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Essay

Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Authorities and Methods

Bridget C.E. Dooling & Laura Stanley*

INTRODUCTION

In the third week of March 2020, almost two months after the Secretary of the Department of Health and Human Services (HHS) declared COVID-19 a public health emergency,¹ officers in Wyoming County, West Virginia responded to fourteen opioid overdose calls.² This was not unusual. From 2014 to 2016, Wyoming County had the highest overdose death rate in West Virginia.³ One report indicates that Wyoming County has the highest rate of prescription drug overdose deaths in the United States.⁴

Buprenorphine and methadone help alleviate the withdrawal

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1. U.S. DEP'T OF HEALTH & HUM. SERVS., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> [<https://perma.cc/ATY7-8JWT>].

2. Mary Catherine Brooks, *Wyoming County Hit With 9 Overdoses in 36 Hours*, REGISTER-HERALD (Apr. 2, 2020), https://www.register-herald.com/news/crime/wyoming-county-hit-with-9-overdoses-in-36-hours/article_cc4a34a9-b874-5da7-8415-b1d1e941e183.html [<https://perma.cc/KSB8-HGE4>].

3. W. VA. DEP'T OF HEALTH & HUM. RES., 2016 WEST VIRGINIA OVERDOSE FATALITY ANALYSIS 1, 9 (2017), https://dhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf [<https://perma.cc/9LW8-AJZD>].

4. Wendy Holdren, *Report Shows Wyoming County Worst in Country for Prescription Drug Deaths*, REGISTER-HERALD (Aug. 21, 2016), https://www.register-herald.com/news/report-shows-wyoming-county-worst-in-country-for-prescription-drug-deaths/article_123649b7-d708-5896-8cd6-040aae835ebd.html [<https://perma.cc/G8VF-3M5H>].

symptoms associated with discontinuing opioid use, reducing illicit opioid use and resulting overdoses.⁵ But it is challenging for patients in rural locations like Wyoming County to access these lifesaving medications. In Wyoming County, for example, there is only a single practitioner permitted by federal regulation to prescribe buprenorphine.⁶ Practitioners are required to obtain a special waiver to prescribe buprenorphine to patients with opioid use disorder, which limits the number of available practitioners. It is even more difficult to obtain methadone, as patients can only obtain it directly from highly regulated opioid treatment programs. The closest opioid treatment program is an hour-long drive away from the center of Wyoming County.⁷

Access to these treatments is highly regulated, with jurisdiction split at the federal level between different agencies.⁸ It took a pandemic to break through some of the restrictions.⁹ To allow providers to follow social distancing designed to limit the spread of COVID-19, federal regulatory agencies dramatically reduced barriers to accessing buprenorphine and methadone. Although there is hope that the COVID-19 pandemic will soon be behind us, that means the flexibilities that eased the treatment of opioid use disorder are at risk of lapsing. The opioid epidemic, on the other hand, is only getting worse.

5. See NAT'L ACADS. OF SCIS., ENG'G & MED., MEDICATION FOR OPIOID USE DISORDER SAVES LIVES 1, 34 (2019) (noting that buprenorphine and methadone "reduce opioid cravings and help to sever ties between opioid use and established situational or emotional triggers").

6. *Buprenorphine Practitioner Locator*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator> [<https://perma.cc/A27L-PUJZ>].

7. *Opioid Treatment Program Directory*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://dpt2.samhsa.gov/treatment/directory.aspx> [<https://perma.cc/7826-WLY3>].

8. See 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, 15–23 (2017) (describing the complex regulatory environment for opioid addiction treatment). See generally Taleed El-Sabawi, *Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances*, 16 N.Y.U. J.L. & BUS. 317 (2020) (describing the shift of certain responsibilities from the Food and Drug Administration to the Drug Enforcement Agency).

9. Many others remain in place. See, e.g., Kevin Fiscella, Sarah E. Wakeman, & Leo Beletsky, *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder, X the X-Waiver*, 76 JAMA PSYCHIATRY 229, 229–30 (2019) (describing the X-waiver process, which requires prescribers to undergo more training to treat opioid addiction than to prescribe opioids); Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 55 (2010) (describing barriers that inhibit physician prescription of medication to treat addiction).

Drug overdose deaths surged during 2020. Preliminary data suggests more than 90,000 Americans died of drug overdoses last year.¹⁰

This Essay evaluates two specific flexibilities granted during the COVID-19 pandemic that made it easier for patients to access buprenorphine and methadone. First, the Drug Enforcement Administration (DEA) allowed practitioners to prescribe buprenorphine using telemedicine without first conducting an in-person medical exam. Second, the Substance Abuse and Mental Health Services Administration (SAMHSA) made it easier for patients to have a take-home supply of methadone, reducing many patients' need to make a daily trip to an opioid treatment program. The White House Office of National Drug Control Policy indicated that extending pandemic flexibilities for treating opioid use disorder is a priority for the Biden Administration, and this Essay provides a roadmap for the executive branch to do so.¹¹

While Congress could certainly make the changes permanent through legislation, this Essay provides an independent assessment of whether DEA and SAMHSA have the statutory authority to extend these flexibilities after the COVID-19 public health emergency ends by making changes to their regulations using the notice-and-comment rulemaking process under the Administrative Procedure Act (APA). The main finding is that DEA and SAMHSA have regulatory mechanisms available to extend the flexibilities described above. In addition, the U.S. HHS Secretary's opioid-specific public health emergency declaration could offer a longer term, but still impermanent, legal pathway to extend these flexibilities beyond the current pandemic.

This Essay proceeds as follows. First, it explains the existing regulations that apply to buprenorphine induction¹² using telemedicine and the flexibilities that have been granted during the COVID-19 public health emergency. It then analyzes the authorizing statutes and finds that DEA has the authority to extend the telemedicine flexibilities by making regulatory changes. Next, this Essay explains the

10. Paige Winfield Cunningham, *The Health 202: Overdose Deaths May Have Topped 90,000 in 2020*, WASH. POST, (Apr. 7, 2021), <https://www.washingtonpost.com/politics/2021/04/07/health-202-overdose-deaths-may-have-topped-90000-2020/> [<https://perma.cc/L577-BJM2>].

11. OFF. OF NAT'L DRUG CONTROL POL'Y, THE BIDEN-HARRIS ADMINISTRATION'S STATEMENT OF DRUG POLICY PRIORITIES FOR YEAR ONE (Apr. 1, 2021), <https://www.whitehouse.gov/ondcp/briefing-room/2021/04/01/biden-harris-administration-announces-first-year-drug-policy-priorities/> [<https://perma.cc/3F77-DYPP>].

12. "Induction" is the process by which practitioners help patients begin buprenorphine treatment and set their initial dosing. Walter Ling, Larissa Mooney, & Matthew Torrington, *Buprenorphine for Opioid Addiction*, 2 PAIN MGMT. 345, 347 (2012).

existing regulations that apply to unsupervised use of methadone and the take-home flexibilities that SAMHSA granted during the COVID-19 public health emergency. It then analyzes the authorizing statutes and finds that SAMHSA has the authority to extend the take-home flexibilities by making regulatory changes. Lastly, it considers how DEA and SAMHSA could use the HHS Secretary's opioid-specific public health emergency declaration to extend both pandemic flexibilities after the COVID-19 public health emergency expires.

I. BUPRENORPHINE INDUCTION USING TELEMEDICINE

Buprenorphine, along with methadone, is considered a gold standard for the treatment of opioid use disorder.¹³ Before the Drug Addiction Treatment Act of 2000 (DATA 2000), practitioners could only treat patients with buprenorphine at highly regulated opioid treatment programs.¹⁴ DATA 2000 allowed practitioners to prescribe buprenorphine to patients outside of opioid treatment programs, so long as they obtain an "X" waiver from SAMHSA and DEA. To obtain an X-waiver, a practitioner is generally required to complete a specialized eight-hour or twenty-four-hour training, submit a notification of intent to SAMHSA, and follow certain conditions while providing buprenorphine treatment—although HHS recently exempted practitioners from the training requirement if they comply with certain conditions.¹⁵

Although SAMHSA and DEA are both responsible for regulatory oversight of "DATA-waived practitioners," the regulations that limit these practitioners from using telemedicine, rooted in concerns about diversion of controlled substances, were issued by DEA. This Part explains the DEA regulations that apply to buprenorphine induction using telemedicine, describes the flexibilities that the agency provided to patients and practitioners during the COVID-19 public health emergency, and finds that DEA has the authority to extend the telemedicine flexibilities through regulatory changes.

A. DEA REGULATION OF BUPRENORPHINE INDUCTION USING TELEMEDICINE

In 2009, DEA promulgated regulations implementing the Ryan

13. *See id.* at 346 (noting that buprenorphine "is arguably the most significant advance in the history of pharmacotherapy for opioid addiction, heralded by the introduction of methadone maintenance a half century ago").

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

15. *Id.*; Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 Fed. Reg. 22,439 (Apr. 28, 2021).

Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act).¹⁶ These regulations prohibit various methods of distributing and dispensing controlled substances over the Internet, including prescribing and dispensing controlled substances without first conducting an in-person medical evaluation.¹⁷ Since buprenorphine is a schedule III-controlled substance, it falls under these regulations.¹⁸

The goal of the Ryan Haight Act and DEA's implementing regulations is to halt rogue websites that allow individuals to obtain prescriptions and purchase controlled substances based on inadequate medical evaluations.¹⁹ The primary tool the regulations use to combat the sale of controlled substances over the Internet is the requirement that a practitioner must give a patient at least one in-person medical evaluation before prescribing a controlled substance. A practitioner or facilitator who knowingly or intentionally fills a prescription for a controlled substance without conducting an in-person medical evaluation can be held criminally liable.²⁰

A practitioner is only permitted to prescribe controlled substances without conducting the in-person medical evaluation when engaged in one of the rule's seven exceptions for the "practice of telemedicine."²¹ The exceptions are narrow, and patients cannot be located in their own homes to take advantage of many of them. For example, under one exception, a practitioner can initiate treatment using telemedicine if the patient is located in and being treated by a DEA-registered hospital or clinic.²² Alternatively, a practitioner can initiate treatment using telemedicine if the patient is in the physical

16. DEA released an interim final rule in 2009 that was effective immediately but did not release a final action affirming the interim final rule until 2020. *See* Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15,596 (Apr. 6, 2009); Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 85 Fed. Reg. 61,594 (Sept. 30, 2020).

17. Congress named the Act after Ryan Haight, a young man who died of an overdose on prescription painkillers that he bought from an online pharmacy without a valid prescription. S. REP. NO. 110-521, at 7 (2008).

18. 21 C.F.R. § 1308.13 (2019).

19. Implementation of the Ryan Haight Act, 74 Fed. Reg. 15,600-04 (Apr. 6, 2009).

20. 21 U.S.C. § 841(h)(1) of the Controlled Substances Act lays out the various criminal liabilities for violations. A practitioner can be convicted of violating the Controlled Substances Act if they had knowledge of the illegal activity or enough information that they engaged in willful blindness. *See, e.g.,* United States v. Katz, 445 F.3d 1023, 1031 (8th Cir. 2006).

21. 21 C.F.R. § 1300.04 (i)(1-7) (2019).

22. 21 C.F.R. § 1300.04 (i)(1) (2019).

presence of and being treated by a DEA-registered practitioner.²³

The Ryan Haight Act gives DEA the discretion to allow for telemedicine in a few other circumstances. For example, if there is a public health emergency, such as the ongoing coronavirus public health emergency, DEA can allow for the use of telemedicine.²⁴ In practice, prior to the pandemic, patients could not be prescribed controlled substances via telemedicine without an in-person medical examination unless they were at a DEA-registered hospital or clinic or in the presence of a DEA-registered practitioner.

DEA argues that the Ryan Haight Act and the implementing regulations were effective in targeting rogue online pharmacies. DEA points out that “it shut the door on the internet diversion of controlled substances almost overnight.”²⁵ However, as an unintended consequence it also forced legitimate telemedicine providers to first conduct in-person medical evaluations, and practitioners have pointed to these DEA regulations as a substantial barrier to the adoption of telemedicine for treating opioid use disorder.²⁶

The SAMHSA regulations applicable to DATA-waived practitioners are silent on whether they can initiate buprenorphine treatment using telemedicine.²⁷ Rather, DEA regulation of controlled substances is the regulation that prohibits DATA-waived practitioners from initiating buprenorphine using telemedicine.

Several other regulations apply to buprenorphine induction 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,

23. The practitioner must also be acting in “the usual course of professional practice,” in accordance with state law, and be registered in the state where the patient is located. 21 C.F.R. § 1300.04 (i)(2) (2019).

24. Specifically, the statute states when telemedicine is conducted “during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act . . . and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates,” it is considered an exempted “practice of telemedicine.” 21 C.F.R. § 1300.04 (i)(4) (2019).

25. 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 20, 2020), 45:04, https://www.youtube.com/watch?v=t_lu9t-AJug [<https://perma.cc/FVH5-KDCA>].

26. See Y. Tony Yang, Eric Weintraub, & Rebecca L. Haffajee, *Telemedicine’s Role in Addressing the Opioid Epidemic*, 93 MAYO CLINIC PROC. 1177, 1178 (2018) (noting that in-person examination requirements under the Haight Act “impede the ability of providers to prescribe buprenorphine . . . via telemedicine”).

27. 42 C.F.R. § 8 (2019).

including brief check-ins for established patients.²⁸ In response to the COVID-19 public health emergency, CMS significantly relaxed reimbursement requirements for telemedicine, including for substance use disorder treatment.²⁹ As another example, HHS promulgated regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to protect health information involved in telemedicine, and the associated regulations require practitioners to use video communication technology provided by certain third-party vendors.³⁰ In response to the COVID-19 public health emergency, HHS announced it would use its enforcement discretion and not impose penalties on practitioners as long as they avoid certain technologies (e.g., TikTok) and operate in good faith.³¹ Although these regulations are outside the scope of this Essay, they have the potential to reestablish barriers to providing ongoing treatment using telemedicine and merit future research.

B. DEA COVID-19 EMERGENCY FLEXIBILITIES

In response to the COVID-19 public health emergency, DEA released guidance allowing practitioners to prescribe buprenorphine to new and existing patients with opioid use disorder over the telephone without first requiring an in-person examination or an examination using an audio-visual connection.³²

DEA placed few limitations on practitioners' use of the exception. Prescriptions for buprenorphine must be issued "for a legitimate

28. 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).

29. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE TELEMEDICINE HEALTH CARE PROVIDER FACT SHEET (Mar. 2020), <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet> [<https://perma.cc/8WEF-C5SV>].

30. U.S. DEP'T OF HEALTH & HUM. SERVS., BUSINESS ASSOCIATE CONTRACTS (Jan. 25, 2013), <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html> [<https://perma.cc/92DB-ER9N>].

31. U.S. DEP'T OF HEALTH & HUM. SERVS., 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> [<https://perma.cc/86N5-M7LW>].

32. Letter from Thomas Prevoznik, Deputy Assistant Admin., Diversion Control Div., Drug Enf't Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf) [<https://perma.cc/48M5-6M5S>].

medical purpose by a practitioner acting in the usual course of his/her professional practice.”³³ Practitioners also must determine that an adequate evaluation can be conducted over the telephone or using an audio-visual connection.³⁴

DEA relies on a section of the Ryan Haight Act to provide this exception to practitioners during the pandemic. Under 21 U.S.C. § 802(54)(D), DEA has the authority to allow for the “practice of telemedicine” when it is being “conducted during a public health emergency declared by the Secretary.”³⁵ DEA cites the COVID-19 public health emergency declaration in its guidance.³⁶ Accordingly, the exemption will expire when that emergency declaration expires.

C. APPROACHES TO EXTENDING FLEXIBILITIES FOR BUPRENORPHINE INDUCTION

This Part describes two approaches DEA could take to extend the telemedicine flexibilities granted during the COVID-19 public health emergency post-pandemic without additional authorization from Congress. First, DEA could issue joint regulations with SAMHSA allowing practitioners to prescribe buprenorphine without first conducting an in-person medical evaluation. Second, DEA could establish a special registration for telemedicine program.

1. DEA and SAMHSA Issue Joint Regulations

DEA and SAMHSA have the authority under the Ryan Haight Act to extend the telemedicine flexibilities granted during the COVID-19 pandemic by jointly issuing regulations that allow practitioners to prescribe buprenorphine without first conducting an in-person medical evaluation.

DEA and SAMHSA’s authority to promulgate regulations allowing practitioners to prescribe buprenorphine using a telephone or two-way, audio-visual connection is well grounded in the law. The Ryan Haight Act expressly gives the agencies the authority to prescribe such regulations in 21 U.S.C. § 802(54)(G), and the history of the Ryan Haight Act is in line with the agencies taking this action.

The language of the Ryan Haight Act unambiguously gives DEA and SAMHSA the authority to promulgate regulations allowing for

33. *Id.*

34. *Id.*

35. 21 U.S.C. § 802(54)(D).

36. Letter from Thomas Prevoznik, *supra* note 32.

wider adoption of telemedicine.³⁷ The Act says:

No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act . . . may be delivered, distributed, or dispensed by means of the Internet without a valid prescription The term “valid prescription” means a prescription that is issued . . . by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient[,] or . . . a covering practitioner.³⁸

The Act defines “covering practitioner” as “a practitioner who . . . has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine.”³⁹ The Act then defines seven distinct instances when a practitioner can use telemedicine.⁴⁰ These are colloquially referred to as the “seven exceptions” to the requirement to conduct an in-person exam prior to prescribing a controlled substance using telemedicine.⁴¹

The seventh exception allows DEA and SAMHSA to issue joint regulations that permit practitioners to use telemedicine:

The term “practice of telemedicine” means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of title 42, which . . . is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.⁴²

This language gives DEA and SAMHSA the discretion to promulgate regulations allowing practitioners to prescribe controlled substances using telemedicine under “any other circumstances” that the agencies determine qualify under the Act.⁴³ The Act also gives the agencies discretion to ensure the regulations effectively control against diversion and are “consistent with the public health and safety.”⁴⁴ While choices about the content of the regulations are

37. 21 U.S.C. § 802(54)(G).

38. 21 U.S.C. § 829(e)(1–2).

39. 21 U.S.C. § 829(e)(2)(C).

40. 21 U.S.C. § 802(54).

41. Thomas B. Ferrante & Sunny J. Levine, *COVID-19: DEA Confirms Public Health Emergency Exception for Telemedicine Prescribing of Controlled Substances*, FOLEY INSIGHTS (Mar. 18, 2020), <https://www.foley.com/en/insights/publications/2020/03/covid19-public-health-exception-telemedicine> [https://perma.cc/JKW6-H6KG].

42. 21 U.S.C. § 802(54)(G).

43. *Id.*

44. *Id.*

generally left to the agencies, there is no ambiguity that the agencies have the discretion to issue the regulations.

The plain language of the statute forecloses any ambiguity regarding DEA and SAMHSA's ability to promulgate regulations that extend the telemedicine flexibilities granted during the pandemic, so agencies and courts do not have to follow interpretive aids like legislative history.⁴⁵

Although it is not authoritative, the legislative history of the Ryan Haight Act is in tandem with the interpretation that DEA and SAMHSA can issue regulations allowing for broader use of telemedicine.

As a Senate Judiciary Committee report explains, some Senate leaders were concerned about hindering emerging telemedicine markets and did not intend for the Ryan Haight Act to restrict legitimate telemedicine.⁴⁶ The report points out that telemedicine can "improve health outcomes and reduce costs" as well as offer care that is "not available in many remote areas."⁴⁷ The Committee did not want to place "unnecessary restrictions on the operations or growth of telemedicine," thus, the committee report notes that:

[T]he statute provides that the Attorney General and the Secretary of Health and Human Services may promulgate regulations that allow for the full practice of telemedicine consistent with medical practice guidelines, so long as those regulations continue to effectively control diversion. The Committee anticipates that the Attorney General and Secretary may update these regulations on an ongoing basis to reflect changes in telemedicine.⁴⁸

Although not controlling in interpreting legislative intent, DEA agreed that the initial medical evaluation could be conducted using telemedicine in a 2007 hearing on the various legislative paths to regulate online pharmacies.⁴⁹ When asked if Congress should require practitioners to conduct in-person evaluations, Deputy Assistant Administrator Joseph Rannazzisi responded that "DEA believes that any legislation that would effectively address the fraudulent prescribing of controlled substances via the Internet must include the requirement of a legitimate medical evaluation by the prescribing practitioner, either through an in-person meeting or a valid telemedicine

45. See, e.g., *Caminetti v. United States*, 242 U.S. 470, 485 (1917).

46. See S. REP. NO. 110-521, at 13 (2008).

47. *Id.*

48. *Id.*

49. *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 65 (2007) (statement of Joseph Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration).

consultation meeting appropriate criteria.”⁵⁰ Thus, during the development of the Ryan Haight Act, DEA signaled to legislators that, in its view, the initial evaluation could be conducted via telemedicine.

a. Potential Legal Barriers to Extending the Pandemic Flexibilities Through Joint Regulations

Although DEA and SAMHSA have the legal authority to issue joint regulations, there are two potential legal barriers to address should the agencies issue regulations replicating the pandemic-related flexibilities. First, the Ryan Haight Act requires providers to use a “telecommunications system.” The definition of that term determines the type of telemedicine (e.g., audio-visual only) that DEA and SAMHSA could authorize. Second, this approach raises the question of whether DEA and SAMHSA have discretion to issue joint regulations without incorporating additional diversion controls. This section concludes that neither is a legal barrier that should interfere with this approach.⁵¹

i. The Requirement to Use a “Telecommunications System”

The Ryan Haight Act, which established the seven telemedicine exceptions, also includes a relevant limitation to those exceptions.⁵² The statute requires that the “practice of telemedicine” be conducted “using a telecommunications system referred to” in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2001 (BIPA).⁵³

Both DEA and SAMHSA pandemic flexibilities allow practitioners prescribing buprenorphine to do so over the telephone (i.e., using only

50. *Id.* at 14.

51. This Essay does not go into significant depth on two other statutes applicable to DATA-waived practitioners and opioid treatment programs because they are not legal barriers. First, DATA 2000 amended the Controlled Substances Act to provide a process for practitioners to get a waiver to prescribe buprenorphine without registering with DEA as an opioid treatment program, but the statute is silent on prescribing buprenorphine using telemedicine. Drug Addiction Treatment Act of 2000, 21 U.S.C. § 823(g)(2) (2018). Second, the Narcotic Addict Treatment Act of 1974 amended the Controlled Substances Act to require practitioners dispensing controlled substances for maintenance or detoxification treatment to obtain a separate registration with DEA and comply with standards developed by HHS for opioid treatment programs, but the statute is also silent on prescribing controlled substances using telemedicine. Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g)(2) (2018).

52. 21 U.S.C. § 802(54).

53. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2001, 42 U.S.C. § 1395m(m); 21 U.S.C. § 802(54).

an audio connection). The agencies did not limit practitioners to use of a two-way, audio-visual connection.⁵⁴ The agencies also permit telephone consultations to suffice, which is important from a policy perspective because many low-income, homeless, or recently incarcerated patients do not have reliable access to computers or smartphones with video cameras.⁵⁵ Thus, when considering whether a Ryan Haight Act exception could be the basis for additional telemedicine flexibility, this raises the question of whether a telephone qualifies as a “telecommunications system.”

As mentioned, the “practice of telemedicine” must be conducted “using a telecommunications system referred to” in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2001 (BIPA).⁵⁶ BIPA, however, does not define “telecommunications system.” The relevant provision simply states that HHS will pay for “telehealth services furnished via a telecommunications system by a physician.”⁵⁷ Although BIPA does not define “telecommunications systems,” the CMS promulgated a regulatory definition to be used in its programs. In the preamble to the proposed rule implementing BIPA, CMS confirmed that Congress did not define “telecommunications system.”⁵⁸ In response, CMS promulgated a definition of “telecommunications system” that excludes telephones.⁵⁹ While the CMS definition shows one approach to interpreting the term “telecommunications system,” CMS did not purport to bind DEA or SAMHSA to its definition.

The plain language of the statute suggests that DEA and SAMHSA may interpret “telecommunications system” broadly to include an audio-only connection. The dictionary definition of the word “telecommunication” expressly includes “communication at a distance (as by

54. Letter from Thomas Prevoznik, *supra* note 32; SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., FAQs: PROVISION OF METHADONE AND BUPRENORPHINE FOR THE TREATMENT OF OPIOID USE DISORDER IN THE COVID-19 EMERGENCY (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf> [<https://perma.cc/G87S-N9XG>] [hereinafter SAMHSA FAQs].

55. Jocelyn Guyer & Karen Scott, *State Strategies for Helping Individuals with Opioid Use Disorder Through the COVID-19 Epidemic*, HEALTH AFFS. BLOG (May 2, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200429.476954/full/> [<https://perma.cc/QEK4-8RDV>].

56. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2001, 42 U.S.C. § 1395m(m) (2018); 21 U.S.C. § 802(54).

57. 42 U.S.C. § 1395m(m)(1).

58. Medicare Programs; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2002, 66 Fed. Reg. 40,372–40,393 (Aug. 2, 2001).

59. 42 CFR § 410.78(a)(3) (2019).

telephone).”⁶⁰

More directly relevant, and as discussed above, both DEA and SAMHSA pandemic flexibilities allow practitioners prescribing buprenorphine to do so over the telephone (i.e., using only an audio connection).⁶¹ Importantly, in taking this posture, DEA and SAMHSA signaled that they read “telecommunications system” expansively to include telephone communications for purposes of their own programs. Therefore, as applied to DEA and SAMHSA, the definition of “telecommunications system” does not appear to be a legal barrier to DEA-SAMHSA joint regulations under 21 U.S.C. § 802(54)(G).

ii. Incorporating Additional Diversion Controls

The Ryan Haight Act limits the practice of telemedicine pursuant to DEA-SAMHSA joint regulations to circumstances “determined [by the agencies] to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.”⁶² That language raises the question of whether DEA and SAMHSA need to incorporate additional diversion controls if they issue joint regulations, or if the diversion controls included in the pandemic-related flexibilities are sufficient to satisfy the statute.

Although Congress has spoken to the issue, the statutory language is ambiguous because it does not articulate what constitutes an effective control.⁶³ The legislative history of the Ryan Haight Act is silent as to the types of diversion control requirements the agencies ought to place on practitioners using telemedicine.⁶⁴

Given that Congress deferred to the agencies’ discretion on this matter, it is instructive to consider their pandemic approach. The agencies’ pandemic-related flexibilities suggests that DEA and SAMHSA were not concerned enough about the potential for diversion to place additional controls on practitioners.⁶⁵ To take advantage of the pandemic-related flexibilities, a practitioner must ensure that he or she can conduct an adequate evaluation using telemedicine, which includes the use of telephone.⁶⁶ The current regulations already require

60. *Telecommunication*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/telecommunication> [<https://perma.cc/F8NS-HLGW>].

61. Letter from Thomas Prevoznik, *supra* note 32; SAMHSA FAQs, *supra* note 54.

62. 21 U.S.C. § 802(54)(G).

63. 21 U.S.C. § 802(54).

64. *Id.*; see *supra* Part I.C.1 for more discussion on the legislative history.

65. Letter from Thomas Prevoznik, *supra* note 32; SAMHSA FAQs, *supra* note 54.

66. The exception does not apply to new opioid treatment program patients treated with methadone. Letter from Thomas Prevoznik, *supra* note 32; SAMHSA FAQs,

an evaluation—the pandemic-related flexibilities simply allow evaluation to be conducted over the telephone or using an audio-visual connection. The flexibilities require the telemedicine practitioner to be state-licensed and DEA-registered, which is also consistent with current regulations.⁶⁷ Additionally, and consistent with current regulations, prescriptions for buprenorphine must be issued “for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.”⁶⁸

Of course, when DEA and SAMHSA crafted these regulatory flexibilities, they did so prospectively. Careful research could help inform the impact these flexibilities are having on controlled substance diversion. Research could further reveal whether DEA and SAMHSA should issue regulations similar to the flexibilities granted during the pandemic public health emergency or should change course. In the meantime, and absent any evidence of increased diversion, it is reasonable to conclude that it is within DEA and SAMHSA’s discretion to issue joint regulations without imposing additional diversion controls.⁶⁹

2. DEA Establishes a Special Registration for Telemedicine Program

As a second potential path to extend the telemedicine pandemic flexibilities, DEA can use its authority to establish a special registration for telemedicine programs. One of the seven telemedicine exceptions in the Ryan Haight Act gives DEA the discretion to register practitioners to prescribe controlled substances using telemedicine.⁷⁰ The statute says, “the term ‘practice of telemedicine’ means, for purposes of this subchapter, the practice of medicine . . . which . . . is being conducted by a practitioner who has obtained from the Attorney General

supra note 54.

67. Letter from Thomas Prevoznik, *supra* note 32.

68. *Id.*

69. While the exact content and process of these rules are outside the scope of this Essay, the agencies would need to promulgate these rules consistent with the Administrative Procedure Act and in such a manner as to survive judicial review under the *Chevron* doctrine. *Chevron U.S.A. Inc. v. NRDC Inc.*, 467 U.S. 837 (1984). In this Essay, we focus on the agencies’ statutory authorities to take these actions, which is only one of the issues that could come up in subsequent litigation.

70. DEA planned to create a special registration program in 2009 when it first released rules implementing the Ryan Haight Act. Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15,596 (Apr. 6, 2009). In the Special Registration for Telemedicine Act of 2018, Congress directed DEA to finalize a special registration program to increase access to telemedicine for substance use disorder by October 24, 2019. DEA missed the deadline and has yet to release proposed regulations. Special Registration for Telemedicine Act of 2018, 21 U.S.C. § 831(h)(2).

a special registration.”⁷¹ Therefore, DEA’s legal authority to create such a program is clear.

In fact, recent legislation requires DEA to create a special registration program. The Special Registration for Telemedicine Act of 2018, part of the SUPPORT for Patients and Communities Act, gave DEA until October 2019 to release final regulations “specifying . . . the limited circumstances in which a special registration . . . may be issued to a practitioner to engage in the practice of telemedicine.”⁷² Although DEA missed the initial deadline, it remains legally obligated to create this special registration program.⁷³

Whether a special registration promotes the use of telemedicine depends on how it is designed. DEA’s special registration for telemedicine program could open up a new pathway for the practice of telemedicine compared to current regulations. The special registration could also be so burdensome for practitioners that it has no significant effect on telemedicine uptake. If DEA designs a program that requires a practitioner to undergo extensive training and then apply and wait for DEA to grant the registration, such a special registration is unlikely to lead to increased uptake.

DEA has the authority to pursue a creative approach when activating the special registration program. The statute gives DEA the discretion to “specif[y] . . . the limited circumstances in which a special registration” may be issued.⁷⁴ The statute does not require DEA to pre-approve each individual practitioner seeking a special registration for telemedicine.⁷⁵ DEA could automatically issue a special registration to each practitioner who applies for a regular DEA registration or renews his or her registration, for example. Alternatively, DEA could require practitioners to submit a separate application for a special registration program. With either method, DEA could impose the same requirements on practitioners using a special registration for telemedicine as it did on practitioners utilizing the telemedicine flexibility during the COVID-19 pandemic.⁷⁶

71. 21 U.S.C. § 802(54)(E).

72. 21 U.S.C. § 831(h)(2).

73. Malka Berro, *DEA Misses Deadline for Teleprescribing Special Registration*, NAT’L COUNCIL FOR BEHAVIORAL HEALTH (Oct. 31, 2019), <https://www.thenationalcouncil.org/capitol-connector/2019/10/dea-misses-deadline-for-teleprescribing-special-registration/> [https://perma.cc/QG8M-RJKN].

74. 21 U.S.C. § 831(h)(2).

75. *Id.*

76. It is permissible for DEA to both release a special registration program and promulgate joint regulations with SAMHSA. Although this approach would require

II. UNSUPERVISED USE OF METHADONE

Over 400,000 people in the United States receive methadone from an opioid treatment program to treat their opioid use disorders.⁷⁷ Methadone is significantly more effective at reducing opioid use and retaining patients in treatment than approaches that do not use medication.⁷⁸ For many people, taking methadone to treat opioid use disorders involves a daily trip to the opioid treatment facility to receive medication administered at the facility.⁷⁹

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.⁸⁰ There are also reports of crowded waiting rooms and long lines of people not socially distanced.⁸¹

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.⁸² Studies have established that longer travel distance reduces the likelihood that people with substance use disorder complete treatment or seek aftercare.⁸³ One

DEA to write two separate regulations and go through the notice-and-comment process twice, it might save the agency administrative resources in the long run.

77. 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> [<https://perma.cc/5FDH-Y5L8>].

78. Richard P. Mattick, Courtney Breen, Jo Kimber, & Marina Davoli, *Methadone Maintenance Therapy Verses No Opioid Replacement Therapy for Opioid Dependence*, 3 COCHRANE LIBR. 1, 2 (2009).

79. See, e.g., Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. CHI. L. REV. ONLINE (NOV. 16, 2020), <https://lawreviewblog.uchicago.edu/2020/11/16/covid-oliva/> [<https://perma.cc/LCA2-S8DG>].

80. Kate Briquet, *Don't Forget the Other Pandemic Killing Thousands of Americans*, DAILY BEAST (May 4, 2020), <https://www.thedailybeast.com/opioid-deaths-surge-during-coronavirus-in-americas-overdose-capitals> (last visited Oct. 25, 2021).

81. 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/> [<https://perma.cc/Q53W-62PY>].

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

83. 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, 279 (2003); Susan K. Schmitt, Ciaran S. Phibbs, &

study found that patients traveling more than a mile to treatment programs were roughly fifty percent less likely to complete treatment than patients who traveled less than a mile.⁸⁴

Allowing patients to take home extra doses of methadone from an opioid treatment program is an effective way to ensure that patients have access to methadone, but SAMHSA has traditionally placed significant limits on allowing patients to have take-home doses. This Part explains the SAMHSA regulations that apply to the unsupervised use of methadone, describes the flexibilities that agency provided to patients and practitioners during the COVID-19 public health emergency, and finds that SAMHSA has the authority to extend the unsupervised use flexibilities through regulatory changes.

A. REGULATIONS FOR TAKE-HOME SUPPLIES OF OPIOID TREATMENT MEDICATION

Under the Narcotic Addict Treatment Act of 1974, SAMHSA is responsible for regulatory oversight of “opioid treatment programs,” which SAMHSA defines as inclusive of 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.⁸⁵ This definition includes practitioners and programs that use buprenorphine or methadone as part of a protocol to treat opioid use disorder. As of 2018, there were 1,605 opioid treatment programs in the United States.⁸⁶ When used to treat opioid use disorder, methadone can only be dispensed at an opioid treatment program.⁸⁷

SAMHSA’s requirements for opioid treatment programs are extensive. For example, opioid treatment programs must provide counseling services to patients, document patient care and outcomes, and limit the amount of a medication a patient can take home.⁸⁸

John D. Piette, *The Influence of Distance on Utilization of Outpatient Mental Health Aftercare Following Inpatient Substance Abuse Treatment*, 28 *ADDICTIVE BEHAVIORS* 1183, 1183 (2003).

84. Beardsley et al., *supra* note 83, at 283.

85. Narcotic Addict Treatment Act of 1974, 21 U.S.C. § 823(g)(2) (2018); 42 C.F.R. § 8.2 (2019).

86. Christopher M. Jones, Danielle J. Byrd, Thomas J. Clarke, Tony B. Campbell, Chideha Ohuoha & Elinore F. McCance-Katz, *Characteristics and Current Clinical Practices of Opioid Treatment Programs in the United States*, 205 *DRUG & ALCOHOL DEPENDENCE* 1, 2 (2019).

87. 42 C.F.R. § 8 (2019); 21 C.F.R. § 1306.04(c) (2019).

88. 42 C.F.R. § 8 (2019).

The requirements for the take-home supply, or unsupervised use, of methadone 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.⁸⁹

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 ninety days of treatment, patients can only take home one dose per week of methadone.⁹⁰ This means patients must still go to the opioid treatment program the other six days of the week for their daily dose of methadone.⁹¹ In the second ninety days of treatment, a patient can take home two doses per week.⁹² The number increases with the time-in-treatment; after a year of continuous treatment, a patient can take home a two-week supply.⁹³ After two years of continuous treatment, the flexibility maxes out and a patient can begin to take home a one-month supply.⁹⁴

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

89. 42 C.F.R. § 8.12(i)(2).

90. 42 C.F.R. § 8.12(i)(3)(i).

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

92. 42 C.F.R. § 8.12(i)(3)(ii).

93. 42 C.F.R. § 8.12(i)(3)(v).

94. 42 C.F.R. § 8.12(i)(3)(vi).

likelihood he or she has of being assessed properly against the [eight criteria].”⁹⁵ 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.⁹⁶

DEA regulations do not impose specific requirements regarding the unsupervised use of methadone or buprenorphine. Rather, the agency defers to SAMHSA regulations regarding unsupervised use.⁹⁷ Although DEA regulations apply multiple restrictions to narcotic treatment programs, those restrictions do not appear to bear on take-home supplies.⁹⁸

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.⁹⁹ 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

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

96. 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). This test looks especially overdue for policy review. A number of the criteria appear so subjective as to amplify problematic biases where they exist. The extent to which these criteria serve as a barrier to treatment is beyond the scope of this Essay but would benefit from additional study.

97. 21 C.F.R. § 1301.74(k) (2019). The DEA regulations refer to SAMHSA regulations and state that “[a]ll 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.” *Id.*

98. 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. 21 C.F.R. § 1301.72(a–b) (2019); 21 C.F.R. § 1301.74(c) (2019).

99. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., OPIOID TREATMENT PROGRAM (OTP) GUIDANCE (Mar. 19, 2020), <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf> [<https://perma.cc/QBQ8-MQ32>] [hereinafter SAMHSA OTP GUIDANCE].

handle this level of Take-Home medication.¹⁰⁰

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.”¹⁰¹ Others interpreted it differently to mean the eight take-home criteria should be used to determine if a patient is “stable” or “less stable.”¹⁰²

In its guidance, SAMHSA did not place any specific requirements on practitioners who want to take advantage of this flexibility once their state adopts the blanket exemption. SAMHSA neither mentions the statute or regulation that authorizes it to provide this flexibility to opioid treatment programs, nor specifies whether the flexibility is set to expire when the COVID-19 emergency declaration expires or is revoked.¹⁰³

Some states, such as Massachusetts and New Jersey, requested the exemption to permit some patients in their states to receive the larger take-home supply of fourteen to twenty-eight days of medication.¹⁰⁴ Some localities allowed for smaller increases in take-home supplies. New York City, for example, allowed patients to start with a two or three-day take-home supply.¹⁰⁵

C. APPROACHES TO EXTENDING FLEXIBILITIES FOR THE UNSUPERVISED USE OF OPIOID TREATMENT MEDICATIONS

This Part finds that SAMHSA has the legal authority to extend the flexibilities granted during the COVID-19 public health emergency without additional authorization from Congress. It describes two

100. *Id.*

101. Insinger, *supra* note 81.

102. Helen Redmond, *SAMHSA’s Absurd Criteria for Identifying “Stable” Methadone Patients*, FILTER (Mar. 31, 2020), <https://filtermag.org/samhsa-methadone-criteria/> [[https://perma.cc/QA\]6-7WAA](https://perma.cc/QA]6-7WAA)].

103. This differs from guidance issued by DEA in response to the COVID-19 public health emergency declaration that allows DATA-waived practitioners to prescribe buprenorphine to new and existing patients over the telephone without first requiring an in-person examination. In that guidance, DEA wrote that it provided the flexibility due to the COVID-19 public health emergency, and it is set to expire when the emergency declaration expires or is revoked. Letter from Thomas Prevoznik, *supra* note 32.

104. Guyer & Scott, *supra* note 55.

105. Insinger, *supra* note 81.

approaches that the agency could take. 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.

1. SAMHSA Issues Regulations After Consultation with DEA

SAMHSA has the authority under the Narcotic Addict Treatment Act to extend the pandemic-related flexibilities by issuing regulations through the notice-and-comment rulemaking process.¹⁰⁶ The only condition the statute places on SAMHSA is the requirement that the agency consult with DEA before issuing the regulations.¹⁰⁷

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.¹⁰⁸

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 twenty-eight days of take-home medication and less stable patients to receive fourteen 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

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

107. *Id.*

108. *Id.*

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 fourteen or twenty-eight 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.¹⁰⁹ This is one of many approaches SAMHSA could take to modify its regulations for unsupervised use.

To support regulatory changes like this, SAMHSA would need to build an administrative record to support the changes. 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.¹¹⁰ 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 rulemaking record before issuing the rule.¹¹¹

SAMHSA explained that the restrictions on unsupervised use “are intended to reduce the risk of abuse and diversion of opioid treatment

109. 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 Essay, they warrant further scrutiny.

110. Research is already beginning to be published. See, e.g., Sarah Brothers, Adam Viera, & Robert Heimer, *Changes in Methadone Program Practices and Fatal Methadone Overdose Rates in Connecticut During COVID-19*, 131 J. SUBSTANCE ABUSE TREATMENT 1, 4 (2021) (“We see no evidence that increased take-home doses led to increased methadone-related fatal overdoses.”); 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, 1 (2021) (finding minimal amounts of reported diversion among participants receiving take-home doses under the COVID-19 flexibility).

111. 21 U.S.C. § 823(g)(1).

medication that have abuse potential.”¹¹² However, recent research suggests that there has been minimal diversion associated with unsupervised use during the COVID-19 public health emergency.¹¹³ A study anonymously surveyed eighty-seven 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.¹¹⁴

2. 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.¹¹⁵ 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.¹¹⁶ This 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 regulatory requirements set forth under this section and § 8.12 . . . SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate.”¹¹⁷ Opioid treatment programs seeking an exemption must provide rationale for the exemption with thorough documentation, and SAMHSA can approve or deny the exemption after consulting with the state regulatory authority.¹¹⁸

Although this regulatory authority clearly grants SAMHSA the ability to consider exemption requests from opioid treatment programs on a case-by-case basis, SAMHSA also used this regulatory authority to grant broad relief in other guidance related to the COVID-19 public health emergency. For example, SAMHSA released a guidance

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

113. Figgatt et al., *supra* note 110.

114. *Id.*

115. SAMHSA OTP GUIDANCE, *supra* note 99.

116. 42 CFR § 8.11(h) (2019).

117. *Id.*

118. *Id.*

document that exempts opioid treatment programs from the requirement to conduct an in-person evaluation before admitting a new patient to the program for buprenorphine treatment.¹¹⁹ In that guidance document, SAMHSA points to its regulatory authority at 42 C.F.R. § 8.11(h), as opposed to its authorizing statute or the public health emergency declaration, for the legal authority to grant the exception.

Thus, SAMHSA is not bound by the presence of a public health emergency to draw again on this regulatory authority to grant a broad exception expanding unsupervised use. Based on its prior assessment of its authority in 42 C.F.R. § 8.11(h), SAMHSA can release a guidance document that, for example, allows states to request blanket exemptions for all stable patients to receive twenty-eight days of take-home medication and less stable patients to receive fourteen days of take-home medication after consultation. This approach could be especially helpful if the guidance clarifies that opioid treatment programs have discretion to determine what “stable” means and are not required to use the eight take-home criteria to determine when a patient can have a take-home supply. SAMHSA could pair this approach with an effort to evaluate its effects to inform future decision making.

III. A SEQUENCED APPROACH TO EXTENDING THE FLEXIBILITIES

The suggested pathways above give SAMHSA and DEA options to extend the pandemic flexibilities on an ongoing basis. If the agencies pursue rulemaking, they will need time to complete it, perhaps longer than the duration of the rest of this pandemic. In the meantime, the agencies could pivot to the opioid-specific public health emergency to justify extensions of these flexibilities. The Secretary of HHS can declare a public health emergency under the Public Health Service Act.¹²⁰ A public health emergency determination triggers emergency powers that permit the federal government to engage in special activities like spending funds on the emergency or suspending or modifying regulatory requirements.¹²¹ On October 26, 2017, Acting Secretary of HHS Eric Hargan declared the opioid crisis a nationwide public health emergency.¹²² The opioid crisis public health emergency has since been renewed fourteen times; most recently by HHS Secretary

119. SAMHSA FAQs, *supra* note 54. Although buprenorphine is more leniently regulated and can be prescribed by DATA-waived practitioners, it is occasionally dispensed directly to patients at opioid treatment programs.

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

121. *Id.*

122. U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 1.

Xavier Becerra on April 7, 2021.¹²³ To the extent that this public health emergency declaration continues to be extended, it could be used to support the extension of the pandemic flexibilities long enough to give the agencies time to complete rulemaking.

Turning to the DEA flexibilities first, DEA relied on the COVID-19 public health emergency as the basis for its action to permit telemedicine. As discussed above, under 21 U.S.C. § 802(54)(D), DEA has the authority to allow the “practice of telemedicine” when it is being “conducted during a public health emergency declared by the Secretary under section 247d of title 42.”¹²⁴ Both the opioid crisis and the COVID-19 public health emergencies were declared under section 247d. Just as DEA used its authority to allow for the initial evaluation to be conducted via telemedicine during the COVID-19 public health emergency, it has the discretion as a matter of law to use that authority to extend that policy under the opioid-specific public health emergency.

Second, just as SAMHSA used its regulatory authority at 42 C.F.R. § 8.11(h) to exempt opioid treatment programs from the requirement to conduct an in-person evaluation to admit a new patient for the purposes of buprenorphine treatment during the COVID-19 public health emergency, it can use that regulatory authority to extend this exemption under the opioid-specific public health emergency. It can also use that regulatory authority to allow for increased unsupervised use, but it could choose to make this exemption contingent on the continuation of the opioid-specific public health emergency. As explained above, the regulatory authority at 42 C.F.R. § 8.11(h) does not require a public health emergency declaration for SAMSHA to provide exemptions to the regulations in § 8.12.¹²⁵ That provision gives the agency the discretion to exempt opioid treatment programs from any regulations in § 8.12 and does not stipulate the circumstances in which SAMHSA can provide the exemption.¹²⁶

This option would not provide a permanent solution standing on its own, since the flexibilities would expire if or when the opioid-

123. U.S. DEP’T OF HEALTH & HUM. SERVS., RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids-7April2021.aspx> [<https://perma.cc/3EV4-TRLF>]. A public health emergency determination remains in effect for ninety days or until the Secretary determines the emergency no longer exists, meaning the Secretary must renew an emergency in ninety-day increments. 42 U.S.C. § 247d.

124. 21 U.S.C. § 802(54)(D); 42 U.S.C. § 247d.

125. 42 C.F.R. § 8.11(h) (2019).

126. *Id.*

specific public health emergency expires or is revoked. However, it could give the agencies time to study whether the ongoing flexibilities strike the right balance between treatment and diversion.

CONCLUSION

In response to the COVID-19 public health emergency, federal regulators reduced barriers to initiating buprenorphine treatment using telemedicine and providing patients with a take-home supply of methadone. This Essay provides an independent assessment of DEA and SAMHSA's authority to extend the flexibilities after the COVID-19 public health emergency ends. It finds that DEA and SAMHSA possess the legal authority to extend the flexibilities without legislative changes from Congress.

DEA could issue joint regulations that clear the path for additional use of telemedicine. Alternatively, DEA could fulfill its legal obligation to implement a special registration program for telemedicine. SAMHSA could use its statutory authority to issue a rule codifying the take-home flexibilities for methadone after consulting with DEA. SAMHSA could instead release a new guidance document implementing these changes. As another alternative, SAMHSA and DEA could use the opioid-specific emergency declaration to offer a longer term, but not permanent, option to extend these flexibilities, perhaps while they work on longer-term solutions like regulations.

With the hope that the COVID-19 pandemic will be behind us in 2021, there is a risk that these flexibilities will also come to an end. As explained in this Essay, the agencies have multiple, lawful pathways to extend these flexibilities beyond the pandemic and in support of patients. To the extent that the evidence supports a policy shift in this direction, the agencies have all the legal authority they need to chart a new course.