



EXTENDING

PANDEMIC

FLEXIBILITIES

FOR OPIOID USE DISORDER TREATMENT:

UNSUPERVISED USE OF OPIOID TREATMENT MEDICATIONS



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Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Unsupervised Use of Opioid Treatment Medications

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EXECUTIVE SUMMARY

Methadone, a medication used to treat opioid use disorder, can only be dispensed to patients at federally regulated opioid treatment programs. This restriction grew out of concerns about diversion and overdose. Many patients must wait in line each day at an opioid treatment program to receive their dose of methadone because they are not permitted to take additional doses home. Buprenorphine, a medication also used to treat opioid use disorder, is more leniently regulated and can be prescribed to patients by practitioners outside of opioid treatment programs, but it is also occasionally dispensed directly to patients at opioid treatment programs. Although it is easier for practitioners at opioid treatment programs to dispense a take-home supply of buprenorphine than methadone, patients still face considerable barriers to obtaining a take-home supply. Public health advocates have long argued that these barriers should be reduced or removed, but these rules have remained in place for decades. In response to the COVID-19 public health emergency declaration and to promote social distancing, however, federal regulators made it easier for patients to receive take-home supplies of methadone and buprenorphine.

Practitioners and public health experts are concerned that, after the pandemic-related public health emergency expires, this new flexibility will also expire and erode this promising new expansion of access to treatment. This report provides an independent assessment of whether the Substance Abuse and Mental Health Services Agency (SAMHSA) has the legal authority to extend the flexibility after the COVID-19 public health emergency ends.

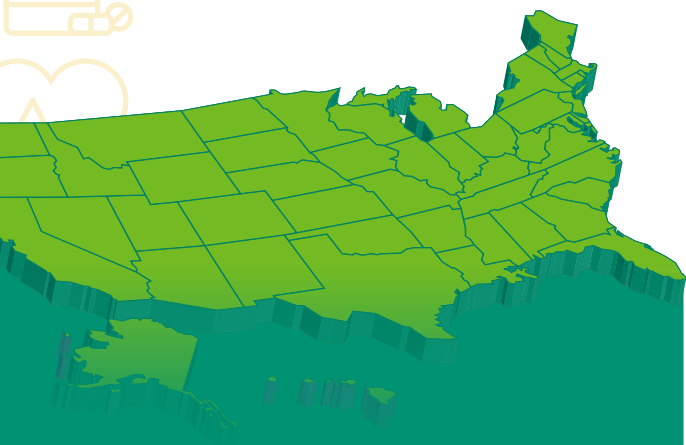
This report concludes that SAMHSA has the legal authority to extend the flexibility it granted during the COVID-19 public health emergency without additional authorization from Congress. SAMHSA could use its statutory authority to issue a rule making codifying this change. Alternatively, SAMHSA could release a guidance document implementing this change, consistent with how it issued guidance for the pandemic. Finally, SAMHSA could use the opioid-specific public health emergency declaration to extend these flexibilities for a longer period.

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I. Introduction

Over 400,000 people in the United States receive methadone from an opioid treatment program.¹ Methadone is significantly more effective at reducing opioid use and retaining patients in treatment than approaches that do not use medication.² For many people, taking methadone to treat their opioid use disorders involves a daily trip to the opioid treatment facility to receive medication administered at the facility.³



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An additional 35,000 people go to opioid treatment programs to receive buprenorphine to treat their opioid use disorders.⁴ Buprenorphine and methadone are considered gold standard treatments for opioid use disorder.⁵ Both medications alleviate the withdrawal symptoms associated with discontinuing opioid use and have been proven to reduce overdose deaths and illicit opioid use.⁶

In January 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared COVID-19 a public health emergency.⁷ Although taking a daily trip to an opioid treatment program was already a logistical challenge for patients, the COVID-19 pandemic heightened obstacles for patients who need to travel every day to receive their medication. Practitioners reported that many opioid treatment programs reduced their hours, and some stopped accepting new patients altogether.⁸ There are also reports of crowded waiting rooms and long lines of people not socially distanced.⁹

1. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., NATIONAL SURVEY OF SUBSTANCE ABUSE TREATMENT SERVICES (N-SSATS): 2019, at 113 (July 2020), <https://www.samhsa.gov/data/sites/default/files/reports/rpt29389/NS-SATS-2019.pdf>.
2. Richard P. Mattick, Courtney Breen, Jo Kimber & Marina Davoli, *Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence*, 3 COCHRANE LIBRARY (2009).
3. See, e.g., Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. CHICAGO L. REV. ONLINE (2020), <https://lawreviewblog.uchicago.edu/2020/11/16/covid-oliva/>.
4. This does not include the number of patients treated with buprenorphine by DATA 2000-waived practitioners who are not affiliated with an opioid treatment program. Methadone can only be dispensed at opioid treatment programs, while buprenorphine can be prescribed by practitioners with a DATA 2000 waiver. This more lenient regulation of buprenorphine explains why significantly fewer patients receive buprenorphine than methadone from opioid treatment programs. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., NATIONAL SURVEY OF SUBSTANCE ABUSE TREATMENT SERVICES (N-SSATS): 2019, at 113 (July 2020), <https://www.samhsa.gov/data/sites/default/files/reports/rpt29389/NSSATS-2019.pdf>.
5. See NAT'L ACADS. OF SCI., ENG'G, AND MED., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES (2019).
6. *Id.* at 38-39; see also Tara Mariolis, Jordon Bosse, Stephen Martin, Amanda Wilson, & Lisa Chiodo, *A Systematic Review of the Effectiveness of Buprenorphine for Opioid Use Disorder Compared to Other Treatments: Implications for Research and Practice*, 10 J. ADDICTION RESEARCH THEORY 379 (2019).
7. U.S. DEPT. OF HEALTH & HUMAN SERV., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.
8. Kate Briquette, *Don't Forget the Other Pandemic Killing Thousands of Americans*, DAILY BEAST (May 3, 2020), <https://www.thedailybeast.com/opioid-deaths-surge-during-coronavirus-in-americas-overdose-capitals>.
9. Alison Insigner, *Methadone Clinic Lines and Packed Waiting Rooms Leave Clients Vulnerable to the Coronavirus*, STAT NEWS (Apr. 9, 2020).

Even before the pandemic, access to opioid treatment programs was limited. Over 90 percent of opioid treatment programs are located in urban areas, making it challenging for rural patients to make the daily trip to receive their medication.¹⁰ Studies established that longer travel distance reduces the likelihood that people with substance use disorder complete treatment or seek aftercare.¹¹ One study found that patients traveling more than a mile to treatment programs were roughly 50 percent less likely to complete treatment than patients who traveled less than a mile.¹²

In response to the COVID-19 public health emergency declaration, the federal government eased providers' ability to provide patients with a take-home supply of methadone or buprenorphine.¹³ This flexibility increased patient access to these critical medications, but the policy may be jeopardized when the COVID-19 public health emergency declaration expires or is revoked.¹⁴

This report provides an independent assessment of whether SAMHSA has the statutory authority to extend the take-home supply flexibility after the public health emergency ends by making changes to its regulations using the notice-and-comment rule making process under the Administrative Procedure Act (APA) and without additional legislative changes from Congress. The main finding is that SAMHSA has regulatory mechanisms available to extend the unsupervised use flexibilities described above. In addition, this report finds that the HHS Secretary's opioid-specific public health emergency declaration could offer a longer-term legal pathway to extend the flexibility beyond the current pandemic.

This report proceeds as follows. First, it explains the existing regulations that apply to the unsupervised use of methadone and buprenorphine and the take-home flexibilities that SAMHSA granted during the COVID-19 public health emergency. Numerous statutes and regulations apply to the treatment of substance use disorder, but this report focuses on those federal requirements that specifically regulate the unsupervised use of methadone and



Over 90 percent of the opioid treatment programs are located in urban areas, making it challenging for rural patients to make the daily trip to receive their medication.

10. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11,008 (Feb. 26, 2020).
11. Kyle Beardsley, Eric D. Wish, Dawn Bonanno Fitzelle, Kevin O'Grady, and Amelia M. Arria, *Distance traveled to outpatient drug treatment and client retention*, 25 J. SUBSTANCE ABUSE TREATMENT 279 (2003); Susan K. Schmitt, Ciaran S. Pibbs, and John D. Piette, *The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment*, 28 ADDICTIVE BEHAVIORS 1183 (2003).
12. Beardsley et al., *supra* note 11, at 283.
13. 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>.
14. DEA is considering removing other barriers, like its ban on approving new mobile methadone clinics, in actions that are not tied to the COVID-19 public health emergency. These flexibilities are outside the scope of this report, but they are likely to increase access to medication. See, e.g., Laura Stanley, *Regulations Teed Up at the DEA*, GW Regulatory Studies Center (Sept. 23, 2020), <https://regulatorystudies.columbian.gwu.edu/regulations-teed-dea>; Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11,008.



buprenorphine. It also considers the impact of these regulations on ongoing telemedicine treatment. Next, it analyzes SAMHSA's authority to extend these flexibilities by making regulatory changes. Lastly, it describes an option for SAMHSA to use the opioid-specific public health emergency declaration to extend the pandemic flexibilities after the COVID-19 public health emergency declaration expires.

II. Regulations for Take-Home Supplies of Opioid Treatment Medication

This section explains the regulations that apply to the unsupervised use of methadone and buprenorphine and the flexibilities the government provided during the COVID-19 public health emergency.

A. Existing SAMHSA and DEA Regulation of Take-Home Supplies

Under existing SAMHSA regulations, practitioners at opioid treatment programs who want to dispense more than a single dose of methadone or buprenorphine to patients for unsupervised use must comply with multiple requirements. This section explains the reasoning behind the regulations and describes the challenges they pose for ongoing treatment using telemedicine.

While SAMHSA regulations are the relevant regulations that restrict practitioners at opioid treatment programs from providing patients with a take-home supply of medication, this section also briefly explains that the Drug Enforcement Administration (DEA) regulations governing opioid treatment programs are silent with regard to unsupervised use.

i. SAMHSA Regulations

Under the Narcotic Addict Treatment Act of 1974, SAMHSA promulgates the regulations for opioid treatment programs, which are defined to include any practitioner or program that is registered with DEA and treats a patient with a drug that is approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder.¹⁵ When used to treat opioid use disorder, methadone can only be dispensed at an opioid treatment program.¹⁶ Buprenorphine is more leniently regulated and can sometimes be prescribed to patients by practitioners outside of opioid treatment programs, but it is also sometimes dispensed directly to patients at opioid treatment programs.¹⁷

The regulations for opioid treatment programs in 42 C.F.R. § 8 are based on a system of program certification and practitioner accreditation.¹⁸ SAMHSA approves accreditation bodies, such as state agencies or nonprofit organizations, which then provide accreditation to the opioid treatment programs. Once an opioid treatment program receives accreditation, the opioid treatment program can apply to SAMHSA for certification.

15. Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g); 42 C.F.R. § 8.2 (2019).

16. 42 C.F.R. § 8 (2019); 21 C.F.R. § 1306.04(c) (2019).

17. The regulations state that "[T]he Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified...to dispense opioid drugs in the treatment of opioid use disorders." 42 C.F.R. § 8.1 (2019). The Food and Drug Administration approves both methadone and buprenorphine for the treatment of opioid use disorder, but SAMHSA also provides waivers to practitioners to prescribe or dispense buprenorphine outside of opioid treatment programs who do not have to follow traditional requirements for opioid treatment programs. Drug Addiction Treatment Act of 2000, 21 U.S.C. § 823(g)(2).

18. 42 C.F.R. § 8.

The standards with which opioid treatment programs must comply are extensive. For example, opioid treatment programs must provide counseling services to patients, document patient care and outcomes, maintain a written plan documenting practices to reduce the diversion of controlled substances, and conduct “random drug abuse tests” for patients.¹⁹ SAMHSA explained in a 1999 rule that the regulations for opioid treatment programs “include careful professional oversight and the availability of specialized support services” but also “reflect[] the risks of abuse and diversion that are endemic to opioid agonist therapy.”²⁰

The requirements for the take-home supply, or unsupervised use, of methadone and buprenorphine are particularly extensive. Practitioners must take into consideration eight criteria when determining if a patient is “responsible” enough to have a take-home supply of medication:

In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

- (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
- (viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risk of diversion.²¹

If a practitioner determines that a patient is sufficiently responsible under these eight criteria to be eligible to receive a take-home supply of methadone, the number of doses is initially limited and gradually increases. For example, during the first 90 days of treatment, patients can only take home one dose per week of methadone.²² This means patients must still go to the opioid treatment program the other six days of the week for their daily dose of methadone.²³ In the second 90 days of treatment, a patient can take home two doses per week.²⁴ The number increases with the time-in-treatment; after a year of continuous treatment, a patient can take home a 2-week supply.²⁵ After 2 years of continuous treatment, the flexibility maxes out and a patient can begin to take home a one-month supply.²⁶

19. *Id.*

20. Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence, 64 Fed. Reg. 39,810 (proposed July 22, 1999).

21. 42 C.F.R. § 8.12(i)(2) (2019).

22. 42 C.F.R. § 8.12(i)(3)(i) (2019).

23. A patient might only need go for five other days if the opioid treatment program closes for a day on Sunday or for State or Federal holidays. 42 C.F.R. § 8.12(i)(1) (2019).

24. 42 C.F.R. § 8.12(i)(3)(ii) (2019).

25. 42 C.F.R. § 8.12(i)(3)(v) (2019).

26. 42 C.F.R. § 8.12(i)(3)(vi) (2019).

There is no time-in-treatment requirement for buprenorphine, but practitioners must still use the eight take-home criteria to determine if a patient is responsible enough to take home buprenorphine.²⁷ The rationale originally put forward to support the time-in-treatment requirement was that “the longer the patient is in treatment[,] the greater the likelihood he or she has of establishing a therapeutic relationship with the counselor and the program and the greater likelihood he or she has of being assessed properly against the [eight criteria].”²⁸

The agency, which was the FDA at the time, did not offer evidence to support the idea that the time-in-treatment requirement encourages patients to stay in treatment longer. When SAMHSA took over this regulatory program, it maintained this eight-criteria test.²⁹

SAMHSA regulations governing unsupervised use are not relevant to practitioners who use a waiver from SAMHSA and DEA to prescribe buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000).³⁰ SAMHSA is also responsible for the regulatory oversight of these practitioners, referred to as “DATA-waived practitioners,” but unlike opioid treatment programs which administer methadone and buprenorphine directly to patients, waived prescribers are permitted to write prescriptions for buprenorphine that patients fill at a pharmacy.³¹ DATA-waived practitioners must document any decision to provide a patient a take-home supply of medication and ensure the methadone or buprenorphine is properly labeled to avoid identify theft or diversion and packaged to reduce the risk of accidental ingestion.³²

Although additional statutes pertain to SAMHSA’s regulation of opioid treatment programs, they are silent on unsupervised use. For example, SAMHSA has promulgated regulations designed to protect the confidentiality of records for patients with opioid use disorder.³³ The statute under which SAMHSA regulates confidentiality, however, is silent on and unrelated to unsupervised use.³⁴ SAMHSA also regulates interim maintenance treatment for patients who seek admission to an opioid treatment program but are waiting due to limited program capacity, but the relevant statute is also silent on unsupervised use.³⁵

ii. SAMHSA Regulations and the Impact on Access to Treatment

Patients who cannot fulfill the eight take-home criteria or who have not been in treatment long enough to satisfy the time-in-treatment requirement must make daily visits to an opioid treatment program. Practitioners have documented that take-home policies serve as a barrier to patient access.³⁶ For example, in a study based on interviews with 85 patients with opioid

27. 42 C.F.R. § 8.12(i)(3) (2019).

28. Drugs Used for Treatment of Narcotic Addicts; Joint Revision of Conditions for Use, 45 Fed. Reg. 62,692, 62,704 (Sept. 19, 1980).

29. Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence, 64 Fed. Reg. 39,810, 39,822 (proposed July 22, 1999); Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4,076, 4,098 (Jan. 17, 2001).

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

31. *Id.*

32. 42 C.F.R. § 8.12(i)(3)-(5) (2019).

33. 42 C.F.R. § 2 (2019).

34. 42 U.S.C. § 290dd-2.

35. 42 C.F.R. § 8.11(g) (2019); 42 U.S.C. § 300y-11.

36. 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).

use disorder, the patients cited restrictions in take-home allowances as one of the primary barriers to treatment.³⁷ Another study found that allowing patients to have a take-home supply early in treatment increased retention.³⁸

The burden of making a daily trip to get medication is particularly acute for patients in rural areas. Research demonstrates that the longer the travel distance, the less likely it is that patients complete treatment.³⁹ One study found that patients who had to travel more than a mile were roughly 50% less likely to complete treatment than patients who traveled less than a mile.⁴⁰ Although this study evaluated travel distance rather than unsupervised use, allowing for increased unsupervised use can be understood to reduce the number of those trips patients must take, lessening their burden.

SAMHSA also signaled the value of unsupervised use. In its 2015 guidance for opioid treatment programs, SAMHSA asserted how critical unsupervised use is for treating patients with opioid use disorder. It wrote that “[p]rogram policies that do not permit take-homes for any patients are unacceptable because the 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.”⁴¹

SAMHSA put forth similar reasoning in the preamble to its 2012 final rule that removed the time-in-treatment requirement for buprenorphine.⁴² SAMHSA explained that the time-in-treatment requirements for unsupervised use “impart a burden on patients and may affect their adherence to treatment.”⁴³ In addition, from a practical perspective, the restrictions on unsupervised use also require opioid treatment programs to see patients more frequently than they otherwise would. This may reduce their overall patient capacity.

iii. SAMHSA Regulations and the Impact on Telemedicine

The regulations limiting unsupervised use create de facto barriers for opioid treatment programs that want to provide ongoing patient treatment using telemedicine. As discussed in a companion report “Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Telemedicine & Initiating Buprenorphine Treatment,” SAMHSA prohibits opioid treatment programs from admitting a new patient without first conducting an in-person evaluation.⁴⁴

In one study based on interviews, patients cited restrictions in take-home allowances as one of the primary barriers to treatment.

37. Deering et al., *supra* note 36, at 638.

38. Kourounis et al., *supra* note 36, at 5.

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

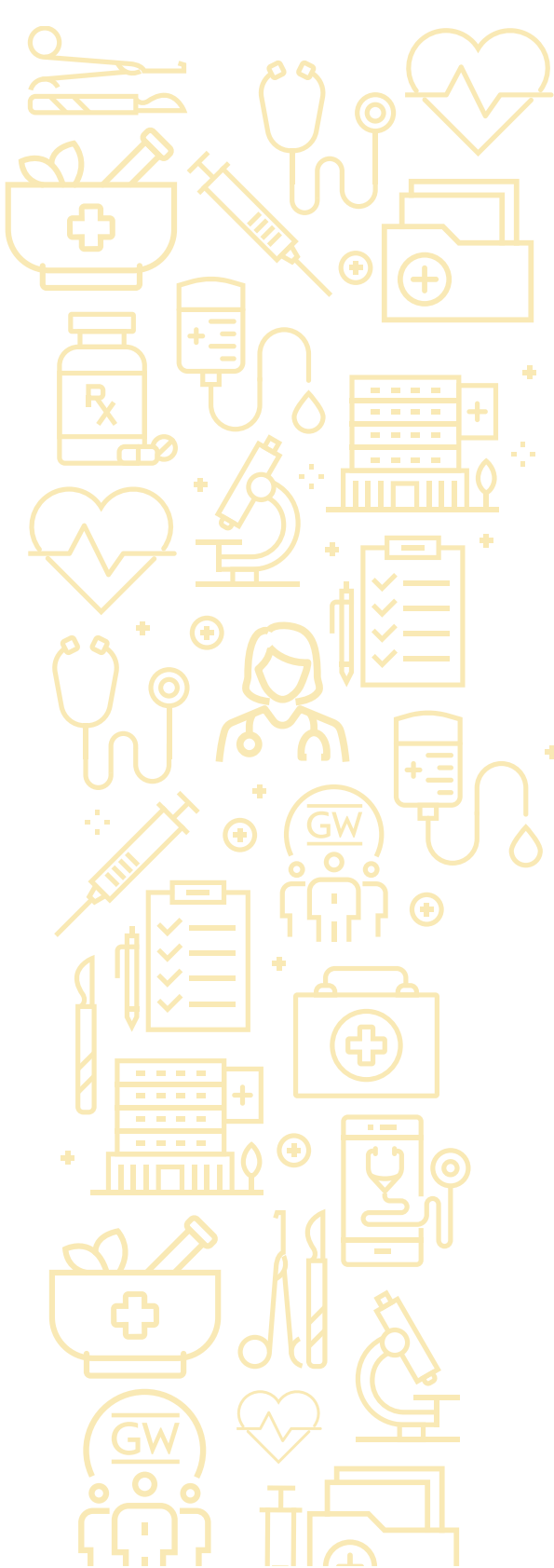
40. *Id.*

41. 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>.

42. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 77 Fed. Reg. 72,752, 72,753 (Dec. 6, 2012).

43. *Id.*

44. 42 C.F.R. § 8.12(f)(2) (2019); Bridget C.E. Dooling & Laura E. Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Telemedicine & Initiating Buprenorphine Treatment* (Feb. 23, 2021), <https://regulatorystudies.columbian.gwu.edu/telemedicine-initiating-buprenorphine-treatment>.



While this requirement prevents opioid treatment programs from initiating treatment using telemedicine, it is not relevant to the ongoing treatment of patients using telemedicine.

In fact, SAMHSA regulations are silent on whether opioid treatment programs can use telemedicine for treatment after conducting the initial in-person medical evaluation.⁴⁵ However, the unsupervised use restrictions effectively limit the extent to which programs can use telemedicine. Patients who can only take home one dose per week of methadone must go to an opioid treatment program the other days of the week to get their daily dose. This limits the benefits of conducting the other services using telemedicine, such as counseling. Why conduct counseling using telemedicine when the patient is already required to visit the opioid treatment program in person six days a week and can participate in counseling in person one of those days?

DATA-waived practitioners, on the other hand, do not face any regulatory barriers from SAMHSA or DEA for providing ongoing treatment using telemedicine.⁴⁶

iv. DEA Regulations

DEA regulations do not impose specific requirements regarding the unsupervised use of methadone or buprenorphine. Rather, and as explained below, the agency defers to SAMHSA regulations regarding unsupervised use. DEA regulations do not otherwise appear to pose barriers to take-home supplies or to ongoing use of telemedicine.

DEA refers to opioid treatment programs as “narcotic treatment programs” in its regulations, which are defined in 21 C.F.R. § 1300 as “program[s] engaged in maintenance and/or detoxification treatment with narcotic drugs.”⁴⁷ To become certified with SAMHSA as an opioid treatment program, a program must register with DEA as a narcotic treatment program and comply with the relevant DEA regulations for narcotic treatment programs.⁴⁸

45. See 42 C.F.R. § 8 (2019).

46. Similar to opioid treatment programs, DATA-waived practitioners face regulatory barriers to initiating treatment using telemedicine. While SAMHSA regulations prohibit opioid treatment programs from admitting a new patient without first conducting an in-person medical evaluation, DEA regulations prohibit DATA-waived practitioners from prescribing buprenorphine without first conducting an in-person medical evaluation. See Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 85 Fed. Reg. 61,594 (Sept. 30, 2020).

47. 21 C.F.R. § 1300.01 (2019).

DEA only permits narcotic treatment programs to administer or dispense methadone and buprenorphine directly to patients; they cannot prescribe the medications to be filled elsewhere.⁴⁹ Although the DEA regulations state that a narcotic treatment program can only administer or dispense methadone and buprenorphine when “in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act,”⁵⁰ the DEA regulations only include distinct requirements for treatment qualifications, security, and record keeping.⁵¹ The DEA regulations regarding unsupervised use refer to the SAMHSA regulations:

All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.⁵²

DEA's security controls for narcotic treatment programs, for example, require such programs to keep controlled substances in a safe or steel cabinet and to notify DEA of theft and significant loss of methadone and buprenorphine.⁵³ DEA also requires narcotic treatment programs to keep inventories and records of methadone and buprenorphine, as well as a dispensing log that tracks the amount of medication dispensed or administered to a patient.⁵⁴

Therefore, while DEA regulations apply multiple restrictions to narcotic treatment programs, those restrictions do not appear to bear on take-home supplies or ongoing telemedicine use.⁵⁵

v. Other Federal Regulations

Several other federal statutes and regulations apply to the ongoing treatment of opioid use disorder using telemedicine.

For example, prior to the public health emergency, the Centers for Medicare & Medicaid Services (CMS) only authorized Medicare reimbursement for telemedicine in a few circumstances, like for brief check-ins for established patients.⁵⁶ In response to the COVID-19

48. 21 C.F.R. § 1306.07(a)(1)-(2) (2019).

49. A practitioner can prescribe buprenorphine, a Schedule III narcotic drug, if he or she has a DATA-2000 waiver from SAMHSA. A practitioner at an opioid treatment program could use a DATA-2000 waiver to write a prescription. See 21 C.F.R. § 1306.07(d) (2019).

50. 21 C.F.R. § 1306.07(a)(2) (2019).

51. See 21 C.F.R. § 1301.72 (2019); 21 C.F.R. § 1301.74 (2019).

52. 21 C.F.R. § 1301.74(k) (2019).

53. 21 C.F.R. § 1301.72(a)-(b) (2019); 21 C.F.R. § 1301.74(c) (2019).

54. 21 C.F.R. § 1304.04(f) (2019); 21 C.F.R. § 1304.24(b) (2019).

55. Although DEA regulations prohibit the prescribing or dispensing of buprenorphine without conducting an in-person medical evaluation, DEA has taken efforts to clarify that these restrictions do not apply to ongoing treatment using telemedicine. DEA Section Chief Loren Miller stated, “We routinely get questions [from] practitioners asking...how often they must physically see a patient if they are going to continue telemedicine. Once that physical exam takes place between the prescriber and the patient...that’s the point at which the practitioner and patient can communicate orally in any way shape or form they wish, so long as you’re compliant with any state laws or regulations....That’s become quite a frustrating point because there are practitioners who are telling patients they must come back each time to do telemedicine and be physically examined...that is not the case at the federal level.” Loren Miller, Section Chief, Drug Enforcement Admin., Remarks at the American College of Medical Toxicology’s Mitigating the Intersection of COVID-19 and Opioid Use Disorder Panel (May 2, 2020), 47:02, https://www.youtube.com/watch?v=t_lu9t-AJug.

56. Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, 83 Fed. Reg. 59,452 (Jan. 1, 2019).

public health emergency, CMS significantly relaxed reimbursement requirements for telemedicine, including for substance use disorder treatment.⁵⁷

As another example, HHS promulgated regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to protect health information involved in telemedicine.⁵⁸ The regulations require practitioners to have an agreement with the third-party vendor that provides the video communication technology to describe the measures the vendor will take to protect the information.⁵⁹ In response to the COVID-19 public health emergency, HHS announced that it would use its enforcement discretion and not impose penalties on practitioners who fail to have an agreement in place so long as they avoid a list of certain technologies (e.g., TikTok) and operate in good faith.⁶⁰

In both examples, these additional flexibilities may be jeopardized if the COVID-19 public health emergency expires or is revoked. Although these federal statutes and regulations are outside the scope of this report, they have the potential to create additional barriers to providing ongoing treatment using telemedicine and therefore merit future research.⁶¹

B. COVID-19 Related Flexibilities

In response to the COVID-19 public health emergency, SAMHSA released a guidance document that allows state regulatory authorities to request blanket exceptions to allow patients to take home more doses of methadone and buprenorphine.⁶² The guidance says that for all states,

[t]he state may request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder. The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.⁶³

The guidance document and the regulations at 42 CFR § 8.12 do not define "stable patient" or "less stable patient," nor do they include any description about who qualifies as "stable." Thus, SAMHSA's guidance is unclear about whether opioid treatment programs should use the eight take-home criteria laid out in 42 CFR § 8.12(i)(2) or different criteria. Some practitioners interpreted the pandemic-related guidance to mean that SAMHSA is deferring to the opioid treatment programs to decide when a patient is "stable" or "less stable."⁶⁴ Others interpreted

57. CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE TELEMEDICINE HEALTH CARE PROVIDER FACT SHEET (Mar. 2020), <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>.

58. 45 C.F.R. § 164 (2019).

59. U.S. DEPT OF HEALTH & HUMAN SERV., BUSINESS ASSOCIATE CONTRACTS (Jan. 25, 2013), <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>.

60. U.S. DEPT OF HEALTH & HUMAN SERV., NOTIFICATION OF ENFORCEMENT DISCRETION FOR TELEHEALTH REMOTE COMMUNICATIONS DURING THE COVID-19 NATIONWIDE PUBLIC HEALTH EMERGENCY (2020), <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>.

61. The same is true with respect to the state medical boards and their requirements associated with telemedicine inside their states and across state lines.

62. 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>.

63. *Id.*

64. Alison Insinger, *Methadone Clinic Lines and Packed Waiting Rooms Leave Clients Vulnerable to the Coronavirus*, STAT NEWS (Apr. 9, 2020), <https://www.statnews.com/2020/04/09/methadone-clinics-leave-clients-vulnerable-to-coronavirus/>.

process.⁶⁹ The only condition the statute places on SAMHSA is the requirement that the agency consult with DEA before issuing the regulations.⁷⁰

The language of the Act unambiguously gives SAMHSA this authority. The Act says:

The Attorney General shall register a [practitioner] to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both) (A) 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;...and (C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.⁷¹

This language plainly gives SAMHSA broad authority to establish the standards that practitioners must follow to dispense narcotic drugs to individuals for maintenance or detoxification treatment (i.e., the standards that opioid treatment programs must follow).

It also gives SAMHSA broad authority to set standards regarding the quantity of methadone or buprenorphine an opioid treatment program can give a patient to take home, and it does not limit the circumstances for which SAMHSA can authorize unsupervised use. SAMHSA has the authority, for example, to extend the pandemic-related flexibilities by promulgating a regulation allowing states to request blanket exemptions for all stable patients to receive 28 days of take-home medication and less stable patients to receive 14 days of take-home medication after consultation with DEA.

In fact, SAMHSA has the authority to provide flexibilities that extend beyond the pandemic-related flexibilities. For example, SAMHSA could modify its regulations at 42 CFR § 8.12(i)(3) to remove or modify the time-in-treatment requirement for all patients who have been deemed stable enough to have a take-home supply. Alternatively, the regulations could permit any patient who an opioid treatment program deems “stable” to have access to 14 or 28 days of take-home supply. SAMHSA could remove the eight take-home criteria from the regulations and defer to the opioid treatment program to make the decision about when a patient is “stable.” If SAMHSA amended the regulations in this manner, states would not need to request an exemption from SAMHSA, and states that incorporate SAMHSA’s regulations by reference would not need to take any additional action to allow for such in-state flexibility.⁷² This is one of many approaches SAMHSA could take to modify its regulations for unsupervised use.

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

70. *Id.*

71. *Id.*

72. New Jersey’s regulations, for example, stipulate that opioid treatment programs only need to request an exemption from the take-home requirements if the “treatment decision . . . differs from the Federal regulatory requirements at 42 CFR Part 8.” N.J. ADMIN. CODE §10:161B-11.1 (2020). Thus, New Jersey would not need to modify its administrative code to allow for expanded take-home use. Alternatively, Massachusetts promulgates regulations that are more stringent than the federal regulations for take-home use. For example, during the first two months of treatment, patients can have no take-home doses. 105 MASS. CODE REGS. § 164.000 (2016). Massachusetts would need to amend its regulations to allow for expanded take-home use. These scenarios, where state action is needed to implement SAMHSA’s regulatory changes, create an additional barrier to extending the pandemic-related flexibilities. Although state-level barriers are outside the scope of this report, they warrant further scrutiny.

To support regulatory changes like this, SAMHSA would need to build an administrative record to support the changes, including an evidence-based rationale. This is one area where on-the-ground experience with the current regulations and pandemic flexibilities could help support SAMHSA's rationale for a regulatory change. The statute also requires SAMHSA to consult with DEA prior to issuing such regulations, so the agency would need to communicate with DEA and include a description of the consultation in the rule making record before issuing the rule.⁷³ SAMHSA explained that the restrictions on unsupervised use "are intended to reduce the risk of abuse and diversion of opioid treatment medication that have abuse potential."⁷⁴ However, recent research suggests that there has been minimal diversion associated with unsupervised use during the COVID-19 public health emergency.⁷⁵ This study anonymously surveyed 87 patients receiving methadone take-home doses since SAMHSA issued the pandemic-related flexibility doses and found minimal reported levels of diversion of the take-home doses.⁷⁶



A recent study anonymously surveyed patients receiving methadone take-home doses since SAMHSA issued the pandemic-related flexibility doses and found minimal reported levels of diversion.

B. SAMHSA Issues a New Guidance Document

As noted above, in response to the COVID-19 public health emergency, SAMHSA released a guidance document that allows state regulatory authorities to request blanket exceptions to allow patients to take home additional doses of methadone and buprenorphine.⁷⁷ This guidance document does not reference the COVID-19 public health emergency declaration. It also does not discuss SAMHSA's legal authority to provide this flexibility. However, SAMHSA's clearest authority to extend these flexibilities through guidance comes from 42 C.F.R. § 8.11(h).

SAMHSA has the regulatory authority at 42 C.F.R. § 8.11(h) to grant opioid treatment programs exemptions from various requirements.⁷⁸ This regulation states that "[a]n [opioid treatment program] may, at the time of application for certification or any time thereafter,

73. 21 U.S.C. § 823(g)(1).

74. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 77 Fed. Reg. 72,752, 72,753 (Dec. 6, 2012).

75. Mary C. Figgatt, Zach Salazar, Elizabeth Day, Louise Vincent, & Nabarun Dasgupta, *Take-Home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19*, 123 J. SUBSTANCE ABUSE TREATMENT 1 (Sep. 2, 2020), <https://doi.org/10.1016/j.jsat.2021.108276>.

76. *Id.*

77. 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>.

78. 42 CFR § 8.11(h) (2019).



flexibilities, although it would be in jeopardy if the opioid-specific public health emergency expires or is revoked.

The Secretary of HHS can declare a public health emergency under the Public Health Service Act, which permits the federal government to take actions like spending emergency funds or suspending regulatory requirements.⁸³ As this report is being drafted, there are two different public health emergency declarations in effect. On October 26, 2017, Acting Secretary of HHS Eric Hargan determined that a public health emergency exists as a result of the consequences of the opioid crisis.⁸⁴ The opioid crisis public health emergency has been renewed fourteen times and is currently in effect.⁸⁵ On January 31, 2020, Secretary of HHS Alex Azar declared another public health emergency as a result of the COVID-19 pandemic, which has been renewed five times.⁸⁶ It is unclear when the COVID-19 pandemic and the associated declaration of a public health emergency will end. Public health experts have suggested that we could be out of it in 2021. Because of the ongoing nature of the opioid crisis, however, there is reason to believe that the opioid-related public health emergency declaration will persist past that of the COVID-19 pandemic.

In that case, SAMHSA could draw on the same legal authority as the second option, but link it more clearly to the opioid emergency declaration. Just as SAMHSA used its regulatory authority at 42 C.F.R. § 8.11(h) to allow for increased unsupervised use, it can also use that regulatory authority to extend this exemption under the opioid-specific public health emergency. As noted above, the regulatory authority at 42 C.F.R. § 8.11(h) does not require a public health emergency declaration for SAMHSA to provide exemptions to the regulations in § 8.12.⁸⁷ The regulation gives SAMHSA the discretion to exempt opioid treatment programs from any regulations in § 8.12 and does not stipulate the circumstances in which SAMHSA can provide exemptions.⁸⁸

However, SAMHSA could choose to make the exemptions contingent on the continuation of the opioid-specific public health emergency. The unsupervised use flexibilities fit neatly into the objectives of responding to the opioid crisis. Improving access to treatment is an essential aspect of response to the opioid crisis, so steps intended to improve access to take-home supplies and ongoing telemedicine can reasonably be understood to advance the public interest during a public health emergency.

This third option would not provide a permanent solution, since the flexibility would expire if or when the opioid-specific public health emergency expires or is revoked. This more incremental approach could also be linked to an effort to study the effects of the ongoing flexibility to determine whether ongoing flexibility strikes the right balance between treatment and diversion. If so, SAMHSA could pursue one of the more permanent options described above.

83. Public Health Service Act of 1944, 42 U.S.C. § 247d.

84. U.S. DEPT OF HEALTH & HUMAN SERV., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2017), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>.

85. U.S. DEPT OF HEALTH & HUMAN SERV., RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids-7April2021.aspx>.

86. U.S. DEPT OF HEALTH & HUMAN SERV., RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid-15April2021.aspx>.

87. 42 C.F.R. § 8.11(h) (2019).

88. *Id.*

IV. Conclusion

In response to the COVID-19 public health emergency, SAMHSA reduced the barriers that prevent patients from receiving a take-home supply of methadone and buprenorphine. Public health experts have long argued that take-home supplies can improve access to treatment. This report provides an independent assessment of SAMHSA's authority to extend these flexibilities after the COVID-19 public health emergency expires or is revoked. It finds SAMHSA has three different options to extend the flexibilities without needing additional authorization from Congress.

First, SAMHSA could use its statutory authority to issue a rule codifying the flexibilities after consulting with DEA. Second, SAMHSA could release a new guidance document implementing these changes. Third, SAMHSA could release a new guidance document implementing these changes but tie it to the opioid-specific public health emergency declaration.

With the hope that the COVID-19 pandemic will be behind us in 2021, there is a risk that SAMHSA's take-home supply flexibility will also come to an end. As explained in this report, SAMHSA has multiple, lawful pathways to extend these flexibilities beyond the pandemic and in support of patients.



