

EXTENDING

PANDEMIC

FLEXIBILITIES

FOR OPIOID USE DISORDER TREATMENT:

TELEMEDICINE & INITIATING BUPRENORPHINE TREATMENT



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Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Telemedicine & Initiating Buprenorphine Treatment

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EXECUTIVE SUMMARY

Federal regulators dramatically reduced the barriers to using telemedicine to treat opioid use disorder in response to the COVID-19 public health emergency. Public health experts have long argued that health care practitioners can provide high-quality treatment for opioid use disorder via telemedicine. Until now, federal regulation has limited the ability of practitioners to prescribe buprenorphine, one of the medications considered the gold standard for treatment of opioid use disorder, using telemedicine.

Regulations limiting telemedicine, rooted in concerns about diversion of controlled substances, restrict practitioners from treating patients. This has particularly troublesome effects for patients located in geographic areas facing a shortage of practitioners because it further restricts the available pool of practitioners. The Drug Enforcement Administration (DEA) stated that after the COVID-19 public health emergency, telemedicine will return to the way it was before the emergency because the law requires it. Practitioners and public health experts are concerned that this would erode access to treatment. Congress could certainly make this change permanent using legislation. Setting that possibility aside, this report provides an independent assessment of whether DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) have the legal authority to extend the flexibilities after the public health emergency ends.

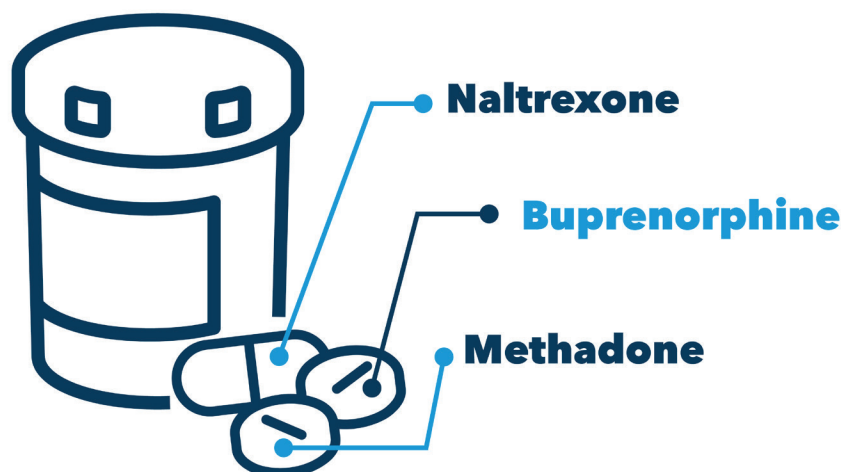
This report concludes that DEA and SAMHSA have the legal authority to extend the flexibilities granted during the COVID-19 public health emergency without additional authorization from Congress. DEA and SAMHSA have the authority to jointly issue regulations allowing practitioners to prescribe buprenorphine without first conducting an in-person medical evaluation. As an alternative, DEA can use its authority to establish a special registration for telemedicine program while SAMHSA issues an associated policy. As another alternative, SAMHSA and DEA can use the opioid-specific public health emergency declaration to offer a longer term, but not permanent, option to extend these flexibilities.

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I. Introduction

In the third week of March 2020, almost two months after the Secretary of the U.S. Department of Health and Human Services (HHS) declared COVID-19 a public health emergency,¹ officers in Wyoming County, West Virginia responded to 14 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 is one of the medications considered the gold standard for treating opioid use disorder.⁵ Buprenorphine helps alleviate the withdrawal symptoms associated with discontinuing opioid use and has been shown to reduce illicit opioid use and increase patient retention.⁶ But it is challenging for patients in rural locations like Wyoming County to access buprenorphine. At the end of 2017, Wyoming County did not have a single physician, nurse practitioner, or physician's assistant with a waiver from the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe buprenorphine for the treatment of opioid use disorder.⁷



Buprenorphine is one of the medications considered the gold standard for treating opioid use disorder.

1. U.S. Dep't of Health & Human Serv., Determination that a Public Health Emergency Exists (2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.
2. Mary Catherine Brooks, *Wyoming County hit with 9 overdoses in 36 hours*, The 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.
3. W. Va. Dep't of Health & Human Res, 2016 West Virginia Overdose Fatality Analysis 9 (2017), https://dhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf.
4. Wendy Holdren, *Report shows Wyoming County worst in country for prescription drug deaths*, The 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.
5. Medication-assisted treatment is the use of medication, combined with other forms of therapy, to treat opioid use disorder and is more effective than approaches that do not use medication. See, e.g., The Pew Charitable Trusts, *Medication-Assisted Treatment Improves Outcomes for Patients with Opioid Use Disorder Fact Sheet* (Nov. 2016), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder>. See Walter Ling, Larissa Mooney, and Matthew Torrington, *Buprenorphine for opioid addiction*, 2 Pain Mgmt. 345 (2012).
6. Tara Mariolis, Jordan Bosse, Stephen Martin, Amanda Wilson, & Lisa Chiodo, *A Systematic Review of the Effectiveness or Buprenorphine for Opioid Use Disorder Compared to Other Treatments: Implications for Research and Practice*, 10 J. Addiction Research Theory 379 (2019).
7. C. Holly A. Andrilla, Tessa E. Moore, Davis G. Patterson, & Eric H. Larson, *Geographic Distribution of Providers with a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update*, 35 J. Rural Health 108, 111 (2019).

For practitioners who do have a waiver to prescribe buprenorphine, federal regulation prohibits them from prescribing buprenorphine using telemedicine without first conducting an in-person medical exam. These regulations exist out of a concern that consumers will obtain controlled substances for illegitimate purposes from online prescribers and pharmacies.⁸ The result, though, is that patients in rural areas like Wyoming County must travel a significant distance to find practitioners who can help them begin buprenorphine treatment and set their initial dosing, a process referred to as “induction.”⁹ It is well established that significant travel distances interfere with treatment. Studies show that the longer the travel distance, the less likely it is that people with substance use disorder obtain treatment.¹⁰ One study found that patients traveling more than a mile to treatment programs were roughly 50% less likely to complete treatment than patients who traveled less than a mile.¹¹

Recognizing these concerns about patient access to treatment, public health experts have argued that practitioners could provide high-quality treatment for opioid use disorder using telemedicine.¹² These arguments were made before the COVID-19 pandemic, but they were not met with relief.

Then, in response to the COVID-19 public health emergency declaration, the federal government eased providers’ ability to treat patients with opioid addiction so that providers and patients can follow social distancing guidelines. DEA and SAMHSA provided flexibilities

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8. Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 85 Fed. Reg. 61,594 (Sep. 30, 2020).
9. Ling, Mooney, & Torrington, *supra* note 5, at 347.
10. 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. Phibbs, 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).
11. Beardsley, Wish, Fitzelle, O’Grady & Arria, *supra* note 10, at 283.
12. E.g., Haiden A. Huskamp, Alisa B. Busch, Jeffrey Souza, Lori Uscher-Pines, Sherri Rose, Andrew Wilcok, Bruce E. Landon, & Attev Mehrotra, *How Is Telemedicine Being Used In Opioid And Other Substance Use Disorder Treatment*, 37 Health Affairs 1940 (2018).

such as allowing practitioners to prescribe controlled substances using telemedicine, which includes buprenorphine used to treat opioid use disorder.¹³ Although these flexibilities increase patient access to critical opioid use disorder medications, they will lapse when the COVID-19 public health emergency designation expires or is revoked.¹⁴ Termination of state-level emergency declarations may jeopardize these reforms as well. DEA has stated that after the COVID-19 public health emergency, telemedicine will return to the way it was before the emergency, on the theory that the telemedicine restrictions are statutory and therefore can only be changed by Congress.¹⁵

While Congress could certainly make this change permanent through legislation, this report provides an independent assessment of whether DEA and SAMHSA have the statutory authority to extend the 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), and without additional legislative changes from Congress. The main finding is that DEA and SAMHSA have regulatory mechanisms available to extend the telemedicine flexibilities described above. In addition, this report finds that the HHS Secretary's opioid-specific public health emergency declaration could offer a longer term, but still not permanent, legal pathway to extend these flexibilities beyond the current pandemic.

This report proceeds as follows. First, it explains the existing regulations that apply to buprenorphine induction using telemedicine and the flexibilities that have been granted during the COVID-19 public health emergency. While myriad statutes and regulations apply to the provision of health care and the practice of medicine, this report focuses on those federal requirements that specifically regulate the treatment of substance use disorder.¹⁶ Next, it analyzes the authorizing statutes and evaluates whether DEA and SAMHSA have the authority to extend these 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 the pandemic flexibilities after the corona virus public health emergency expires.

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13. DEA and SAMHSA provided a variety of other flexibilities in response to the pandemic, such as permitting opioid treatment programs to dispense a take-home supply of methadone or buprenorphine and not requiring an opioid treatment program to sign an invoice for deliveries of narcotic drugs at the time of delivery. 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>; Letter from William T. McDermott, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Apr. 10, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-027\)\(DEA083\)_DEA_Dist_MNF_narcotics_shipments_to_OTP_signed_delivery_exception_\(final\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-027)(DEA083)_DEA_Dist_MNF_narcotics_shipments_to_OTP_signed_delivery_exception_(final).pdf).
 14. Lev Facher, *Covid-19 has streamlined addiction medicine. Will the changes stick?*, STAT News (May 12, 2020), <https://www.statnews.com/2020/05/12/coronavirus-addiction-medicine-reforms-future/>.
 15. Scott A. Brink, 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), 43:07, https://www.youtube.com/watch?v=t_lu9t-AJug. DEA Section Chief Scott Brink stated, "[O]nce the declared public health emergency expires, all these exceptions to regulations and guidance documents that DEA issued...will expire...Telemedicine will also return to how it was before the COVID-19 public health emergency. Telemedicine regulations, or the Ryan Haight Act, are law. They are in statute and they can only be changed by Congress. DEA does not have the ability to change those." *Id.*
 16. The role of state medical board regulation is a topic outside the scope of this report, but one which merits additional study.

II. Regulations for Buprenorphine Induction & COVID-19 Emergency Flexibilities

This section explains the regulations that apply to buprenorphine induction using telemedicine and the flexibilities the government provided to patients and practitioners during the COVID-19 public health emergency.



In response to the COVID-19 public health emergency:

- SAMHSA released guidance exempting opioid treatment programs from the requirement to conduct an in-person evaluation to initiate buprenorphine treatment,
- SAMHSA clarified that DATA 2000-waived practitioners can prescribe or dispense buprenorphine to patients over the telephone or using an audio-visual connection, and
- DEA released guidance allowing practitioners to prescribe buprenorphine to patients with opioid use disorder without first requiring an in-person examination.

A. Existing SAMHSA and DEA Regulations for the Initiation of Buprenorphine Treatment

Under existing SAMHSA and DEA regulations, practitioners are generally not permitted to prescribe or dispense buprenorphine to patients without first conducting an in-person evaluation. This section delves into the reasoning behind these regulations and describes some of the challenges they pose for patient care.

i. SAMHSA Regulations

a. SAMHSA Regulation of Opioid Treatment Programs

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.¹⁷ 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.¹⁸

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

18. 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).

SAMHSA's opioid treatment program regulations are based on a framework of program certification and practitioner accreditation.¹⁹ SAMHSA promulgated a set of regulations at 42 C.F.R. § 8 that include the relevant certification and accreditation standards.²⁰ SAMHSA approves accreditation bodies, such as state agencies or nonprofits, which then provide accreditation to the opioid treatment programs. Once an opioid treatment program receives accreditation, the program can apply for a SAMHSA certification.

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.²¹ SAMHSA explained in its 1999 proposed rule that it "include[s] careful professional oversight and the availability of specialized support services" but that it also "reflects the risks of abuse and diversion that are endemic to opioid agonist therapy."²²

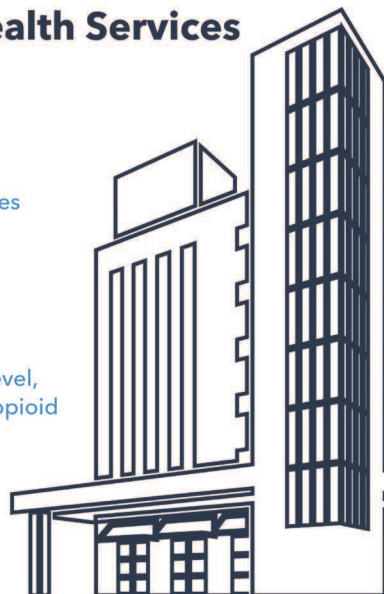
There is one requirement that SAMHSA interprets to limit practitioners' ability to admit a patient to an opioid treatment program using telemedicine. 42 C.F.R. § 8.12(f)(2) requires an opioid treatment program to complete a physical evaluation before admitting a patient to the program:

OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.²³

Substance Abuse and Mental Health Services Administration (SAMHSA)

- Established 1992
- Part of the U.S. Department of Health & Human Services
- Headquarters in Rockville, Maryland
- 494 full-time equivalent employees (2020)
- Provides oversight of "opioid treatment programs," approves accreditation bodies at the state and local level, and issues regulations pertaining to the treatment of opioid use disorder.

SAMHSA.gov; Department of Health & Human Services, *The Budget for Fiscal Year 2021*, <https://www.govinfo.gov/content/pkg/BUDGET-2021-APP/pdf/BUDGET-2021-APP-1-11.pdf>.



19. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4,076 (Jan. 17, 2001).

20. 42 C.F.R. § 8 (2019).

21. *Id.*

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

23. 42 C.F.R. § 8.12(f)(2) (2019).

In its 1999 proposed rule, SAMHSA gave practitioners 30 days to receive the serology and other test results, but the agency shortened that time to 14 days in the final rule.²⁴

The regulation does not explicitly state that the physical evaluation must be conducted in person rather than via telemedicine. The preamble to the final rule hints that the evaluation should be done in-person so that the practitioner can receive the result of serology and other tests, but it does not explain why a practitioner could not refer the patient to a laboratory while conducting the remainder of the evaluation over telemedicine.²⁵ This may be because telemedicine was less common when the SAMHSA was working on its rule in the late 1990s and early 2000s.²⁶

More recently, SAMHSA guidance suggests that the agency interprets its regulations to require in-person exams. For example, SAMHSA issued guidance in 2015 stating that “telemedicine may not substitute for a physical examination when one is needed, although it may be used to support the decision making of a physician when a different provider qualified to conduct physical examinations and make diagnoses is physically located with the patient.”²⁷ Although this interpretation allows a remote practitioner to conduct an exam and provide input that can be “used to support the decision making of a physician,” the guidance does not elaborate on exactly which decisions can be made on this basis.²⁸ The agency also adopted the interpretation that the physical evaluation must be conducted in person in its recent guidance released in response to the coronavirus public health emergency.²⁹

In sum, while SAMHSA’s regulations do not expressly require that physical examinations be conducted in person, SAMHSA guidance implies that they do. As a general matter, agency guidance does not have the force of law.³⁰ In practice, it can have a significant influence as regulated parties try to avoid compliance risk.³¹ Therefore, it is understandable that opioid treatment programs might steer clear of telemedicine for induction. The problem with this approach—apart from SAMHSA using guidance to regulate—is that public health advocates have documented that regulations barring telemedicine prevent practitioners from increasing access to medication assisted treatment.³² This is particularly relevant to patients living in rural areas, where many patients experience long travel times.³³ Simply put, regulations that discourage telemedicine reduce patient access to treatment.

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24. Narcotic Drugs in Maintenance and Detoxification, 64 Fed. Reg. at 39,839; Opioid Drugs in Maintenance and Detoxification, 66 Fed. Reg. at 4,084.
 25. Opioid Drugs in Maintenance and Detoxification, 66 Fed. Reg. at 4,084. SAMHSA wrote that “[s]ection 8.12(f)(2) has been revised to clarify the requirement for a physical exam upon admission, with serology and other test results completed [within] 14 days.” *Id.*
 26. Studies have shown telemedicine has been rising in recent years. See Jamal H. Mahar, Gregory J. Rosencrance, & Peter A. Rasmussen, *Telemedicine: Past, Present, and Future*, 85 Cleveland Clinic J. Medicine 938 (2018).
 27. Substance Abuse & Mental Health Services Admin., Federal Guidelines for Opioid Treatment Programs (Jan. 2015) <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>.
 28. *Id.*
 29. In the guidance, SAMHSA exempts opioid treatment programs from the requirement to conduct an in-person evaluation to initiate buprenorphine treatment, suggesting it interprets this to be a requirement. See *infra* part B.i for more discussion.
 30. See Nicholas Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 Yale J. on Reg. 165 (2019).
 31. *Id.* at 184-219.
 32. See Y. Tony Yang, Eric Weintraub, & Rebecca L. Haffajee, *Telemedicine’s Role in Addressing the Opioid Epidemic*, 93 Mayo Clinic Proceedings, 1177 (2018).
 33. Ling, Mooney, & Torrington, *supra* note 5, at 347.

b. SAMHSA Regulation of DATA-Waived Practitioners

SAMHSA regulations covering opioid treatment programs do not apply to practitioners who have a waiver from SAMHSA and DEA to prescribe or dispense buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000).³⁴ SAMHSA is also responsible for the regulatory oversight of these practitioners, referred to as “DATA-waived practitioners.”³⁵ DATA-waived practitioners can prescribe or dispense buprenorphine outside of opioid treatment programs and are waived from the traditional requirements for opioid treatment programs.³⁶

To obtain a DATA waiver, a practitioner must complete a specialized 8-hour or 24-hour training, submit a notification of intent to SAMHSA, and follow certain conditions while offering buprenorphine treatment.³⁷ Practitioners must also have a valid state license and DEA registration.³⁸

The SAMHSA regulations applicable to DATA-waived practitioners are silent on whether they can initiate buprenorphine treatment, or prescribe or dispense buprenorphine, using telemedicine.³⁹ Rather, as described in the next section, DEA regulation of controlled substances is what prohibits DATA-waived practitioners from initiating buprenorphine using telemedicine.

ii. DEA Regulations

In 2009, DEA promulgated regulations implementing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act).⁴⁰ 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.⁴¹ Since buprenorphine is a schedule III-controlled substance, it falls under these regulations.⁴²

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.⁴³ 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.

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

35. See, e.g., Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act, 65 Fed. Reg. 69,513 (Nov. 2, 2020).

36. 21 U.S.C. § 823(g)(2) (2018).

37. *Id.*

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

39. 42 C.F.R. § 8 (2019).

40. 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).

41. 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. 110-521, at 7 (2008).

42. 21 C.F.R. § 1308.13 (2019).

43. See Implementation of the Ryan Haight Act, 74 Fed. Reg. at 15,600-04.

Specifically, DEA regulations at 21 C.F.R. § 1300.04 prohibit the dispensing or distributing of drugs without a “valid prescription.”⁴⁴ The regulations define a “valid prescription” as one prescribed by “[a] practitioner who has conducted at least one in-person medical evaluation of the patient.”⁴⁵ 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.⁴⁶

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.”⁴⁷ The exceptions are limited and patients cannot be located in their own homes to take advantage of many of them. For example, a practitioner can use telemedicine if the patient is located in and being treated by a DEA-registered hospital or clinic.⁴⁸ Alternatively, a practitioner can engage in telemedicine if the patient is in the physical presence of and being treated by a DEA-registered practitioner.⁴⁹ 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 increased use of telemedicine.⁵⁰

DEA also has the discretion to promulgate regulations or create a special registration program to license practitioners to engage in more forms of telemedicine, but it has not

Drug Enforcement Administration (DEA)

- Established 1973
- Part of the U.S. Department of Justice
- Headquarters in Alexandria, Virginia
- 6,229 full-time equivalent employees (2020)
- Promulgates and enforces rules to control the diversion of opioids and sets standards for the initiation of treatment for opioid use disorder via telemedicine.

DEA.gov; Department of Justice, The Budget for Fiscal Year 2021, <https://www.govinfo.gov/content/pkg/BUDGET-2021-APP/pdf/BUDGET-2021-APP-1-15.pdf>.



44. 21 C.F.R. § 1300.04 (2019).

45. *Id.*

46. 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 he or she had knowledge of the illegal activity or enough information that he or she engaged in willful blindness. *See, e.g., United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006).

47. 21 C.F.R. § 1300.04 (i)(1-7) (2019).

48. 21 C.F.R. § 1300.04 (i)(1) (2019).

49. 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).

50. 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).

done so.⁵¹ Therefore, 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.

When DEA implemented the Ryan Haight Act, it codified the text of the seven statutory exceptions for the “practice of telemedicine” directly into the Code of Federal Regulations. For example, rather than promulgating a special registration program, DEA used Congress’ language to repeat that it has the authority to promulgate a special registration program.⁵² Thus, the language of DEA’s regulations comes from Congress, not from DEA.⁵³

The DEA requirement to conduct an in-person medical evaluation before prescribing a controlled substance applies to practitioners broadly. However, it does not apply when an opioid treatment program directly administers or dispenses buprenorphine to a patient.⁵⁴ Thus, the requirement to conduct an in-person medical evaluation before prescribing a controlled substance falls on DATA-waived practitioners.⁵⁵

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.”⁵⁶ 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.⁵⁷

B. COVID-19 Flexibilities

In response to the public health emergency declaration related to the COVID-19 pandemic, SAMHSA and DEA provided novel flexibilities to the requirements described above. This allowed for increased use of telemedicine for the treatment of opioid use disorder.⁵⁸ DEA and SAMHSA permitted practitioners, inside and outside the opioid treatment program context, to initiate buprenorphine treatment for new patients over the telephone or using an audio-visual connection without first requiring an in-person evaluation.⁵⁹ This section explains how

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51. DEA planned to create a special registration program in 2009 when it first released rules implementing the Ryan Haight Act. See 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 propose regulations. See Special Registration for Telemedicine Act of 2018, 21 U.S.C. 831§ (h)(2) (2018).
 52. See 21 C.F.R. § 1300.04 (i)(1-7) (2019).
 53. The use of a “parroting regulation” means that when evaluating DEA’s legal authority to take an action, the relevant authority is the statute, rather than the parroted regulations. See *Gonzales v. Oregon*, 446 U.S. 243, 257 (2006). In section III.A, this report analyzes the relevant portion of the statute.
 54. 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>.
 55. *Id.*
 56. 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.
 57. Yang, Weintraub & Haffajee, *supra* note 32.
 58. *E.g.*, Beth Connolly & Leslie Paulson, Expanded Telehealth Helps Communities Address Opioid Use Disorder During Pandemic (July 1, 2020) <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/01/expanded-tele-health-helps-communities-address-opioid-use-disorder-during-pandemic>.
 59. For an overview of the deregulation of telemedicine and opioid use disorder treatment during the COVID-19 pandemic, see Stacey A. Tovino, *COVID-19, Telehealth, and Substance Use Disorders*, 2 *Ariz. St. L.J. Online* 147 (2020) *Ariz. St. L.J. Online* 147 (2020) <https://arizonastatelawjournal.org/wp-content/uploads/2020/11/Tovino-Final.pdf>.

KEY LEGISLATION



Ryan Haight Online Pharmacy Consumer Protection Act of 2008

Prevents the illegal distribution and dispensing of controlled substances by means of the Internet.

Drug Addiction Treatment Act of 2000

Allows individual practitioners to administer schedule III - V controlled substances for the purpose of treating substance use disorder outside of an opioid treatment program.

Narcotic Addict Treatment Act of 1974

Permits practitioners at opioid treatment programs to treat opioid use disorder with schedule III - V controlled substances that have been approved by the Food and Drug Administration for that purpose.

these flexibilities are structured, as a legal matter, and their relationship to the public health emergency declaration.

i. SAMHSA Regulations

In response to the COVID-19 public health emergency, SAMHSA released a guidance document that exempts opioid treatment programs from the in-person evaluation prerequisite to initiating buprenorphine treatment.⁶⁰ In the guidance, SAMHSA exempts opioid treatment programs from the in-person physical evaluation requirement for a patient who will be treated with buprenorphine, but does not extend this exemption to new patients treated with methadone:

With respect to new patients treated with buprenorphine, SAMHSA has made the decision to pre-emptively exercise its authority to exempt [opioid treatment programs] from *the requirement to perform an in-person physical evaluation...* This exemption does not apply to new [opioid treatment program] patients treated with methadone.⁶¹

SAMHSA placed minimal limitations on which practitioners may take advantage of the exception. First, the practitioner must be able to conduct an adequate evaluation using telemedicine (which includes the use of telephone in addition to an audio-visual connection).⁶² Second, the practitioner must be licensed by the relevant state regulatory authority as well as DEA-registered to prescribe controlled substances.⁶³

SAMHSA also clarified that DATA-waived practitioners working outside the context of an opioid treatment program can prescribe buprenorphine to new and existing patients over the

60. Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

61. *Id.* at 1 (emphasis added).

62. The exception does not apply to new opioid treatment program patients treated with methadone. *Id.*

63. *Id.*

telephone or using an audio-visual connection, in line with DEA guidance described below. The exemption will continue during the HHS-declared public health emergency but is set to lapse when the emergency declaration expires.⁶⁴

In its guidance, SAMHSA points to a regulation, as opposed to its authorizing statute or the public health emergency declaration, for the legal authority to grant the exception. SAMHSA writes that 42 C.F.R. § 8.11(h) gives it the authority to grant opioid treatment programs exemptions from various requirements.⁶⁵ This regulation states that “[a]n OTP 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.”⁶⁶ The regulation also requires the opioid treatment program seeking an exemption to provide thorough documentation in support of its request and allows SAMHSA to approve the exemption after consulting the relevant state regulator.⁶⁷ Rather than consider these requests on a case-by-case basis, SAMHSA used this authority to grant broad relief.

ii. DEA Regulations

Similarly, and also 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 telemedicine (i.e., “using a real-time, two-way, audio-visual connection”).⁶⁸

DEA placed few limitations on practitioners’ use of the exception. Prescriptions for buprenorphine must be issued “for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.”⁶⁹ Practitioners also must determine that an adequate evaluation can be conducted over the telephone or using an audio-visual connection.⁷⁰

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.”⁷¹ DEA cites the COVID-19 public health emergency declaration in its guidance.⁷² Accordingly, the exemption will expire when that emergency declaration expires.

64. The guidance states that the “exemption will continue for the period of the national emergency declared in response to the COVID-19 pandemic, and applies exclusively to [opioid treatment program] patients treated with buprenorphine.” Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>. See Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. Chicago L. Rev. Online (Nov. 16, 2020); see also *infra* part III.C for more discussion about emergency declarations.

65. *Id.*

66. 42 CFR § 8.11(h) (2019).

67. *Id.*

68. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf).

69. *Id.*

70. *Id.*

71. 21 U.S.C. § 802(54)(D) (2018).

72. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf).

III. Three Approaches to Extending Flexibilities for Buprenorphine Induction

This section finds that DEA and SAMHSA have the legal authority to extend the telemedicine flexibilities granted during the COVID-19 public health emergency post-pandemic without additional authorization from Congress. It describes three potential agency approaches. First, DEA and SAMHSA could issue joint regulations allowing practitioners to prescribe buprenorphine without first conducting an in-person medical evaluation. Second, DEA could establish a special registration for telemedicine program. In the first and second approaches, SAMHSA would also issue a companion policy to apply the telemedicine flexibilities to opioid treatment programs. Third, SAMHSA and DEA could rely on the separate, opioid-specific public health emergency declaration to offer a longer term, but not permanent, option to extend these flexibilities.

A. DEA and SAMHSA Issue Joint Regulations and SAMHSA Issues a Companion Policy

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. The joint regulations would be relevant to DATA-waived practitioners, so SAMHSA would also need to issue a companion policy to exempt opioid treatment programs from the requirement to conduct an in-person medical evaluation before admitting a new patient. This section first discusses DEA and SAMHSA's authority to jointly issue these regulations, and then discusses two potential legal barriers. It then evaluates SAMHSA's authority to issue a companion policy.

i. Issuing Joint Regulations under 21 U.S.C. § 802(54)(G)

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 wider adoption of telemedicine.⁷³ 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.⁷⁴

73. See 21 U.S.C. § 802(54)(G) (2018).

74. 21 U.S.C. § 829(e)(1)&(2) (2018).

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.”⁷⁵ The Act then defines seven distinct instances when a practitioner can use telemedicine.⁷⁶ These are the “seven exceptions” to the requirement to conduct an in-person exam prior to prescribing a controlled substance using telemedicine.⁷⁷ For example, the first exception allows a practitioner to use telemedicine if the patient is located in and being treated by a DEA-registered hospital or clinic.⁷⁸ The second exception allows a practitioner to use telemedicine if the patient is in the presence of and being treated by a DEA-registered practitioner.⁷⁹

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 sub-chapter, 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.⁸⁰

This language plainly 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.⁸¹ The Act also gives the agencies discretion to ensure the regulations effectively control against diversion and are “consistent with the public health and safety.”⁸² While choices about the content of the regulations are generally left to the agencies, there is no question that the agencies have the discretion to issue the regulations in the first place.

Because 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, the agencies and courts do not have to follow interpretive aids like legislative history.⁸³ But just as the Ryan Haight Act’s plain language supports the interpretation that DEA and SAMHSA can issue regulations allowing for broader use of telemedicine, so too does its legislative history.

75. 21 U.S.C. § 829(e)(2)(C).

76. 21 U.S.C. § 802(54).

77. 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>.

78. 21 U.S.C. § 802(54)(A).

79. 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).

80. 21 U.S.C. § 802(54)(G).

81. *Id.*

82. *Id.*

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

As a Senate Judiciary Committee report explains, Senate leaders were concerned about hindering emerging telemedicine markets and did not intend for the Ryan Haight Act to restrict legitimate telemedicine.⁸⁴ 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.”⁸⁵ Strikingly, the report provides evidence that Congress may have even expected DEA to promulgate regulations to allow for the use of telemedicine to prescribe controlled substances. 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.⁸⁶

Although these phrases are qualified, the committee report highlighted this telemedicine exception as the only one it anticipated being updated on a regular basis.⁸⁷ Regardless of whether Congress expected DEA and SAMHSA to promulgate such regulations, this language provides evidence that Congress intended to give the agencies the legal authority to do so.

While it is 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.⁸⁸ 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 consultation meeting appropriate criteria.”⁸⁹ 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.

ii. Potential Legal Barriers to Extending the Pandemic Flexibilities through Joint Regulations

DEA and SAMHSA have the legal authority to issue joint regulations, but 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

84. See S. Rep. 110-521, at 13 (2008).

85. *Id.*

86. *Id.*

87. *Id.* at 12-13.

88. *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 14 (2007)* (statement of Joseph Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration).

89. *Id.*

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.⁹⁰

a. 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.⁹¹ 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).⁹²

Both DEA and SAMHSA pandemic flexibilities allow practitioners prescribing buprenorphine to do so over the telephone (i.e., using only an audio connection). The agencies did not limit practitioners to use of a two-way, audio-visual connection.⁹³ 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 smart phones with video cameras.⁹⁴ 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).⁹⁵ 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....”⁹⁶

The 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 telephone).”⁹⁷

90. This report 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, as discussed in part II.A.i, 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).

91. 21 U.S.C. § 802(54) (2018).

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

93. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf); Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

94. Jocelyn Guyer and Karen Scott, *State Strategies For Helping Individuals With Opioid Use Disorder Through The COVID-19 Epidemic*, Health Affairs (May 2, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200429.476954/full/>.

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

96. 42 U.S.C. § 1395m(m)(1) (2018).

97. *Telecommunication*, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/telecommunication> (last visited Aug. 17, 2020).

And nothing in the legislative history indicates that Congress intended to exclude telephones. Instead, the legislative history includes concern about the possibility of hindering the burgeoning telemedicine market.⁹⁸

Although BIPA does not define “telecommunications systems,” the Centers for Medicare & Medicaid Services (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.”⁹⁹ In response, CMS promulgated a definition of “telecommunications system” that explicitly excludes telephones.¹⁰⁰ CMS argued that “the patient’s presence and use of an interactive audio and video telecommunications system permitting the distant site practitioner to interact with the patient provides a reasonable substitute for a face-to-face encounter.”¹⁰¹ 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.

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).¹⁰² Importantly, in taking this posture, DEA and SAMHSA signaled both that the CMS interpretation was not binding on them and that they read “telecommunications system” more expansively 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).

b. 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.”¹⁰³ 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. This section concludes that it is within DEA and SAMHSA’s discretion to issue joint regulations without additional diversion controls.

Although Congress has spoken to the issue, the statutory language is ambiguous because it does not articulate what constitutes an effective control.¹⁰⁴ The Ryan Haight Act legislative history, however, suggests that DEA and SAMHSA have broad discretion to decide which

98. See S. Rep. 110-521, at 13 (2008).

99. See Medicare Programs; Revisions to Payment Policies, 66 Fed. Reg. 40372, 40392-3 (proposed Aug. 2, 2001).

100. 42 CFR § 410.78(a)(3) (2019).

101. Medicare Programs; Revisions to Payment Policies, 66 Fed. Reg. at 40,393.

102. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esigin.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esigin.pdf); Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

103. 21 U.S.C. § 802(54)(G) (2018).

104. 21 U.S.C. § 802(54) (2018).



Public health experts have long argued that practitioners can provide high-quality treatment for opioid use disorder via telemedicine, but federal regulation limits the ability of practitioners to prescribe buprenorphine using telemedicine without first conducting an in-person medical evaluation.

requirements are sufficient to control diversion. As noted above, legislators expressed that DEA and SAMHSA would promulgate regulations that allow for the “full practice of telemedicine” so long as they control diversion.¹⁰⁵ The legislative history is silent as to the types of diversion control requirements the agencies ought to place on practitioners using telemedicine.¹⁰⁶

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.¹⁰⁷ 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.¹⁰⁸ The current regulations already require an evaluation; the pandemic-related flexibilities simply allow that 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.¹⁰⁹ 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.”¹¹⁰

105. See S. Rep. 110-521, at 13 (2008).

106. *Id.* See *supra* part III.A.i for more discussion on the legislative history.

107. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf); Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

108. The exception does not apply to new opioid treatment program patients treated with methadone. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf); Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

109. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf).

110. *Id.*

Of course, when DEA and SAMHSA crafted these regulatory flexibilities, they did so prospectively. DEA and SAMHSA should learn from the experience of this pandemic. 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. As noted above, DEA and SAMHSA have discretion to choose whether to impose additional diversion controls. Research is needed to clarify how telemedicine works in practice. 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.¹¹¹

iii. SAMHSA Issues a Companion Policy

The joint regulations would only be relevant to DATA-waived practitioners, so SAMHSA would also need to issue a companion policy to exempt opioid treatment programs from the in-person medical evaluation pre-admission requirement. In response to the COVID-19 public health emergency, SAMHSA released a guidance document that exempts opioid treatment programs from the requirement to conduct an in-person physical evaluation prior to initiating buprenorphine treatment.¹¹² SAMHSA could draw on that same legal authority to do so post-pandemic.

In its guidance, SAMHSA points to a regulatory authority, as opposed to its authorizing statute or the public health emergency declaration, for the legal authority to grant the exception. SAMHSA writes that 42 C.F.R. § 8.11(h) gives it the authority to grant opioid treatment programs exemptions from various requirements.¹¹³ That regulatory provision states that an 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.”¹¹⁴ The availability of an exemption is not tied, as a matter of law, to a public health emergency declaration. That is an important difference from a flexibility that draws upon the emergency declaration for its authority because SAMHSA's flexibilities do not need to automatically terminate when the emergency declaration expires. SAMHSA's guidance states that the “exemption will continue for the period of the national emergency declared in response to the COVID-19 pandemic.”¹¹⁵ Thus, as a matter of policy and not as a matter of law, SAMHSA determined in its discretion that its COVID-19 flexibilities will expire with the emergency declaration. SAMHSA, therefore, has already taken the position that it has the legal authority to issue guidance that exempts opioid

111. While the exact content and process of these rules are outside the scope of this report, 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. See *Chevron U.S.A. Inc. v. NRDC Inc.*, 467 U.S. 837 (1984). In this report, 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.

112. Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

113. *Id.*

114. 42 C.F.R. § 8.11(h) (2019).

115. Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

treatment programs from the requirement to perform an in-person physical evaluation once the public health emergency lapses.

B. DEA Establishes a Special Registration for Telemedicine Program and SAMHSA Issues a Companion Policy

There is a second potential path for DEA and SAMHSA to extend the pandemic flexibilities beyond the conclusion of the COVID-19 public health emergency. DEA can use its authority under the Ryan Haight Act to establish a special registration for a telemedicine program while SAMHSA issues the same companion policy described above in part III.A.iii.

i. DEA Establishes a Special Registration for Telemedicine Program

One of the seven telemedicine exceptions in the Ryan Haight Act gives DEA the discretion to register practitioners to prescribe controlled substances using telemedicine.¹¹⁶ The statute says “the term ‘practice of telemedicine’ means, for purposes of this sub-chapter, the practice of medicine...which...is being conducted by a practitioner who has obtained from the Attorney General a special registration.”¹¹⁷ 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.”¹¹⁸ Although DEA missed the initial deadline, it remains legally obligated to create this special registration program.¹¹⁹

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.¹²⁰ The statute does not require DEA to pre-

116. 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 propose regulations. Special Registration for Telemedicine Act of 2018, 21 U.S.C. § 831(h)(2) (2018).

117. 21 U.S.C. § 802(54)(E) (2018).

118. 21 U.S.C. § 831(h)(2).

119. 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/>.

120. 21 U.S.C. § 831(h)(2).



As of 2018, there were 1,605 opioid treatment programs in the U.S.

That's approximately one treatment program for every 205,000 Americans.

approve each individual practitioner seeking a special registration for telemedicine.¹²¹ 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.¹²²

ii. SAMHSA Issues a Companion Policy

In order to extend all of the pandemic-related flexibilities, SAMHSA would also need to issue a companion policy that exempts opioid treatment programs from the requirement to conduct an in-person evaluation to initiate buprenorphine treatment. This would be the same approach SAMHSA took in response to the COVID-19 public health emergency by releasing a guidance document that exempts opioid treatment programs from the requirement to conduct an in-person physical evaluation to initiate buprenorphine treatment.¹²³ See section III.A.iii for additional discussion about this approach.

C. DEA and SAMHSA Extend the Flexibilities for Buprenorphine Induction Relying on the Opioid Emergency Declaration

A third option offers a longer-term—albeit not as durable as the first two options—approach to extending the pandemic flexibilities. As explained above, SAMHSA and DEA provided

121. *Id.*

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

123. Substance Abuse & Mental Health Services Admin., FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency (Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

the flexibilities described throughout this report in response to the COVID-19 public health emergency declaration. Should the COVID-19 public health emergency declaration expire or be revoked, SAMHSA and DEA could ground the flexibilities in the opioid-specific public health emergency declaration.

The Secretary of HHS can declare a public health emergency under the Public Health Service Act.¹²⁴ 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.¹²⁵ On October 26, 2017, Acting Secretary of HHS Eric Hargan declared the opioid crisis a nationwide public health emergency.¹²⁶ The opioid crisis public health emergency has since been renewed eleven times; most recently by HHS Secretary Alex Azar on January 7, 2021.¹²⁷ A public health emergency determination remains in effect for 90 days or until the Secretary determines the emergency no longer exists, meaning the secretary must renew an emergency in 90-day increments.¹²⁸

The Secretary characterized the emergency declaration as “a powerful action...which empowers the real heroes of this fight: the communities on the front lines of the epidemic.”¹²⁹ To date, SAMHSA and DEA have taken a variety of actions to combat the opioid epidemic. For example, SAMHSA administers the Opioid State Targeted Response grant program, and DEA released a rule that allows nurse practitioners and physician assistants to obtain a DATA waiver.¹³⁰ During or after the COVID-19 pandemic, regulatory flexibilities that encourage telemedicine could complement these efforts to provide enhanced access to medication-assisted treatment.

In its pandemic guidance, DEA explained that it was “exercising its authorities to provide flexibility in the prescribing and dispensing of controlled substances to ensure necessary patient therapies remain accessible.”¹³¹ While DEA issued this guidance in light of the unique public health risks posed by a pandemic, there are several logistical barriers to opioid use disorder treatment—unrelated to the pandemic—that telemedicine alleviates. DEA’s pandemic guidance explains that it offered these regulatory flexibilities “to ensure authorized practitioners may admit and treat new patients with opioid use disorder (OUD) during the public health emergency.”¹³² While the two public health emergency declarations respond to different crises, the policy goal of both is enhanced access to treatment.

124. Public Health Service Act of 1944, 42 U.S.C. § 247d (2018).

125. *Id.*

126. U.S. Dep’t of Health & Human Serv., Determination that a Public Health Emergency Exists (2017), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>.

127. U.S. Dep’t of Health & Human Serv., Renewal of Determination that a Public Health Emergency Exists (2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids-7Jan2021.aspx>.

128. 42 U.S.C. § 247d.

129. U.S. Dep’t of Health & Human Serv., HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis (2017) <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

130. Substance Abuse & Mental Health Services Admin., SAMHSA Reaffirms Efforts to Address the Public Health Emergency on the Opioid Crisis (Oct. 26, 2017) <https://www.samhsa.gov/newsroom/press-announcements/201710260100>; Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder, 83 Fed. Reg 3,071 (Jan. 22, 2018).

131. Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement 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).

132. *Id.*



Options to Extend these Flexibilities

First, DEA and SAMHSA could issue joint regulations that clear the path for additional use of telemedicine for prescribing buprenorphine.

Second, DEA could fulfill its legal obligation to implement a special registration program for telemedicine. In either case, SAMHSA would need to issue a companion policy to exempt opioid treatment programs from the requirement to conduct an in-person medical evaluation before admitting a new patient.

Third, SAMHSA and DEA could use the opioid-specific emergency declaration to offer a longer term, but not permanent, option to extend these flexibilities.

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 initiate 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. As explained 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 § 8.12.¹³³ 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.¹³⁴

Turning to the DEA flexibilities, 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.”¹³⁵ 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.

IV. Conclusion

Federal regulators extended flexibilities to practitioners to use telemedicine to begin opioid use disorder treatment during the COVID-19 public health emergency. Public health experts have long argued that practitioners can provide high-quality treatment for opioid use disorder via telemedicine, but federal regulation limits the ability of practitioners to prescribe buprenorphine, one of the medications considered the gold standard for treatment

133. 42 C.F.R. § 8.11(h) (2019).

134. *Id.*

135. 21 U.S.C. § 802(54)(D) (2018); 42 U.S.C. § 247d. (2018).

of opioid use disorder, using telemedicine without first conducting an in-person medical evaluation. This report 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 in three ways, without legislative changes from Congress.

First, DEA and SAMHSA could issue joint regulations that clear the path for additional use of telemedicine. Second, DEA could fulfill its legal obligation to implement a special registration program for telemedicine. In either case, SAMHSA could issue a companion guidance to exempt opioid treatment programs from the requirement to conduct an in-person medical evaluation before admitting a new patient. Third, SAMHSA and DEA could use the opioid-specific emergency declaration to offer a longer term, but not permanent, option to extend these flexibilities.

During the COVID-19 pandemic, DEA commented that the pandemic-related flexibilities must, as a matter of law, expire when the pandemic ends. In contrast, and as explained in this report, DEA and SAMHSA have multiple pathways to extend these flexibilities. While more research is needed to establish the extent to which telemedicine improves patients' access to opioid use disorder treatment without increasing diversion, the law gives DEA and SAMHSA discretion to extend these flexibilities for the sake of patient access.





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