense methadone for treatment of opioid use disorder to the set of providers with a separate registration for this purpose. In the statute, “dispense” means “to deliver a controlled substance to an ultimate user . . . by . . . a practitioner, including the prescribing and administering of a controlled substance.”⁷⁹ The definition of “practitioner,” used to limit who may “deliver” a controlled substance to a user, includes pharmacies.⁸⁰ Yet, DEA regulations state that practitioners may only “administer or dispense *directly* (but not prescribe),” meaning that methadone must be given to patients physically located in the opioid treatment program.⁸¹ This restricts practitioners from prescribing methadone for patients to receive at a pharmacy.

The interpretive question is how to understand the “including the prescribing and administering” language in the statute’s definition of “dispense.” This language could be understood to mean that either (1) prescribing or administering is dispensing, or that (2) “dispense” means the combined act of prescribing and administering. From a textual perspective, the first interpretation takes the words after “including” to be a list of two options, while the second takes them to be an expression of the only permissible option. The second interpretation is therefore flawed, because it presumes that “prescribing” only means ordering medication for administration physically inside an opioid treatment program. This is a problematically narrow interpretation of “prescribing,” particularly because the legislative history uses “prescribing” to mean prescriptions that are filled at a pharmacy.⁸² In the absence of a very strong reason to infer that legislators made a mistake, common methods of statutory interpretation presume that legislative drafters chose their language with care and intention. Reading “prescribing” to essentially mean “ordering for internal administration” may therefore be an interpretive error of the statutory text.

⁷⁸ 21 U.S.C. § 823(g) (2018).

⁷⁹ 21 U.S.C. § 802(10) (2018). NATA does not define the term “prescribing,” but it defines the term “administer” as the “direct application of a controlled substance to the body of a patient . . . by a practitioner . . . or the patient at the direction and in the presence of the practitioner.” *Id.*

⁸⁰ 21 U.S.C. § 802(21) (2018).

⁸¹ 21 C.F.R. § 1306.07(a) (emphasis added).

⁸² H. REP. NO. 93-884, at 3 (1974) (noting that earlier FDA regulations allowed for methadone to be prescribed).

In its 1974 proposed rule, however, DEA seems to have adopted this second interpretation, promulgating a rule that practitioners can “administer or dispense directly (but not prescribe)” narcotic drugs.⁸³ Commenters on DEA’s 1974 proposed rule argued that this interpretation would “cause the demise of ‘out-patient’ detoxification programs.”⁸⁴ DEA noted in response that the prescription limit was not designed to stop practitioners from providing patients with a take-home supply of medication, so long as it was provided at the opioid treatment program rather than at a pharmacy.⁸⁵ If DEA had not taken this approach, pharmacies could be considered “dispensers” for purposes of NATA and could register to be narcotic treatment programs.

DEA did not specifically explain why it interpreted the NATA provision in this manner, but it did refer to legislative history for support that NATA was enacted to address problems with unsupervised use of methadone.⁸⁶ DEA did not expressly make the connection between unsupervised use and prescriptions, but the rationale may have been that medication supplies picked up at pharmacies would involve some amount of supply for unsupervised use, and that this was unacceptable due to the risk of diversion. Take-home supplies, though, could trigger this same concern. It is not clear why pharmacy-dispensed methadone is more risky than take-home supplies provided by opioid treatment programs. This question of delivery pathway does not control how much methadone may be provided to patients, or in what manner, just the issue of where patients may collect it.

This analysis also does not fully account for NATA’s legislative history. The committee report that DEA cited in its 1974 final rule reflected the view that “the quantity of narcotic drugs for unsupervised use” was “a matter best determined by the Department of Health, Education, and Welfare, after consultation with the Department of Justice.”⁸⁷ By promulgating a rule that prohibited any methadone prescribing, DEA foreclosed an opportunity for the Department of Health, Education, and Welfare (or HHS in the future) to consider and issue rules about what amount of pharmacy-delivered unsupervised supply was acceptable. Instead, the DEA regulation locked in a prohibition on pharmacy prescribing that has endured for almost 50 years.⁸⁸

Because DEA’s regulation appears to be more restrictive than what was required by NATA, DEA could issue a revised regulation that is more permissive towards prescription of

⁸³ 21 C.F.R. § 1306.07(a).

⁸⁴ Narcotic Treatment Programs Regulatory Controls Relating to Registration, Security, and Recordkeeping, 38 Fed. Reg. 37,983 (Oct. 25, 1974).

⁸⁵ *Id.*

⁸⁶ Narcotic Treatment Programs, Proposed Regulatory Controls Relating to Registration, Security, and Recordkeeping, 39 Fed. Reg. 26,424, 26,424 (July 19, 1974) (noting that, in enacting NATA, “Congress recognized that the release of quantities of narcotic drugs to individuals for their unsupervised use, primarily a medical judgment, may have some law enforcement ramifications”). *See also* H. REP. NO. 93-884, at 6.

⁸⁷ H. REP. NO. 93-884, at 5.

⁸⁸ It is not obvious that the Department of Health, Education, and Welfare would have adopted a posture that was more favorable towards methadone prescribing in the 1970s. However, the purpose of this analysis is to explain that the underlying statute is not what constrains pharmacy prescribing.

methadone. To promulgate the regulation, DEA would need to go through the rulemaking process and build a record to support the changes.⁸⁹

Table 2. DEA Prescribing Prohibition (21 C.F.R. § 1306.07(a))

Requirements	Access Issues	Options
Requirement that methadone not be prescribed	Prohibits patients from collecting methadone doses at pharmacies	DEA amends its regulations to remove the prohibition

IV. Methadone's as a Schedule II Controlled Substance

Practitioners can prescribe or dispense Schedule III, IV, and V controlled substances to treat opioid use disorder without registering as a narcotic treatment program with DEA or as an opioid treatment program with SAMHSA.⁹⁰ Methadone, however, is a Schedule II controlled substance, and is therefore subject to special rules that make it more challenging to treat patients with methadone for opioid use disorder. This section finds that DEA could, as a legal matter, reschedule methadone to bring it into line with other drugs used to treat opioid use disorder.⁹¹

A. DEA Regulation of Methadone on Schedule II

Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 established a federal framework to regulate “controlled substances.”⁹² Controlled substances are a class of drugs, substances, and chemicals that are viewed as potentially dangerous to public health because they pose a significant risk of abuse and diversion. “Diversion” is not defined in the CSA but can be understood to mean the “selling/trading, sharing or giving away,” either voluntarily or involuntarily (e.g., by way of theft), of a prescription medication to someone to whom it was not prescribed.⁹³

⁸⁹ If DEA allowed pharmacies to administer doses or fill prescriptions for take-home supplies of methadone, other regulatory accommodations for pharmacies might also be in order. Pharmacies, for example, are not well-positioned to meet the various requirements for opioid treatment programs—such as providing counseling—as they stand today. DEA’s security and recordkeeping requirements, discussed below, should also be evaluated to assess how well they apply to pharmacies.

⁹⁰ Drug Addiction Treatment Act of 2000, 21 U.S.C. § 823(g) (2018).

⁹¹ As with many of the issues discussed in this report, regulators need to weigh the policy considerations of making changes like rescheduling methadone. Here, as in the rest of this report, we are primarily concerned with assessing whether DEA has the legal authority to change methadone’s placement on Schedule II.

⁹² Controlled Substances Act, Pub. L. No. 91-513 (current version at 21 U.S.C. Chapter 13 (2018)).

⁹³ Briony Laran , Louisa Degenhardt, Nick Lintzeris, Adam Winstock & Richard Mattick, *Definitions Related to the Use of Pharmaceutical Opioids: Extramedical Use, Diversion, Non-adherence and Aberrant Medication-Related Behaviors*, 30 DRUG & ALCOHOL REV. 236, 238-39 (2011).

Under the CSA, DEA has the authority to categorize drugs as controlled substances and then assign them to one of five schedules (I–V) based on their medicinal utility and relative potential for abuse.⁹⁴ The CSA defines Schedule I substances, which include, among other things, heroin, lysergic acid diethylamide (LSD), and peyote, as drugs “with no currently accepted medical use in treatment in the United States” and “a high potential for abuse.”⁹⁵ Because Schedule I drugs are those determined to be unsafe even under medical supervision, they are illegal to manufacture, distribute, possess, or use in the United States outside of federally-approved research.⁹⁶

Schedule II drugs are those that have both a medically accepted use and a high potential for abuse.⁹⁷ According to the DEA, Schedule II drugs have “a high potential for abuse, with use potentially leading to severe psychological or physical dependence,” and, therefore, are “considered dangerous.”⁹⁸ Schedule II drugs are the most dangerous class of drugs that are permitted to be prescribed in the United States. Consequently, most prescription opioids, including methadone, are classified as Schedule II controlled substances.⁹⁹

Schedule III drugs are those that have both a medically accepted use and a higher potential for abuse than the prescription drugs on numerically higher schedules (IV and V) and all unscheduled drugs.¹⁰⁰ Buprenorphine—another medication used to treat opioid use disorder—is classified as Schedule III drug.¹⁰¹ Schedules IV and V controlled substances generally have fewer risks than drugs in Schedules II and III.¹⁰² As a result, they are subject to fewer restrictions and controls under the CSA.¹⁰³

When Congress enacted the CSA, it added methadone to Schedule II, along with other opiate drugs like hydrocodone and morphine.¹⁰⁴ However, as described below, Congress also gave DEA the authority to reschedule any drugs it scheduled.¹⁰⁵

B. Impact on Access to Treatment

By definition, controlling a medication limits access to it. The question is what level of restriction is appropriate for the substance in question. Methadone is controlled more strictly

⁹⁴ 21 U.S.C. § 811 (2018).

⁹⁵ 21 U.S.C. § 812 (2018).

⁹⁶ *See* 21 U.S.C. § 823 (2018).

⁹⁷ 21 U.S.C. § 812 (2018).

⁹⁸ Drug Enforcement Admin., Drug Scheduling, <https://www.dea.gov/drug-information/drug-scheduling> (last accessed June 2022).

⁹⁹ 21 C.F.R. § 1308.12.

¹⁰⁰ 21 U.S.C. § 812 (2018).

¹⁰¹ 21 C.F.R. § 1308.13.

¹⁰² 21 U.S.C. § 812 (2018).

¹⁰³ *See* 21 U.S.C. §§ 812, 823 (2018).

¹⁰⁴ Controlled Substances Act, Pub. L. No. 91-513, § 202 (current version at 21 U.S.C. § 812 (2018)); *see* INSTITUTE OF MEDICINE, FEDERAL REGULATION OF METHADONE TREATMENT 124 (1995), <https://www.ncbi.nlm.nih.gov/books/NBK232108/?report=reader> (discussing history of scheduling methadone).

¹⁰⁵ 21 U.S.C. § 811(a) (2018).

than other medications used to treat opioid use disorder. Under the Drug Addiction Treatment Act of 2000 (“DATA 2000”), individual practitioners can prescribe or dispense Schedule III, IV, and V controlled substances to treat opioid use disorder without registering as a narcotic treatment program with DEA or as an opioid treatment program with SAMHSA.¹⁰⁶ These practitioners must complete a specialized 8-hour or 24-hour training and obtain a waiver from SAMHSA, but they are otherwise not covered by the requirements for opioid treatment programs, including SAMHSA’s patient care regulations.¹⁰⁷ They are, however, subject to caps on the number of patients they may treat.¹⁰⁸

Because methadone is a Schedule II controlled substance, it is not eligible for a DATA 2000 waiver.¹⁰⁹ The waiver extends to buprenorphine, a Schedule III controlled substance that is also effective to treat opioid use disorder.¹¹⁰ If methadone was a Schedule III controlled substance, practitioners who have already obtained their DATA 2000 waiver to treat patients would be permitted to prescribe methadone. Expanding the treatment options might also encourage more practitioners to obtain a waiver.¹¹¹

C. Rescheduling Methadone

DEA could reschedule methadone from a Schedule II controlled substance to a Schedule III controlled substance. This would mean that the DATA 2000 waiver applies to methadone.

While it must follow fairly extensive procedures to do so, the CSA specifically allows DEA to “transfer [any drug] between such schedules.”¹¹² To reschedule methadone, DEA would have to work with HHS to build the requisite administrative record to support such a move. DEA must first ask HHS for a “scientific and medical evaluation” and a recommendation for scheduling.¹¹³ FDA takes the lead on these evaluations to determine if a drug warrants controls, and the HHS Assistant Secretary for Health produces scheduling recommendations that are transmitted to DEA.¹¹⁴ DEA is not allowed to reschedule a drug if HHS does not agree that it meets the criteria for a particular schedule.¹¹⁵

¹⁰⁶ Drug Addiction Treatment Act of 2000, 21 U.S.C. § 823(g)(2) (2018).

¹⁰⁷ *Id.*

¹⁰⁸ 21 U.S.C. § 823(g)(2)(B)(iii) (2018).

¹⁰⁹ 21 C.F.R. § 1308.12.

¹¹⁰ 21 C.F.R. § 1308.13.

¹¹¹ The policy interactions between possible changes to the DATA 2000 waiver and rescheduling methadone are worthy of additional study, but outside the scope of this report.

¹¹² 21 U.S.C. § 811(a) (2018).

¹¹³ 21 U.S.C. § 811(b) (2018). The Secretary of the Department of Health and Human Services delegated its statutory authority to conduct these evaluations to the FDA. FOOD & DRUG ADMIN., CONSULTING THE CONTROLLED SUBSTANCE STAFF ON DRUG ABUSE POTENTIAL AND LABELING, DRUG SCHEDULING, DEPENDENCE LIABILITY AND DRUG ABUSE RISKS TO THE PUBLIC HEALTH at 1, <https://www.fda.gov/media/71652/download>.

¹¹⁴ FOOD & DRUG ADMIN., CONSULTING THE CONTROLLED SUBSTANCE STAFF ON DRUG ABUSE POTENTIAL AND LABELING, DRUG SCHEDULING, DEPENDENCE LIABILITY AND DRUG ABUSE RISKS TO THE PUBLIC HEALTH at 3, <https://www.fda.gov/media/71652/download>.

¹¹⁵ 21 U.S.C. § 811(b) (2018).

A central consideration for the HHS Assistant Secretary for Health and DEA is how the following eight statutory factors apply to methadone:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.¹¹⁶

The agencies have gone through the rescheduling process before, which offers a blueprint for the kind of analysis and record-building that might be required.¹¹⁷ Although building the record would be resource intensive and likely to take many months or longer, the eight factors confer quite a bit of discretion upon the agencies. For example, the first factor considers is the drug's "actual or relative potential for abuse."¹¹⁸ The CSA does not define the term "abuse," but to implement it DEA uses factors such as the level of diversion of the drug from legal drug channels and whether individuals are taking drugs in an amount sufficient to create a hazard to their health.¹¹⁹ HHS considers the risk of the drug based on animal and epidemiological data when conducting its evaluation, but it also relies on factors such as the prevalence of use among various populations and the reputation of the substance "on the street" when making its assessment of the "abuse" potential.¹²⁰

This evaluation process is inherently subjective. In its regulation that rescheduled hydrocodone combination products, for example, DEA argued that there were roughly 82,000 emergency department visits related to hydrocodone products, and this counted as "abuse."¹²¹ There is no bright line, however, to delineate what counts as "abuse" such that a substance must be controlled in a particular manner. For example, that are roughly 56,000 overdose-related emergency room visits from acetaminophen each year, but this fact, in

¹¹⁶ 21 U.S.C. § 811(c) (2018).

¹¹⁷ Drug Enforcement Admin., Supporting Document on Final Rule to Reschedule Hydrocodone Combination Products (Aug. 22, 2014), <https://www.regulations.gov/document/DEA-2014-0005-0003>. This example is one of "upscheduling," in which DEA moved a controlled substance to a more restrictive schedule. We are not aware of an instance of "downscheduling" a controlled substance. We are aware of an example of "unscheduling," in which a substance was removed from the schedules of controlled substances, suggesting that at least sometimes it is feasible to move a substance down from a higher category. Schedules of Controlled Substances: Removal of [¹²³I]Ioflupane From Schedule II of the Controlled Substances Act, 80 Fed. Reg. 31,521 (2015). This was not an opioid. *Id.* DEA's prior actions to reschedule different substances is an area ripe for additional study.

¹¹⁸ 21 U.S.C. § 811(c) (2018).

¹¹⁹ Drug Enforcement Admin., Supporting Document on Final Rule to Reschedule Hydrocodone Combination Products at 4-5 (Aug. 22, 2014), <https://www.regulations.gov/document/DEA-2014-0005-0003>.

¹²⁰ *Id.* at 5.

¹²¹ *Id.* at 6.

combination with the other factors, has not resulted in DEA scheduling acetaminophen as a controlled substance.¹²² The agencies could determine that the levels of methadone diversion and use are not high enough to count as “abuse” such that it warrants placement on Schedule II. For example, if DEA and HHS observe that methadone-related emergency room visits, overdoses, and diversion occur at lower rate than they do for other Schedule II controlled substances, or for various drugs on lower schedules, then the agencies could find that methadone no longer meets the first “abuse” factor. A more detailed assessment of each statutory factor is outside the scope of this report, but the main point of this analysis is to show that the agencies have statutory discretion to begin a process to reconsider the level at which methadone is controlled.

Although the vast majority of executive branch rulemaking is promulgated through the rulemaking process, DEA’s rescheduling actions must be issued through the formal rulemaking process.¹²³ Under formal rulemaking, the agency must engage in trial-like procedures. For example, parties that are adversely affected by a proposed rule can request a hearing, and DEA and the parties present oral evidence before a hearing officer regarding fact findings and legal conclusions, and both sides can conduct cross examinations.¹²⁴ For example, in formal rulemaking, a party that disagrees with DEA’s medical claims is entitled to cross-examine DEA on this issue.¹²⁵ A written decision is then issued based on the hearing.¹²⁶ DEA has the burden of proof and must issue rules “on consideration of the whole record” that are supported by “substantial evidence.”¹²⁷

In sum, DEA has the statutory authority to revisit the schedule to which methadone is assigned. Converting methadone from a Schedule II controlled substance to a Schedule III controlled substances would allow the DATA 2000 waiver to apply to methadone. However, to reschedule methadone, DEA would have to build the record required by the CSA and follow formal rulemaking procedures.

¹²² William Lee, *Acetaminophen and the U.S. Acute Liver Failure Study Group: lowering the risks of hepatic failure*, 40 HEPATOLOGY 6 (2004).

¹²³ The CSA requires rescheduling actions to be “made on the record after opportunity for a hearing.” 21 U.S.C. § 811(a) (2018). The Supreme Court has interpreted the Administrative Procedure Act to trigger the formal rulemaking requirements only when a statute requires actions be “made on the record after opportunity for an agency hearing.” *United States v. Florida E. Coast Ry.*, 410 U.S. 224, 251 (1973). If such a rule was subject to a legal challenge, DEA would likely be given *Chevron* deference by a reviewing court because Congress left the interpretation of the eight factors up to DEA. *See Nat’l Cable & Telecommunications Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 1004 (2005) (Breyer, K., concurring).

¹²⁴ 5 U.S.C. §§ 553, 556-557 (2018).

¹²⁵ 5 U.S.C. § 556 (2018). *See generally* Aaron L. Nielson, *In Defense of Formal Rulemaking*, 75 OHIO STATE L.J. 237 (2014) (explaining the formal rulemaking process).

¹²⁶ 5 U.S.C. § 557 (2018).

¹²⁷ 5 U.S.C. § 556 (2018).

Table 3. Methadone on Schedule II (21 C.F.R. § 1308.12)

Requirements	Access Issues	Options
Placement of methadone on Schedule II	Places limits on methadone unlike those applied to other medications used to treat opioid use disorder	DEA & HHS assess whether methadone must be Schedule II—if not, DEA formal rulemaking

V. Additional Entry Barriers & Operating Costs

Practitioners interested in treating patients for opioid use disorder using methadone face a host of additional up-front barriers to entry and ongoing, regulatory operating costs. For example, opioid treatment programs must obtain an extra registration from DEA before they are permitted to administer methadone to treat opioid use disorder. Opioid treatment programs must also obtain certification from SAMHSA and submit to ongoing accreditation and certification renewal requirements. They must also comply with various DEA requirements for physical security measures and recordkeeping.

The provisions discussed in Section II-IV of this report more directly determine the supply of treatment for opioid use disorder with methadone because they determine who may administer methadone and who may receive it. The requirements discussed in this section, on the other hand, are more subtle, in that they indirectly inhibit patient access to treatment by making it more costly to establish and run an opioid treatment program.¹²⁸ Such requirements have the potential to accumulate into significant, even if unintended, barriers that reduce the supply of treatment providers.

A. Entry Barriers & Operating Costs

i. DEA Registration Requirement for Narcotic Treatment Programs

Only a subset of FDA-approved medications are controlled substances. Most of them are not.¹²⁹ As explained above, methadone is a controlled substance. DEA requires each person

¹²⁸ This is not an exhaustive list. SAMHSA's Part 2 confidentiality regulations are another example. These regulations apply special confidentiality provisions to opioid treatment programs and, although the regulations do not prohibit all disclosures, they require patients to provide written consent prior to disclosure. *See* 42 C.F.R. § 2.11; 42 C.F.R. § 2.12(b); 42 C.F.R. § 2.13; 42 C.F.R. § 2.31. The regulations also require that each disclosure is accompanied by a written statement that says the information cannot be disclosed again. 42 C.F.R. § 2.32. The rules trigger compliance costs that are unique for healthcare providers offering substance use disorder treatment.

¹²⁹ Some examples of medications that are controlled substances include benzodiazepines (e.g., Valium), opioids (e.g., Hydrocodone), and hypnotics or sedatives (e.g., Ambien). DEA maintains a list of controlled substances, informally called the Orange Book. *See e.g.*, DRUG ENFORCEMENT ADMIN., LISTS OF: SCHEDULING ACTIONS CONTROLLED

who manufactures, dispenses, or distributes a controlled substance to obtain a registration (i.e., a license) from the agency.¹³⁰ DEA generally requires practitioners to obtain a separate registration for each principal place of business.¹³¹

Individual practitioners, hospitals, and retail pharmacies that want to prescribe or dispense a controlled substance must register with DEA as “dispens[ers],” but these registrants are not permitted to prescribe or dispense methadone for the purpose of treating opioid use disorder.¹³² Paradoxically, these registrants are permitted to prescribe methadone to treat patients with severe pain.¹³³

To dispense methadone for the treatment of opioid use disorder, however, practitioners must register as a “narcotic treatment program” with DEA.¹³⁴ In theory, individual practitioners, hospitals, or retail pharmacies that register with DEA as dispensers for controlled substances could also register with DEA as narcotic treatment programs, but to do this they would need to comply with the various regulations imposed by DEA and SAMHSA described in this report. In practice, standalone opioid treatment programs are generally the only healthcare facilities that comply with this unusual set of restrictions and register with DEA as narcotic treatment programs.¹³⁵

ii. SAMHSA Accreditation and Certification Requirements

SAMHSA’s opioid treatment program regulations are based on a framework of program certification and accreditation. SAMHSA approves accreditation bodies, which are state agencies or nonprofits, which then provide accreditation to individual opioid treatment programs.¹³⁶ Once an opioid treatment program receives accreditation, it can apply to SAMHSA to obtain the required certification.¹³⁷

The SAMHSA certification can only be granted for a maximum 3 years.¹³⁸ An opioid treatment program must submit a variety of information to SAMHSA in its application, including a “description of the organizational structure” of the opioid treatment program as

SUBSTANCES REGULATED CHEMICALS (Apr. 2022),
<https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.

¹³⁰ 21 C.F.R. § 1301.11(a).

¹³¹ 21 C.F.R. § 1311.12(a).

¹³² 21 C.F.R. § 1301.13(e)(1); 21 C.F.R. § 1306.07(a).

¹³³ See Melissa M. Ferrara, *The Disparate Treatment of Addiction-Assistance Medications and Opiate Pain Medications Under the Law: Permitting the Proliferation of Opiates and Limiting Access to Treatment*, 42 SETON HALL L. REV. 741 (2012) (discussing different regulatory approaches for methadone as a pain treatment and methadone as a treatment for addiction).

¹³⁴ 21 C.F.R. § 1306.07(a).

¹³⁵ State scope of practice laws also bear on which kinds of providers may provide different kinds of treatment. Requirements like this are outside the scope of this report.

¹³⁶ 42 C.F.R. §§ 8.3 - 8.4. SAMHSA promulgated extensive regulations that govern the administrative process accreditation bodies must follow, and the substantive requirements they must meet to get approved and maintain accreditation. 42 C.F.R. §§ 8.3 - 8.4.

¹³⁷ 42 C.F.R. § 8.11.

¹³⁸ 42 C.F.R. § 8.11(a)(3).

well as its sources of funding.¹³⁹ SAMHSA may grant the certification after completing a consultation with the relevant state agency that oversees opioid treatment programs.¹⁴⁰

iii. DEA Security and Recordkeeping Requirements

DEA's security controls for controlled substances are extensive. Registrants must notify DEA of theft and significant loss of controlled substances, including methadone.¹⁴¹ This includes various criteria that registrants must consider in determining whether a loss is significant, including patterns of losses over time, local trends, and the type of controlled substance at issue.¹⁴² Only a licensed practitioner or an authorized individual can sign an invoice for the controlled substances that the program receives, and patients must wait in a separate area from the narcotic storage area.¹⁴³

Registrants may not provide a patient with a complimentary sample unless it satisfies a legitimate medical need, the practitioner obtains a written request from a customer, and the drug is provided "only in reasonable quantities."¹⁴⁴ Programs are also required to keep controlled substances in a safe, steel cabinet, or vault that meets DEA's specifications. For example, a safe or steel cabinet that is less than 750 pounds must be bolted or cemented to the floor and, depending on the quantity and type of controlled substance, the safe or steel cabinet must be equipped with an alarm system.¹⁴⁵

DEA also requires registrants to keep methadone inventories and records, as well as a dispensing log that tracks the amount of medication dispensed or administered to a patient.¹⁴⁶ When practitioners dispense methadone, they must record in the dispensing log the amount of methadone dispensed, the dosage form, the date dispensed, the identification of the patient, the amount consumed, the amount taken home by the patient, and the dispenser's initials.¹⁴⁷ There are also some requirements that are specific to narcotic treatment programs. For example, narcotic treatment programs are permitted to use a computer for data storage, but the automatic system must be preapproved by DEA, and the program must print a hard copy of each day's dispensing log and have it initialed by each person who dispensed the medication.¹⁴⁸

While only some of these requirements are specific to methadone, the prohibition of prescribing methadone—discussed in Section II—means that to treat patients for opioid use disorder with methadone, a practitioner must have the infrastructure on site to manage

¹³⁹ 42 C.F.R. § 8.11(b).

¹⁴⁰ 42 C.F.R. § 8.11(c).

¹⁴¹ 21 C.F.R. § 1301.74(c).

¹⁴² *Id.* § 1301.74(c).

¹⁴³ *Id.* §§ 1301.74(h) & 1301.74(j).

¹⁴⁴ *Id.* § 1301.74(d).

¹⁴⁵ *Id.* § 1301.72(a)(1).

¹⁴⁶ *Id.* § 1304.04(f); *Id.* § 1304.24(b).

¹⁴⁷ *Id.* § 1304.24(a).

¹⁴⁸ *Id.* § 1304.24(b).

controlled substances. This would not be the case for practitioners who merely prescribe controlled substances for pickup at a pharmacy.

B. Impact on Access to Treatment

The requirements discussed in this section are not the barriers that advocates frequently identify, but this report bundles them together as provisions that should be evaluated to ensure that they are serving the public interest because they have the potential to reduce access.

Regulations can act as “barriers to entry” when they make it costly to open a business and deter people from entering a market.¹⁴⁹ For example, occupational licensing is one of the most prevalent types of barriers to entry. To obtain a license to work as a florist in Louisiana, an individual is required to take an exam and pay a \$189 fee.¹⁵⁰ These requirements deter entrepreneurs from opening such a business. Instead, they may enter a profession that does not have such a costly licensing process. This may reduce the supply and raise the price of the good or service.¹⁵¹ In the context of methadone treatment, a practitioner might be deterred from opening an opioid treatment program because of the costs of starting and maintaining the program. For example, a practitioner would face the cost of obtaining an accreditation and certification, which includes the lost wages associated with the time spent completing the applications as well as any fees associated with the applications. The practitioner would also have to invest in the necessary security equipment. These costs accumulate and, when combined with the other barriers described in this report, they may deter practitioners from starting an opioid treatment program. Instead, practitioners may decide to become general practitioners who do not face these costs and who federal regulation prohibits from treating patients for opioid use disorder with methadone. This reduces the available supply of treatment providers. Sensitivity to costs like these came up repeatedly in a qualitative study examining why so few practitioners take the steps needed to treat patients with opioid use disorder with medication.¹⁵²

¹⁴⁹ See generally Harold Demsetz, *Barriers to Entry*, 72 AM. ECON. REV. 47 (1982); George Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 2 (1971).

¹⁵⁰ DICK M CARPENTER, LISA KNEPPER, KYLE SWEETLAND, & JENNIFER McDONALD, INST. FOR JUSTICE, LICENSE TO WORK: A NATIONAL STUDY OF BURDENS FROM OCCUPATIONAL LICENSING 163 (2017), https://ij.org/wp-content/uploads/2017/11/License_to_Work_2nd_Edition.pdf.

¹⁵¹ See e.g., Patrick Rivers, Myron Fottler & Jemima Frimpong, *The Effects of Certificate of Need Regulation on Hospital Costs*, 36 J. HEALTH CARE FIN. 1 (2010) (finding that increased stringency of certificate of need regulations had a positive statistically significant relationship with hospital costs). See also Morris M. Kleiner & Alan Krueger, *The Prevalence and Effects of Occupational Licensing*, 48 BRITISH J. INDUS. REL. 676, 677-78 (2010); Carl Shapiro, *Investment, Moral Hazard, and Occupational Licensing*, 53 REV. ECON. STUD. 843-62 (1986); OCCUPATIONAL LICENSING: A FRAMEWORK FOR POLICYMAKERS (July 2015), https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.

¹⁵² See generally Suzanne McMurphy, Judy Shea, Julia Switzer & Barbara Turner, *Clinic-based Treatment for Opioid Dependence: A Qualitative Inquiry*, 30 AM. J. HEALTH BEHAV. 544 (2006).

A multi-disciplinary literature considers how seemingly small hurdles can put access to services out of reach.¹⁵³ The number and type of hurdles can range significantly. As an example, the paperwork required for an individual to apply for a public benefit could be extensive, requiring various forms of proof of identity or legal status, documentation of residency, family, or income information, or even physical samples like urine tests. At the other end of the spectrum, an individual could be automatically enrolled into a benefit program. A similar continuum exists for organizations. The process for a restaurant to obtain a liquor license could be cumbersome, requiring a lengthy application with supporting documentation and a large application fee, or it could be a simple web form with a small fee. As these hurdles accumulate, research indicates that fewer individuals or organizations will surmount them.

Therefore, attention to seemingly small or limited barriers is especially warranted if, in the aggregate, they could shift the supply of providers. While this report does not offer an empirical assessment of these various barriers to determine which ones are the most costly, it provides the following examples for purposes of working through the applicable legal authorities.

i. DEA Registration Requirement for Narcotic Treatment Programs

The DEA's registration requirement acts as a barrier to entry for opioid treatment programs and thereby contribute to the shortage of facilities available to treat patients with methadone. DEA has acknowledged that the demand for methadone from opioid treatment programs has resulted in "long waiting lists and high service fees."¹⁵⁴ DEA's registration requirement is only one of the restrictions that contribute to the shortage of treatment centers in which patients can receive methadone for opioid use disorder.¹⁵⁵ However, when DEA initially issued regulations requiring opioid treatment programs to register separately from other types of practitioners, it indicated that it did not expect the requirement to be particularly burdensome. Instead, the agency contended that the registration was "not intended to impose a heavy new burden on practitioners," and committed to make "every effort . . . to use registration forms which are brief, simple, and similar to the other forms already in use."¹⁵⁶

¹⁵³ See generally PAMELA HERD & DONALD P. MOYNIHAN, ADMINISTRATIVE BURDEN: POLICYMAKING BY OTHER MEANS (2018); Cass R. Sunstein, *Sludge and Ordeals*, 68 DUKE L.J. 1843 (2019). The terms "administrative burdens," "hassles," "ordeals," "transaction costs," and "sludge" are used in different sets of academic literature to describe similar ideas.

¹⁵⁴ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,009 (Feb. 26, 2020). DEA did not state that its registration requirements limit the supply of practitioners eligible to treat patients with methadone, but implied that this is the case when it argued that lifting its longstanding moratorium on new mobile opioid treatment programs would help alleviate the limited supply of methadone treatment. See Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,009 (Feb. 26, 2020).

¹⁵⁵ This report describes additional up-front barriers to providing this kind of treatment in Section V.

¹⁵⁶ Proposed Regulatory Controls Relating to Registration, Security, and Recordkeeping, 39 Fed. Reg. 26,424, 26,424 (July 19, 1974).

Although DEA may have envisioned that any type of healthcare practitioner could easily obtain a registration as a narcotic treatment program, DEA's rule predated the opioid treatment program regulations put in place by the FDA and the National Institute on Drug Abuse (NIDA) a few years later.¹⁵⁷ Those regulations, which are now implemented by SAMHSA and described in Section II, placed extensive restrictions on opioid treatment programs. For example, opioid treatment programs must obtain a certification, provide ancillary services to patients such as counseling, and limit the amount of methadone a patient may take home. The DEA registration requirement for narcotic treatment programs, in concert with numerous other regulatory burdens, discourages practitioners from treating patients for opioid use disorder with methadone.

ii. SAMHSA Accreditation and Certification Requirements

An accreditation model shifts some of the cost of regulatory enforcement from the government to the accreditor. Opioid treatment programs pay accrediting bodies to review their applications and conduct on-site surveys.¹⁵⁸ To the extent that accreditation diverts resources that would otherwise be devoted to patient care, the accreditation model can serve as a barrier to access.

A related question is how accreditation relates to quality. Some have critiqued the accreditation model in healthcare, generally, and for opioid treatment programs, specifically, questioning whether accreditors can be relied upon to ensure quality in light of the incentives they face to retain providers as customers.¹⁵⁹ This is in tension with the need to maintain sufficient credibility as an accreditor, and may lead to problematic accommodations.¹⁶⁰ More research is needed to explore how the accreditation model influences access to as well as the quality of services provided by opioid treatment programs.

The certification process likely involves comparatively fewer resources for opioid treatment programs than the accreditation process, but the workload associated with certification should not be overlooked. SAMHSA estimates that the SMA-162, Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11, takes up

¹⁵⁷ Joint Revision of the Conditions for Use of Methadone for Treating Narcotic Addicts, 45 Fed. Reg. 62,694 (Sep. 19, 1980). Opioid treatment program regulations were initially issued jointly by the Food and Drug Administration and the National Institute on Drug Abuse, and SAMHSA took over in 1999. Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence, 64 Fed. Reg. 39,810 (July 22, 1999).

¹⁵⁸ American Association for the Treatment of Opioid Dependence, Press Release, Change in Federal Oversight for Methadone Treatment, <http://www.aatod.org/media/archived-aatod-news/notice-for-proposed-rule-making-change-in-federal-oversight-for-methadone-treatment/> (noting that in 1999 the cost of accreditation could range from \$7500 to \$11,000) (undated, accessed July 11, 2022).

¹⁵⁹ See generally Mary Eleanor Wickersham & Stephanie Basey, *Is Accreditation Sufficient? A Case Study and Argument for Transparency When Government Regulatory Authority is Delegated*, 39 J. HEALTH & HUMAN SERVS. ADMIN. 245 (2016).

¹⁶⁰ *Id.*

to one hour to complete on average.¹⁶¹ Based on the list of materials that must accompany the SMA-162, this is likely an underestimate.¹⁶²

iii. DEA Security and Recordkeeping Requirements

As noted above, practitioners treating patients for opioid use disorder with methadone—currently limited to opioid treatment programs—must dispense it on site. As such, they must comply with DEA’s security requirements that apply to all controlled substances. These requirements would not apply to providers who prescribe controlled substances for pharmacy pickup.

A common challenge in evaluating regulatory requirements is establishing a comparative benchmark. For example, if someone went into business selling gems, they would likely keep their stock secure by use of a safe or vault. If the government required gem vendors to use a certain kind of safe or specified the type of force that the safe must be able to withstand, a relevant question (apart from one of authority) would be how different those requirements were from what gem businesses were already doing. If the government’s requirements are more difficult to satisfy, compliance costs go up.

These comparative analyses are more complex in healthcare. In addition to a healthcare provider’s own incentives to keep their on-site medications secure, they face many layers of regulation including state and local code requirements. To the extent that, in practice, these requirements match what providers would do in their absence, it suggests the requirements do not function as a set of costs that have downstream effects on the supply of providers. If, however, the requirements go beyond what prudent healthcare providers would otherwise deploy, then the requirements trigger additional cost. We include the DEA security requirements as a potential barrier in this report because—in combination with the prohibition on prescribing—they trigger incremental costs and, therefore, influence the decision to treat this patient population with methadone.

Paperwork is similar in that most entities retain records for their own business purposes. The question is the extent to which DEA recordkeeping goes beyond what practitioners would otherwise do. Paperwork also carries a more straightforward set of costs like those discussed above for certification. While reporting requirements can offer benefits to the public, the cost of the paperwork is borne by the reporting entity and thus may factor into decisions about whether to enter this market.

¹⁶¹ Substance Abuse & Mental Health Administration, Online SMA-162 Form, <https://dpt2.samhsa.gov/sma162/sma162.aspx>.

¹⁶² Substance Abuse & Mental Health Administration, Certification of Opioid Treatment Programs, <https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program> (requiring new applicants to provide, *inter alia*, “[f]acilities description and diagram and description demonstrating the adequacy of the facilities for drug dispensing and individual and group counseling,” and “shall specify how the OTP will provide adequate medical, counseling, vocational, educational, and assessment services at the primary facility, unless the program sponsor has entered into a formal documented agreement with another entity”).

C. Reducing Entry Barriers and Operating Costs

This section describes the agencies' discretion to remove or amend certain entry barriers and operating costs for opioid treatment programs. First, it describes DEA's unclear authority to waive its registration requirement for narcotic treatment programs. Second, it describes SAMHSA's authority to remove or amend its accreditation and certification requirements through rulemaking. Finally, it describes DEA's authority to remove or amend its security and recordkeeping requirements through rulemaking.

i. Unclear Authority for DEA to Waive Registration Requirement for Narcotic Treatment Programs

NATA directs DEA to register narcotic treatment programs separately from other types of practitioners.¹⁶³ NATA amended the CSA, which contains broad authority at 21 U.S.C. § 822(d) for DEA “to waive the requirement for registration of certain manufacturers, distributors, or dispensers if [the agency] finds it consistent with the public health and safety.”¹⁶⁴ The interpretive question is how this waiver authority applies to the registration requirement for narcotic treatment programs.

A standard interpretive approach is to construe words used multiple times in a statute to mean the same thing, under the presumption of consistent usage. This can be overcome, however, with evidence that a difference was intended. Legislative history for NATA refers to the registration for narcotic treatment programs to be “in addition to the customary registration under the Controlled Substances Act.”¹⁶⁵ Therefore, a reasonable interpretation is that NATA created a new kind of registration for narcotic treatment providers, beyond those registration types already created by the CSA.

This interpretation does not necessarily speak to the scope of DEA's waiver authority, however. NATA amended the CSA but did not make changes to DEA's waiver authority in Section 822(d). Congress could have, for example, excluded NATA's registration requirement from Section 822(d), which would more clearly restrict DEA's ability to waive it. Instead, NATA is silent on the interaction of the registration requirement and DEA's waiver authority. This silence could mean that DEA is able to waive the registration requirement for narcotic treatment programs when consistent with public health and safety, or it could mean that the registration requirement for narcotic treatment programs is different enough to be out of reach for DEA's waiver authority. To apply its waiver authority, DEA would have to argue that NATA's very specific requirement for narcotic treatment program registration could be waived, in whole, using general waiver authority that pre-dates it. While this argument is available to DEA, the authority is less clear than other provisions explored in this report.

¹⁶³ 21 U.S.C. § 824(a) (2018).

¹⁶⁴ 21 U.S.C. § 822(d) (2018).

¹⁶⁵ See H. REP. NO. 93-884, at 9 (1974).

To pursue this interpretive tack, DEA would be required to do so by regulation.¹⁶⁶ To support its waiver, DEA would need to build an administrative record to show that the ordinary registration requirements that would apply in the absence of a registration requirement for narcotic treatment programs would be sufficiently protective of public health and safety.¹⁶⁷ In that case, practitioners treating patients with methadone for opioid use disorder would still need to register with DEA to be able to dispense a controlled substance. They would obtain the same type of registration as individual practitioners, hospitals, and retail pharmacies, and these registration requirements carry security and recordkeeping provisions that may be sufficiently protective of public health and safety.

ii. SAMHSA Removes or Amends Accreditation and Certification Requirements through Rulemaking

First, NATA extends to SAMHSA the authority to remove or amend the accreditation and certification requirements at 42 C.F.R. § 8.3-8.6 and 42 C.F.R. § 8.11.

The Act says:

The Attorney General shall register [a practitioner] to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both) . . . if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought. . . .¹⁶⁸

This language gives SAMHSA the implicit authority to establish an accreditation-based system of oversight but does not require SAMHSA to use an accreditation-based system. Some history is relevant here. Congress enacted NATA in 1974, which amended the CSA and gave DEA and HHS the authority to increase the control of opioid treatment programs. FDA and the National Institute on Drug Abuse (NIDA) promulgated rules implementing NATA a few years later. In 1992, Congress created SAMHSA to, *inter alia*, “coordinate Federal policy with respect to the provision of treatment services for substance abuse utilizing anti-addiction medications, including methadone.”¹⁶⁹ In 1999, HHS shifted the responsibility for the oversight of opioid treatment programs to SAMHSA.¹⁷⁰ Despite these changes, the statutory language added by NATA in 1974 and codified at 21 U.S.C. §

¹⁶⁶ 21 U.S.C. § 822(d) (2018).

¹⁶⁷ As part of this review, DEA could also determine how to handle any security and recordkeeping requirements that attach uniquely to narcotic treatment programs.

¹⁶⁸ Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g)(1) (2018).

¹⁶⁹ Alcohol Drug Abuse and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, Title I, § 501 (1992).

¹⁷⁰ Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence, 64 Fed. Reg. 39,810 (Jul. 22, 1999); Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076 (Jan. 17, 2001).

823(g)(1) is still the language that establishes DEA and SAMHSA’s authority to regulate opioid treatment programs.¹⁷¹

When HHS shifted the responsibility for the oversight of opioid treatment programs from the FDA to SAMHSA, it voluntarily established the accreditation model through regulation in 42 C.F.R. Part 8.¹⁷² HHS argued that the authority to delegate accreditation responsibilities to third-party accreditation bodies was “[p]art and parcel with the Secretary’s general authority to establish treatment standards, and to ensure those treatment standards will be met.”¹⁷³ However, SAMHSA is not obligated by statute to follow the accreditation model. Rather, SAMHSA is only required to determine if an opioid treatment program applicant is “qualified. . . to engage in . . . treatment.”¹⁷⁴

This language also gives SAMHSA the authority to remove or amend certification requirements at 42 C.F.R. § 8.11 through the rulemaking process. Although NATA requires SAMHSA to determine if an opioid treatment program is qualified to treat patients for substance use disorder, the statute is not prescriptive as to how SAMHSA must do that. Instead, NATA effectively delegates to SAMHSA the authority to determine the particulars of how an opioid treatment program shows that they are qualified. Thus, SAMHSA has authority to alter its certification requirements. SAMHSA could, for example, move away from an accreditation model or, more modestly, extend the number of years for which a certification may be granted as a way to reduce administrative burden.

iii. DEA Amends Security and Recordkeeping Requirements through Rulemaking

The CSA also gives DEA broad discretion to design the security and recordkeeping requirements:

The Attorney General shall register a [practitioner] to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both) . . . if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records . . . on such drugs¹⁷⁵

This language requires DEA to establish standards that ensure that methadone will be secure and that records will be kept, but it gives DEA the authority to determine the details. Just as

¹⁷¹ 21 U.S.C. § 823(g)(1) (2018).

¹⁷² Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence, 64 Fed. Reg. 39,810 (Jul. 22, 1999); Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076 (Jan. 17, 2001).

¹⁷³ *Id.* at 39,824.

¹⁷⁴ 21 U.S.C. § 823(g)(1) (2018).

¹⁷⁵ *Id.*

DEA relied on this statutory provision as authority for its regulations, DEA could rely on it to amend security and recordkeeping requirements through rulemaking.

Table 4. Additional Entry Barriers and Operating Costs

Requirements	Access Issues	Options
DEA Registration Requirement for Narcotic Treatment Programs 21 C.F.R. § 1306.07(a)	Incremental cost contributes to cumulative cost of providing treatment	DEA could consider using its waiver authority to waive registration for narcotic treatment programs
SAMHSA Accreditation and Certification Requirements 42 C.F.R. § 8.11		SAMHSA removes or amends accreditation and certification requirements through regulation
DEA Security (21 C.F.R. § 1301.74) and Recordkeeping (21 C.F.R. §§ 1304.04 & 1304.24) Requirements		DEA could amend security and recordkeeping requirements through rulemaking

Conclusion

The report identifies four groups of SAMHSA and DEA regulations that limit or may limit access to methadone treatment, including SAMHSA’s patient care regulations, DEA’s prescription prohibition, methadone’s status as a Schedule II controlled substance, and a bundle of entry barriers and operating costs that are unique to opioid treatment programs. The report concludes that SAMHSA and DEA have significant discretion to remove or alter almost all of these regulatory barriers to methadone treatment, as shown in Table 5.

Ultimately, the SAMHSA and DEA possess extensive statutory discretion, which gives them options to improve access to treatment for opioid use disorder without necessarily returning to Congress for additional authority.

Paring back the federal regulatory thicket surrounding the use of methadone to treat opioid use disorder is only part of the solution for improving access to care for patients suffering from opioid use disorder. A number of other factors influence access, too. By focusing on the federal statutory and regulatory regimes, this report offers an assessment of where federal regulators have authority to take administrative action that better aligns their rules with the goal of improving access to care.

Table 5. Summary of Findings

Requirements	Access Issues	Options
SAMHSA Patient Care Regulations (42 C.F.R. § 8.12)		
Admission Criteria	Constrains who may be admitted to opioid treatment program	SAMHSA removes or amends patient care regulations through regulation or guidance
Ancillary Services	Unclear – provider costs; negative patient experience	
Toxicological Testing	Provider costs; negative patient experience	
Mode of Administration	Limits to take-home supplies	
Interim Maintenance Treatment	Unclear – may discourage treatment	
DEA Prescribing Prohibition (21 C.F.R. § 1306.07(a))		
Requirement that methadone not be prescribed	Prohibits patients from collecting methadone doses at pharmacies	DEA amends its regulations to remove the prohibition
Methadone as Schedule II Controlled Substance (21 C.F.R. § 1308.12)		
Placement of methadone on Schedule II	Places limits on methadone unlike those applied to other medications used to treat opioid use disorder	DEA & HHS assess whether methadone must be Schedule II—if not, DEA formal rulemaking
Additional Entry Barriers and Operating Costs		
DEA Registration Requirement for Narcotic Treatment Programs 21 C.F.R. § 1306.07(a)	Incremental cost contributes to cumulative cost of providing treatment	DEA could consider using its waiver authority to waive registration for narcotic treatment programs
SAMHSA Accreditation and Certification Requirements 42 C.F.R. § 8.11		SAMHSA removes or amends accreditation and certification requirements through regulation
DEA Security (21 C.F.R. § 1301.74) and Recordkeeping (21 C.F.R. §§ 1304.04 & 1304.24) Requirements		DEA could amend security and recordkeeping requirements though rulemaking