DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–948]

RIN 1117-AB78

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Expansion of Buprenorphine Treatment via Telemedicine Encounter

AGENCY: Drug Enforcement Administration, Department of Justice; Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration and the Department of Health and Human Services are amending their regulations to expand the circumstances under which practitioners registered by the Drug Enforcement Administration are authorized to prescribe schedule III-V controlled substances approved by the Food and Drug Administration for the treatment of opioid use disorder via a telemedicine encounter, including an audio-only telemedicine encounter. Under these new regulations, after a practitioner reviews the patient's prescription drug monitoring program data for the state in which the patient is located during the telemedicine encounter, the practitioner may prescribe an initial six-month supply of such medications (split amongst several prescriptions totaling six calendar months) through audio-only means. Additional prescriptions can be issued under other forms of telemedicine as authorized under the Controlled Substances Act, or after an in-person medical evaluation is conducted. This regulation also requires the pharmacist to verify the identity of the patient prior to filling a prescription. The *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* generally

requires an in-person medical evaluation prior to issuance of a controlled substance prescription. However, this regulation falls under one of the exceptions found within the *Ryan Haight Act*. Additionally, this regulation does not affect practitioner-patient relationships in cases where an in-person medical evaluation has previously occurred. The purpose of this regulation is to prevent lapses of care by continuing some of the telemedicine flexibilities that currently exist for those patients seeking treatment for opioid use disorder.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

This final rule falls under the last category of telemedicine under the *Ryan Haight Act*, Pub. L. 110-425, 122 Stat. 4820 (2008), which authorizes the practice of telemedicine in specified circumstances when no in-person medical evaluation has occurred. The Administrator of the Drug Enforcement Administration (DEA) (pursuant to delegation by the Attorney General)[1] and the Substance Abuse and Mental Health Services Administration (on behalf of the Secretary of Health and Human Services (HHS) jointly issue this regulation and have each determined that this regulation is consistent with effective controls against diversion and with the public health and safety as required under 21 U.S.C. 802(54)(G).

In March 2023, DEA published a notice of proposed rulemaking (NPRM) titled *Expansion of Induction of Buprenorphine via Telemedicine Encounter*.[2] DEA and HHS are now finalizing the rule, with several modifications to the proposed provisions to address concerns

[1] The Attorney General has delegated this authority to the Administrator of DEA under 28 CFR 0.100.
[2] 88 FR 12890 (Mar. 1, 2023).

brought forth by commenters. Under this final rule, a DEA-registered practitioner, prior to issuing a prescription via telemedicine for a schedule III-V controlled substance approved by the Food and Drug Administration (FDA) for use in the treatment of opioid use disorder (OUD),[3] must review the prescription drug monitoring program (PDMP) data of the state in which the patient is located when the telemedicine encounter occurs, and the pharmacist must verify the identity of the patient[4] prior to filling the prescription. The practitioner is authorized to prescribe up to an initial six-month supply (split amongst several prescriptions totaling six calendar months); additional prescriptions may be issued under other forms of telemedicine as authorized by the Controlled Substances Act (CSA) or after an in-person medical evaluation is conducted.

This final rule pertains to practitioners prescribing controlled substances to patients for the treatment of OUD in circumstances where the prescribing practitioner has not conducted an in-person medical evaluation of the patient prior to the issuance of the prescription. Therefore, it is important to emphasize that the limitations set forth in this final rule, and those associated with the "practice of telemedicine" as defined in 21 U.S.C. 802(54) generally, do not apply to practitioner-patient relationships in which there has already been a prior in-person medical evaluation of the patient by the prescribing practitioner.

II. Legal Authority and Background

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the 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 through 1399. These regulations are designed to ensure a

[3] Treatment of OUD means the use of effective FDA-approved medications including methadone, buprenorphine, and naltrexone to treat opioid use disorder. See NIDA. 2021, December 2. Overview.https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview. Last accessed on January 8, 2025.

[4] DEA understands there are situations where the patient (for whom the prescription was written) may not be the individual picking up the prescription at the pharmacy. In these situations, DEA defers to the definition of "ultimate user" as found in 21 U.S.C. 802(27). As such, this regulation authorizes the pharmacist to verify the identity of the patient by accepting identification from any individual who falls under the definition of "ultimate user" prior to filling a prescription.

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.[5] The CSA further authorizes the Attorney General (and the Administrator of DEA by delegation through 28 CFR part 0) 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.[6]

The Ryan Haight Act

The *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (*Ryan Haight Act*) amended the CSA, in part, by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. The *Ryan Haight Act* generally requires that a practitioner conduct an in-person medical evaluation before issuing a prescription to a patient. This requirement is set forth in 21 U.S.C. 829(e), which provides that "[n]o controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be . . . dispensed by means of the Internet without a valid prescription."[7] A "valid prescription" is defined as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient."[8] Section 829(e) further provides an exception to the in-person medical evaluation when a practitioner is "engaged in practice of telemedicine."[9] The practice of telemedicine is defined as "the practice of medicine

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[5] "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. 21 U.S.C 802(10).
[6] 21 U.S.C. 871(b), 958(f).
[7] 21 U.S.C. 829(e)(1).
[8] *Id.* 829(e)(2)(A)(i).
[9] *Id.* 829(e)(3)(A).

in accordance with applicable Federal and state laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system[10] referred to in section 1395m(m) of Title 42."[11]

The *Ryan Haight Act* sets forth seven distinct categories in which a prescribing practitioner may engage in the practice of telemedicine even though no in-person medical evaluation has been conducted.[12] In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the practice of telemedicine is able to conduct a *bona fide* medical evaluation of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the *Ryan Haight Act* contemplates that the practitioner will be permitted to prescribe controlled substances via telemedicine encounters despite not having conducted an in-person medical evaluation prior to prescribing. Specifically, the last category provides that a telemedicine encounter may occur between the practitioner and the patient "under any other circumstances that the Attorney General and the Secretary [of Health and Human Services] have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."[13]

As noted above, when practitioners engage in the practice of telemedicine, the practitioner must use "a telecommunications system referred to in section 1395m(m) of Title 42." For purposes of section 1395m(m), the Centers for Medicare and Medicaid Services (CMS) has defined "interactive telecommunications system" as multimedia communications equipment

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[10] 42 U.S.C. 1395m(m) references, but does not define, such *telecommunications systems*. The Center for Medicare and Medicaid Services (CMS) promulgated regulations implementing these statutory provisions and define the term *interactive telecommunications system*. 42 CFR 410.78(a)(3) defines *interactive telecommunications system* as the 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. Interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using 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.

[11] 21 U.S.C. 802(54).

[12] *See* 21 U.S.C. 802(54).

[13] *Id*. 802(54)(G).

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. Interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using 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.[14] DEA and HHS are utilizing the aforementioned definition of "interactive telecommunications system" within this final rule.

COVID-19 Public Health Emergency.

In response to the COVID-19 Public Health Emergency (PHE), as declared by the Secretary of HHS on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247),[15] DEA granted temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations under 21 U.S.C. 802(54)(D), one of the seven distinct categories of telemedicine envisioned under the statutory definition of the practice of telemedicine. In order to prevent lapses in care, these exceptions authorized the prescribing of controlled-substance medications via telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient. These telemedicine flexibilities authorized practitioners to prescribe schedule II-V controlled substances via audio-video telemedicine encounters, including schedule III-V controlled substances approved by the FDA for the treatment of OUD via audio-only telemedicine encounters. DEA granted the temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations via two letters published in March 2020:

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[14] 42 CFR 410.78(a)(3).

[15] Determination That a Public Health Emergency Exists, U.S. Department of Health and Human Services. https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx. Last accessed May 1, 2024.

- A March 25, 2020 "Dear Registrant" letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division (the McDermott Letter);[16] and

- A March 31, 2020 "Dear Registrant" letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division (the Prevoznik Letter).[17]

Temporary Rules and Telemedicine Listening Sessions.

On May 10, 2023 DEA, jointly with HHS (with the Substance Abuse and Mental Health Services Administration (SAMHSA) acting on behalf of HHS), issued a temporary extension (First Temporary Rule) pursuant to 21 U.S.C. 802(54)(G), which extended the full set of telemedicine flexibilities regarding the prescribing of controlled substances that had been in place under the COVID-19 PHE, through November 11, 2023.[18] On September 12 and 13, 2023, DEA hosted live, in-person *Telemedicine Listening Sessions*, to receive additional input concerning the practice of telemedicine, namely, the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation. Approximately 58 stakeholders, including DEA-registered institutional and individual practitioners, pharmacists, trade associations, state agencies, and other public interest groups, presented at the listening sessions. On October 10, 2023, DEA, jointly with HHS, issued a second temporary extension (Second Temporary Rule), also pursuant to 21 U.S.C. 802(54)(G), thereby extending the full set of telemedicine flexibilities regarding prescription of controlled substances as were in place during the COVID–19 PHE through December 31, 2024.[19] This extension authorized all DEA-registered practitioners to prescribe schedule II-V controlled substances via telemedicine through December 31, 2024. On November 19, 2024, DEA, jointly

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[16] William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (Mar. 25, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf.
[17] Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.
[18] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 30037 (May 10, 2023).
[19] Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 69879 (Oct. 10, 2023).

with HHS, issued a third temporary extension (Third Temporary Rule) extending the current telemedicine flexibilities that have been in place since March 2020 through December 31, 2025.[20]

III. The Opioid Overdose Epidemic and Buprenorphine Use in Treating Opioid Use Disorder

One way to assist individuals experiencing acute opioid withdrawal symptoms and seeking treatment for OUD is with the administration of certain narcotic controlled substances. The use of medications approved by the FDA for the treatment of OUD can effectively assist an individual in successfully recovering from opioid dependence. Currently, the only schedule III-V controlled substance narcotic drug approved by the FDA for the treatment of OUD is buprenorphine.[21]

DEA classifies buprenorphine as a schedule III narcotic controlled substance because it has a currently accepted medical use in treatment, and has less potential for misuse than controlled substances in schedules I and II under the CSA.[22] Buprenorphine is a long-acting partial opioid agonist. Its effects last for a longer period of time compared to a short-acting medication.[23] For people who are not used to taking opioids, it can cause effects such as euphoria or respiratory depression, but these effects are weaker, and with less risk, including lower risk of overdose, than those caused by full opioid agonists such as heroin or fentanyl.[24] When buprenorphine is taken as prescribed and at the appropriate dosage, it can significantly diminish cravings, lower physical dependence on other opioids, eliminate withdrawal symptoms, and reduce morbidity and cases of death from overdose.[25] Buprenorphine is an effective

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[20] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FR 91253 (Nov. 19, 2024).
[21] 42 CFR 8.12(h)(2)(ii).
[22] *See* 21 U.S.C. 812(b)(3)(A)-(C); 21 CFR 1308.13(e)(2)(i).
[23] Buprenorphine, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine. Last accessed Apr. 11, 2024.
[24] *Id.*
[25] *Id.*

medication for treating OUD, especially when used as part of a complete, individualized, treatment plan.

However, because buprenorphine is itself an opioid, it can be misused or abused, and it should be used under the care of a practitioner to decrease the likelihood of diversion. As explained below, this final rule will expand access to OUD treatments by authorizing DEA-registered practitioners with schedule III-V authority the ability to prescribe schedule III-V controlled substances approved by the FDA for the treatment of OUD via audio-only telemedicine encounter, while also mitigating the risks of diversion.

A. The Opioid Overdose Epidemic and Treatments

The estimated number of deaths from opioid overdoses for the 12-month period ending in October 2023 was 79,695, with a peak of 83,985 opioid overdose deaths in the 12-month period ending in May 2023.[26] Although the opioid overdose epidemic has plagued the United States for many decades, overdose deaths have been attributed to "several distinct waves" beginning in the late 1990s with expanded opioid analgesic prescribing for pain; another wave following in 2010 involving heroin; and a third wave began in 2013 related to illicit fentanyl, primarily illicitly made fentanyl[27] The United States is currently experiencing a fourth wave related to rising polysubstance use and co-involvement of fentanyl and stimulant drugs such as methamphetamine.[28]

To combat substance abuse and assist individuals in receiving proper treatment, DEA published regulations in October 1974 to implement the Narcotic Addict Treatment Act of 1974

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[26] Provisional Drug Overdose Death Counts, National Center for Health Statistics, Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm. Updated Mar. 3, 2024. Last accessed Apr. 12, 2024.

[27] *Opioid-Related Outcomes Among Individuals With Co-occurring Behavioral Health Conditions*, National Quality Forum Final Report. https://www.qualityforum.org/Publications/2022/09/2022_Opioid_and_Behavioral_Health_Final_Report.aspx. Published September 26, 2022. Last accessed Apr. 12, 2024. *See also 'Fourth wave' of opioid epidemic crashes ashore, propelled by fentanyl and meth*, Washington State Standard. https://washingtonstatestandard.com/2024/03/18/fourth-wave-of-opioid-epidemic-crashes-ashore-propelled-by-fentanyl-and-meth/. Published March 18, 2024. Last accessed Apr. 12, 2024.

[28] Ciccarone, D, *The Rise of Illicit Fentanyls, Stimulants and the Fourth Wave of the Opioid Overdose Crisis*, Curr Opin Psychiatry (July 1, 2021), The Rise of Illicit Fentanyls, Stimulants and the Fourth Wave of the Opioid Overdose Crisis - PMC. Last accessed Oct. 28, 2024.

(NATA), authorizing practitioners to administer and dispense certain narcotic controlled substances, like methadone (schedule II) for detoxification treatment or maintenance treatment as long as the practitioners were separately registered as a narcotic treatment program (NTP or Opioid Treatment Program (OTP) as termed by SAMHSA).[29] The Drug Addiction Treatment Act of 2000 (DATA) further expanded treatment options for OUD by authorizing physicians who met certain qualifications to treat OUD with FDA-approved medications, like buprenorphine, in treatment settings other than NTPs/OTPs.[30] These DEA-registered practitioners became known as "DATA-waived practitioners." Most recently, the Consolidated Appropriations Act, 2023 (CAA, 23) (Pub. L. 117-328) removed the DATA-waiver requirement, expanding practitioner ability to prescribe buprenorphine.[31] Under the CAA, DEA-registered practitioners with the authority to prescribe schedule III controlled substances can prescribe buprenorphine to their patients without needing a DATA waiver or having a limit or cap as to the number of patients they can treat.[32]

B. Barriers to Access and Risk of Diversion of Buprenorphine

Access to buprenorphine decreases the risk of opioid-related overdose.[33] Increasing access to buprenorphine after a drug overdose has also been associated with a reduced risk of death.[34] However, barriers to access remain. One study showed that of those Americans who likely would benefit from treatment for OUD, only 28% actually received such treatment.[35]

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[29] 37 FR 37986; *see also* 21 CFR 1306.07(a).
[30] Title XXXV of Pub. L. 106-310. DATA was subsequently amended in 2005 (Pub. L. 109-56), 2016 (sec. 303 of Title III of the Comprehensive Addiction and Recovery Act of 2016, Pub. L. 114-198) and in 2018 (sec. 3202 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. 115-271).
[31] Section 1262 of Pub. L. 117-328.
[32] *Id*.
[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. Last accessed Apr. 11, 2024.
[34] Larochelle, *et al., Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality,* Annals of Internal Medicine (Aug. 7, 2018), https://www.acpjournals.org/doi/10.7326/M17-3107. Last accessed Apr. 11, 2024.
[35] *Only one in Four People Needing Treatment for Opioid Use Disorder Received Medication,* Columbia University School of Public Health (Mar. 23, 2022), https://www.publichealth.columbia.edu/public-health-now/news/only-one-four-people-needing-treatment-opioid-use-disorder-received-medication. Last accessed Apr. 11, 2024.

Another impediment occurs at pharmacies where pharmacists decline to fill buprenorphine prescriptions. For example, during the *Telemedicine Listening Sessions*, one speaker stated that pharmacies have sometimes declined to fill telemedicine prescriptions for buprenorphine, which they may perceive as inferior or suspect solely because the prescription was issued through telemedicine.[36]

Expanding the circumstances under which practitioners are authorized to prescribe buprenorphine 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 to find consistent access to wireless internet and/or data plans adequate to support bandwidth demands of audio-video telemedicine encounters.[37]

This final rule authorizing audio-only telemedicine of buprenorphine in certain circumstances does not imply that buprenorphine cannot be, or is not, diverted. Some presenters spoke to these issues during the *Telemedicine Listening Sessions*. According to one presentation, there is a "robust illicit market for buprenorphine," and patients may be selling buprenorphine to fund abuse of other controlled substances.[38] Another presenter said that drugs that contain Suboxone®, which contains buprenorphine[39] prescribed to treat OUD, can be used as a "currency" to purchase other drugs like methamphetamine, adding that, in the individual's

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[36] Telemedicine Listening Sessions, Dr. Juan Hincapie-Castillo (National Pain Advocacy Center), 173:7-13 (Sept. 13, 2023) (available: https://www.deadiversion.usdoj.gov/Telemedicine_listening_session.html).
[37] DeLaCruz et al., *Telemental Health for the Homeless Population: Lessons Learned when Leveraging Care* (December 8, 2022), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9734763/.*
[38] Telemedicine Listening Sessions, Daniel Reck (Matclinics), 104:3-9 (Sept. 12, 2023).
[39] Suboxone is a medication containing buprenorphine, and is a schedule III controlled substance. Buprenorphine, SAMHSA.gov, https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine. Last accessed Apr. 20, 2024.

community, "if [abuse or misuse of] methamphetamine is involved, you can pretty much be assured the diversion of buprenorphine is involved."[40]

Though, as with all transactions involving controlled substances, there is an inherent risk of diversion, DEA and HHS believe these regulatory provisions have been narrowly tailored to enable DEA and HHS to mitigate the risk of diversion associated with buprenorphine prescriptions issued pursuant to these new regulations. Moreover, considering the efficacy of treating OUD with buprenorphine when taken appropriately and subject to the additional safeguards in this rule, DEA and HHS believe that expanding access to buprenorphine through audio-only telemedicine outweighs the relatively lower risk of misuse and diversion of buprenorphine.

IV. Summary of Notice of Proposed Rulemaking

DEA published an NPRM titled *Expansion of Induction of Buprenorphine via Telemedicine Encounter*, jointly with HHS, on March 1, 2023.[41] Within this NPRM, DEA and HHS proposed adding definitions for "prescription drug monitoring program" and "telemedicine encounter." This NPRM proposed to authorize practitioners to prescribe buprenorphine for maintenance treatment and detoxification treatment[42] of OUD via telemedicine encounter, to include an audio-only telemedicine encounter, if all of the following certain conditions were met: 1) the practitioner would have needed to be registered under 21 U.S.C. 823(g), *see* 21 CFR 1301.13(e)(1)(iv), in the state in which the practitioner was located; 2) the practitioner would have needed to be authorized by state law to engage in the practice of telemedicine in both the state where the practitioner is located and the patient is located; 3) the practitioner would have needed to be authorized under 21 CFR 1301.28; and 4) the practitioner would have needed to be technologically capable of conducting a telemedicine encounter by using audio and video

[40] Telemedicine Listening Sessions, Jerome Cohan (Catalyst Health Solutions), 268:2-20 (Sept. 12, 2023).
[41] 88 FR 12890 (Mar. 1, 2023).
[42] For the purposes of this rule, reference to treatment of OUD via telemedicine encounters refers to all stages of treatment of OUD, including "maintenance treatment" and "detoxification treatment" as defined under 21 U.S.C. 802(29)-(30).

equipment. Prior to prescribing, the practitioner would have been required to review and consider the PDMP data of the state in which the patient is located regarding any controlled substance prescriptions issued to the patient in the last year, or if less than one year's worth of PDMP data was available, the entire available period.

The practitioner would have been required to review the PDMP data within seven days of the telemedicine encounter and would then have been authorized to prescribe an initial 30-day supply of schedule III-V buprenorphine-containing medication until a subsequent in-person medical evaluation of the patient had been conducted. Specifically, in order to prescribe more than a 30-day supply, the practitioner would have had three options as to how to conduct that subsequent in-person medical evaluation: 1) an in-person medical evaluation in which the patient would be in the physical presence of the prescribing practitioner; 2) an in-person medical evaluation in which the patient would be in the physical presence of a DEA-registered practitioner (other than the prescribing practitioner) and the two practitioners and patient were participating in a simultaneous real-time audio-video conference ("Telepresenter" Model); or 3) an in-person medical evaluation would be conducted by a DEA-registered practitioner who then issued a written "qualifying telemedicine referral" for the patient to a prescribing practitioner before sharing an electronic medical record for the patient with the prescribing practitioner. Ultimately, under any of these three pathways, the patient would have been required to be in the physical presence of a DEA-registered practitioner at some point to receive more than a 30-day supply of medication. Furthermore, additional recordkeeping requirements would have been mandatory if the medical evaluation occurred in the presence of another DEA-registered practitioner or through a qualifying telemedicine referral. For example, the prescribing practitioner would have been required to record whether the encounter was conducted via audio-video or audio-only means and record the reason a patient chose an audio-only telemedicine encounter when applicable. The NPRM also would have required practitioners to maintain copies of all qualifying telemedicine referrals, if the referral pathway had been used to conduct

the subsequent in-person medical evaluation. If the practitioner was unable to access the required PDMP data, the practitioner would have been authorized to issue a seven-day buprenorphine prescription and would have been required to record both the dates and times of any attempts to access the PDMP data, as well as why the practitioner was unable to access the PDMP data.

V. Summary of Changes from the NPRM

After reviewing comments received in response to the NPRM, as will be discussed in more detail below, DEA and HHS have amended the requirements for this rulemaking. Most significantly, DEA and HHS have expanded the initial 30-day prescription supply limitation via audio-only telemedicine to a six calendar month supply limitation. In addition, DEA is no longer amending 21 CFR part 1300 relating to definitions and part 1304 relating to records and reports of registrants. Specifically, DEA and HHS are no longer defining the terms "prescription drug monitoring program" or "telemedicine encounter" that were found in the NPRM. DEA and HHS have also removed the requirement that in order to prescribe more than the initial supply of buprenorphine, an in-person medical evaluation of some sort *must* be conducted. In other words, DEA and HHS have removed the three options through which a subsequent in-person medical evaluation may be conducted and specified instead that continued prescribing may occur pursuant to other forms of the practice of telemedicine as defined in 21 U.S.C. 802(54).

In drafting the NPRM, DEA and HHS sought to ensure that patient access to buprenorphine via telemedicine encounters, including audio-only telemedicine encounters, would still be authorized to continue once the COVID flexibilities ended, but also included additional requirements, not found within the flexibilities, to ensure that effective controls are in place to combat diversion. To this end, DEA and HHS created a framework under which specific types of in-person medical evaluations would have been required to be conducted after the initial 30-day prescription. However, a review of the comments persuaded DEA and HHS that the requirements found within the NPRM would be overly burdensome for the majority of

patients, contradicting an important goal of this rulemaking. Therefore, in its place, DEA and HHS have expanded the 30-day supply limitation to an initial six-month prescription supply limitation, after which two options can be used by the practitioner in order to continue prescribing to the patient: 1) conduct an in-person medical evaluation as defined in 21 U.S.C. 829(e)(2)(B); or 2) continue treating the patient via another form of telemedicine as defined in 21 U.S.C. 802(54). Since the supply limitation has been increased and a patient will not necessarily need to be seen in-person by the prescribing practitioner at any point, DEA and HHS have included an identification verification requirement, wherein the pharmacist must verify a patient's identity prior to filling a prescription issued under these regulations.

Additionally, pursuant to this final rule, the practitioner will be required to review the PDMP data of the state in which the patient is located when the telemedicine evaluation occurred, prior to issuing a prescription. The practitioner will also be required to annotate the date and time that the PDMP was reviewed. If the PDMP is unavailable or inaccessible for any reason, the practitioner will be required to notate the date and time that such review was attempted and will be authorized to prescribe renewable seven-day prescriptions until the six-month limitation is reached; attempts must be made to review the PDMP every seven days in this situation. The remaining recordkeeping requirements from the NPRM, including maintaining a record of whether the encounter was conducted via audio-visual or audio-only means, why the patient chose an audio-only telemedicine encounter, and maintaining copies of all qualifying telemedicine referrals, have not been promulgated within the final rule.

Lastly, DEA and HHS invited comments for any additional safeguards or flexibilities that should be considered with respect to the proposed regulatory changes. Based on comments received in response, and as noted above and discussed in more detail below, DEA and HHS are promulgating an additional provision which would require pharmacists to verify the

identification of the patient receiving the prescription under this framework prior to dispensing the controlled substance medication.[43]

VI. Discussion of Public Comments Received

DEA and HHS received a total of 2,915 comments in response to the NPRM. Of those comments, 68 were intended for the separately published NPRM titled *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*[44] and 178 were deemed outside the scope of the proposed rulemaking. As such, those comments will not be discussed further within this rulemaking. DEA and HHS received comments from practitioners, pharmacists, lawyers, professional associations, government entities, Tribal nations and associations, law firms and law school clinics, private companies, medical organizations, hospitals and medical practices, pharmacies, educational institutions, health insurance companies, and other members of the general public. DEA and HHS thank all commenters for their input during the rulemaking process.

All comments have been reviewed. DEA and HHS have grouped the comments into several distinct categories below in order to more easily summarize and respond to the large number of comments received in response to the NPRM. Of the comments received, some comments pertained to only one issue while others involved several issues.

In-Person Medical Examination Requirement

Comment: DEA and HHS received the largest number of comments pertaining to the NPRM's proposed in-person medical evaluation requirement following the initial 30-day supply. Commenters raised several issues and concerns with this requirement. The following is a summary of the comments received. One thousand two hundred and eighty (1,280) commenters expressed concern that the proposed in-person medical evaluation requirement would be costly and/or time-prohibitive to patients. Commenters stated that the in-person medical evaluation

[43] 21 CFR 1306.51(b)(4).
[44] 88 FR 12875 (Mar. 1, 2023).

requirement created obstacles, such as: living in a rural area, work responsibilities or an inability to take leave from work, family and childcare obligations, and transportation issues. Three hundred and fifty-nine (359) commenters stated that the in-person medical evaluation requirement would result in a lack of care or reduced access to care because the in-person medical evaluation requirement would be a barrier to treatment. These commenters stated that patients may drop out of their treatment program and potentially relapse due to the in-person medical evaluation requirement potentially limiting access to buprenorphine via remote care. Two hundred and thirty (230) commenters stated that there still remains stigma within their community regarding OUD treatment and requiring patients to be seen in-person could expose them to harm, "out them" to the general public, and/or reduce their ability to keep their treatment private. Two hundred and seventeen (217) commenters expressed concern about a physical or mental hardship or risk potentially limiting their ability to fulfill an in-person medical evaluation requirement; these included mental health conditions such as agoraphobia, physical conditions, other conditions such as autism, and/or wanting to avoid interactions with other patients receiving OUD treatment out of concern that such interactions could increase the likelihood of a relapse. One hundred and twenty one (121) commenters stated that an evaluation conducted in-person is generally the same as one conducted via a virtual appointment and there is no separate benefit in receiving a medical evaluation in-person for purposes of OUD treatment. Sixty nine (69) commenters stated that an in-person medical evaluation requirement would have a disparate impact on or discriminate against certain persons, including those with disabilities, persons of color, American Indians/Alaska Natives, the elderly, and those recently incarcerated.

Sixty seven (67) commenters stated that an in-person medical evaluation would be nearly impossible for them to schedule because of a general practitioner shortage and 44 commenters expressed the same concern because of a buprenorphine practitioner shortage within their geographic area. Fifty three (53) commenters, many of whom identified themselves as practitioners, stated that the decision to conduct or not conduct an in-person examination

constitutes a clinical decision that should be left to the practitioner's discretion and therefore, there should be no in-person medical evaluation requirement imposed by regulation. Twenty two (22) commenters stated that in-person medical evaluations are rarely utilized for those receiving OUD treatment. One commenter stated that the *Ryan Haight Act* does not require an in-person medical evaluation, and if an in-person medical evaluation is required under the *Ryan Haight Act*, the in-person medical evaluation can be conducted by the prescribing practitioner or a practice group. Nine hundred and eleven (911) commenters expressed general disapproval of the in-person medical evaluation requirement.

Response: DEA and HHS understand the many hardships an in-person medical evaluation requirement could cause patients and notes the multitude of reasons provided by commenters as to why this requirement would be burdensome to many patients. Therefore, DEA and HHS have expanded the initial prescription supply that may occur pursuant to audio-only telemedicine encounters from 30 days to six months. In addition, DEA and HHS have promulgated this final rule offering two options pursuant to which the prescribing practitioner is authorized to issue additional prescriptions for the treatment of OUD via telemedicine encounters subsequent to this initial six-month supply: 1) the practitioner can conduct an in-person medical evaluation; or 2) the practitioner can engage in other forms of the practice of telemedicine as defined in 21 U.S.C. 802(54). DEA and HHS believe this solution, which will allow subsequent prescribing pursuant to additional telemedicine pathways as DEA (and for rules that must be issued jointly, HHS) promulgate regulations permitting them, likely will further alleviate the various concerns raised by commenters as to the options for continued treatment.

Comment: DEA and HHS received 11 comments agreeing with the inclusion of the in-person medical evaluation requirement. These commenters stated that the requirement is important because in-person medical evaluations prior to buprenorphine induction allow a practitioner to better determine the state of the patient and ensure the patient is not under the influence of any other substances.

Response: DEA and HHS agree that an in-person medical evaluation provides a prescribing practitioner with valuable information about the patient that might not be fully discerned via a telemedicine encounter. The in-person medical evaluation allows a prescribing practitioner to conduct a thorough physical assessment of the patient, more accurately assess the patient's physical and mental health, and provides more accurate treatment options.[45] Additionally, DEA and HHS believe an in-person medical evaluation can serve as an effective control against diversion by allowing the practitioner to better discern whether the medications the patient has been prescribed are working effectively and are being taken appropriately by the patient.[46] However, DEA and HHS understand that not all patients are able to schedule and attend an in-person medical evaluation. As mentioned above, given the unique circumstances of increasing access to potentially life-saving medications for the treatment of OUD during the overdose epidemic, DEA and HHS believe that removing the in-person medical evaluation requirement is appropriate in this situation. Therefore, within this final rule, DEA and HHS have provided the option for the practitioner to conduct an in-person medical evaluation; otherwise, practitioners are able to continue prescribing via other forms of telemedicine authorized under the CSA after the initial six-month prescription.

In-Person Medical Evaluation Requirement Alternatives

Comment: DEA and HHS received 144 total comments regarding the non-traditional methods of fulfilling the in-person medical evaluation requirement," *i.e.*, the Telepresenter Model or the qualifying telemedicine referral, listed within the NPRM. Seven comments addressed the Telepresenter Model, *i.e.*, a scenario in which the patient attends an in-person medical evaluation in the physical presence of a DEA-registered practitioner (other than the prescribing practitioner) and the two practitioners and patient participate in a simultaneous real-time audio-video

[45] K. Moulaei et al., *Patients' perspectives and preferences toward telemedicine versus in-person visits: a mixed-methods study on 1226 patients* (Nov. 15, 2023). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10647122/#:~:text=The%20primary%20reasons%20for%20selecting,better%20treatment%20of%20the%20disease. Last accessed Aug. 5, 2024.
[46] *Id.*

conference; 137 comments addressed the qualifying telemedicine referral model. For the Telepresenter Model, commenters expressed concern that this model also requires a substantial amount of travel (especially if the patient resides in a rural area); that it would be extremely difficult for the patient to try to coordinate the schedules of two practitioners; that these consults would be cumbersome and unmanageable; that this model is not common practice in this type of medical care; and that getting an in-person appointment would be difficult especially for those who face stigma within their community for receiving OUD treatment. With regards to the qualifying telemedicine referral, the commenters stated that the referral process would be overly cumbersome and unnecessary; some practitioners may refuse to conduct an in-person medical evaluation for the purpose of issuing a referral; it takes too long to get a referral; some patients don't have medical insurance and requiring an in-person medical evaluation and a referral would not be possible; it is hard to make an in-person appointment with a primary care physician (PCP) as many people don't have PCPs; if a patient needs care from an addiction specialist the patient would need to wait for the referral before beginning treatment; and the referral process would be a barrier and diminish success of the treatment program.

Response: DEA and HHS acknowledge that these non-traditional methods for fulfilling the in-person medical evaluation requirement may not represent feasible options for many patients. As noted above, DEA and HHS have removed both the Telepresenter Model and the qualifying telemedicine referral process from the final rule. DEA and HHS agree that, for many patients, these proposed provisions were not practicable and would create an undue burden on both patients and practitioners. After the initial six-month period, the option to conduct a traditional in-person medical evaluation remains should the practitioner and patient wish to continue treatment in such a manner.

30-day Prescription Supply Limitation

Comment: DEA and HHS received many comments related to the 30-day time period limitation. The comments asserting that 30 days was too short a time period in which to obtain an in-person

medical evaluation are summarized in the above sections relating to in-person medical evaluations. DEA and HHS received a total of 68 comments related specifically to the 30-day prescription supply limitation. Some commenters stated that 30 days was too short a duration for buprenorphine dispensing before an in-person medical evaluation could be obtained, while other commenters generally supported the 30-day supply limitation. The commenters who believed 30 days was not enough time cited to various reasons: 10 commenters believed that the 30-day supply limitation was arbitrary and that it is not the typical length of prescription provided for OUD treatment; three commenters stated that 30 days represents insufficient supply and will interrupt a treatment regimen that has already been established; and one commenter stated the limit should be removed if the patient is clinically indicated for a buprenorphine prescription. 41 commenters stated there should be a prescription limitation but requested that the time period be increased from 30 days. Five commenters stated the supply limitation should be removed and prescriptions should be issued indefinitely; while two commenters stated that the prescribing practitioner should decide how long a prescription should be issued for.

Four commenters expressed support for the 30-day supply limitation and indicated that 30 days was an appropriate time period. One of these commenters (a patient) stated they currently receive a 30-day supply of buprenorphine at a time and had no concerns with that limit. Two commenters indicated a 30-day supply prior to an in-person medical evaluation was too permissive: one commenter stated that after the initial 30-day supply, refills should only occur seven days at a time until an in-person medical evaluation could be obtained; and the other commenter stated that prescriptions should be restricted to three-to-seven days for new patients with documentation that an in-person medical evaluation was not practical with one three-to-seven-day refill prescribed by a fully trained addiction physician. Additionally, some of these commenters asked clarifying questions about whether the 30-day supply limitation was only for a buprenorphine initiation period and not for every 30-day period of buprenorphine treatment, and also requested clarification about how the proposed regulations would have addressed a

patient who started with a 30-day supply and then was "lost to follow-up" but later re-engaged with treatment.

Response: DEA and HHS acknowledge the commenters' concerns and agree that 30 days is too short of a timeframe to receive an initial buprenorphine prescription before being required to obtain an in-person medical evaluation to receive additional prescriptions. After reviewing the comments and feedback from the various listening sessions, DEA and HHS agree that many patients would have difficulty in scheduling an in-person medical evaluation with a practitioner and/or specialist within a 30-day time period. At the same time however, DEA and HHS believe that prescriptions issued pursuant to audio-only telemedicine should not be issued indefinitely or solely at the discretion of the practitioner, given the increased risks of abuse, misuse, or other forms of diversion posed by audio-only telemedicine without a visual or in-person component. Several commenters suggested 180 days (six months) as a supply limitation before an in-person medical evaluation should be conducted. DEA and HHS agree and believe a six-month supply provides adequate time for a patient to be stabilized on medication via audio-only medical encounter(s) without unduly increasing the risk of diversion. Therefore, the final rule allows for an initial prescription limitation of six calendar months after which time either an in-person medical evaluation must be conducted or the practitioner can continue prescribing via another form of telemedicine. DEA is also clarifying that the six-month (previously 30-day) supply limitation applies when the patient is treated by the same practitioner, regardless of when the six-month prescriptions are issued. For example, if a patient receives a prescription for a one-month supply three times by a practitioner, then stops treatment with that practitioner, the patient can only receive prescriptions for another three months of supply upon resuming treatment with that same practitioner, regardless of the reason treatment was stopped and time period that treatment was paused. Once an in-person medical evaluation has been conducted, the practitioner and patient are no longer engaged in the practice of telemedicine under 21 U.S.C. 802(54) and are thus no longer bound to the requirements found within this rule.

Mandatory PDMP Review

Comment: DEA received 30 comments opposing the mandatory PDMP review prior to issuing a buprenorphine prescription under this framework. These commenters, many of whom identified themselves as practitioners or as part of professional medical associations, stated that PDMP checks do not provide valuable information because they only show prescribed medications, not substances bought on the street illegally; state PDMPs do not all require practitioners to report the same medications (as which medications must be reported is based on state law); telehealth appointments are already limited in duration and valuable time would be spent by the practitioner reviewing the PDMP; DEA should defer to state law as to whether a PDMP check is required; patients should not be penalized and limited to a seven-day supply if the PDMP is inaccessible or inoperable; practitioners may not have access to a state's PDMP; and the recordkeeping requirement associated with the PDMP review is too burdensome. Conversely, 15 commenters agreed with the PDMP requirement.

Response: DEA and HHS believe it is essential for a practitioner to review the PDMP data for possible drug interactions and to discern whether there is any potential misuse or abuse of prescribed medications within a patient's history. PDMP reviews have been shown to combat the fraudulent prescribing of medications, reduce incidences of multiple overlapping prescriptions for the same controlled medications, known as doctor shopping, aid in the monitoring of controlled substance abuse and misuse, and help reduce drug-poisoning deaths.[47] For these reasons, this final rule requires practitioners to review PDMP data prior to prescribing buprenorphine and restricts prescriptions to seven days at a time when the PDMP cannot be accessed. A review of PDMP laws and regulations of the 50 states, along with the District of Columbia, Guam, Puerto Rico, and the Northern Mariana Islands, shows that at least four states require a review of PDMP data prior to issuing any prescriptions and at least three states require

[47] F. Alogaili et al., *Prescription drug monitoring programs in the US: A systematic literature review on its strengths and weakness,* Journal of Infection and Public Health (Sept. 30, 2020). *https://www.sciencedirect.com/science/article/pii/S1876034120305657?via%3Dihub.* Last accessed Aug. 5, 2024.

the PDMP to be reviewed prior to issuing any telemedicine prescriptions. Further, 54 states/territories require that buprenorphine prescriptions be reported to a PDMP and 48 states/territories require review of a patient's PDMP data prior to issuing a buprenorphine prescription. Since most states/territories already have PDMP requirements, DEA and HHS believe this requirement poses a minimal administrative burden on practitioners, which are significantly outweighed by the benefits of reviewing this data.

As for recordkeeping requirements, this final rule will require practitioners to review the PDMP data and notate the date and time that such a review took place within the patient's electronic health record (EHR) or paper record. This notation will ensure that the prescribing practitioner has reviewed, or attempted to review, the PDMP prior to a prescription being issued. DEA and HHS understand that many EHR systems already contain this capability as this information is automatically integrated into the patient's record as soon as the data has been reviewed by the prescribing practitioner. If the PDMP data is inaccessible for any reason, the prescribing practitioner will be required to notate the date and time that such review was attempted, indicate why the PDMP was inaccessible, and will be limited to prescribing a seven-day supply. This seven-day supply can be renewed (up to six calendar months) if, every time the prescribing practitioner tries to review the PDMP data, the PDMP system is inoperable. While this is not meant to penalize either the practitioner or the patient, it should be a rare occurrence for a PDMP to be inaccessible for a full six-month time period. DEA and HHS believe the benefits of requiring a practitioner to review the patient's data for signs of abuse or misuse of controlled substances as soon as it becomes available outweigh any potential "harms" to the patient should the patient only receive an initial seven-day supply, especially since this seven-day supply can be renewed for up to six months.

Recordkeeping Requirements

Comment: DEA and HHS received 105 comments voicing disapproval and eight comments supporting the recordkeeping requirements found within the NPRM. Specifically, 75

commenters stated the requirements were administratively burdensome, time consuming, and confusing; would cause delays in workflow and patient care; practitioners should not need to record why audio-only telemedicine was chosen; the NPI and registration number of practitioners should not be required to be recorded; and practitioners were uncomfortable recording their home or physical address.

Twenty four (24) comments pertained to the requirement that the practitioner maintain a record that the encounter was conducted via audio-visual or audio-only means. Commenters indicated that this requirement would exacerbate the already common occurrence of pharmacies refusing to fill telemedicine prescriptions; there would be no clinical value; and it would create confusion. Six commenters asked for a 12-month grace period in order to update EHR systems to comply with the requirements.

Response: DEA and HHS agree with the commenters who raised concern with the stated recordkeeping requirements and does not believe the requirements would fulfill their intended purpose. The majority of the recordkeeping requirements detailed within the NPRM therefore have been removed and the final rule contains only one recordkeeping requirement that pertains to the PDMP review (explained in the previous comment response). DEA and HHS believe the other safeguards found within this final rule will help to prevent diversion without being overly burdensome for either patients or practitioners. The prescribing practitioner will need to notate the date and time the PDMP review was conducted or, if such review could not be completed, the date and time the PDMP review was attempted and why the review could not be completed. As many EHR systems already have this functionality integrated within their systems, DEA and HHS do not believe additional time needs to be allocated in order to update systems or bring them into compliance with this requirement.

Diversion of Buprenorphine

Comment: DEA and HHS received 791 comments regarding diversion of buprenorphine. Five hundred and twenty (520) commenters stated that the proposed rule would result in an increase

of drug poisonings or overdoses due to patients having limited access to or losing access to their current buprenorphine treatment. One hundred and thirty five (135) commenters stated that there is no evidence to show that telemedicine care leads to higher diversion of buprenorphine than in-person care and cited to studies concluding that the COVID-19 PHE flexibilities did not lead to higher diversion or misuse of buprenorphine. The remainder of the comments stated that if legitimate prescriptions were easier to obtain there would be less diversion; if buprenorphine is diverted, then it is diverted for therapeutic purposes or to mitigate withdrawal; the buprenorphine combination product with naloxone (Suboxone®) actually deters diversion and is harder to overdose on when misused because of its chemical makeup; and increasing access to buprenorphine should outweigh any potential harm from diversion. Twelve (12) commenters voiced approval for the rule and stated that diversion and overdoses of buprenorphine are of real concern and there is further cause for concern because for-profit telehealth companies or "virtual pill mills" have been expanding their buprenorphine business, which could lead to more diversion of the medication.

Response: DEA and HHS understand that the COVID-19 PHE flexibilities have allowed for greater access to buprenorphine and it is DEA and HHS's intention to continue expanding access to buprenorphine via telemedicine for patients who have a legitimate need for treatment as the flexibilities come to an end. DEA and HHS have relaxed many of the requirements found within the NPRM, in response to concerns raised by commenters that patients may have limited access or lose access to treatment otherwise.

However, DEA has a mandate and commitment to detect and prevent the diversion of controlled substances, regardless of the reason for diversion, so DEA and HHS must nevertheless place certain safeguards on the telemedicine prescribing of buprenorphine. DEA and HHS note that several commenters expressed concern over buprenorphine diversion and the growth of "virtual pill mill" companies during the time the COVID-19 PHE flexibilities have been in place. Determining the reasons for diversion of buprenorphine in any particular case may prove

difficult to discern, and a patient may divert buprenorphine for both claimed therapeutic and non-therapeutic purposes. Specifically, and as noted above, buprenorphine constitutes an effective treatment for OUD, but it can also create euphoric feelings similar in kind – even if not in intensity – to other opioid agonists. For these reasons, it is possible that some diverted buprenorphine might be used for reasons other than therapeutic purposes or mitigation of withdrawal. As the practice of telemedicine facilitates wider access to buprenorphine, DEA must ensure certain safeguards remain in place to deter potential diversion—whether for claimed therapeutic or non-therapeutic uses.

DEA and HHS have promulgated this final rule taking into consideration the many concerns raised by the thousands of comments received in response to the NPRM. DEA and HHS have amended the requirements from the NPRM to the final rule in large part in response to the comments and concerns expressed by the public, and the data they have provided. The safeguards that are found within the final rule will continue to expand access to OUD treatment by allowing for buprenorphine treatment via audio-only encounters and will allow patients and practitioners to continue using telemedicine as a means of receiving treatment. The telemedicine flexibilities established during the COVID-19 PHE were intended to be temporary flexibilities during a time when in-person care was not universally routinely and safely available. The COVID-19 PHE flexibilities should not continue indefinitely at a time when receiving in-person care no longer poses a significant risk to public health and safety. This final rule acknowledges that telemedicine encounters are more flexible and convenient to many patients but also acknowledges that safeguards need to be in place to prevent misuse and abuse of controlled substances, especially during a time when an increasing number of for-profit telehealth companies continue to grow their practices without any permanent regulatory requirements or safeguards.

Additional Safeguards Requested by Commenters

Comment: DEA and HHS received 41 comments requesting additional regulatory safeguards be put in place on top of the requirements already laid out in the NPRM. Commenters suggested requiring urine drug screens or blood tests, monthly pill counts, testing for alcohol use, psychological and physical monitoring, psychosocial support, and/or follow-up in-person medical evaluations every three months for the first year of treatment. Some commenters were in favor of buprenorphine prescribing via telehealth only if an in-person medical evaluation and drug screen were required while others believed that even with an in-person medical evaluation and drug screen, buprenorphine should not be prescribed via telehealth encounter.

Response: DEA and HHS acknowledge these concerns. As noted above the detection and prevention of diversion of buprenorphine is a significant priority of this rulemaking. At the same time, DEA and HHS understand that the addition of too many regulatory requirements may cause some patients to abandon their current OUD treatment or to decline to enter treatment in the first place. Within this rulemaking, DEA and HHS are attempting to continue to expand treatment options for OUD and make permanent some of the flexibilities permitted during the COVID-19 PHE. DEA and HHS are confident that the safeguards in place within this final rule will help alleviate diversion concerns while also allowing for patients to seek and obtain safe treatment for OUD.

Additionally, as noted above, practitioners who have conducted an in-person medical evaluation of a patient are not required to adhere to the telemedicine requirements established by the *Ryan-Haight Act* when prescribing a controlled substance to that patient. More generally, those practitioner-patient relationships no longer constitute telemedicine as defined by the *Ryan Haight Act* and are outside the scope of this rulemaking.

DEA 823(g) Registration of Practitioners

Comment: DEA and HHS received 18 comments regarding DEA registrations under 21 U.S.C. 823(g). Three commenters stated that a practitioner should only need one DEA registration and be legally authorized to practice telemedicine in the state in which the patient is located. Six

commenters stated that the practitioner should only need to be DEA-registered and fully licensed in the state in which the patient is located. Two commenters stated that a practitioner should be able to prescribe controlled substances via telemedicine as long as they are licensed to practice medicine in the state the patient is located and that, furthermore, the practitioner should not also need a DEA registration for the state the patient is located in. Four commenters stated it was unclear if the NPRM was requiring that a practitioner needs a DEA registration in both the state in which the practitioner is located and state in which the patient is located. One commenter agreed generally with the NPRM and stated that telemedicine companies should be required to have a DEA registration in every state they want to prescribe. Two commenters requested an exception for separate DEA registrations for practitioners that have medical licensing reciprocity requirements.

Response: DEA and HHS understand some confusion may have arisen from the NPRM regarding registration. As DEA has made clear elsewhere, under current statutes and regulations, practitioners are required, unless subject to an exception, to obtain a DEA registration both in the state in which the practitioner dispenses controlled substances and in the state in which the patient is located.[48]

Definitions

Comment: DEA and HHS received 14 comments relating to definitions found within the NPRM. Seven commenters requested a definition of "mental health disorders" be included in

[48] The CSA requires all practitioners to be registered in the state in which the patients to which they are prescribing controlled substances are located, regardless of whether the prescribing is taking place via telemedicine. The CSA provides that every person who dispenses, or who proposes to dispense, any controlled substance shall obtain from DEA a registration issued in accordance with DEA rules and regulations. *See* 21 U.S.C. 822(a)(2). Under the CSA, such dispensing includes prescribing and administering controlled substances. *Id*. 802(10). DEA may only register a person to dispense a controlled substance if that person is permitted to do so by the jurisdiction in which his or her patients are located. *See id*. 802(21), 823(f). Thus, unless an applicable exception applies, DEA regulations require a practitioner to obtain a separate DEA registration in each state in which a patient to whom he or she prescribes a controlled substance is located when the prescription is made, regardless of whether the prescription is made via telemedicine. The CSA also contains provisions (added by the Ryan Haight Act) expressly requiring a practitioner to be registered in the state in which the patient to whom he is prescribing is located when he or she is engaged in certain forms of telemedicine. Under the CSA, a prescription for a controlled substance issued by means of the Internet must generally be predicated on an in-person medical evaluation. *See id*. 829(e)(1). This requirement does not apply, however, when a practitioner is practicing telemedicine as defined by the CSA.

the rule; two commenters requested removal of the "prognosis" of OUD requirement as it relates to the qualifying telemedicine referral; two commenters requested a definition for "telemedicine prescription"; two commenters requested amending the definition of "patient's location"; and one commenter stated that DEA should not rely on the CMS definition of "interactive telecommunications system."

Response: DEA and HHS have greatly simplified the final rule, which includes omitting any changes to current definitions within the Code of Federal Regulations. Additionally, as certain requirements from the NPRM have been removed, such as the qualifying telemedicine referral and the need for a notation on the telemedicine prescription, there is no need to provide definitions for those terms. DEA and HHS do not believe a definition for "mental health disorders" is needed as that question falls outside the scope of this rule. Furthermore, HHS regulations define the terms "drug abuse" and "drug addiction" in 42 CFR 34.2(h) and (i) as "current substance use disorder or substance-induced disorder, mild" and "current substance use disorder or substance-induced disorder, moderate to severe", respectively, using the most recent edition of the Diagnostic and Statistical Manual for Mental Disorders. This rule authorizes the treatment of OUD through audio-only means solely to treat substance use disorders under this definition. The final rule also does not enact any regulations that explicitly require the "patient's location" to be disclosed, so no definition is needed. While DEA and HHS anticipate that many of these audio-only encounters will occur in a private setting, such as a patient's home, this rule is not placing any additional regulations or requirements upon the practitioner or the patient to verify the patient's location. DEA and HHS will continue to rely on the CMS definition of "interactive telecommunications system" within this rule, as the current definition of the term "practice of telemedicine" uses the CMS definition.[49]

Rule's Applicability to Pharmacists

[49] *See* 21 U.S.C. 802(54).

Comment: DEA and HHS received seven comments related to the rule's applicability to pharmacists. Four commenters requested clarification as to whether DEA-registered pharmacists who are granted controlled substance prescriptive authority within their state would be allowed to prescribe and dispense medications under this rule, and whether they could conduct the in-person medical evaluation (or serve as the referring provider) under the framework proposed in the NPRM. Additionally, three commenters were concerned that the rulemaking would require pharmacists to "police" the practice of telemedicine, placing an undue burden on pharmacists and overwhelming pharmacy operations. These commenters expressed concern and sought clarity as to if, and how, a pharmacist would be required to verify that the in-person medical evaluation requirement had been fulfilled; how a pharmacist would discern which prescriptions are telemedicine prescriptions absent an indicator on the face of the prescription denoting it as such; and how a pharmacist would access or receive this information without violating the Health Insurance Portability and Accountability Act (HIPAA) and other patient privacy laws.

Response: DEA and HHS understand the important role pharmacists play when they fill controlled substance prescriptions and appreciates the legitimate concerns raised by these comments. DEA and HHS are aware there still remains stigma associated with OUD treatment and has decided not to require a notation on the face of the prescription denoting that the prescription is one issued via telemedicine. DEA and HHS understand this may place more responsibility on a pharmacist and urges pharmacists to treat all buprenorphine prescriptions equally, while continuing to fulfill their longstanding corresponding responsibilities, without attempting to discern whether the prescription was issued via a telemedicine encounter. Pharmacists will not be required to access a patient's record to figure out whether the in-person medical evaluation has been conducted or whether an evaluation was completed via telemedicine. This rule is not intended to place pharmacists in the role of "policing" the practice of telemedicine, but rather reflects that pharmacists play an integral role in helping to prevent drug misuse. As set forth in 21 CFR 1306.04(a), "The responsibility for the proper prescribing

and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Therefore, the pharmacist will be required to verify the identity of the patient prior to filling a prescription. As explained in further detail below, many states already have placed on pharmacists an identification verification requirement for many controlled substances, including buprenorphine, as a matter of state law, and DEA and HHS believe placing an identity verification responsibility on pharmacists as a matter of Federal law generally should not represent an additional burden in the vast majority of cases.

Effective Date

Comment: DEA and HHS received 43 comments solely concerned with the potential effective date of the final rule. Twenty (20) comments requested that the COVID-19 PHE flexibilities continue indefinitely for the duration of the ongoing opioid epidemic PHE; 19 commenters requested that the COVID flexibilities continue for six months after publication of the final rule, until the end of calendar year 2023, or until the end of calendar year 2024; and five commenters requested that the COVID flexibilities continue until the final rule is published.

Response: The NPRM for this final rule was published on March 1, 2023, and at the time the NPRM was published, the COVID-19 PHE flexibilities were set to expire on May 11, 2023. The COVID-19 PHE flexibilities have since been temporarily extended until December 31, 2025, while DEA and, for rules that must be issued jointly, HHS have worked on other rulemakings. Once published, this final rule will be effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. DEA and HHS believe this effective date, in concert with the latest extension of the telemedicine flexibilities, satisfies the concerns of those who commented on this issue.

Executive Order 12866 – 60 Day Comment Period

Comment: DEA and HHS received nine comments stating that the 30-day comment period found within the NPRM violated Executive Order (E.O.) 12866, which allegedly requires a 60-day comment period.

Response: The language contained within E.O. 12866 states "each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases *should* include a comment period of not less than 60 days."[50] Since the 60-day comment period is not a requirement and because, at the time of publication of the NPRM, the COVID-19 PHE telemedicine flexibilities were set to expire on May 11, 2023, DEA chose to use a 30-day comment period to ensure all comments were received and to allow adequate time to publish a final rule.

Indian Tribes and Tribal Organizations

Comment: DEA and HHS received two comments regarding the effect of this rulemaking on American Indian and Alaska Native (AI/AN) Tribes and Tribal organizations. One commenter requested an exemption from registration for all Indian Health Service (IHS) and Tribal health system and Indian Health Care providers.

Both commenters indicated that consultation and coordination with Indian Tribes and Tribal organizations is required under Executive Order 13175 and requested that DEA meaningfully consult with Tribal officials prior to promulgating the final rule.

Response: DEA and HHS thank these commenters for voicing their concerns. DEA held *Telemedicine Listening Sessions* on September 12 and 13, 2023, and held Tribal Consultations with various Tribal governments and organizations on June 13 and 27, 2024. DEA and HHS have taken the opinions and concerns raised during both the listening sessions and consultations into account when promulgating this final rule. As such, DEA and HHS believe the requirements of Executive Order 13175 have been satisfied.

Other Comments

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[50] Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993) (emphasis added).

Comment: One commenter asked for clarification on how patients in various stages of buprenorphine treatment would be impacted by the rule, given the rule's focus on "induction" of buprenorphine. The commenter stated that there are various stages of buprenorphine treatment, including: (1) patients being prescribed buprenorphine to initiate therapy (general understanding of "induction"); (2) patients being re-established on buprenorphine treatment when previously prescribed the controlled substance medication; and (3) patients being moved from the "induction" phase to maintenance phase. The commenter sought clarification as to whether DEA intended to include all these stages under the proposed rule, and if not, the commenter asked that the rule allow buprenorphine at all stages of treatment.

Response: Both the NPRM and this final rule are published with the intent of authorizing buprenorphine treatment via telemedicine. This final rule allows for any patient, beginning on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to either begin treatment for OUD or continue treatment for OUD (i.e., all "stages" of treatment) via audio-only telemedicine encounter if the requirements of 42 CFR 410.78(a)(3) are met. Beginning on this date, when a practitioner provides the patient with a prescription or prescription refill for buprenorphine as medication for OUD via telemedicine, the practitioner must review the PDMP prior to issuing the prescription. And the pharmacist, prior to filling the prescription, must verify the identity of the patient.

Once the initial six-month supply has been prescribed, the practitioner and patient can choose to continue treatment either once an in-person medical evaluation has been conducted or through other forms of telemedicine pursuant to 21 U.S.C. 802(54). In other words, a patient has six months from the date a prescription (or prescription refill) has been issued pursuant to this final rule to either obtain an in-person medical evaluation or continue with another form of telemedicine.

Comment: DEA and HHS received one comment stating DEA lacks the legal authority to limit telemedicine prescriptions to the FDA-approved indications contained in a medication's FDA-

approved labeling. This commenter argued that DEA would effectively be attempting to define general standards of accepted medical practice, a power which is usually reserved for states.

Response: DEA and HHS, jointly, have the legal authority to promulgate regulations regarding the practice of telemedicine that are consistent with the public health and safety.[51] DEA reiterates that practitioners who are otherwise authorized under state and Federal law (including under the *Ryan Haight Act*) might prescribe buprenorphine for indications other than for treatment of OUD. This final rule only applies to circumstances where the prescribing practitioner has not conducted an in-person medical evaluation of the patient and is otherwise unable to prescribe buprenorphine while engaged in the practice of telemedicine under 21 U.S.C. 802(54) but for the authority provided in this final rule.

Comment: One commenter stated that DEA should hold an annual review of the efficacy and burden of the in-person medical evaluation requirement and this review should be published in the *Federal Register*.

Response: DEA appreciates this comment and will take this recommendation under consideration and advisement; however, no definitive response can be provided on this issue at this time.

VII. Provisions of the Final Rule

Under this final rule, a DEA-registered practitioner may prescribe buprenorphine via audio-only or audio-video telemedicine encounter as defined by 42 CFR 410.78(a)(3). After a practitioner reviews the PDMP data for the state in which the patient is located and annotates in the patient's EHR that such a review was conducted, the practitioner may prescribe an initial six-month supply of buprenorphine. DEA and HHS expect that the practitioner will not issue the six-month prescription at one time but will rather issue prescriptions as medically appropriate. Following the initial six-month supply, practitioners may prescribe buprenorphine only by other forms of telemedicine or practices authorized by the CSA, or after conducting an in-person

[51] *See* 21 U.S.C. 821, 21 U.S.C. 871, and 21 U.S.C. 802(54)(G).

medical examination. Additionally, prior to dispensing under this framework, the pharmacist will need to verify the identity of the patient[52] with either a state or Federal Government-issued photographic identification card or other form of identification.

A. Prescription Drug Monitoring Program Check by Prescribing Practitioner

The regulation at 21 CFR 1306.51(b)(1), found within this final rule, provides that the prescribing practitioner must review the PDMP data of the state in which the patient is located. The prescribing practitioner will then need to ensure that the date and time of the PDMP review is annotated in the patient's EHR or paper record. If, for any reason, the PDMP is unavailable or inaccessible and the practitioner is unable to review the PDMP data for the patient, the prescribing practitioner should annotate in the patient's EHR the reason such a review was unable to be completed.

1. *If PDMP data can be reviewed*

Prior to prescribing buprenorphine to the patient, the practitioner will be required to review the PDMP data of the state in which the patient is located and ensure that the date and time of such review is annotated in the patient's EHR or paper record. The prescribing practitioner will be required to review the PDMP data for the last year, or if less than one year's worth of data is available, for the entire period. The inclusion of this requirement prior to prescribing is to ensure that the practitioner has the information needed in order to make the clinical decision of whether or not to prescribe buprenorphine to a patient under this framework. Inherent in the telemedicine context, and especially through audio-only means, there may be situations where it is difficult for a practitioner to ascertain if a patient is being truthful about their medical history and prior usage of controlled substances. The requirement of a mandatory PDMP review can furnish the prescribing practitioner with valuable information regarding a

[52] As noted previously, DEA understands there are situations where the patient (for whom the prescription was written) may not be the individual picking up the prescription at the pharmacy. In these situations, DEA defers to the definition of "ultimate user" as found in 21 U.S.C. 802(27). As such, this regulation authorizes the pharmacist to verify the identity of the patient by accepting identification from any individual who falls under the definition of "ultimate user" prior to filling a prescription.

patient's controlled substance prescription history, and by using their own clinical judgment, the practitioner can make an informed decision.

Regarding the date and time requirement, DEA and HHS understand that many EHR systems already integrate state PDMP data into their systems. For these systems, a date and time stamp recording when a prescribing practitioner reviews PDMP data should be automatically integrated into the patient's EHR. For other EHR systems where only the date of PDMP access is integrated into the patient's EHR or no integrations exist at all, the prescribing practitioner will be required to manually input the date and time the PDMP review was conducted prior to closing or signing off on a patient's chart. DEA and HHS understand this may be burdensome to practitioners but DEA and HHS are confident that as technology changes, many EHR systems will likely update their platforms to enable automatic integration.

2. *If PDMP data cannot be reviewed*

The regulation at 21 CFR 1306.51(b)(3) provides that if, for any reason, the PDMP data cannot be reviewed for a patient, the prescribing practitioner should ensure that the reason for this is noted in the patient's EHR or paper record. For example, if a state PDMP is inaccessible or unavailable due to technological issues, the prescribing practitioner should note the date and time that an attempt to view such data was made. In these situations, when PDMP data cannot be reviewed, a practitioner would only be permitted to prescribe an initial seven-day supply of buprenorphine. The practitioner may not prescribe an additional supply without again checking the PDMP data for that patient. However, the practitioner would be authorized to issue additional limited seven-day supply prescriptions (up until the six-calendar month limitation is reached) if the PDMP remained unavailable or inaccessible, as long as each time a review is attempted, the date and time of each attempt is annotated in the patient's EHR or paper record.

B. Time Limitation of Buprenorphine Prescriptions

The regulation at 21 CFR 1306.51(b)(2) provides that buprenorphine prescriptions issued pursuant to audio-visual or audio-only telemedicine encounters are limited to a period ending no

later than six calendar months after the date of the first prescription. This six-month supply must be split across multiple prescriptions or refills as the practitioner deems medically appropriate. Subsequent prescriptions may be issued once the practitioner has met with the patient for a follow-up evaluation either through any other form of telemedicine as defined in 21 U.S.C. 802(54) or through an in-person examination of the patient by the prescribing practitioner. Additionally, this requirement would comport with the current regulations found in 21 CFR 1306.22(a) regarding refilling of prescriptions for controlled substances listed in schedule III or IV.

1. *Other authorized forms of telemedicine or practices established by regulation*

After an initial six-month prescription of buprenorphine via audio-visual or audio-only means, additional prescriptions may be written pursuant to any other form of telemedicine as defined in 21 U.S.C. 802(54). This includes the regulations found within any final rule that may be issued setting forth a special registration framework. In the event DEA issues future regulations setting forth practices DEA determines to be consistent with effective controls against diversion, pursuant to 21 U.S.C. 829(e)(3)(B), additional prescriptions would also be permitted to be issued pursuant to those practices.[53]

2. *In-person medical evaluation*

Practitioners who conduct an in-person medical evaluation of a patient subsequent to the initial six-month supply restriction would, from that point on, no longer be required to adhere to the telemedicine requirements established by the *Ryan-Haight Act* for that patient. As explained above, this rulemaking contemplates situations only wherein the prescribing practitioner has never conducted an in-person examination. Once an in-person examination has been conducted by the prescribing practitioner, the duties and obligations found within this final rule no longer apply.

[53] No such practices have yet been determined by future DEA regulation to be consistent with effective controls against diversion.

C. ID Requirement for Pharmacists

Under new 21 CFR 1306.51(b)(4), prior to filling a prescription that was issued pursuant to the authorities created by this final rule, the pharmacist will be required to verify that, as a general matter, the identity of the individual picking up the prescription at the pharmacy matches the name of the patient listed on the prescription itself.[54] Before the pharmacist can fill a prescription issued pursuant to the regulations found in this final rule, they must inspect the patient's state or Federal Government-issued photographic identification card, or in the absence of such identification, any other form of documentation showing that the patient is the same person as the patient listed on the prescription. The form of identification presented need not contain the patient's address. Such forms of identification include, but are not limited to: state issued driver's licenses and identification cards; U.S. passport; U.S. military card or military dependent's identification card; Native American tribal documents; paycheck; bank or credit card statement; utility bill; tax bill; or voter registration card. For minors under the age of 18, unhoused persons, and those without photographic identification, examples of other permissible forms of identification include: school transcripts; school report cards; or a letter from a homeless shelter employee or a letter from a Tribal government official or other Tribal leader verifying the identity of the patient. As indicated, the acceptable forms of identification provided as examples within this final rule are not intended to be an exhaustive list.

As mentioned above, even absent the ID provision, DEA and HHS believe that the requirements as proposed in the NPRM and modified as a result of public comment and promulgated herein would be sufficient to mitigate and provide effective controls against diversion under this framework. As a result of the *Telemedicine Listening Sessions*, DEA's survey of state law, input received from public comments, and DEA's collaboration with HHS,

[54] As noted previously, DEA understands there are situations where the patient (for whom the prescription was written) may not be the individual picking up the prescription at the pharmacy. In these situations, DEA defers to the definition of "ultimate user" as found in 21 U.S.C. 802(27). As such, this regulation authorizes the pharmacist to verify the identity of the patient by accepting identification from any individual who falls under the definition of an "ultimate user" prior to filling a prescription.

DEA and HHS are promulgating 21 CFR 1306.51(b)(4) as an additional layer of protection against diversion. In sum, verifying the identity of the patient prior to dispensing is intended to ensure that the individual who is receiving the controlled substance medication from the pharmacist is the same individual for whom the prescription was issued.

During the *Telemedicine Listening Sessions*, seven presenters spoke on the importance of verifying a patient's identification prior to dispensing a controlled substance. Many of these presenters, who are practitioners themselves, indicated they already require a valid form of identification during a telemedicine encounter and require patients to provide proof of identification prior to prescribing. The practitioners subsequently keep a record of that identification. These presenters emphasized this policy helps to prevent illegal access to and misuse of medication. Since DEA and HHS believe that many prescribers already require proof of identification during the telemedicine encounter itself and since practitioners will be required to review PDMP data, DEA and HHS have promulgated this identification verification requirement for the pharmacist to provide an extra layer of protection against diversion by ensuring the prescription is being dispensed to the patient for whom the prescription was issued.

DEA and HHS further believe this requirement is a codification of widely employed current practice, as many state laws currently require pharmacists to verify the identity of the patient prior to dispensing. DEA conducted a review of the laws and regulations of all 50 states along with the District of Columbia and found that there are currently 43 states that have an identification requirement placed on pharmacists prior to filling a prescription. The situations in which identification verification is required varies: some states require verification outright, some states indicate that the pharmacist "may" verify identification, and some states only require verification if the patient is "unknown" to the pharmacist. Additionally, states vary as to what medications require verification: some states only require it for schedule II controlled substances, some for controlled substances found within schedules II-V, and some for ephedrine or pseudoephedrine products or precursors. Since several states already impose identification

verification requirements on pharmacists, DEA and HHS do not believe imposing this requirement on buprenorphine prescriptions will create an undue burden on pharmacists. Additionally, as DEA and HHS are not requiring government-issued photo identification, DEA and HHS believe providing the pharmacist with any documentation that sufficiently verifies identity will not be a burden on patients. Even though some states do not have statutes which mirror this new provision, DEA and HHS believe this provision largely codifies existing practice and assists in mitigating the risk of diversion.

DEA and HHS have thus chosen to include this requirement in the context of schedule III-V prescriptions for the treatment of OUD issued pursuant to this final rule, which permits prescriptions based on audio-only telemedicine encounters, in order to assist in reducing the risk of unauthorized individuals diverting buprenorphine for illicit purposes. DEA and HHS believe this additional layer of protection will help curtail any potential diversion. This identification requirement will help ensure that the patient using the buprenorphine prescription picked up at the pharmacy is the same patient that received the buprenorphine prescription from the audio-only telemedicine encounter.[55]

Should the identification requirements described in 21 CFR 1306.51(b)(4), or 42 CFR 12.3(b)(4), be held to be invalid or unenforceable as applied to any person or circumstance, or stayed pending agency action, it shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the identification requirements described in 21 CFR 1306.51(b)(4), or 42 CFR 12.3(b)(4), are invalid and unenforceable in all circumstances, in which event 21 CFR 1306.51(b)(4) and 42 CFR 12.3(b)(4), shall be severable from the remainder of 21 CFR 1306.51(b) and 42 CFR 12.3(b).

[55] As noted previously, DEA understands there are situations where the patient (for whom the prescription was written) may not be the individual picking up the prescription at the pharmacy. In these situations, DEA defers to the definition of "ultimate user" as found in 21 U.S.C. 802(27). As such, this regulation authorizes the pharmacist to verify the identity of the patient by accepting identification from any individual who falls under the definition of an "ultimate user" prior to filling a prescription.

D. Scope-Clarifying Provisions

The three remaining provisions of 21 CFR 1306.51 serve to clarify the scope of the final rule. The regulation at 21 CFR 1306.51(b)(5) provides that this final rule only applies to prescriptions issued for the treatment of OUD, even if the schedule III-V controlled substance approved by the FDA for use in the treatment of OUD also has other medical uses; for example, there are drugs containing buprenorphine that have been approved by the FDA to treat acute moderate-to-severe pain.[56] Though buprenorphine-containing drugs have other FDA-approved uses, the intention of this paragraph, and this final rule writ large, is to increase patient access to buprenorphine for the treatment of OUD. The regulation at 21 CFR 1306.51(b)(6) makes explicit that this final rule only applies to practitioners who are already registered, or otherwise exempt from registration, to dispense buprenorphine.

Finally, 21 CFR 1306.51(b)(7) provides that prescriptions issued pursuant to this final rule must otherwise comply with relevant DEA regulations. For example, a prescription issued under this final rule must be dated and signed and must include the patient's name and address, the name, strength, dosage, form and quantity of the drug, directions for use, and the practitioner's name, address, and DEA registration number of the practitioner.[57]

VIII. Regulatory Analyses

Executive Orders 12866, 13563, and 14094 (Regulatory Review)

DEA and HHS have determined that this rulemaking is a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, but it is not a section 3(f)(1) significant action. Accordingly, this final rule has been submitted to the Office of Management and Budget (OMB) for review. This final rule has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation; Executive Order 13563, "Improving Regulation and Regulatory

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[56] Poliwoda, *et al.* Buprenorphine and its formulations: a comprehensive review. Health Psychology Research. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9392838/. Published Aug. 20, 2022. Last accessed Ap. 20, 2024.
[57] 21 CFR. 1306.05(a).

Review," section 1(b), General Principles of Regulation; and Executive Order 14094, "Modernizing Regulatory Review."

DEA and HHS are amending their regulations to expand the circumstances under which DEA-registered practitioners are authorized to prescribe schedule III-V controlled substances approved by the FDA for the treatment of OUD via a telemedicine encounter, including an audio-only telemedicine encounter. Under these new regulations, after a prescribing practitioner reviews the patient's state PDMP data, the practitioner can prescribe an initial six-month prescription (split amongst several prescriptions totaling six calendar months) of such medications through audio-only means. This final rule does not affect practitioner-patient relationships in cases where an in-person medical evaluation has previously occurred.

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 COVID-19 PHE forms the basis for estimating the number of audio-only telemedicine encounters pursuant to this final rule.

Based on CMS claims data provided by the Department of Health & 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 were identified as being linked to buprenorphine Part D prescription fills.[58] These telemedicine services were rendered by 7,733 providers to 15,521 patients.[59] Of the 24,285 matching telemedicine services, 3,083 were billed with audio-only procedure codes, rendered by 1,806 providers to 2,548 patients.[60]

Based on the CMS data, the telemedicine services and associated buprenorphine prescriptions identified spiked at the beginning of the COVID-19 PHE and stayed relatively

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[58] "Monthly summary of telemedicine visits matched to a subsequent buprenorphine prescription between March 2020 and December 2021", HHS OIG, Mar. 2022.
[59] Ibid.
[60] 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 as or related to the billing or rendering provider of the telemedicine visit.

steady in 2021. Therefore, 2021 data is used to estimate the number of 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.[61] 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.[62] These telemedicine services were provided by 4,533 providers to 8,182 patients.[63] The 1,929,151 Part D buprenorphine claims associated with 1,332,353 beneficiaries equates to a ratio of 1.45[64] claims per beneficiary. Therefore, the 11,956 services represent an estimated 8,257 (11,956 / 1.45) initial prescriptions, which equates to 0.428 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.[65] 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 67,552 (0.428 percent x 15,782,652) initial prescriptions. DEA and HHS believe 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 final rule would affect practitioners prescribing schedule III-V controlled substances for the treatment of OUD using audio-video or audio-only technology and the patients being treated using this technology. Based on the analysis above, DEA and HHS expect the final rule to affect 67,552 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,

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[61] *Id*.
[62] *Id*.
[63] HHS OIG, May 2022.
[64] Numbers shown are rounded for presentation and clarity. Calculations using the provided numbers may not yield the same results due to this rounding.
[65] IQVIA, National Prescription Audit, September 2022.

equating to a ratio of approximately 1.80 patients per provider. Applying this ratio to the number of affected patients, DEA and HHS estimate 37,425 providers are affected by this final rule.

Impact on Physicians or Practitioners

The final rule would permit the use of audio-video or audio-only telemedicine provided that 1) the DEA-registered practitioner meets all requisite state and Federal registration requirements for both prescribing of controlled substances and engaging in the practice of telemedicine, 2) reviews state PDMP data regarding any controlled substance prescriptions issued to the patient and annotates this within the patient's EHR, 3) is limited to prescribing a six-month supply, across all such prescriptions, until the practitioner conducts an in-person medical evaluation or engages in other forms of authorized telemedicine, and 4) the pharmacist filling the prescription confirms the patient identity using a valid government-issued ID or other acceptable form of identification. Below is the analysis of the four requirements stated above:

1. DEA registration requirement: DEA and HHS assume all practitioners who would issue prescriptions via telemedicine encounters pursuant to this final 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 PDMP data and annotate within the EHR: Based on a 2018 study, it takes a practitioner 27 seconds to log in and 37 seconds to retrieve a report once logged in. The total time it takes to retrieve a PDMP report is roughly a minute (27 + 37 = 64 seconds) or 0.0167 of an hour (1/60).[66] Based on an estimated loaded hourly rate of $169.80,[67] the cost of a review of the PDMP is $2.83 ($169.80 x 0.0167). Applying

[66] Bachhuber MA, Saloner B, LaRochelle M, Merlin JS, Maughan BC, Polsky D, Shaparin N, Murphy SM. Physician Time Burden Associated with Querying Prescription Drug Monitoring Programs. Pain Med. 2018 Oct.

[67] 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 2023,* https://www.bls.gov/oes/current/oes291229.htm. The average hourly wage is $119.54, with benefits estimated at an additional 42.05% of the base wage. The load factor is calculated by comparing the benefits for private workers as a

this cost to 67,552 services, the total cost of PDMP review is $191,171 ($2.83 x 67,552), annually.[68] While many practitioners already check PDMP data prior to issuing a prescription for controlled substances for a variety of reasons, DEA and HHS will consider the full cost of checking the PDMP, $191,171, as a cost of this final rule to be conservative.

3. Limited to a six-month supply: Increasing the limit to a six-month supply under this final rule will give patients and prescribing practitioners more time to schedule follow-up appointments and reduce the likelihood of a relapse by a patient due to lack of medication, and will allow prescribing practitioners greater flexibility in managing their patient populations. While DEA and HHS do not have a basis to quantify the economic impact of the six-month supply limit, six months of medication for treatment is believed to be a net benefit compared to a baseline of zero to seven days of medication for treatment.
4. Pharmacist ID verification: Pharmacists must verify the patient's identity with either a state or Federal Government-issued photographic identification card, or another acceptable form of identification as listed above. The practice of checking identification when providing prescriptions is already well-established and widespread, and DEA expects any additional labor costs for pharmacists to be minimal.

In summary, the total cost to practitioners is $191,171 annually, which is the cost associated with checking PDMPs.

Impact on Patients

share of wages, 29.6% / 70.4% = 42.05%. Bureau of Labor Statistics, *Employer Costs for Employee Compensation – December 2023*, https://www.bls.gov/news.release/archives/ecec_03132024.pdf. The loaded wage was therefore $119.54 x 1.4205 = $169.80 per hour for private physicians, all other.

[68] Numbers shown are rounded for presentation and clarity. Calculations using the provided numbers may not yield exactly the same results due to this rounding

As discussed earlier, DEA and HHS estimate this final rule will affect 67,552 patients per year. DEA and HHS anticipate that patients will fall into one of two categories:

1) Patients who would otherwise not receive treatment or prescriptions for OUD absent this final rule. These patients have no other means to receive treatment. They are unable to visit a practitioner in-person or otherwise visit a practitioner engaged in the practice of telemedicine as defined in 21 CFR 1300.04(i), but are able to have an audio-video or audio-only telemedicine visit pursuant to this final rule.
2) Patients who would eventually receive treatment and prescriptions even absent the final rule. These patients are able to either visit a practitioner in-person or have a telemedicine visit with a practitioner engaged in the practice of telemedicine as defined in 21 CFR 1300.04(i); however, such visit is delayed for any variety of reasons, *e.g.*, long wait times for an appointment with the practitioner, personal hardship, etc. This final rule, if implemented, would create additional flexibilities, potentially allowing the patient to more quickly start treatment, absent this final rule.

DEA and HHS do not have a basis to estimate how many of the estimated 67,552 patients fall into the two groups. However, DEA and HHS anticipate 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 final rule. The impact on the second group would be the result of receiving treatment sooner than they would have without this final rule. For both groups, the impact could potentially be lifesaving. However, DEA and HHS do not have access to data that would permit them 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 costs 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.[69] 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 suggests 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.[70] At the costs listed above, the savings from the treatment of one person would cover the cost of buprenorphine treatment for ten others.

A study published in 2021 of the societal costs for OUD found that the "costs for opioid use disorder and fatal opioid overdose 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 overdose."[71] According to the report, in 2017 total non-fatal costs were $471 billion and total fatal costs were $550 billion and there were 2.1 million persons ages 12 years and older with OUD, and 47,000 fatal opioid overdoses.[72] 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 OUD of 2.1 million, the societal cost of non-fatal OUD is approximately $224,000 ($471 billion / 2.1 million) per person per year. While DEA and HHS are unable to quantify how many of the affected patients will be successfully treated for OUD or how many fatal opioid overdoses will be avoided as a result of this final rule, the potential economic benefit is disproportionally large compared to any cost associated with this rule.

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[69] *How much does opioid treatment cost?*, NIDA. (Apr. 13, 2021), https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-much-does-opioid-treatment-cost.
[70] Fairley *et al.*. *Cost-effectiveness of Treatments for Opioid Use Disorder*. JAMA Psychiatry (July 1, 2021).
[71] Florence C, Luo F, Rice K. The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017. *Drug Alcohol Depend*. 2021;218:108350. doi:10.1016/j.drugalcdep.2020.108350.
[72] *Id*.

Risk of Diversion

This final rule will reduce the requirements imposed on practitioners who wish to prescribe schedule III-V controlled substances as part of treatment for OUD. DEA and HHS understand that there is potential for the misuse of controlled substances approved for OUD treatment, which could be worsened by an increase in prescribing.

While this final rule may increase the risk of diversion, with the safeguards, DEA and HHS estimate this increased risk will be minimal. Requirements to check the state PDMP prior to issuance of a prescription, in-person requirements for follow-up appointments under current law, and the requirement that pharmacists verify identification prior to filling a prescription are expected to minimize the diversion of buprenorphine via telemedicine, including audio-only telemedicine. Practitioners already have the authority to prescribe buprenorphine. 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.[73] 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 slower among prescribers working in small nonmetropolitan counties than urban counties. Prescribers in rural counties were associated with low buprenorphine dispensing.[74] DEA and HHS believe that by providing increased access for rural areas, the benefits of increasing access to buprenorphine outweigh any added risk of diversion as the result of this rule.

Other Potential Costs

DEA and HHS also examined the cost of technology, both capital investment and operation expenses, in order to provide audio-only telemedicine in compliance with the final

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[73] 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.
[74] *Id.*

rule. DEA and HHS believe 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 final rule, and any additional time is expected to be minimal. EHRs may be updated in the future to reflect the final rule change, such as the integration of state PDMP data into a patient's EHR, but such changes are likely to be minor and included as part of any normal software update.

Summary

In summary, DEA and HHS estimate this rule would affect 37,425 providers and 67,552 patients, annually. DEA and HHS believe that this rule would increase patient access to buprenorphine 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 buprenorphine is expected to reduce the number of opioid drug poisonings annually, however, DEA and HHS 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 37,425 providers is $191,171 annually. DEA and HHS estimate recordkeeping requirements are likely to have a minimal impact because current recordkeeping practices are likely to meet the requirements imposed by this final 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 and HHS believe that any increase would be small and outweighed by the benefit to patients and reduction in the societal cost of OUD.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

DEA and HHS are committed to the principles of collaboration and consultation with Tribal governments, as demonstrated through its plans to conduct the appropriate Executive Order 13175 Tribal consultations and recognizes the significance of these consultations and their role in shaping regulations that impact Tribal communities. DEA and HHS have determined that there is a reasonable basis to believe that this rule may have Tribal implications, consistent with the definition in Executive Order 13175.

On June 13 and 27, 2024, DEA held virtual consultations with numerous Tribal governments and organizations. DEA and HHS considered the valuable insights from Tribal persons and organizations received during the comment period of the Buprenorphine NPRM from March 2023 (88 FR 12890), the *Telemedicine Listening Sessions* held in September 2023, and the most recent virtual consultations from June 2024. DEA's intentions have been to engage in consultations as appropriate throughout the rulemaking process, fostering a collaborative environment that respects the sovereignty and interests of Tribal governments, while enhancing the overall quality and effectiveness of DEA's regulatory efforts. As such, DEA and HHS have incorporated these concerns, as necessary, within this final rule to ensure DEA and HHS's regulations align with the diverse needs and considerations of various stakeholders impacted by DEA oversight.

Regulatory Flexibility Act

The Administrator and the Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), have 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 PHE, 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.[75] To continue the flexibilities of audio-only telemedicine prescribing of schedule III-V controlled substances approved by the FDA for the treatment of OUD beyond the COVID-19 PHE, DEA and HHS have promulgated regulations which would balance the need to increase patient access to legitimate medical treatment with the goal of providing effective controls against diversion. Thus, within this final rule, DEA and HHS are explaining the conditions in which a practitioner is authorized to prescribe buprenorphine via an audio-only telemedicine encounter, and the obligations which arise once a practitioner prescribes to patients.

Affected Persons

This final rule affects DEA-registered practitioners prescribing schedule III-V controlled substances for the treatment of OUD via telemedicine, including audio-only telemedicine. As stated above, DEA and HHS estimate this final rule will affect 37,425 DEA-registered practitioners and 67,552 patients annually. Because patients are individuals and not small entities, this analysis examines the impact of the final rule on affected practitioners and small entities that employ the affected practitioners.

With respect to practitioners, this final rule would permit the use of 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, and 3) is limited to prescribing a six-month supply, across all

[75] Prevoznik Letter.

such prescriptions, until the practitioner conducts an in-person medical evaluation or engages in other forms of telemedicine.

A significant number of practitioners work in offices and institutions that meet the RFA's definition of small entities. To estimate the number of affected entities, DEA and HHS first determined the North American Industry Classification System (NAICS) codes that most closely represent businesses that would employ the practitioners who would prescribe buprenorphine via an audio-only telemedicine encounter. Then, DEA and HHS 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).[76] The following business NAICS codes are estimated to represent businesses that employ the affected persons:

- 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 and HHS 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

[76] 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. Small Business Administration, *Firm Size Data*, https://www.sba.gov/advocacy/firm-size-data (last visited Apr 25, 2024). The data table is available at https://www.sba.gov/sites/default/files/files/static_us_11.xls (last visited April 25, 2024).

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.

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 and HHS estimate there are 161,286, 10,561, 6,523, 2,560, and 396 entities in the 621111, 621112, 621420, 622110, and 622210 industries. Based on the SUSB data on the firm sizes, DEA and HHS estimate there are 157,060, 10,392, 5,849, 1,047, and 204 small entities in the 621111, 621112, 621420, 622110, and 622210 industries. In total, DEA and HHS estimate there are 181,326 entities in the three potentially affected industries, of which 174,552 (96.3 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	5,849
622110-General Medical and Surgical Hospitals	2,560	41,500,000	1,047
622210-Psychiatric and Substance Abuse Hospitals	396	41,500,000	204
Total	**181,326**		**174,552**
Percent of Total			**96.3%**

* Not all decimal places shown.

From above, E.O. 12866 section, DEA and HHS estimate that audio-only telemedicine services will be provided by 37,425 providers to 67,552 patients, annually. Therefore, this final rule is estimated to affect 37,425 individual practitioners employed by some of the 174,552 small businesses in industries potentially affected by this final rule. Since some small entities will employ more than one practitioner, the number of affected small entities is expected to be less

than 37,425 and is expected to be concentrated in the 621111, 621112, and 621420 industries, with a combined total of 173,301 small entities. Therefore, the number of small entities affected by this final rule is estimated to be approximately 21.6%, which is a substantial number of the representative industries.

The cost of the final rule will impact the affected entities and small entities on a "per person" basis. Rather than estimating the number of practitioners per firm, then the cost per firm, then whether the cost is significant, DEA and HHS employed a more direct approach based on the following logic:

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

From 2021 data provided by CMS, DEA and HHS estimate that 67,552 patients received telemedicine services prior to receiving a prescription for buprenorphine. These services were provided by 37,425 separate providers, for approximately 1.8[77] patients per provider.

DEA and HHS estimate a non-loaded median hourly wage of $119.54[78] and $62.11[79] for potentially affected physicians and MLPs, respectively. Applying the hourly wage rates to the estimated time to apply, DEA and HHS estimate the labor cost per PDMP review is $1.99 ($119.54 x 1 / 60) and $1.04 ($62.11 x 1 / 60) per physician and MLP, respectively. The non-

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[77] Numbers shown are rounded for presentation and clarity. Calculations using the provided numbers may not yield exactly the same results due to this rounding

[78] Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2023, 29-1229 Physicians, All Others*, http://www.bls.gov/oes/current/oes291229.htm.

[79] Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2023, 29-1071 Physician Assistants*, http://www.bls.gov/oes/current/oes291071.htm.
Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2023, 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%).

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 $3.59 and $1.88, respectively.

The loaded unit cost of conducting a PDMP review is compared to the non-loaded annual wage rate for practitioners. Based on the Bureau of Labor Statistics' ("BLS") Occupational and Employment and Wages data, DEA and HHS estimate an average annual wage of $248,640 for physicians and $118,553 for MLPs. Unit costs of $3.59 and $1.88 represent 0.001 0.002 percent of those wages. Table 2 presents the details of the calculation.

Table 2: 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	119.54	0.0167	1.99	3.59	248,640	0.001%
MLP	62.11	0.0167	1.04	1.88	118,553	0.002%

The economic impact of additional time spent conducting PDMP reviews represents a small fraction (0.001 and 0.002 percent) of annual wages. DEA and HHS estimate this final rule will not have a significant economic impact on individual practitioners. The entities and small entities that employ the potentially affected practitioners are expected to generate enough revenue to pay their wages.

In addition to DEA-registered prescribers detailed above, the proposed rule would require pharmacists to verify the identification of any person receiving a prescription for Buprenorphine via an audio-only telemedicine visit. Identity verification is already a common practice and DEA believes that this would not impose any significant additional time or labor costs to the actions of pharmacist registrants. Therefore, DEA and HHS conclude this final 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 rule is minimal. Thus, DEA and HHS have 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.

Congressional Review Act

Pursuant to subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), the Office of Information and Regulatory Affairs has determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2).

Paperwork Reduction Act of 1995

This final rule is finalizing a new collection of information under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. As required under PRA, DEA proposed the creation of a new collection of information in the NPRM, which OMB assigned the following control number: 1117-NEW. 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 Final Rule*

1. Title: **Recordkeeping Related to PDMP**

OMB Control Number: **1117-NEW**

Form Number: **N/A**

DEA and HHS are amending their regulations by authorizing initiation of schedule III-V controlled medications approved for use in the treatment of OUD via telemedicine encounter, to include audio-only means. Prior to prescribing, the practitioner must review the PDMP data of

the state in which the patient is located and annotate the date and time that such a review was conducted in the patient's EHR. If the PDMP is unavailable or inaccessible for any reason, the prescribing practitioner must annotate the date and time that such a review was attempted in the patient's EHR and provide a reason as to why a review was unable to be completed.

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

- Number of respondents: 37,425
- Frequency of response: 1.804996
- Number of responses: 67,552
- Burden per response: 1 minute (0.01666667 hours)
- Total annual hour burden: 1,126 Hours

If you need a copy of the 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 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

Any additional comments on this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to OMB Control Number 1117-NEW.

List of Subjects

21 CFR Part 1306

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

42 CFR Part 12

Administrative practice and procedure.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on January 13, 2025, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

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Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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Miriam E. Delphin-Rittmon,
Assistant Secretary for Mental Health and Substance Use,
Department of Health and Human Services.

Drug Enforcement Administration

For the reasons set out above, the Drug Enforcement Administration amends 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

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

Authority: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

§§ 1306.28 through 1306.49 [Added and Reserved]

2. Add reserved §§ 1306.28 through 1306.49.

3. Add an undesigned center heading and § 1306.51 to read as follows:

Special Circumstances for Telemedicine Prescribing

§ 1306.51 Telemedicine prescribing of schedule III-V medications for the treatment of Opioid Use Disorder.

(a) For purposes of this section, terms defined in part 1300 of this chapter, elsewhere in this chapter, or in 21 U.S.C. 802 and 829 shall have the definitions set forth therein.

(b) A practitioner may issue a prescription for schedule III-V controlled substances listed in 42 CFR 8.12(h)(2) as approved by the Food and Drug Administration (FDA) for use in the treatment of Opioid Use Disorder (OUD), defined as the use of an effective medication such as buprenorphine to treat OUD, pursuant to a communication between the prescribing practitioner and the patient using an interactive telecommunications system, including an audio-only telecommunications system, as described in 42 CFR 410.78(a)(3), if the following conditions are met:

(1) Prescription drug monitoring program review. The prescribing practitioner must be authorized to access the applicable prescription drug monitoring program (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter. The prescribing practitioner shall review such 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. The prescribing practitioner shall ensure the date and time of such a review is annotated in the patient's electronic health record (EHR) or paper record. This review, or attempted review, must be conducted prior to issuing a prescription in a manner authorized under this section.

(2) Time limit. The practitioner may issue prescriptions to the patient pursuant to this section for a period not to exceed six calendar months beginning on the date the first prescription is issued. The practitioner may issue additional prescriptions to the patient for schedule III-V controlled substances approved by the FDA for use in the treatment of OUD either:

(i) After the prescribing practitioner has conducted at least one in-person medical evaluation of the patient, as defined in 21 U.S.C. 829(e)(2)(B); or

(ii) As otherwise authorized by 21 U.S.C. 829(e), including pursuant to any other form of telemedicine as defined in 21 U.S.C. 802(54) or pursuant to practices as determined by regulation issued pursuant to 21 U.S.C. 829(e)(3)(B).

(3) PDMP inaccessible or unavailable. If the PDMP data is inaccessible or unavailable for any reason, the prescribing practitioner shall annotate in the patient's EHR or paper record the date and time that an attempt to view the PDMP data was made and the reason the data could not be reviewed. A practitioner may prescribe a seven-day supply of medication and must perform another PDMP review before prescribing another seven-day supply. Each time the PDMP is reviewed or attempted to be reviewed, the date and time must be annotated in the patient's EHR. A seven-day supply prescribed pursuant to this paragraph (b)(3) counts toward the time limit described in paragraph (b)(2) of this section.

(4) Pharmacy identification requirement. The pharmacist shall verify the identity of the patient prior to filling a controlled substance prescription issued under the authority of this section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any qualifying "ultimate user" as defined in 21 U.S.C. 802(27) prior to filling the prescription.

(5) Prescription only for treatment of OUD. Controlled substance prescriptions issued pursuant to this section may only be issued for the treatment of OUD, and subject to the requirements of this section.

(6) Authorization to prescribe. The practitioner must be:

(i) Authorized under §§ 1301.11, 1301.12(a), and 1301.13(e)(1)(iv) of this chapter to prescribe the basic class of controlled substance specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d).

(7) Consistent with general prescription requirements. The issuance of the controlled substance prescription otherwise complies with the requirements set forth in this part.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set out above, the Department of Health and Human Services amends 42 CFR part 12 as follows:

PART 12 — TELEMEDICINE FLEXIBILITIES

4. The authority citation for part 12 continues to read as follows:

Authority: 21 U.S.C. 802(54)(G).

5. Add subpart B to read as follows:

Subpart B – Telemedicine Prescribing

§ 12.3 Telemedicine prescribing of schedule III-V medications for the treatment of Opioid Use Disorder.

(a) For purposes of this section, terms defined in 21 CFR part 1300, elsewhere in 21 CFR chapter II, or in 21 U.S.C. 802 and 829 shall have the definitions set forth therein.

(b) A practitioner may issue a prescription for schedule III-V controlled substances listed in 42 CFR 8.12(h)(2) as approved by the Food and Drug Administration (FDA) for use in the treatment of Opioid Use Disorder (OUD), defined as the use of an effective medication such as buprenorphine to treat OUD, pursuant to a communication between the prescribing practitioner and the patient using an interactive telecommunications system, including an audio-only telecommunications system, as described in 42 CFR 410.78(a)(3), if the following conditions are met:

(1) Prescription drug monitoring program review. The prescribing practitioner must be authorized to access the applicable prescription drug monitoring program (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter. The prescribing

practitioner shall review such data regarding any controlled medication prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The prescribing practitioner shall ensure the date and time of such a review is annotated in the patient's electronic health record (EHR) or paper record. This review, or attempted review, must be conducted prior to issuing a prescription in a manner authorized under this section.

(2) Time limit. The practitioner may issue prescriptions to the patient pursuant to this section for a period not to exceed six calendar months beginning on the date the first prescription is issued. The practitioner may issue additional prescriptions to the patient for schedule III-V controlled substances approved by the FDA for use in the treatment of OUD either:

(i) As authorized by 21 U.S.C. 829(e), including pursuant to any other form of telemedicine as defined in 21 U.S.C. 802(54) or pursuant to practices as determined by regulation issued pursuant to 21 U.S.C. 829(e)(3)(B); or

(ii) After the prescribing practitioner has conducted at least one in-person medical evaluation of the patient, as defined in 21 U.S.C. 829(e)(2)(B).

(3) PDMP inaccessible or unavailable. If the PDMP data is inaccessible or unavailable for any reason, the prescribing practitioner shall annotate in the patient's EHR or paper record the date and time that an attempt to view the PDMP data was made and the reason the data could not be reviewed. A practitioner may prescribe a seven-day supply of medication and must perform another PDMP review before prescribing another seven-day supply. Each time the PDMP is reviewed or attempted to be reviewed, the date and time must be annotated in the patient's EHR. A seven-day supply prescribed pursuant to this paragraph (b)(3) counts toward the time limit described in paragraph (b)(2) of this section.

(4) Pharmacy identification requirement. The pharmacist shall verify the identity of the patient prior to filling a controlled medication prescription issued under the authority of this

section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any qualifying "ultimate user" as defined in 21 U.S.C. 802(27) prior to filling the prescription.

(5) Prescription only for treatment of OUD. Controlled medication prescriptions issued pursuant to this section may only be issued for the treatment of OUD.

(6) Authorization to prescribe. The practitioner must be:

(i) Authorized under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled medication specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d).

(7) Consistent with general prescription requirements. The issuance of the controlled substance prescription otherwise complies with the requirements set forth in 21 CFR part 1306.

[FR Doc. 2025-01049 Filed: 1/15/2025 8:45 am; Publication Date: 1/17/2025]