

Please note: This is the text of the Expansion of induction of buprenorphine via telemedicine encounter rule as signed by Drug Enforcement Administration Administrator Anne Milgram, but the official version of the NPRM will be as it is published in the Federal Register.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306

Docket No. DEA-948

RIN 1117-AB78

Expansion of induction of buprenorphine via telemedicine encounter

AGENCY: Drug Enforcement Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY:

An estimated 107,477 fatal drug poisonings occurred between September 1, 2021 and August 31, 2022, the majority of which involved illegal synthetic drugs.¹ The Drug Enforcement Administration (DEA) is doing everything in its power to safely expand access to treatment to prevent further drug poisoning deaths.

To combat these catastrophic trends, the DEA is amending its regulations, in concert with the Department of Health and Human Services (HHS), to expand the circumstances under which individual practitioners are authorized to prescribe schedule III-V narcotic² drugs or combinations of such drugs that have been approved for use in continuous medical treatment (also referred to as maintenance) or withdrawal management treatment (also referred to as detoxification)—via a telemedicine encounter, including an audio-only telemedicine encounter.

¹ Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics, Provisional Drug Overdose Death Counts, 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>. (Accessed January 17, 2023)(Sum of Predicted Value for the Number of Drug Overdose Deaths).

² DEA's use of "narcotic" in this rulemaking refers to "narcotic drug" under the Controlled Substances Act 21 U.S.C. 802(17). At the time of publication, the only controlled substances that fits this description under the proposed rule is buprenorphine and combinations of drugs containing buprenorphine, but no other narcotics.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA–948” on all correspondence, including any attachments.

Electronic Comments: The Drug Enforcement Administration encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov/> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper Comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement

Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

Paperwork Reduction Act Comments: All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB78/Docket No. DEA-948.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received, including attachments and other supporting materials, are considered part of the public record. They will be made available by DEA for public inspection online at <https://www.regulations.gov/>. The Freedom of Information Act applies to all comments received. Confidential information or personal identifying information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

Comments with confidential information, which should not be made available for public inspection, should be submitted as written/paper submissions. Two written/paper copies should be submitted. One copy will include the confidential information with a heading or cover sheet that states "CONTAINS CONFIDENTIAL INFORMATION." DEA will review this copy, including the claimed confidential information, in its consideration of comments. The second

copy should have the claimed confidential information redacted/blacked out. DEA will make this copy available for public inspection online at <https://www.regulations.gov/>. Other information, such as name and contact information, that should not be made available, may be included on the cover sheet but not in the body of the comment, and must be clearly identified as “confidential.” Any information clearly identified as “confidential” will not be disclosed.

I. Legal Authority and Background

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to end. These regulations are designed to ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed system of control for manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA, unless they meet an exemption, pursuant to 21 U.S.C. 822. “Dispense” in the context of this rulemaking means to deliver a controlled substance to an ultimate user, which includes the prescribing of a controlled substance.³ The CSA further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA.⁴

³ 21 U.S.C 802(10).

⁴ 21 U.S.C. 871(b), 958(f).

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (The Ryan Haight Act)⁵ amended the CSA by, among other things, adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. While the Ryan Haight Act amended the CSA to generally require that the dispensing of controlled substances by means of the Internet be predicated on a valid prescription involving at least one in-person medical evaluation, it also established seven distinct categories of telemedicine pursuant to which a practitioner may prescribe controlled substances for a patient despite never having evaluated that patient in person, provided that, among other things, such practice is in accordance with applicable Federal and State laws.⁶ Notably, the Ryan Haight Act does not limit a practitioner's ability to prescribe controlled substances for a patient after there has been an in-person medical evaluation. In other words, the Ryan Haight Act applies only when a prescribing practitioner wishes to prescribe controlled substances via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription. Furthermore, as described below, the Ryan Haight Act and DEA's implementing regulations do not apply to other forms of telemedicine, telehealth, or telepsychiatry that are not otherwise defined in the CSA.

The Ryan Haight Act is intended to address the grave threat to public health and safety caused by practitioners who prescribed controlled substances via the Internet without establishing a valid practitioner-patient relationship through fundamental steps such as performing an in-person medical evaluation of a patient. Prior to the enactment of the Ryan Haight Act, the Internet was being exploited to facilitate the unlawful distribution of legally

⁵ Pub. L. 110-425 (2008). Because the Ryan Haight Act amended the CSA, references in this document will generally be to the CSA.

⁶ 21 U.S.C. 802(54)(A) – (G).

manufactured controlled substances through rogue websites.⁷ These rogue websites facilitated the misuse of prescribed controlled substances, such as hydrocodone and oxycodone by adolescents and others, and thereby increased the number of drug poisonings and other harmful consequences caused by the misuse of these substances.⁸

As indicated above, the Ryan Haight Act generally requires an in-person medical evaluation prior to the prescription of controlled substances. Section 829(e), however, also provides an exception to this in-person medical evaluation requirement where the practitioner is “engaged in the practice of telemedicine”⁹ within the meaning of the Ryan Haight Act (21 U.S.C. 802(54)). Consistent with the Ryan Haight Act’s purpose of preventing diversion of controlled substances by means of the Internet, the Act’s definition of “the practice of telemedicine” does not encompass all forms of telemedicine. Rather, as set forth in 21 U.S.C. 802(54), the Ryan Haight Act’s definition of the “practice of telemedicine” includes seven distinct categories of telemedicine that Congress determined were appropriate to allow for the prescribing of controlled substances despite the practitioner never having evaluated the patient in person.

The CSA and DEA’s regulations only define the “practice of telemedicine” for the purpose of establishing obligations under the CSA and DEA regulations. DEA is not attempting to define what constitutes appropriate telemedicine in other contexts. Thus, the proposed rule would not determine when substances that are not controlled may be appropriately prescribed via telemedicine or the nature of appropriate remote medical treatment more generally. Moreover, this proposed rule would not create any additional regulatory requirements for other categories of telemedicine authorized by the CSA under 21 U.S.C. 802(54). Rather, it would create additional

⁷ H.R. REP. 110-869(I), 11, 2008 U.S.C.C.A.N. 2130, 2131.

⁸ *Id.*

⁹ *Id.* 829(e)(3)(A).

circumstances under which the use of telemedicine to prescribe controlled substances is authorized by the CSA. For example, to fall under the last category of telemedicine, the practice is “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.”¹⁰

As described below, in other circumstances encompassed by the Ryan Haight Act’s definition of the “practice of telemedicine,” the Act contemplates that the practitioner will be permitted to prescribe controlled substances by means of the Internet despite not having conducted an in-person medical evaluation, provided certain safeguards are in place to ensure that the practitioner who is engaged in the practice of telemedicine is able to conduct or participate in a *bona fide* medical evaluation of the patient at the remote location and is otherwise prescribing for a legitimate medical purpose while acting in the usual course of professional practice.

To fall within this definition of the “practice of telemedicine,” the practice also must be “in accordance with applicable Federal and State laws” and use “a telecommunications system referred to in [42 U.S.C. 1395m(m)].”¹¹ Title 42 U.S.C. 1395m(m) references, but does not define, such telecommunications systems. The Centers for Medicare & Medicaid Services (CMS), however, have promulgated regulations implementing those provisions, and those regulations do define “interactive telecommunications system.”¹² In particular, 42 CFR 410.78(a)(3) states:

Interactive telecommunications system means, except as otherwise provided in this paragraph, multimedia communications equipment

¹⁰ *Id.* 802(54)(G).

¹¹ *Id.* 802(54).

¹² 42 CFR 410.78(a)(3)

that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology.

CMS recently revised 42 CFR 410.78(a)(3), to which the definition of “practice of telemedicine” refers, in a final rule published on November 19, 2021 (HHS CMS Rule).¹³ Previously, 42 CFR 410.78(a)(3) had limited an “interactive telecommunications system” to “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.” Revised 42 CFR 410.78(a)(3) retains this requirement of both audio and video real-time communication between the patient and the distant practitioner in most circumstances: as the HHS CMS rule revising 42 CFR 410.78(a)(3) stated, “[T]wo-way, audio/video communications technology is the appropriate, general standard for telehealth services”¹⁴

CMS’s revised definition of “interactive telecommunications systems,” however, now also includes two-way, real-time *audio-only* communication technology under certain limited circumstances; limitations that are designed to maintain audio-video equipment as the general standard and only authorize audio-only equipment when both necessary and appropriate. First,

¹³ Medicare Program; Calendar Year 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (HHS CMS Rule), 86 FR 64996, 65666 (Nov. 19, 2021).

¹⁴ *Id.* at 65060.

to allow the use of audio-only equipment, the medical services at issue must be “furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder.”

CMS recognized that, for many mental health services, visualization between the patient and clinician may be less critical to provision of the service: “[M]ental health services are different from other services because they principally involve verbal exchanges between patient and practitioner.”¹⁵ CMS also responded to comments requesting that audio-only technology be permitted for a broader scope of Medicare telehealth services. CMS distinguished “services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder,” from other services and specified that the scope of the audio-only policy is limited to mental health disorders.¹⁶ CMS also acknowledged that “[T]here may be particular instances where visual cues may help a practitioner’s ability to assess and treat patients with mental health disorders, especially where opioids or mental health medications are involved”¹⁷

Second, to allow the use of audio-only equipment, the mental health services must be provided “to a patient in their home.” CMS reasoned that other sites at which a patient generally receives telehealth services are “medical settings that are far more likely to have access to reliable broadband internet service. When a patient is located at one of these . . . sites, access to care is far less likely to be limited by access to broadband that facilitates a video connection. In contrast, access to broadband, devices, and user expertise is less likely to be available at a patient’s home.”¹⁸ CMS, however, adopted a flexible understanding of “home:” “[O]ur definition of home can include temporary lodging such as hotels and homeless shelters as well as

¹⁵ *Id.* at 65061.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at 65060.

locations a short distance from the [patient's] home” (if the patient, “for privacy or other personal reasons, chooses to travel a short distance away from the exact home location during a telehealth service . . .”).¹⁹

Third, to allow the use of audio-only equipment, the distant site physician or practitioner must be “technically capable” of meeting the usual two-way, audio-video interactive communication standard. And, relatedly, the patient must “not [be] capable of, or . . . not consent to, the use of video technology.” In other words, “because it is generally appropriate to require the use of two-way, real-time audio/video communications technology,”²⁰ the distant practitioner engaging in telehealth must make the option of audio-video communication available to the patient. The audio-only option may only be used if the patient “is unable to use, does not wish to use, or does not have access to two-way, audio/video technology.”²¹

As stated in proposed 21 CFR 1306.34(a)(2), DEA is proposing to promulgate regulations that would require practitioners to otherwise comply with relevant State and Federal law.²² In those States where state law prohibits the prescription of a controlled substance based solely on an audio-only evaluation, the proposed regulation would not authorize the audio-only prescription of buprenorphine for opioid-use disorder (OUD). Thus, this proposed rulemaking’s authorization of audio-only OUD prescribing would only apply in those States where such prescriptions are consistent with State law—it would authorize OUD buprenorphine prescribing based on an audio-video interaction in those states if doing so was otherwise consistent with State and Federal law.

¹⁹ *Id.* at 65059.

²⁰ *Id.* at 65062.

²¹ *Id.* at 65060.

²² The CSA’s definition of “practice of telemedicine” requires that it be “in accordance with applicable Federal and State laws.” 21 U.S.C. 802(54).

DEA has consulted with representatives of the Secretary of Health and Human Services (HHS) regarding the substantive changes to the definition of “interactive telecommunications systems” in the HHS CMS Rule. Subsequent to the promulgation of the HHS CMS Rule, DEA is proposing to promulgate these specific conditions under which practitioners would be authorized to engage in the practice of telemedicine. The proposed changes to DEA’s regulations herein, in conjunction with the changes already implemented in the HHS CMS Rule, are consistent “with effective controls against diversion and otherwise consistent with the public health and safety” pursuant to 21 U.S.C. 802(54)(G). HHS was consulted in the creation of these regulatory provisions and concurs with this proposed rulemaking. HHS also has advised DEA that no additional rulemaking by HHS is necessary as it pertains to the promulgations of these provisions pursuant to 21 U.S.C. 802(54)(G).

II. Background

Buprenorphine Used in Treating Opioid Use Disorder

DEA is proposing to promulgate regulations which would expand the circumstances under which practitioners are authorized to prescribe any schedule III, IV, or V narcotic drug approved by the Food and Drug Administration (FDA) specifically for use in the maintenance or detoxification treatment of OUD via a telemedicine encounter, including an audio-only telemedicine encounter that meets the standard of 42 CFR 410.78(a)(3), provided certain requirements and conditions are met. The only schedule III-V narcotic drug that is currently approved by the FDA for such treatment is buprenorphine.²³ Thus, DEA is proposing to expand

²³ Buprenorphine is a partial mixed opioid agonist that comes in tablets, sublingual, as well as injectable formulations. It produces effects such as euphoria or respiratory depression at low to moderate doses. With buprenorphine, however, these effects are weaker than full opioid agonists such as methadone and heroin.

the situations in which practitioners are authorized to prescribe buprenorphine via telemedicine for maintenance or detoxification treatment under circumstances to expand access to treatment for OUD while maintaining effective controls against diversion.

Buprenorphine comes in two formulations, a sole agent or combined with naloxone, both of which are very effective medications for the treatment of OUD.²⁴ Commonly prescribed formulations of buprenorphine are indicated by the FDA for the treatment of OUD.²⁵ DEA classifies buprenorphine as a schedule III narcotic controlled substance as it has a currently accepted medical use in treatment, and has less of a potential for misuse than the other controlled substances in schedules I and II, and its misuse may lead to moderate to low physical dependence or high psychological dependence.²⁶ Studies have shown that buprenorphine helps to lower physical dependency on other opioids and reduces withdrawal symptoms, drug cravings, and morbidity and mortality for patients with OUD while also providing lower euphoric effects compared to other opioids.²⁷ Moreover, buprenorphine is a partial opioid receptor agonist, it has less of an effect on respiratory depression, has a lower risk of overdose, and produces lower euphoric effects than full agonist opioids.²⁸ Similar to other opioids, some patients and individuals who misuse buprenorphine may experience withdrawal upon stopping the medication. Thus, buprenorphine is an effective medication for treating OUD, especially when

²⁴ Treatment Improvement Protocol 63 for guidance on medication for OUD. *Medications for Opioid Use Disorder, Treatment Improvement Protocol 63*, SAMHSA (2021)

²⁵ *Id.*

²⁶ 21 U.S.C. 812(b)(3)(A)-(C); 21 CFR 1308.13(e)(2)(i).

²⁷ *Buprenorphine*, Substance Abuse and Mental Health Services Administration, (April 19, 2022), <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine>; see *Medications for Opioid Use Disorder Save Lives*, National Academies of Sciences, Engineering, and Medicine. (2019) <https://nap.nationalacademies.org/catalog/25310/medications-for-opioid-use-disorder-save-lives>.

²⁸ A Dahan *et al.*, *Buprenorphine induces ceiling in respiratory depression but not in analgesia*, (March 07, 2006) <https://pubmed.ncbi.nlm.nih.gov/16547090/>.

used as part of a complete treatment plan, but buprenorphine may also be dangerous when not used as prescribed.

Combination products containing buprenorphine and naloxone can potentially deter misuse for certain individuals. For example, Suboxone® combines buprenorphine with naloxone, an opioid antagonist which is largely inactive when the product is administered sublingually as indicated, which is intended to discourage use by injection or insufflation. Specifically, when Suboxone®, or a generic form of buprenorphine/naloxone combination product, is injected or insufflated, naloxone may cause uncomfortable side effects, including precipitated opioid withdrawal, which may deter certain forms of diversion. The issuance of Suboxone® by practitioners may be considered preferable to injectable drugs used to treat OUD, such as long-acting naltrexone or long-acting buprenorphine, as such treatment for OUD must be administered by a health care professional. Moreover, this formulation may be preferred by practitioners as patients must not be physically dependent on opioids before beginning oral or injected naltrexone, which requires a period of several days of abstinence. Inducing buprenorphine requires a shorter period of abstinence before induction to avoid precipitated withdrawal.

The Unprecedented Trafficking of Fentanyl and the Drug Poisoning Crisis

The diversion and misuse of opioids lead to drug poisonings and deaths that can be mitigated by increased access to treatment for OUD. More than one million people in the United States have died from drug poisonings between 1999 and 2021.²⁹ The rate of drug poisoning deaths involving synthetic opioids (including fentanyl) has substantially increased since 2013 to

²⁹ *Drug Overdose Deaths*, Center for Disease Control, National Center for Injury Prevention and Control (Accessed on July 08, 2022), <https://www.cdc.gov/drugoverdose/deaths/>.

2021. More recently, as stated above, an estimated 107,477 drug poisoning deaths occurred between September 1, 2021 and August 31, 2022.³⁰ Approximately 70% of these drug poisoning deaths involved fentanyl and other synthetic opioids.³¹

The availability of fentanyl throughout the United States has reached unprecedented heights. In 2022, DEA seized more than 50 million fake pills and 10,000 pounds of fentanyl powder equating to approximately 379 million deadly doses of fentanyl.³² These seizures have occurred in every State in the country. This is enough fentanyl to supply a potentially lethal dose to every member of the U.S. population.

Access to buprenorphine decreases the risk of drug poisoning.³³ Moreover, increasing access to buprenorphine after a drug poisoning has also been associated with a reduced risk of death.³⁴ Thus, DEA believes increasing patient access to MOUD is necessary to both prevent and ameliorate the catastrophic drug poisonings that are occurring as a result of fentanyl. Importantly, a recent study found that the percentage of opioid overdose deaths involving buprenorphine did not increase in the months after prescribing flexibilities, including the remote

³⁰ Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics, Provisional Drug Overdose Death Counts, 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>. (Accessed January 17, 2023)(Sum of Predicted Value for the Number of Drug Overdose Deaths).

³¹ *Id.*

³² *Drug Enforcement Administration Announces the Seizure of Over 379 million Deadly Doses of Fentanyl in 2022*, (January 04, 2023) <https://www.dea.gov/press-releases/2023/01/04/drug-enforcement-administration-announces-seizure-over-379-million-deadly>.

³³ Dadiomov, *et al.*, *Buprenorphine and naloxone access in pharmacies within high overdose areas of Los Angeles during the COVID-19 pandemic*, *Harm Reduction Journal*. (June 29, 2022)

<https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-022-00651-3>.

³⁴ Larochelle, *et al.*, *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality*, *Annals of Internal Medicine*, (August 07, 2018) <https://www.acpjournals.org/doi/10.7326/M17-3107>.

induction and prescribing of buprenorphine for OUD treatment via telemedicine, were put in place during the COVID-19 pandemic.³⁵

Diversion Risk of Buprenorphine

Buprenorphine is a critical tool in efforts to stem the drug poisoning crisis that is occurring across the country. Still, buprenorphine, when used improperly, may lead to misuse and death.³⁶ Self-medication for the management of symptoms may also be a motivation for non-prescribed misuse of buprenorphine.³⁷ Moreover, issues with availability, accessibility, and acceptability of formal buprenorphine treatment may also contribute to non-prescribed buprenorphine misuse.³⁸ Diversion of buprenorphine and other prescription opioids remains an issue across the country: in the past two years, DEA has seen Federal investigations of

³⁵ Tanz, *et al.* *Trends and characteristics of buprenorphine-involved overdose deaths prior to and during the COVID-19 pandemic*, JAMA. (January 20, 2023)

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

³⁶ See *ex. TDH Finds Some Overdose Deaths Associated With Buprenorphine*. Tennessee Department of Health, (January 08, 2018) <https://www.tn.gov/health/news/2018/1/8/tdh-finds-some-overdose-deaths-associated-with-buprenorphine.html>; Bishop, S. D., *Buprenorphine-Related Deaths in North Carolina from 2010 to 2018*. (September, 2021) pubmed.ncbi.nlm.nih.gov/34145443/. See

³⁷ See Cicero *et al.* *Understanding the use of diverted buprenorphine*, Drug and Alcohol Dependence, (December 01, 2018) <https://www.sciencedirect.com/science/article/pii/S0376871618307245>; McDonald *et al.*, *Assessing Motivations for Nonprescribed Buprenorphine Use Among Rural Appalachian Substance Users*, Journal of Addiction Medicine, (August 31, 2022) <https://pubmed.ncbi.nlm.nih.gov/36044288/>; Silverstein *et al.*, *On my own terms: Motivations for self-treating opioid-use disorder with non-prescribed buprenorphine*, Drug and Alcohol Dependence, (May 01, 2020) <https://pubmed.ncbi.nlm.nih.gov/32203863/>; Butler *et al.*, *How Motivations for Using Buprenorphine Products Differ From Using Opioid Analgesics: Evidence from an Observational Study of Internet Discussions Among Recreational Users*, JMIR public health and surveillance, (March 25, 2020) <https://pubmed.ncbi.nlm.nih.gov/32209533/>.

³⁸ Silverstein *et al.*, *On my own terms: Motivations for self-treating opioid-use disorder with non-prescribed buprenorphine*, Drug and Alcohol Dependence, (May 01, 2020) <https://pubmed.ncbi.nlm.nih.gov/32203863/>; McLean *et al.*, *The international journal on drug policy*, (July 20, 2019) <https://pubmed.ncbi.nlm.nih.gov/31330267/>.

buprenorphine diversion across the country.³⁹ Thus safeguards are necessary to mitigate the risk of diversion.⁴⁰

Purpose and Need for Rulemaking

DEA is proposing to promulgate regulations which would increase patient access to buprenorphine treatment for OUD with the goal of providing effective controls against diversion. Thus, DEA is proposing to promulgate regulations that would expand the circumstances under which registered practitioners would be authorized to prescribe buprenorphine for OUD via telemedicine, including an audio-only telemedicine encounter meeting the requirements of 42 CFR 410.78(a)(3), and inform these practitioners of their related obligations. DEA is also proposing to promulgate regulations that are necessary to mitigate the risk of diversion associated with this authorization.

Unmet Need to Facilitate Patient Access to Treatment for Opioid Use Disorder

³⁹ See, e.g., *United States v. Kesari* (S.D. W.Va. 2021) (Charleston doctor convicted of selling buprenorphine prescriptions for cash); *United States v. Summers* (E.D. Pa. 2018) (Philadelphia doctor operating “National Association for Substance Abuse Prevention & Treatment” pleaded guilty to selling buprenorphine prescriptions to drug dealers); *United States v. SelfRefind* (E.D. Ky. 2014) (largest buprenorphine clinic in the U.S. paid \$15 million to resolve civil allegations regarding urine-testing scams, around the same time Kentucky suspended its director’s authorization to prescribe buprenorphine drugs due to reckless overprescribing).

⁴⁰ See Mance E Buttram et al., *Increasing rates of buprenorphine diversion in the United States, 2002 to 2019* (July, 31 2021) <https://pubmed.ncbi.nlm.nih.gov/34302707/>. See Monico, L.B. et. al., *Exploring nonprescribed use of buprenorphine in the criminal justice system through qualitative interviews among individuals recently released from incarceration*. (April, 2021), <https://pubmed.ncbi.nlm.nih.gov/33612198> (Inmates and correctional officers have diverted buprenorphine, particularly in sublingual strip form, among inmates through illicit channels within correctional facilities as buprenorphine strips can easily be hidden and consumed without detection). See Richert, T. et. al., *Illicit use of methadone and buprenorphine among adolescents and young adults in Sweden*. (October 18, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853648/>. Lofwall MR, Walsh SL. *A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world*. *J Addict Med*. (September 01, 2015) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4177012/>. (showing that individuals may use diverted buprenorphine for the purposes of mitigating withdrawal symptoms in between use of illicit opioids).

The majority of individuals suffering with OUD unfortunately do not receive treatment with FDA-approved medications.⁴¹ DEA is proposing to promulgate regulations that would address the unmet need to increase patient access to treatment for OUD. This rulemaking would enable those patients who, prior to being able to access treatment under the circumstances newly authorized, did not wish to, or did not possess the means to, be inducted for the treatment of OUD.

Until recently, there was a nationwide shortage of practitioners authorized to dispense buprenorphine.⁴² Expanding the circumstances under which practitioners are authorized to prescribe via telemedicine encounters, including audio-only encounters, would increase access to treatment for those individuals with OUD who may not want to seek treatment, or are unable to seek treatment, due to various economic, geographical, sociological, and logistical reasons.

Many patients may lack the financial means to obtain in-person treatment traditionally or through audio-video telemedicine encounters. Patients who are unhoused, unemployed, or facing other challenges may find it prohibitive to afford devices capable of audio-video telemedicine encounters or consistent access to wireless internet and/or data plans adequate to support bandwidth demands of telemedicine encounters.⁴³ Many individuals have unstable access, or experience interruptions in access, to this technology.⁴⁴ Additionally, many rural and

⁴¹ *Only one in Four People Needing Treatment for Opioid Use Disorder Received Medication*, Columbia University School of Public Health, (March 23, 2022), <https://www.publichealth.columbia.edu/public-health-now/news/only-one-four-people-needing-treatment-opioid-use-disorder-received-medication>.

⁴² Conway, Kevin P et al. *Rural and urban differences in undersupply of buprenorphine provider availability in the United States, 2018*, *Addiction science & clinical practice* (January 31, 2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8802270/>.

⁴³ DeLaCruz et. al., *Telemental Health for the Homeless Population: Lessons Learned when Leveraging Care*, (December, 08 2022) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9734763/>.

⁴⁴ *Id.*

frontier communities do not have access to reliable broadband or wireless networks or an unwillingness to engage in telemedicine encounters directly.⁴⁵

Expanding a registered practitioners' authority to prescribe buprenorphine for the treatment for OUD via telemedicine, including an audio-only telemedicine encounter meeting the standards of 42 CFR 410.78(a)(3), would expand access to much needed medical treatment.⁴⁶ Recent studies have revealed that, in some populations, upward of 94 percent of the unhoused community had a cell phone, while a limited amount owned or had access to computers, tablets, or internet access.⁴⁷ Not only would this rulemaking make it easier for patients to obtain treatment, many practitioners have shown a willingness to treat patients using an audio-only telecommunications system. An online survey showed that practitioners who engaged in the practice of telemedicine and prescribed buprenorphine considered telephonic means to be "more accessible."⁴⁸

Increased Access Must Be Consistent with Effective Controls Against Diversion and Public Health and Safety

⁴⁵ *Id.*

⁴⁶ Under the Americans with Disabilities Act (ADA) and section 504 of the Rehabilitation Act, practitioners are generally obligated to ensure effective communication and provide patients with disabilities with equal access to services. *See, e.g.,* 28 CFR 35.130(a); 28 CFR 35.130(b)(1); 28 CFR 35.160; 28 CFR 36.202(b); 28 CFR 36.303(c); 45 CFR 84.4; 45 CFR 84.52. While audio-only telemedicine may be appropriate for some patients, it may not satisfy practitioners' ADA and section 504 obligations in all cases, particularly when patients are deaf or have hearing loss. *See* The Department of Justice, Civil Rights Division, *The Americans With Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery* (April 05, 2022) https://www.ada.gov/opioid_guidance.pdf.

⁴⁷ Molfenter T, Roget N, Chaple M, et al. *Use of Telehealth in Substance Use Disorder Services During and After COVID-19: Online Survey Study*. JMIR Ment Health. (February 08, 2021) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7895293/>.

⁴⁸ *Id.*

In concert with the goal of expanding patient access to MOUD,⁴⁹ however, DEA must address diversion risks associated with the expanding access to narcotics over the phone. As established above, the diversion of buprenorphine is dangerous and may lead to misuse and sometimes fatal drug poisonings. Additionally, DEA must draft regulations which are consistent with public health and safety. Thus, DEA is proposing to promulgate regulations to require a thorough review of Prescription Drug Monitoring Program (PDMP) data prior to prescribing, a medical evaluation of the patient meeting certain conditions within 30 days, as well as comprehensive recordkeeping requirements.

Prescription Drug Monitoring Program Review

DEA is promulgating regulations that would require a practitioner to review and consider PDMP data prior to prescribing buprenorphine under the authority the regulations would grant.⁵⁰ This review would allow the practitioner to make informed clinical decisions and identify and counsel the patient regarding higher risks (such as co-prescribed benzodiazepines), identify patients who may have obtained a buprenorphine or another recent prescription from another source (thereby preventing diversion), monitor for practitioners deliberately misprescribing buprenorphine, and prevent the diversion of such drugs through practitioners' lack of awareness that the patient on the other end of the line does not have an actual medical need or requires a more careful examination.⁵¹

⁴⁹ DEA references "Medication Assisted Treatment" (MAT) in its regulations in 21 CFR 1301.28. For the purposes of this rulemaking, all references to MAT refer to the dispensing or prescribing of Schedule III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs that have been approved by FDA specifically for use in maintenance or detoxification treatment.

⁵⁰ *Proposed* 21 CFR 1306.34(b)(2).

⁵¹ *Id.* Under the proposed rule, a practitioner employed by or contracting with the Department of Veterans Affairs (VA) also would be required to review the VA internal prescription database.

Without requiring practitioners to review and consider PDMP data, different practitioners could prescribe multiple 30-day supplies, or subsequent 30-day supplies indefinitely, to patients without realizing that they are doing so. Some studies have concluded that state rules requiring review of the PDMP are among the most effective interventions for preventing opioid drug poisonings and are correlated with a reduction in the proportion of patients that engage in drug seeking behavior.⁵² Thus, DEA believes it is necessary to require the review and consideration of PDMP data prior to prescribing buprenorphine so as to require due diligence on the part of the practitioner in order to effectively identify patients who have received prior prescriptions for buprenorphine or other prescriptions that might negatively interact with buprenorphine.

DEA believes a PDMP review requirement for prescribers, prior to writing a prescription, would balance the states' interest in regulating the practice of medicine with the overarching interest in mitigating the high risk of diversion for prescriptions which do not require face-to-face interaction with the prescribing physician – a balance in line with the text of 21 U.S.C. 802(54).

Requirement of Medical Evaluation in Person or in Presence of Another DEA Registrant within 30 days

DEA is proposing to promulgate regulations which would require the patient receiving buprenorphine under the expanded authority of these regulations to receive a medical evaluation meeting certain requirements within 30 days of being prescribed buprenorphine for the induction of OUD treatment in order to obtain an additional supply of buprenorphine.⁵³ In particular,

⁵² See Tamara M Haegerich et al., *Evidence for state, community and systems-level prevention strategies to address the opioid crisis*, (Sep 19, 2019), <https://pubmed.ncbi.nlm.nih.gov/31585357/>.

⁵³ Proposed 21 CFR 1306.34(b)(4).

under the proposed regulations, within 30 days, the patient would have to either be examined in person by the prescribing practitioner or practice, or the prescribing practitioner would have to examine the patient remotely while the patient is in the physical presence of another DEA-registered practitioner participating in an audio-video telemedicine encounter with the prescribing practitioner. Alternatively, the requirement of a medical evaluation is satisfied when the prescribing practitioner receives a qualifying telemedicine referral for medically-assisted treatment for opioid use disorder from a DEA-registered practitioner prior to issuing a prescription for controlled substances. Under this scenario, the patient has already received an in-person medical evaluation from the referring practitioner, and thus the prescribing practitioner is authorized to prescribe beyond the 30 day limit.

This requirement is necessary because the CSA generally requires each prescription for a schedule II through V controlled substance to be predicated upon at least one in-person medical evaluation. Although the proposed regulations would create an exception to this requirement, they must still maintain the CSA standard that prescriptions be tied to a medical evaluation in the physical presence of a DEA-registered practitioner. Without this provision, practitioners could theoretically prescribe buprenorphine without ever conducting a thorough medical evaluation of the patient.

Moreover, requiring these medical evaluations subsequent to telemedicine encounters facilitates common practices by which some practitioners treat OUD. The required medical evaluation can enhance treatment by enabling the practitioner to conduct tests which make sure that buprenorphine is safe and appropriate for the patient.⁵⁴ These include, but are not limited to,

⁵⁴ *Buprenorphine Quick Start Guide*, SAMHSA <https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf>.

drug and toxicology screenings, liver enzyme tests, screenings for infectious diseases such as hepatitis, etc.⁵⁵ Additionally, practitioners are able to assess conditions which may or may not be available in audio-only or even audio-video telemedicine encounters, such as signs of opioid intoxication or withdrawal, physical signs of opioid use, as well as the medical consequences of opioid use.⁵⁶ Thus, this required medical evaluation can result in enhanced treatment in some circumstances.

For these reasons, and to comply with congressional directives in the Ryan Haight Act, DEA is proposing to require a medical evaluation meeting these standards in order to prescribe a supply in excess of 30 days to assist DEA in the investigation and prosecution of malicious practitioners to ensure the public health and safety of patients and to help maintain effective controls against diversion.

Recordkeeping

Comprehensive recordkeeping is necessary to provide sufficient documentation of the details of the audio-only telemedicine encounter and ensure practitioners' compliance with the provisions listed herein. Thus, DEA is requiring practitioners to keep comprehensive records establishing the nature of the encounter, the patient's proffered reason for the audio-only encounter (if the patient requests the telemedicine encounter be audio-only rather than audio-video), and all efforts to comply with PDMP checks.⁵⁷

⁵⁵ *Id.*

⁵⁶ *Medications for Opioid Use Disorder, Treatment Improvement Protocol 63*, SAMHSA (2021) https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf.

⁵⁷ *Proposed 21 CFR 1306.34(7)(i)-(iv)*.

Prescribing Buprenorphine for the Induction of Medication for the Treatment of Opioid Use Disorder

DEA recognizes that the induction of buprenorphine via a telemedicine encounter should not constitute the entirety of a treatment protocol for OUD for many patients. As explained by SAMHSA, the use of buprenorphine should be part of a “comprehensive management program that includes other treatment plans such as psychosocial support.”⁵⁸ Thus, this rulemaking would be limited to the prescribing of buprenorphine simply for the treatment for OUD for patients via telemedicine encounters described in this rulemaking, and does not seek to circumvent or replace the individualized treatment protocols present in the usual course of treating an individual with OUD.⁵⁹

Request for Comments

With respect to the proposed rule, DEA invites comments concerning whether any clarifications or other regulatory provisions are warranted to ensure appropriate access to care, consistent with effective controls against diversion and otherwise consistent with the public health and safety. DEA invites comments on the proposed practitioner recordkeeping obligations. DEA also seeks comments about additional safeguards or flexibilities that should be considered with respect to this rule. Moreover, DEA invites comments on whether the Notice of Proposed Rulemaking, entitled “Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation” (RIN 1117-

⁵⁸ *Buprenorphine Quick Start Guide*, SAMHSA <https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf>.

⁵⁹ Registrants may refer to Treatment Improvement Protocol 63 for guidance on medication for OUD. *Medications for Opioid Use Disorder, Treatment Improvement Protocol 63*, SAMHSA (2021) https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf. See also SAMHSA, *Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders*, (2021). https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-06-02-001.pdf.

AB40), published elsewhere in this issue of the FEDERAL REGISTER, should be combined with this rulemaking when publishing the Final Rule as both documents refer to prescribing via telemedicine pursuant to 21 U.S.C. 802(54)(G).

This rule is designed to ensure that patients do not experience lapses in care. It is also designed to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID-19 public health emergency. The COVID-19 public health emergency is set to expire on May 11, 2023. DEA and HHS have provided for a notice-and-comment period of 30 days so that they have an opportunity to fully review and respond to any submissions.

III. Section-by-Section Discussion of Proposed Rule

§ 1300.04 Definitions relating to the dispensing of controlled substances by means of the Internet.

DEA is proposing to amend 21 CFR 1300.04 to add definitions of “prescription drug monitoring program” and “telemedicine encounter.” These terms play significant roles in the proposed regulations. Thus, to avoid any ambiguity about the meaning of those regulations, the proposed rule would specifically define those terms. Under the proposed rule, the term PDMP would mean a state controlled substance monitoring program, including a program supported by the Secretary of HHS under section 399O of the Public Health Service Act, as amended (42 U.S.C. 280g–3). The term “telemedicine encounter” would mean a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3), while the practitioner is engaged in the practice of medicine in accordance with applicable Federal and State laws.

§ 1304.03 Persons required to keep records and file reports.

DEA is proposing to amend 21 CFR 1304.03 by adding new paragraph (k) requiring a practitioner to maintain copies of all qualifying telemedicine referrals that he or she issues.

§ 1304.04 Maintenance of records and inventories.

DEA is proposing to amend 21 CFR 1304.04 by adding new paragraphs (i)(1)-(2) that would require registrants to maintain all records required by 21 CFR 1306.34 at the registered location that is listed on their certificate of registration. In most cases, this will be the practitioner’s primary registration in the state where the practitioner is located.

These recordkeeping requirements will help ensure that all records associated with the prescribing practitioner, as well as any DEA-registered practitioners who are present with the patient pursuant to proposed 21 CFR 1306.34(b)(5)(ii), will be stored in a consolidated location, which will expedite the investigatory process for DEA.

§ 1306.04 Purpose of issue of prescription.

DEA is proposing to amend 21 CFR 1306.04 by adding a new paragraph (e) to clarify when, and for what purpose, a practitioner may issue prescriptions pursuant to a telemedicine encounter under the expanded authority of these regulations. DEA proposes to authorize practitioners to issue prescriptions pursuant to 21 CFR 1306.34 if and only if the prescription is “issued for maintenance or detoxification treatment and . . . not . . . for any other purpose.” As stated above, buprenorphine is, at present, the only schedule III-V narcotic controlled substance that is approved by FDA for maintenance and detoxification treatment. Therefore, absent FDA approval of another schedule III-V narcotic controlled substance for the treatment of OUD, this provision only authorizes prescriptions for buprenorphine pursuant to telemedicine encounters for maintenance or detoxification treatment. This section would not authorize practitioners to

issue prescriptions for other purposes, such as for the treatment of pain, as the overarching purpose of this rulemaking is to facilitate the treatment of OUD in a safe manner.

§ 1306.34 Requirements for individual practitioners who conduct the induction of maintenance or detoxification treatment via telemedicine encounter.

DEA is proposing to amend section 1306 by adding new section 1306.34. This new section would describe the circumstances under which registrants are authorized to use the expanded authority of the proposed rule to prescribe buprenorphine pursuant to telemedicine encounters and the obligations of practitioners when doing so.

DEA is proposing to add paragraph (a), which would list the conditions upon which a practitioner is authorized to prescribe buprenorphine via a telemedicine encounter under the proposed rule. First, unless otherwise excepted,⁶⁰ registrants would be required under paragraph (a)(1) to obtain a DEA dispensing registration under 21 U.S.C. 823(g), 21 CFR 1301.13(e)(1)(iv) in the state where the practitioner is located. Next, in order to issue prescriptions, paragraph (a)(2) would require the practitioner to be authorized by state law, or not otherwise prohibited by state law, to engage in the practice of telemedicine in both the state where the practitioner is located, as well as the state where the patient is located. This requirement is statutory, as the CSA requires that the “practice of telemedicine” involving controlled substances be conducted “in accordance with applicable Federal and State laws” pursuant to 21 U.S.C. 802(54). In those

⁶⁰ The proposed rule would except from this requirement VA practitioners, those practitioners contracting with the VA when treating a patient of the VA healthcare system, and those practitioners exempt from registration under section 303(f) in all States pursuant to § 1301.23 when acting with the scope of the employment or contract that exempted them from the requirement of registration under section 303(f). It would be unduly burdensome to require registrants otherwise exempt from the requirement of DEA registration to become registered with DEA solely to make use of this proposed rule’s telemedicine flexibility. The unique needs and expertise of the VA practitioners similarly weigh in favor of exempting them from this requirement. Moreover, in a related context, Congress indicated a desire, reflected in the Ryan Haight Act, that VA practitioners and those practitioners exempt from registration be uniquely allowed to engage in telemedicine without being registered in their patients’ states. *See* 21 U.S.C. 831(h)(1)(B).

states where state law prohibits the prescription of a controlled substance based solely on an audio-only evaluation,⁶¹ the proposed regulation would not authorize the audio-only prescription of buprenorphine for OUD. Proposed paragraph (a)(3) would clarify that the prescription must comply with the provisions of the relevant CSA and DEA regulations that govern dispensing for maintenance and detoxification treatment (namely, 21 CFR 1301.13(e)(1)(iv), and 21 CFR 1306.05(b)). In other words, the practitioner would have to possess a 21 CFR 1301.13(e)(1)(iv) registration in order to prescribe a schedule III, IV, or V narcotic drug approved by the FDA specifically for use in the maintenance or detoxification treatment. Proposed paragraph (a)(4) would codify the requirement that a practitioner be technically capable of using audio and video equipment permitting two-way, real-time interactive communication with the patient and the time of the telemedicine encounter. Proposed paragraph (a)(5) would state generally that the practitioner must comply with all other relevant requirements listed in this section.

Next, paragraph (b) would list all the requirements for practitioners when issuing prescriptions. Proposed paragraph (b)(1) would require that all prescriptions issued based on a telemedicine encounter under the authority of the rule must be issued for a “Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment” and must be issued pursuant to 21 CFR 1306.04. This paragraph is designed to reduce the risk that buprenorphine will be prescribed for reasons other than a legitimate medical purpose. This paragraph further specifies that such prescriptions may only be issued pursuant to § 1306.04 for the purpose of maintenance or detoxification treatment

⁶¹ Based on DEA’s review of state law, 25 states prohibit controlled substance prescriptions based on audio-only encounters.

– *i.e.*, the practitioner cannot prescribe buprenorphine for pain or any other purpose besides treatment of OUD.

Proposed paragraph (b)(2) would require that practitioners review and consider relevant PDMP data in the state where the patient is located prior to prescribing.⁶² As stated above, this provision is an essential safeguard to ensure practitioners are conducting appropriate due diligence to mitigate risks of diversion and ensure the public health and safety of patients. Practitioners are encouraged to review all PDMP data accessible to them as a predicate to prescribing buprenorphine, but reviewing a period of at least one year prior to issuing a prescription would be required under the proposed rule. If less than one year of data is available, practitioners must review and consider the entire available period.

Proposed paragraph (b)(3) would specify the procedures for practitioners if they are unable to access PDMP data due to the PDMP system being “non-operational or otherwise inaccessible as a result of a temporary technological or electrical failure.” This paragraph includes circumstances involving temporary technological or electrical failures involved with the *practitioner’s* attempts to access the PDMP data. This would include, but is not limited to, circumstances where practitioners are unable to access PDMP data because of public infrastructure failures such as loss of electricity and/or loss of internet as a result of inclement weather or natural disasters. For example, a practitioner could be experiencing state-wide outages in their internet service but otherwise be able to conduct a telemedicine encounter by using a different device such as a mobile phone or tablet that is connected to a satellite internet provider. In such circumstances, DEA notes that the practitioner must otherwise be capable of

⁶² A practitioner employed by or contracting with the VA additionally would have review the VA internal prescription database, subject to the same standards that would apply to a review of PDMP data.

using audio and video equipment permitting two-way, real-time interactive communication with the patient at the time of the telemedicine encounter prior to prescribing but is unable to access the PDMP system through the device at the time. In those exceptionally rare circumstances, DEA would encourage practitioners to use any means available to access PDMP data prior to prescribing, and practitioners must record their attempts to access the system as described below.

Proposed paragraph (b)(3)(i) would require, in those circumstances where the PDMP system is non-operational, practitioners to limit their prescriptions to patients to no more than a 7-day supply until they are able to access the PDMP system again. This limit applies until the practitioners are able to access the PDMP system, complete their review of the patient's prior prescription history, and verify the nature of prescriptions when applicable. Paragraph (3)(ii) would require the practitioner to gain access to the PDMP system and conduct appropriate reviews within 7 days of the telemedicine encounter, and paragraph (3)(iii) would require recordation of the practitioner's attempts to access the system (described in more detail below). The 7-day prescription can be refilled upon successful review of the PDMP by the practitioner, as long as the prescriptions together do not exceed a 30 day supply.

If the practitioner otherwise completes their review of the PDMP system pursuant to paragraph (2), or is otherwise able to comply with all relevant requirements in paragraph (3), proposed paragraph (4) would authorize practitioners to prescribe "no more than a 30-day supply across all such prescriptions" until the practitioner has conducted the required medical evaluation. Put another way, this provision would allow the doctor to provide up to a thirty-day supply in any combination of prescriptions and prohibits the doctor from going beyond that until the medical evaluation is conducted. This requirement would limit the supply of buprenorphine prescribed pursuant to an audio-only telemedicine encounter to a maximum of a 30-day supply.

This supply may include dosages that are titrated up or down depending on the patient's response to the medication and the practitioner's medical judgment, however, it may not exceed a supply sufficient to treat the patient for more than 30 days.

Proposed paragraph (b)(5) would clarify what satisfies the medical evaluation requirement for the purposes of (b)(4). Such a medical evaluation would include the prescribing practitioner conducting a medical evaluation while the patient is in the physical presence of the prescribing practitioner in (b)(5)(i), or by the alternative schemes listed in (b)(5)(ii) and (iii). Under the alternative proposed in (b)(5)(ii), the patient would not be in the physical presence of the prescribing practitioner, but the patient would have to be in the physical presence of another DEA-registered practitioner pursuant to proposed (b)(5)(ii)(A)-(D). This other non-prescribing, physically present practitioner would have to be acting in the usual course of professional practice and in accordance with applicable State law. Also, the prescribing practitioner, the DEA-registered practitioner on site with the patient, and the patient would have to participate in an audio-video conference simultaneously (*i.e.*, these individuals must participate in a two-way, simultaneous interactive communication with both audio and video for this medical evaluation even if audio-only communication had been authorized under the standard of 42 CFR 410.78(a)(3) for prior communications between the prescribing practitioner and the patient). Thus, even though the prescribing practitioner would not be conducting an in-person evaluation him or herself, he or she could rely on the in-person evaluation of the on-site practitioner – and remotely observe this evaluation via video and audio when determining whether to continue prescribing to the patient.

Additionally, the requirement of a medical evaluation is satisfied when the prescribing practitioner receives a qualifying telemedicine referral from a DEA registered practitioner under

(b)(5)(iii). Under this scheme, the patient must have received a face-to-face evaluation from a DEA registered practitioner, referred to simply as the referring practitioner. The referring practitioner may then issue a written qualifying telemedicine referral⁶³ to the prescribing practitioner based on the diagnosis, prognosis, or treatment that was provided for the medical issue upon which the medical evaluation was predicated pursuant to paragraphs (A) and (C). Moreover, under paragraph (B), the referral practitioner must communicate the results of the medical evaluation which include any diagnosis, prognosis, or treatment to the prescribing practitioner prior to the prescribing practitioner issuing the prescription. If the prescribing practitioner issues the prescription to the patient prior to receiving the information provided in (B), this does not qualify as a medical evaluation for the purposes of § 1306.34(b)(5) and the patient must receive a medical evaluation in the manner described in paragraph (b)(5)(i) or (b)(5)(ii). Once a medical evaluation meeting the specified criteria is performed, the proposed rule would allow a practitioner to continue prescribing to the patient, so long as doing so was consistent with legitimate medical purposes and a subsequent evaluation was not required by law or other provisions of this chapter.

Last, proposed paragraph (b)(6) would create recordkeeping requirements for practitioners who issue prescriptions in the manner described by this section. Paragraph (6)(i) would require records indicating whether the telemedicine encounter was conducted using audio-video or audio-only technology. This recordkeeping requirement is essential for investigation purposes, as DEA would have no other means of verifying the nature of the telemedicine encounter. Proposed paragraph (6)(ii) would also require the practitioner to record the patient's

⁶³ Proposed 21 CFR 1300.04(k). Note that this definition was proposed by DEA in a distinct Notice of Proposed Rulemaking that also addresses telemedicine. See RIN 1117-AB40, published elsewhere in this issue of the FEDERAL REGISTER. The public is encouraged to respond to the proposed definition in any/both documents.

reason for requesting an audio-only encounter, if the encounter was audio-only. This provision would also assist DEA, as it may be used as evidence to establish whether the practitioner issued the prescription in the usual course of professional practice. Proposed paragraph (6)(iii) would require practitioners to record all attempts to comply with paragraph (b)(2) when the practitioner is able to access the PDMP system. This provision is necessary as it enables DEA to verify whether the registrant knew or should have known of the patient's prior prescription history. Proposed paragraph (6)(iv) would require practitioners who were unable to access their state PDMP system to record "the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system." This provision is necessary as it enables DEA to verify the practitioner's attempts to access the PDMP system, the reasons for being unable to access, and any subsequent attempts to access the system. Proposed paragraph (6)(v) would require, if the patient seeks a medical evaluation pursuant to 1306.34(b)(5)(ii), the prescribing practitioner to record the full name, DEA registration number, National Provider Identifier (NPI) number of the DEA-registered practitioner in the physical presence of the patient, and if issued a qualifying telemedicine referral, the name and NPI of the referring practitioner, a copy of the referral and any communications shared pursuant to § 1306.31(d)(3)(i)-(iii). This provision is necessary as this information is essential to future investigations and these details of the medical evaluation, such as the physically present practitioner's name, may not otherwise be recorded by the prescribing practitioner.

IV. Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review).

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866.

E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. While this proposed rule is not economically significant, OMB has determined that this proposed rule is a “significant regulatory action” under E.O. 12866, section 3(f). Accordingly, this proposed rule has been submitted to OMB for review.

Due to COVID-19 public health emergency, DEA issued guidance which authorized the prescribing of buprenorphine to new and existing patients with OUD via telemedicine, including audio-only telemedicine (*e.g.*, telephone) by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person.⁶⁴ To continue the

⁶⁴ “Dear Registrant” letter to DEA Qualifying Practitioners and DEA Qualifying Other Practitioners, Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, March 31, 2020.

flexibilities of telemedicine, including audio-only telemedicine, for prescribing schedule III-V controlled substances which are approved for maintenance treatment or withdrawal management beyond the public health emergency, DEA proposes to promulgate regulations which would balance the need to increase patient access to legitimate medical treatment with the goal of providing effective controls against diversion. Thus, DEA is proposing to expand the conditions under which a practitioner is authorized to prescribe buprenorphine via telemedicine, including an audio-only telemedicine encounter, and to describe obligations which arise once a practitioner prescribes to patients.

Number of Telemedicine Encounters, Providers, and Patients

The number of telemedicine encounters, including audio-only telemedicine, leading to buprenorphine prescriptions under the temporary guidance during the public health emergency forms the basis for estimating the number of telemedicine encounters pursuant to this proposed rule.

DEA estimated the number of telemedicine encounters associated with an initial buprenorphine prescription by applying the data provided by the Centers for Medicare & Medicaid (CMS) data on Medicare Part D telemedicine services that led to buprenorphine prescriptions to the number of all buprenorphine prescriptions. Based on CMS claims data provided by the Department of Health and Human Services Office of Inspector General (HHS OIG), from March 2020, the start of the COVID-19 health emergency shutdowns, to December 2021, 24,285 Medicare fee-for-service and managed care telemedicine services, including audio-

only telemedicine, were identified as being linked to buprenorphine Part D prescriptions fills.⁶⁵ These telemedicine services were provided by 7,733 providers to 15,521 beneficiaries.⁶⁶

Based on the CMS data, the telemedicine services and associated buprenorphine prescriptions identified spiked at the beginning of the public health emergency and stayed relatively steady in 2021. Therefore, 2021 data is used to estimate the number of telemedicine, including audio-only telemedicine, encounters for this analysis. In 2021, there were a total of 1,929,151 Part D buprenorphine prescriptions associated with 1,332,353 beneficiaries.⁶⁷ Over the same period, there were 11,956 telemedicine Medicare fee-for-service and managed care telemedicine services, including audio-only telemedicine, identified as being linked to buprenorphine Part D prescriptions fills.⁶⁸ These telemedicine services were provided by 4,533 providers to 8,182 patients.⁶⁹ The 1,929,151 Part D buprenorphine claims associated with 1,332,353 beneficiaries equates to a ratio of 1.45 claims per beneficiary. Therefore, the 11,956 services represent an estimated 8,257 ($11,956 / 1.45$) initial prescriptions, which equates to 0.43 percent ($8,257 / 1,929,151$) of total Part D claims for buprenorphine (1,929,151 total claims). Based on IQVIA data, the total number of new prescriptions for buprenorphine in the U.S. in 2021 was 15,782,652.⁷⁰ Applying the telemedicine share of total Part D buprenorphine prescriptions to the estimated number of total services associated with a buprenorphine prescription yields an estimated 67,458 ($0.43 \text{ percent} \times 15,782,652$) initial prescriptions. DEA

⁶⁵ HHS OIB, March 2022. HHS OIG analyzed telemedicine billing codes and patient information to identify telemedicine visits within a 48-hour period prior to a buprenorphine prescription fill associated with the same patient, and where the prescribing provider is the same or related to the billing or rendering provider of the telemedicine visit.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ HHS OIB, May 2022.

⁷⁰ IQVIA, National Prescription Audit, September, 2022.

believes this is a high estimate, as the telemedicine share of total Part D buprenorphine prescriptions may include telemedicine services allowed by regulation prior to the PHE.

Affected Persons

This proposed rule would affect practitioners prescribing schedule III-V controlled substances for the induction of a maintenance treatment or withdrawal management via telemedicine using audio-video or audio-only technology and the patients they treat using this technology. Based on the analysis above, DEA expects the proposed rule to affect 67,458 patients, annually. As previously discussed, in 2021, 8,182 patients received a prescription for buprenorphine under the Medicare Part D program, from 4,533 providers, equating to a ratio of approximately 1.80 patients per provider. Applying this ratio to the number of affected patients, DEA estimates 37,373 providers are affected by this proposed rule.

Impact on Physicians or Practitioners

The proposed rule would permit the use of audio-video or audio-only telemedicine provided that the practitioner 1) meets all requisite State and Federal registration requirements for both prescribing of controlled substances and engaging in the practice of telemedicine, 2) reviews PDMP data regarding any controlled substance prescriptions issued to the patient in the previous year, 3) is limited to a 30-day supply, across all such prescriptions, until the practitioner conducts an in-person medical evaluation, and 4) maintains records of all prescriptions issued pursuant to a telemedicine encounter, including whether the encounter was audio-only or audio-video, and if by audio-only, the patient's reason for requesting an audio-only encounter. Below is the analysis of the four requirements stated above.

1. Meet all requisite State and Federal registration requirements: Practitioners who would participate in audio-video or audio-only telemedicine pursuant to this proposed

rule are assumed to already be conducting telemedicine and already have the necessary equipment to conduct audio-video or audio-only telemedicine at no or minimal additional cost. Additionally, DEA assumes all practitioners who would participate in telemedicine pursuant to this proposed rule to already meet all requisite registration requirements, i.e., holding a DEA registration in the State where the practitioner is located, holding a DEA registration, etc. Additionally, DEA assumes all practitioners who would issue prescriptions via telemedicine encounters pursuant to this proposed rule are authorized under DEA regulations under 21 CFR 1301.13(e)(1)(iv) as well as the states where the practitioner is located (unless otherwise excepted). Therefore, the impact of this requirement is minimal.

2. Review of PDMP data: DEA estimates each review of the PDMP will take 4 minutes, or 0.067 hours, by a practitioner. Based on an estimated loaded hourly rate of \$157.87,⁷¹ the cost of a review of the PDMP is \$10.52 ($\157.87×0.067). Applying this cost to 67,458 services, the total cost of PDMP review is \$709,970 ($\$10.52 \times 67,458$), annually. While many practitioners already check PDMP prior to issuing a prescription for a controlled substance for a variety of reasons, DEA will consider the full cost of checking PDMP, \$709,970, a cost of this proposed rule to be conservative.

⁷¹ For the purpose of this analysis, the cost per registrant is estimated by multiplying the loaded labor rate by the estimated time to complete the review. The loaded labor rate is based on the estimated loaded hourly wage for 29-1229, Physicians, all other. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2021*, <https://www.bls.gov/oes/current/oes291229.htm>. The average hourly wage is \$111.30, with benefits estimated at an additional 41.84 percent of the base wage. The load factor is calculated by comparing the benefits for private workers as a share of wages, $29.5\% / 70.5\% = 41.84\%$. Bureau of Labor Statistics, *Employer Costs for Employee Compensation – December 2021*, <https://www.bls.gov/news.release/pdf/ecec.pdf>. The loaded wage was therefore $\$111.30 \times 1.4184 = \157.87 per hour for private physicians, all other.

3. Limited to a 30-day supply: Currently, inducting MOUD with schedule III-V controlled substances requires an in-person visit or a telemedicine encounter as defined in § 1300.04(i). This proposed rule would expand the circumstances under which individual practitioners are authorized to prescribe schedule III-V controlled substances which are approved for maintenance treatment or withdrawal management via a telemedicine encounter, including an audio-only telemedicine encounter. Therefore, this proposed rule would enable a treatment option that would otherwise be unavailable. While DEA does not have a basis to quantify the economic impact of the 30-day supply limit, 30 days of medication for inducting treatment is a benefit over not receiving any medication. Additionally, as stated earlier, requiring an in-person visit with the prescribing practitioner within 30 days is consistent with the usual course of MOUD and purpose of the Ryan Haight Act, and necessary to enforce the CSA and its implementing regulations.
4. Maintains records of all prescriptions issued pursuant to a telemedicine encounter, including the supervising physician name where applicable under state law and DEA number when the prescription is issued by a physician assistant or nurse practitioner, whether the encounter was audio-only or audio-video and, if audio-only, the patient's reason for requesting an audio-only encounter: While DEA estimates two minutes for a prescriber to make such recording, DEA believes prescribers are already performing many of these tasks as usual and ordinary practice and any additional recordkeeping as a result of this proposed rule is minimal. Therefore, there is minimal additional cost associated with this requirement.

In summary, the total cost to practitioners is \$709,970 annually, which is the cost associated with checking PDMP for all patients.

Impact on Patients

As discussed earlier, DEA estimates this proposed rule will affect 67,458 patients per year. DEA anticipates that patients will fall into one of two categories:

- 1) Patients who would otherwise not receive treatment or prescription for OUD absent the proposed rule change. These patients have no other means to receive treatment. They are unable to visit a physician in-person or otherwise visit a practitioner engaged in the practice of telemedicine as defined in § 1300.04(i), but able to have an audio-video or audio-only telemedicine visit pursuant to this proposed rule.
- 2) Patients who would eventually receive treatment and prescription even absent the proposed rule change. These patients are able to either visit a physician in-person or have telemedicine visit with a practitioner engaged in the practice of telemedicine as defined in § 1300.04(i); however, such visit might have been delayed for any variety of reason, i.e., lack of reliable transportation, work or caretaking commitments, long wait times for an appointment with the physician, etc. This proposed rule, if implemented, would create additional flexibilities, potentially allowing patients to access treatment more quickly than would be possible absent this proposed rule.

DEA does not have a basis to estimate how many of the estimated 67,458 patients fall into the two groups. However, DEA anticipates a larger impact for the first group. The impact on the first group of patients is a result of receiving treatment for OUD. There would be a cost of treatment and the benefit generated from the treatment, which would not have been possible without this proposed rule. The impact on the second group would be the result of receiving

treatment sooner than they would have without this proposed rule. For both groups, the impact could potentially be lifesaving. However, DEA does not have access to data that would permit it to estimate the number of lives the improved access could save. There would be a cost of treatment and the benefit of earlier treatment, including potential cost-offsets associated with reduced healthcare and public safety expenditures. According to a December 2021 research report, treatment with buprenorphine for a stable patient provided in a certified Opioid Treatment Program, including medication and twice-weekly visits were \$115 per week or \$5,980 per year.⁷² This is likely higher than the cost of treating a stable patient in a primary care setting, where patients are more likely to see providers once per week and where there are no associated specialized costs. However, using the \$5,980 per year estimate serves to establish an upper boundary for potential costs in any cost-benefit comparison. Estimates of the impact of buprenorphine use in the treatment of OUD suggest a 23.7% decrease in total deaths, and 31.2% reduction in drug poisonings (both fatal and nonfatal). In total, the combined cost-savings of buprenorphine (including both health-care costs as well as criminal justice costs) was estimated by one study at \$60,000 per person.⁷³ At the costs listed above, the savings from the treatment of one person would cover the cost of buprenorphine-assisted treatment for ten others.

A study published in 2021 of the societal costs for OUD found that the “[C]osts for opioid use disorder and fatal opioid drug poisoning in 2017 were estimated to be \$1.02 trillion. The majority of the economic burden is due to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid drug poisoning.”⁷⁴ According to the report, in 2017

⁷² *How much does opioid treatment cost?*, NIDA. (April 13, 2021), <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-much-does-opioid-treatment-cost>.

⁷³ Fairley *et al.*. *Cost-effectiveness of Treatments for Opioid Use Disorder*. JAMA Psychiatry, (July 01, 2021).

⁷⁴ Florence *et al.*,. *The economic burden of opioid use disorder and fatal opioid overdose in the United States*, (2017).

total non-fatal costs are \$471 billion and total fatal costs are \$550 billion and there were 2.1 million persons ages 12 years and older with an OUD, and 47,000 fatal opioid drug poisonings.⁷⁵ Non-fatal costs include costs associated with health care, substance use disorder treatment, criminal justice, lost productivity, and the value of reduced quality of life. Dividing the total non-fatal cost of \$471 billion by the number of persons ages 12 and older with an OUD (2.1 million), the societal cost (cost burden on society) of non-fatal OUD is approximately \$224,000 (\$471 billion / 2.1 million) per person with OUD per year. While DEA is unable to quantify how many of the affected patients will be successfully treated for OUD or how many fatal opioid drug poisonings will be avoided as a result of this proposed rule, the potential economic benefit is disproportionately large compared to any cost associated with this rule. A small reduction in OUD has the potential to save money in excess of the total costs of the proposed rule.

Risk of Diversion

The proposed rule will reduce the requirements imposed on practitioners who wish to prescribe schedule III-V controlled substances as part of medication treatment for OUD. DEA understands that there is a risk of misuse and diversion of drugs approved for the use in maintenance treatment or withdrawal management, which could be increased by expanded prescribing.

While the proposed rule may increase the risk of diversion, with the proposed safeguards, and given the safety profile of buprenorphine, DEA estimates this increased risk will be minimal. Requirements to check the PDMP prior to issuance of a prescription, 30-day limitations, in-person requirements for follow-up appointments, and more detailed requirements for recordkeeping are expected to minimize the diversion of buprenorphine via telemedicine,

⁷⁵ *Id.*

including audio-only telemedicine. Practitioners already have the authority to prescribe MOUD. Studies have found that, in 2019, the percentage of buprenorphine misuse among adults with past-year use was 29.2%. Of those adults who misused buprenorphine in a previous year, 71.8%-74.7% did not have their own prescription.⁷⁶ Given the misuse of buprenorphine is often for self-treatment of OUD symptoms, these numbers underscore the need for expanded access to buprenorphine treatment for OUD.

The growth of waivers to prescribe buprenorphine was smallest among prescribers working in small nonmetropolitan counties. Prescribers in rural counties were associated with low buprenorphine dispensing.⁷⁷ DEA believes that by providing increased access for rural areas, the benefits of increasing access to MOUD outweigh any added risk of diversion as the result of this proposed rule.

Other Potential Costs

DEA also examined the cost of technology, both capital investment and operation expenses, in order to provide telemedicine in compliance with the proposed rule. DEA believes that the use of telemedicine will not require any additional capital expenditures on the part of practitioners or patients. Recordkeeping requirements are likely to have a minimal impact because current recordkeeping practices are likely to meet the requirements imposed by the proposed rule, and any additional time is expected to be minimal. Electronic medical records may be updated in the future to reflect the proposed rule change, such as the inclusion of a flag for a telemedicine visit, including an audio-only visit, but such changes are likely to be minor and included as part of any normal software update.

⁷⁶ Han, Beth et al. "Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US." JAMA Netw Open. 2021 Oct 1; 4(10):e2129409. Accessed 9/15/2022

⁷⁷ *Id.*

Summary

In summary, DEA estimates this proposed rule would affect 37,373 providers and 67,458 patients, annually. DEA believes that the proposed rule would increase patient access to MOUD for two types of patients: those who otherwise would be unable or unwilling to seek treatment, as well as those who would seek treatment but with some form of delay. Increased access to MOUD is expected to reduce the number of opioid drug poisonings annually, however DEA cannot quantify the size or total benefits of such a reduction. There would be a slight increase in labor costs per practitioner, due to increased time spent reviewing PDMP databases. The estimated total cost to the 37,373 providers is \$709,970, annually. DEA estimates recordkeeping requirements are likely to have a minimal impact because current recordkeeping practices are likely to meet the requirements imposed by the proposed rule, and any additional time is expected to be minimal. The increase in the availability and flexibility of treatment with schedule III-V controlled substances may increase the risk of diversion, however DEA believes that any increase would be small, and outweighed by the benefit to patients and reduction in the societal cost of opioid use disorder.

Executive Order 12988, Civil Justice Reform

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the

states, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (“RFA”), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

Due to the COVID-19 public health emergency, DEA issued guidance which authorized prescribing of buprenorphine to new and existing patients with OUD via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person.⁷⁸ To continue the flexibilities of telemedicine, including audio-only telemedicine, for prescribing Schedule III-V controlled substances which are approved for maintenance treatment or withdrawal management beyond the public health emergency, DEA proposed to promulgate regulations which would balance the need to increase patient access to legitimate medical treatment with the overarching goal of providing effective controls against diversion. Thus, DEA is proposing to expand the conditions under which a registered practitioner is authorized to prescribe buprenorphine via telemedicine, including through an audio-only telemedicine encounter, and describe the obligations which arise once a practitioner prescribes to patients.

⁷⁸ “Dear Registrant” letter to DEA Qualifying Practitioners and DEA Qualifying Other Practitioners, Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, March 31, 2020.

Affected Persons

This proposed rule would affect practitioners prescribing schedule III-V controlled substances for the induction of maintenance treatment or withdrawal management of patients with OUD using telemedicine and the same patients being treating using telemedicine. As stated above, DEA estimates this proposed rule would affected 37,373 practitioners and 67,458 patients, annually. Because practitioners are individuals and not small entities, this analysis examines the impact of the proposed rule on affected physicians and small entities that employ the affected physicians.

The proposed rule would permit the use of audio-video or audio-only telemedicine provided that the practitioner 1) meets all requisite State and Federal registration requirements for both prescribing of controlled substances and engaging in the practice of telemedicine, 2) reviews PDMP data regarding any controlled substance prescriptions issued to the patient in the previous year, 3) is limited to a 30-day supply, across all such prescriptions, until the practitioner conducts an in-person medical evaluation, and 4) maintains records of all prescriptions issued pursuant to a telemedicine encounter, including the supervising physician name and DEA registration number, in cases where the prescription is issued by a nurse practitioner or physician assistant, whether the encounter was audio-only or audio-video and, if audio-only, the patient's reason for requesting an audio-only encounter.

A significant number of physicians and Mid-Level Practitioners work in offices and institutions that meet the RFA's definition of small entities. To estimate the number of affected entities, DEA first determined the North American Industry Classification System ("NAICS") codes that most closely represent businesses that would employ the physicians and MLP's who would deliver MOUD service via telemedicine, including an audio-only telemedicine encounter.

Then, DEA researched economic data for those codes. The source of the economic data is the Small Business Administration (“SBA”), Office of Advocacy, and is based on data provided by the U.S. Census Bureau, Statistics of U.S. Businesses (“SUSB”).⁷⁹ The following business NAICS codes are estimated to represent businesses that employ the affected persons, potential applicants:

- 621111-Offices of Physicians, Except Mental Health Specialists
- 621112-Offices of Physicians, Mental Health Specialists
- 621420-Outpatient Mental Health and Substance Abuse Centers
- 622110-General Medical and Surgical Hospitals
- 622210-Psychiatric and Substance Abuse Hospitals

SUSB data contains the number of firms by size ranges for each of the NAICS codes.

For the purposes of this analysis, the term “firm” as defined in the SUSB is used interchangeably with “entity” as defined in the RFA.

To estimate the number of affected entities that are small entities, DEA compared the SUSB data for the number of firms in various firm size ranges with SBA size standards for each of the representative NAICS codes. The SBA size standard is the firm size based on the number of employees or annual receipts depending on industry. The SBA size standards for NAICS codes 621111, 621112, 621420, 622110, and 622210 are annual receipts of \$14 million, \$12 million, \$16.5 million, \$41.5 million, and \$41.5 million, respectively.⁸⁰

⁷⁹ SUSB’s employer data contain the number of firms, number of establishments, employment, and annual payroll for employment size of firm categories by location and industry. A “firm” is defined as an aggregation of all establishments owned by a parent company (within a geographic location and/or industry) with some annual payroll. The data table is available at https://www.sba.gov/sites/default/files/files/static_us_11.xls (last visited April 25, 2022).

⁸⁰ SBA. Table of Size Standards, Effective July 14, 2022. <https://www.sba.gov/document/support-table-size-standards> (last visited September 28, 2022.)

The firms in each size range below the SBA size standard are small firms. The number of firms below the SBA size standard was added to determine the total number of small firms in each NAICS code. DEA estimates there are 161,286, 10,561, 6,523, 2,560, and 396 entities in the 621111, 621112, 621420, 622110, and 622210 industries, respectively. Based on the SUSB data on the firm sizes, DEA estimates there are 157,060, 10,392, 5,773, 1,047, and 188 small entities in the 621111, 621112, 621420, 622110, and 622210 industries, respectively. In total, DEA estimates there are 181,326 entities in the five potentially affected industries, of which 174,460 (96.2 percent) are small entities. The analysis is summarized in table 1 below.

Table 1: Number of Affected Entities and Small Entities

| NAICS Code | Number of firms | SBA size standard (\$) | Number of small firms* |
|---|------------------------|-------------------------------|-------------------------------|
| 621111-Offices of Physicians, excepting Mental Health Specialists | 161,286 | 14,000,000 | 157,060 |
| 621112-Offices of Physicians, Mental Health Specialists | 10,561 | 12,000,000 | 10,392 |
| 621420-Outpatient Mental Health and Substance Abuse Centers | 6,523 | 16,500,000 | 5,773 |
| 622110-General Medical and Surgical Hospitals | 2,560 | 41,500,000 | 1,047 |
| 622210-Psychiatric and Substance Abuse Hospitals | 396 | 41,500,000 | 188 |
| Total | 181,326 | | 174,460 |
| Percent of Total | | | 95.8% |

* Not all decimal places shown.

From above, E.O. 12866 section, DEA estimates there will be 67,458 telemedicine services pursuant to this proposed rule, including audio-only telemedicine services, rendered by 37,373 providers to 67,458 patients, annually. Therefore, this proposed rule is estimated to affect 37,373 individual practitioners employed in industries with 173,730 small businesses potentially affected by this proposed rule. Since some small entities will employ more than one

practitioner, the number of affected small entities is expected to be less than 174,460 and are expected to be proportionally across the five industries. DEA considers a substantial number of small entities are affected if more than 30 percent of small entities in the affected industries is affected. Therefore, at 21.4 percent of the total small entities (37,373 providers / 173,730 small entities), the number of small entities affected by this proposed rule is estimated to be not a substantial number for any of the representative industries.

The cost of the proposed rule impacts the affected entities and small entities on a “per person” basis. Rather than estimating the number of physicians and MLPs per firm, then the cost per firm, then whether the cost is significant, DEA employed a more direct approach based on the following logic:

- In order to continue as going concerns, the affected firms must generate enough revenue to pay the wages of physicians and MLPs, and other operating expenses.
- Therefore, revenue for firms must be greater than the wages paid to practitioners and MLPs.
- Therefore, if the cost of the proposed rule is not economically significant when compared to individual wages for practitioners and MLPs, the cost of the proposed rule is not economically significant when compared to the annual revenue of the firms.

From 2021 data provided by HHS OIG, DEA estimates that 8,182 patients received telemedicine services prior to receiving a prescription for buprenorphine. These services were provided by 4,533 separate providers, for approximately 1.8 patients per provider. DEA assumed that this ratio is the same for the general populations of practitioners and patients, at 37,373 providers and 67,458 patients.

DEA estimates a non-loaded median hourly wage of \$111.30⁸¹ and \$56.99⁸² for potentially affected physicians and MLPs, respectively. Applying the hourly wage rates to the estimated time to apply, DEA estimates the labor cost per PDMP review is \$7.42 ($\$111.30 \times 4 / 60$) and \$3.80 ($\$56.99 \times 4 / 60$) per physician and MLP, respectively. The non-loaded wage rates are calculated to represent the cost to the individual, whereas previously the loaded wage rates were calculated to represent the total cost of employment to the entity and to the economy. These rates are multiplied by 1.8 patients, for total labor costs of \$13.39 and \$6.86, respectively.

The non-loaded unit cost of conducting a PDMP review is compared to the non-loaded annual wage rate for physicians and MLPs. Based on the Bureau of Labor Statistics' ("BLS") Occupational and Employment and Wages data, DEA estimates an average annual wage of \$231,500 for physicians, \$118,553 for MLPs.⁸³ Unit costs of \$13.39 and \$6.86 represent 0.01 percent of those wages. Table 3 presents the details of the calculation.

Table 3: Costs and Fees as Percent of Wages

| | Mean Hourly Wage (\$) | Time to review (Hours) | Cost per patient (\$) | Cost Per 1.8 Patients (\$) | Mean Annual Wage (\$) | Additional Costs as percent of wage |
|------------|-----------------------|------------------------|-----------------------|----------------------------|-----------------------|-------------------------------------|
| Physicians | 111.30 | 0.06 | 7.42 | 13.39 | 231,500 | 0.01% |
| MLP | 56.99 | 0.06 | 3.80 | 6.86 | 118,553 | 0.01% |

⁸¹ Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2021, 29-1229 Physicians, All Others*, <http://www.bls.gov/oes/current/oes291229.htm>.

⁸² Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2021, 29-1071 Physician Assistants*, <http://www.bls.gov/oes/current/oes291071.htm>.

Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2021, 29-1171 Nurse Practitioners*, <http://www.bls.gov/oes/current/oes291171.htm>.

DEA calculated the weighted average hourly wage based on the distribution of physician assistants (36.2%) and nurse practitioners (63.8%).

⁸³ Notes 75 and 76.

The economic impact of additional time spent conducting PDMP reviews represents a small fraction (0.01 percent) of annual wages. DEA estimates the proposed rule will not have a significant economic impact on individual physicians and MLPs. The small entities that employ the potentially affected physicians and MLPs are expected to generate enough revenue to pay their wages. Therefore, DEA concludes the proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The estimated annual impact of this proposed rule is minimal. Thus, DEA has determined in accordance with the Unfunded Mandates Reform Act of 1995 (“UMRA”) (2 U.S.C. 1501 *et seq.*) that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act of 1995

This proposed rule would impose a new collection of information under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. The collections of information contained in the proposed rule, and identified as such, have been submitted to OMB for review under section 3507(d). DEA has identified the following collection(s) of information related to this proposed rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

A. Collections of Information Associated with the Notice of Proposed Rulemaking.

Title: Dispensing Records of DEA Registered Practitioners

OMB Control Number: 1117-NEW

Form Number: N/A

DEA is proposing to require practitioners to record additional information than what is currently required in 21 CFR 1304.03(c). Proposed 21 CFR 1306.34(7)(i) would require records indicating whether the telemedicine encounter was conducted using audio-video or audio-only technology. Proposed paragraph (7)(ii) would also require the practitioner to record the patient's reason for requesting an audio-only encounter, if the encounter was audio-only. Proposed paragraph (7)(iii) would require practitioners to record all attempts to comply with paragraph (b)(2) when the practitioner is able to access the PDMP system. Last, proposed paragraph (7)(iv) would require practitioners who were unable to access their state PDMP system to record "the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system." The proposed rule would also require practitioners to record the name and DEA registration number of a supervising physician, in cases where the prescription was issued by a nurse practitioner or physicians assistant.

DEA estimates the following number of respondents and burden associated with this collection of information:

- Number of respondents: 37,373
- Frequency of response: 1.804986 (as needed, calculated)
- Number of responses: 67,458

- Burden per response: 0.06666667 hours
- Total annual hour burden: 4497 hours

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. DEA solicits comment on the following issues:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the DEA, including whether the information will have practical utility.
- The accuracy of the DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB78/Docket No. DEA-948. All comments must be submitted to OMB on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The

final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776-3882.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Administrative practice and procedure, Drug traffic control, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set out above, the Drug Enforcement Administration proposes to amend 21 CFR parts 1300, 1304, and 1306 as follows:

PART 1300—DEFINITIONS

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

2. Amend § 1300.04 by adding new paragraphs (j), and (m), to read as follows:

§ 1300.04 Definitions relating to the dispensing of controlled substances by means of the Internet.

* * * * *

(j) The term *prescription drug monitoring program (or PDMP)* means a State controlled substance monitoring program, including a program supported by the Secretary of Health and Human Services under section 399O of the Public Health Service Act, as amended (42 U.S.C. 280g-3).

* * * * *

(m) The term *telemedicine encounter* means a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3).

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

3. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e)-(g), and 965, unless otherwise noted.

4. In § 1304.03, add new paragraph (j), to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(j) A practitioner shall maintain copies of all qualifying telemedicine referrals, as defined in § 1300.04(k), that they issue.

5. Amend § 1304.04 by adding paragraph (i), to read as follows.

§ 1304.04 Maintenance of records and inventories.

* * * * *

(i)(1) A practitioner who prescribes controlled substances in the course of maintenance or detoxification treatment pursuant to a telemedicine encounter as authorized by § 1306.34 shall maintain records required by this part at the registered location on the practitioner’s certificate of registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)).

(2) If a prescribing practitioner conducts an evaluation during which the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner) pursuant to Section 1306.34(b)(5)(ii), both the prescribing practitioner and the DEA-registered practitioner shall maintain records required by this part at the registered location on the practitioners’ respective certificates of registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)).

* * * * *

PART 1306—PRESCRIPTIONS AND DISPENSING

6. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 829, 871(b), unless otherwise noted.

7. Amend § 1306.04 by adding paragraph (e), to read as follows.

GENERAL INFORMATION

§ 1306.04 Purpose of issue of prescription.

* * * * *

(e) In addition to the requirements of this section, all narcotic prescriptions issued pursuant to § 1306.34 may only be issued for maintenance or detoxification treatment and may not be issued for any other purpose.

* * * * *

8. Amend Part 1306 by adding new § 1306.34, to read as follows.

* * * * *

§ 1306.34 Requirements for individual practitioners who conduct the induction of maintenance or detoxification treatment via telemedicine encounter.

(a) An individual practitioner not otherwise authorized to engage in the practice of telemedicine as defined in § 1300.04(i) is authorized to prescribe any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in the maintenance or detoxification treatment via a telemedicine encounter as defined in § 1300.04(m) if all of the following conditions are met:

(1) The practitioner is registered under section 303(f) of the Act (21 U.S.C. 823(g)), 21 CFR 1301.13(e)(1)(iv) in the State in which the practitioner is located. This requirement does not apply to Department of Veterans Affairs practitioners, those practitioners employed by and treating a patient enrolled in the Department of Veterans Affairs health system, or those practitioners exempt from registration under section 303(f) in all States pursuant to § 1301.23 when acting with the scope of the employment or contract that exempted them from the requirement of registration under section 303(f);

(2) The practitioner is authorized by State law to engage in the practice of telemedicine, or not otherwise prohibited by State law from practicing telemedicine, in the State where the practitioner is located and in the State where the patient is located;

(3) The practitioner is authorized under § 1301.28 of this chapter;

(4) The practitioner must be technically capable of conducting a telemedicine encounter by using audio and video equipment permitting two-way, real-time interactive communication with the patient pursuant to 42 CFR § 410.78(a)(3); and

(5) The practitioner complies in all other respects to the requirements of this section.

(b) An individual practitioner who is authorized to engage in the practice of telemedicine as described in paragraph (a) must comply with the following requirements prior to issuing a prescription.

(1) The prescription must only be issued for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and must be issued for that purpose pursuant to § 1306.04.

(2) Prior to issuing the prescription, the practitioner, including a practitioner employed by the Department of Veterans Affairs, must review and consider the data regarding any controlled substance prescriptions issued to the patient in the last year that is contained in the prescription drug monitoring program (PDMP) described in § 1300.04(o) in the State where the patient is located, or, if less than one year of data is available, in the entire available period. If less than one year of data is available, practitioners must review and consider the entire available period. A practitioner employed by the Department of Veterans Affairs also must review the Department of Veterans Affairs internal prescription database for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period.

(3) If the practitioner is unable to obtain the PDMP data (or, if employed by the Department of Veterans Affairs, the Department of Veterans Affairs internal prescription

database) due to the PDMP (or Department of Veterans Affairs internal prescription database) system being non-operational or otherwise inaccessible as a result of a temporary technological or electrical failure, then:

(i) the practitioner may issue a prescription authorizing the dispensing of no more than a 7-day supply across all such prescriptions for Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment until completing the review described in paragraph (b)(2) of this section, and verifying that any previous prescriptions were not issued pursuant to a telemedicine encounter;

(ii) the practitioner must obtain the PDMP (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data and conduct the review described in paragraph (b)(2) of this section within 7 days of the telemedicine encounter; and

(iii) the practitioner must record the attempts to access the system pursuant to paragraph (b)(6) of this section.

(4) Upon completing the review described in paragraph (b)(2) of this section, the practitioner may issue prescriptions authorizing the dispensing of no more than a 30-day supply across all such prescriptions, including any prescriptions issued pursuant to paragraph (b)(3)(i) of this section, for Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment until the practitioner has conducted a medical evaluation as described in paragraph (b)(5) of this section.

(5) For the purposes of this section, the required medical evaluation may either be:

(i) An evaluation during which the patient is treated by, and in the physical presence of, the prescribing practitioner; or

(ii)(A) An evaluation during which the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner);

(B) This practitioner in the physical presence of the patient is acting in the usual course of professional practice;

(C) The evaluation is conducted in accordance with applicable State law; and

(D) The remote prescribing practitioner, the patient, and the DEA-registered practitioner on site with the patient participate in a real-time, audio-video conference in which both the practitioners and the patient communicate simultaneously; or

(iii) An evaluation that was conducted by a DEA registered practitioner who:

(A) issued a written *qualifying telemedicine referral* under 21 CFR § 1300.04(k) for the patient to the prescribing practitioner;

(B) communicated the results of the evaluation by sharing the electronic medical record which includes, at a minimum, the diagnosis, prognosis, and treatment of the patient prior to the prescribing practitioner issuing the prescription; and

(C) has issued the written referral based on the diagnosis, prognosis or treatment that occurred as a result of the medical evaluation.

(6) Practitioners who issue prescriptions for controlled substances in the course of maintenance or detoxification treatment via a telemedicine encounter under this section must maintain records of all prescriptions issued pursuant to §§ 1304.03 and 1304.04 indicating the following:

(i) whether the telemedicine encounter was conducted using audio-video or audio-only technology;

(ii) if the telemedicine encounter was conducted using audio-only technology, the patient's reason for requesting the audio-only encounter;

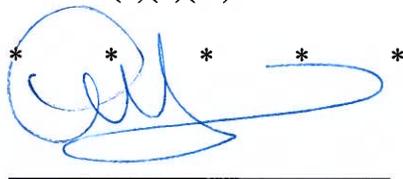
(iii) all efforts to comply with paragraph (b)(2) of this section when the practitioner is able to obtain the PDMP data (and, if employed by the Department of Veterans Affairs, the data from the Department of Veterans Affairs internal prescription database);

(iv) if the practitioner failed to access the PDMP (or, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) system as described in paragraph (b)(2) of this section, the dates and times that the practitioner attempted to obtain the data, the reason why the practitioner was unable to gain access, and any follow-up attempts made to obtain the data;

(v) if a prescribing practitioner conducts an evaluation during which the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner) pursuant to paragraph (b)(5)(ii) of this section, the full name, DEA registration number, and National Provider Identifier (NPI) number for the DEA-registered practitioner in the physical presence of the patient; and

(vi) if issued a qualifying telemedicine referral, the name, and NPI of the referring practitioner and a copy of the referral and any communications shared pursuant to §

1306.34(b)(5)(iii).

A handwritten signature in blue ink, consisting of a cursive name followed by a long horizontal stroke. Above the signature, there are five asterisks (* * * * *) spaced out.

Anne Milgram,
Administrator.

