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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1304, and 1306

[Docket No. DEA–407]

RIN 1117–AB40

Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 and Drug Enforcement Administration's (DEA) implementing regulations, after a patient and a practitioner have had an in-person medical evaluation, that practitioner may use telehealth to prescribe that patient any prescription for a controlled medication that the practitioner deems medically necessary. The Ryan Haight Act and DEA's implementing regulations do not apply to other forms of telemedicine, telehealth, or telepsychiatry that are not otherwise addressed in the Controlled Substances Act. This proposed rule applies only in limited circumstances when the prescribing practitioner wishes to prescribe controlled medications via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before March 31, 2023. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget on or before March 31, 2023.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–407'' on all correspondence, including any attachments.

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

Paper Comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

Paperwork Reduction Act Comments: All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB40/Docket No. DEA–407.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

Comments with confidential information, which should not be made available for public inspection, should be submitted as written/paper submissions. Two written/paper copies should be submitted. One copy will include the confidential information with a heading or cover sheet that states ''CONTAINS CONFIDENTIAL INFORMATION.'' DEA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy should have the claimed confidential information redacted/blacked out. DEA will make this copy available for public inspection online at *https://www.regulations.gov/*. Other information, such as name and contact information, that should not be made available, may be included on the cover sheet but not in the body of the comment, and must be clearly identified as ''confidential.'' Any information clearly identified as ''confidential'' will not be disclosed except as required by law.

I. Executive Summary

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (''Ryan Haight Act'') [1] amended the Controlled Substances Act (''CSA'') in part by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet. While the Ryan Haight Act amended the CSA to generally require that the dispensing of controlled substances by means of the internet be predicated on a valid prescription involving at least one in-person medical evaluation, it also established seven distinct categories [2] of telemedicine pursuant to which a practitioner may prescribe controlled medications for a patient despite never having evaluated that patient in person, provided that, among other things, such practice is in accordance with applicable Federal and State laws.[3] Notably, the Ryan Haight Act does not limit a practitioner's ability to prescribe controlled medications for a patient after there has been at least one in-person medical evaluation. This

[1] Public Law 110–425 (2008). Because the Ryan Haight Act amended the CSA, references in this document will generally be to the CSA, except where additional specificity will improve clarity.

[2] The seven categories are: (1) Treatment in a hospital or clinic; (2) Treatment in the physical presence of a DEA-registered practitioner; (3) Treatment by Indian Health Service or Tribal practitioners; (4) Treatment during a public health emergency as declared by the Secretary of Health and Human Services; (5) Treatment by a practitioner who has obtained a ''special registration''; (6) Treatment by Department of Veterans Affairs practitioners during a medical emergency; and (7) Other circumstances specified by regulation. 21 CFR 1300.04(i)(1)–(7).

[3] 21 U.S.C. 802(54)(A)–(G).

rulemaking would authorize telemedicine pursuant to 21 U.S.C. 802(54)(G) in those instances where (1) the prescribing practitioner has not conducted an in-person medical evaluation with the patient; (2) the prescription was issued pursuant to a telemedicine encounter and (3) the telemedicine encounter results in a prescription for controlled medications. The regulatory requirements proposed in this rulemaking would only apply to practitioners who issue prescriptions pursuant to telemedicine encounters authorized under 802(54)(G). These regulatory requirements would not apply to telemedicine practiced pursuant to (A)–(F). Similarly, as described below, the Ryan Haight Act and DEA's implementing regulations do not apply to other forms of telemedicine, telehealth, or telepsychiatry that are not otherwise defined in the CSA.

The Ryan Haight Act intended to address the threat to public health and safety caused by physicians who prescribed controlled medications via the internet without establishing a valid doctor-patient relationship through such fundamental steps as performing an in-person medical evaluation of a patient. Prior to the enactment of the Ryan Haight Act, the internet was being exploited to facilitate the unlawful distribution of controlled substances through rogue websites. These rogue websites fueled the misuse of controlled prescription medications, such as hydrocodone and oxycodone, thereby contributing to increased drug poisonings and other harmful health, social, and economic consequences.

The Ryan Haight Act was named for a California high school student who died in 2001 from a drug poisoning resulting from a controlled prescription medication he obtained from a rogue online pharmacy. That rogue online pharmacy allowed customers, like Ryan and others, to obtain controlled medications without an in-person medical evaluation by the prescriber. In Ryan's case, and in many others, the ''[e]ase of access to the internet, combined with lack of medical supervision, . . . led to tragic consequences in the online purchase of prescriptions for controlled substances.'' [4]

The Ryan Haight Act also authorizes the Administrator, in conjunction with the Secretary of Health and Human Services (''Secretary''), to promulgate rules that would allow practitioners to treat patients via telemedicine without having had an in-person evaluation in certain circumstances, including where such telemedicine practice is in accordance with applicable Federal and State laws, uses an approved telecommunications system, and is ''conducted under . . . circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.'' [5] Pursuant to this authority, and in concert with the Department of Health and Human Services (''HHS''), DEA and HHS are hereby proposing to amend 21 CFR parts 1300, 1304, and 1306 to specify the circumstances under which practitioners may prescribe controlled medications, pursuant to 21 U.S.C. 802(54)(G), to patients whom the practitioner has never evaluated in person, including that (1) such prescriptions be in accordance with applicable Federal and State [6] laws; and (2) such practitioners possess an active DEA dispensing registration issued pursuant to 21 CFR 1301.13(e)(1)(iv) in the State in which the practitioner is located (unless exempted).

DEA proposes to require practitioners to keep detailed records regarding prescriptions issued as a result of a telemedicine encounter at the registered location of their 21 CFR 1301.13(e)(1)(iv) registration, in digital or paper form that is readily accessible.[7] Under the proposed rule, a prescribing practitioner must include a notation on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription has been issued via a telemedicine encounter.[8]

The proposed rule allows for the prescription of non-narcotic [9] schedule III–V controlled medications when certain circumstances are met. For example, the proposed rule allows for the prescribing of schedule III–V non-narcotic controlled medications when a practitioner, prior to issuing a prescription, reviews recent prescription drug monitoring program (''PDMP'') data, *i.e.,* data made available by the State in which the patient is located, regarding controlled medication prescriptions issued to the patient in the last year or, if less than a year of data is available, the entire available period.[10]

Though excluded from the provisions of this proposed rule that relate to the prescribing of non-narcotic schedule III–V controlled medications, the prescribing of certain narcotic medications such as buprenorphine via telemedicine for the treatment of opioid use disorder is the subject of another notice of proposed rulemaking titled ''Expansion of induction of buprenorphine via telemedicine encounter'' (RIN 1117–AB78), published elsewhere in this issue of the **Federal Register**, that would expand the circumstances under which the induction of buprenorphine for ''maintenance treatment'' [11] and ''detoxification treatment'' [12] of opioid use disorder via telemedicine can occur.

Additionally, the proposed rule generally would subject a practitioner practicing telemedicine to initially limit prescriptions for a controlled medication issued to a patient to a 30-day supply. A practitioner would be allowed to issue multiple prescriptions for the same patient, but would only be allowed to prescribe an amount less than or equal to a total quantity of a 30-day supply of the controlled medication.[13] Thereafter, to continue prescribing to that patient, within 30 days, the prescribing practitioner would be required to examine the patient in person. Alternatively, if the prescribing practitioner receives a qualifying telemedicine referral for the patient in the manner described herein, the practitioner may rely on the referring practitioner's in-person medical evaluation in order to prescribe the controlled substance via telemedicine.[14]

II. Legal Authority and Background

DEA implements and enforces 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 to end. These regulations are designed to ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed

[4] S. Rep. No. 110–521, at 5 (2008).

[5] 21 U.S.C. 802(54)(G).

[6] Under the CSA, ''State'' means ''a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.'' 21 U.S.C. 802(26).

[7] *Proposed* 21 CFR 1304.04(i).

[8] *Proposed* 21 CFR 1306.05(i).

[9] Under the CSA, narcotic drugs are drugs that contain opiates, cocaine, or ecgonine, as well as certain related plant material. 21 U.S.C. 802(17). This definition includes buprenorphine, a narcotic drug that has been approved by the FDA for maintenance and detoxification treatment of opioid use disorder.

[10] *Proposed* 21 CFR 1306.31(e)(1).

[11] 21 U.S.C. 802(29).

[12] 21 U.S.C. 802(30).

[13] *Proposed* 21 CFR 1306.31(c)(2).

[14] *Proposed* 21 CFR 1300.04(k), 1306.31(d).

system of control for manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA, unless they meet an exemption, pursuant to 21 U.S.C. 822. ''Dispense'' in the context of this rulemaking means to deliver a controlled substance to an ultimate user, which includes the prescribing of a controlled substance.[15] The CSA further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA.[16]

The Ryan Haight Act amended the CSA by, among other things, adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet. The Ryan Haight Act applies only in limited circumstances where the prescribing practitioner wishes to prescribe controlled medications via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription. As described below, the Ryan Haight Act and DEA's implementing regulations do not apply to other forms of telemedicine, telehealth, or telepsychiatry that are not otherwise defined in the CSA.

As indicated above, in 21 U.S.C. 829(e), the Ryan Haight Act generally requires an in-person medical evaluation prior to the prescription of controlled substances. Section 829(e), however, also provides an exception to this in-person medical evaluation requirement where the practitioner is ''engaged in the practice of telemedicine'' [17] within the meaning of the Ryan Haight Act (21 U.S.C. 802(54)). To fall within this definition of the ''practice of telemedicine,'' the practice first must be ''in accordance with applicable Federal and State laws'' and use ''a telecommunications system referred to in [42 U.S.C. 1395m(m)].'' [18] Title 42 U.S.C. 1395m(m) references, but does not define, such telecommunications systems. The Centers for Medicare & Medicaid Services (''CMS''), however, has promulgated regulations for the Medicare program implementing those provisions, and those regulations do define ''interactive telecommunications system.'' In particular, 42 CFR 410.78(a)(3) states: ''Interactive telecommunications system means, except as otherwise provided in this paragraph, 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. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology.'' [19]

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

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

Accordingly, as set forth in 21 U.S.C. 802(54), the Ryan Haight Act's definition of the ''practice of telemedicine'' includes seven distinct categories of telemedicine that Congress determined were appropriate to allow for the prescribing of controlled substances despite the practitioner never having evaluated the patient in person.[20] For example, to fall under the first category of the ''practice of telemedicine,'' the patient must be physically located in a DEA-registered hospital or clinic, and the remote prescribing practitioner generally must be properly registered with DEA in the State in which the patient is located.[21] To fall under the second category, the patient generally must be being treated by, and in the physical presence of, a practitioner who is registered with DEA in the State in which the patient is located.[22]

The definition of the ''practice of telemedicine'' also includes as one of its seven categories a practice ''being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.'' [23] Pursuant to this authority, DEA and HHS are hereby proposing a rule specifying the circumstances under which practitioners may prescribe controlled substances to patients whom the practitioner has never evaluated in person. This rulemaking would not impose any new requirements on practitioners authorized to practice telemedicine under other statutory exceptions in 21 U.S.C. 802(54), such as Indian Health Service (''IHS'') and Tribal practitioners, who are authorized to engage in the practice of telemedicine under a different statutory paragraph,

[15] 21 U.S.C 802(10).

[16] 21 U.S.C. 871(b), 958(f).

[17] *Id.* 829(e)(3)(A).

[18] *Id.* 802(54).

[19] *See infra* for discussion of the use of audio-only technology in telemedicine under this proposed rule.

[20] The fifth such category contemplates the prescription of controlled substances via telemedicine encounters conducted by practitioners to whom the DEA Administrator has issued ''special registration[s].'' *See* 21 U.S.C. 802(54)(E). In the SUPPORT for Patients and Communities Act (SUPPORT Act), signed into law on October 24, 2018, Congress required DEA to promulgate regulations concerning such special registrations. *See id.* 831(h)(2). This instance of rulemaking, which sets forth circumstances under which telemedicine encounters may result in the prescription of controlled substances without an in-person evaluation and also provides safeguards for such prescriptions, is consistent with, and fulfills, DEA's obligations under both the Ryan Haight Act and the SUPPORT Act.

[21] *Id.* 802(54)(A). If practitioners are exempted from registration in all States under DEA regulations or are employees or contractors of the VA and meet certain conditions, they do not have to be registered.

[22] *Id.* 802(54)(B). If practitioners are exempted from registration in all States under DEA regulations or are employees or contractors of the VA and meet certain conditions, they do not have to be registered.

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

802(54)(C). The proposed changes to DEA's regulations herein are consistent ''with effective controls against diversion and otherwise consistent with the public health and safety'' pursuant to 21 U.S.C. 802(54)(G).

DEA is proposing these regulatory changes in concert with HHS, and HHS was consulted in the creation of these regulatory provisions and concurs with this proposed rulemaking. HHS also has advised DEA that no additional rulemaking by HHS is necessary as it pertains to the promulgations of these provisions pursuant to 21 U.S.C. 802(54)(G).

III. Section-by-Section Discussion of Proposed Rule

This proposed rule describes the circumstances under which, pursuant to 21 U.S.C. 802(54)(G), a practitioner may prescribe controlled substances to patients whom the practitioner has not evaluated in person.

A. Part 1300: Definitions

In section 21 CFR 1300.04, DEA is proposing to add definitions for the following terms: practice of telemedicine; qualifying telemedicine referral; telemedicine encounter; telemedicine prescription; and telemedicine relationship established during the COVID–19 public health emergency. In addition, DEA proposes to amend its regulations to clarify one aspect of the definition of the practice of telemedicine, and to remove an expired paragraph that provided a temporary definition of the practice of telemedicine.

DEA proposes to amend its regulatory definition of the term ''practice of telemedicine'' to better explain, but not alter, its requirements. The current regulatory definition, 21 CFR 1300.04(i), follows the Ryan Haight Act's statutory definition, 21 U.S.C. 802(54), by requiring that the practice of telemedicine take place ''using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)).'' As noted above, 42 U.S.C. 1395m(m) references, but does not define, such telecommunications systems. CMS, however, has promulgated regulations for the Medicare program implementing those provisions that define ''interactive telecommunications system,'' 42 CFR 410.78(a)(3), and it is to this CMS definition that the Ryan Haight Act and DEA regulatory definitions of the ''practice of telemedicine'' ultimately refer.

The proposed rule would revise the DEA regulatory definition of ''practice of telemedicine'' [24] in accordance with this CMS regulation to require that telemedicine take place ''using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3).'' This would not be a substantive change to DEA's regulations, but merely a clarification of the existing requirements—updating the language in 21 CFR 1300.04 to save readers from having to cross-reference 42 U.S.C. 1395m(m) (and then ascertain what CMS regulations implement it) to determine the nature of the telecommunications systems that can be used to engage in the practice of telemedicine under DEA regulations.

That said, CMS recently revised 42 CFR 410.78(a)(3),[25] and some explanation of revised § 410.78(a)(3)—and its implications for this proposed rule—may be useful. Previously, § 410.78(a)(3) had limited an ''interactive telecommunications system'' to ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.'' Revised § 410.78(a)(3) retains this requirement of both audio and video real-time communication between the patient and the distant practitioner in most circumstances: as the CMS rule revising § 410.78(a)(3) stated, ''[T]wo-way, audio/video communications technology is the appropriate, general standard for telehealth services . . . .'' [26]

CMS's revised definition of ''interactive telecommunications systems,'' however, now also includes two-way, real-time *audio-only* communication technology under certain limited circumstances, limitations that are designed to maintain audio-video equipment as the general standard and only authorize audio-only equipment when both necessary and appropriate. First, to allow the use of audio-only equipment, the medical services at issue must be ''furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder.'' CMS recognized that, for many mental health services, visualization between the patient and clinician may be less critical to provision of the service: ''[M]ental health services are different from other services because they principally involve verbal exchanges between patient and practitioner.'' [27]

CMS also responded to comments requesting that audio-only technology be permitted for a broader scope of Medicare telehealth services. CMS distinguished ''services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder'' from other services, and specified that the scope of the audio-only policy is limited to mental health disorders.[28] CMS also acknowledged that ''[T]here may be particular instances where visual cues may help a practitioner's ability to assess and treat patients with mental health disorders, especially where opioids or mental health medications are involved . . . .'' [29]

Second, to allow the use of audio-only equipment, the mental health services must be provided ''to a patient in their home.'' CMS reasoned that other sites at which a patient generally receives telehealth services are ''medical settings that are far more likely to have access to reliable broadband internet service. When a patient is located at one of these . . . sites, access to care is far less likely to be limited by access to broadband that facilitates a video connection. In contrast, access to broadband, devices, and user expertise is less likely to be available at a patient's home.'' [30] CMS, however, adopted a flexible understanding of ''home'': ''[O]ur definition of home can include temporary lodging such as hotels and homeless shelters as well as locations a short distance from the [patient's] home'' (if the patient, ''for privacy or other personal reasons, chooses to travel a short distance ways from the exact home location during a telehealth service . . . .'').[31]

Third, to allow the use of audio-only equipment, the distant site physician or practitioner must be ''technically capable'' of meeting the usual two-way, audio-video interactive communication standard. And, relatedly, the patient must ''not [be] capable of, or . . . not consent to, the use of video technology.'' In other words, ''because it is generally appropriate to require the use of two-way, real-time audio/video communications technology,'' [32] the distant practitioner engaging in telehealth must make the option of

[24] *Proposed* 21 CFR 1300.04(j).

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

[26] *Id.* at 65060.

[27] *Id.* at 65061.

[28] *Id.*

[29] *Id.*

[30] *Id.* at 65060.

[31] *Id.* at 65059.

[32] *Id.* at 65062.

audio-visual communication available to the patient. The audio-only option may only be used if the patient ''is unable to use, does not wish to use, or does not have access to two-way, audio/video technology.'' [33]

Because the proposed rule's definitions of ''practice of telemedicine'' and ''telemedicine encounter'' [34] are linked to 42 CFR 410.78(a)(3)'s definition of ''interactive telecommunications system,'' they would also incorporate that definition's requirements. Accordingly, under most circumstances, a remote practitioner would have to be using both audio and video equipment permitting two-way, real-time interactive communication with a patient to be part of a ''telemedicine encounter'' in the course of the ''practice of telemedicine.'' If that practitioner, however, met all of § 410.78(a)(3)'s various requirements for using audio-only equipment (mental health services, etc.), then that practitioner could engage in the ''practice of telemedicine'' and conduct ''telemedicine encounters'' as defined in the proposed rule using audio-only equipment—so long as that practitioner also complied with the proposed rule's other requirements and doing so was medically appropriate and also complied with relevant State and Federal law.

The current regulatory definition of the ''practice of telemedicine'' requires that it be conducted ''in accordance with applicable Federal and State laws.'' [35]

Proposed paragraph (k) would define what constitutes a ''qualifying telemedicine referral'' for the purposes of this rulemaking. This definition would clarify the nature of the medical evaluation relationship that is required for the referral to enable the prescribing practitioner to issue prescriptions in excess of the 30-day limit as described in proposed § 1306.31(c)(2). This definition would require the referring practitioner to have conducted at least one medical evaluation of the patient in the physical presence of the referring practitioner, without regard to whether portions of the evaluation are conducted by other practitioners. This means that if multiple practitioners were physically present during the medical evaluation, they would all have the ability to issue a qualifying telemedicine referral under this section as long as they otherwise complied with DEA regulations. Any other referrals, such as those predicated on a telemedicine visit exclusively, would not constitute a qualifying telemedicine referral. Both the referring practitioner and the prescribing practitioner would be required to maintain records of the referral.

DEA proposes to add paragraph (n) to define the term ''telemedicine prescription'' as a prescription issued pursuant to § 1306.31 by a physician, or a ''mid-level practitioner'' as defined in 21 CFR 1300.01(b), engaging in the practice of telemedicine as defined in 21 CFR 1300.04(j).

DEA proposes to add paragraph (o) to add a definition of the term ''telemedicine relationship established during the COVID–19 public health emergency.'' Such a relationship exists if the practitioner has not conducted an in-person medical evaluation of the patient and has prescribed one or more controlled medications based on telemedicine encounters during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 and pursuant to the designation pursuant to that public health emergency on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under section 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States.[36] Other proposed provisions, discussed in detail below, would use this defined term to facilitate a six-month transition of doctor-patient relationships from the use of telehealth prescribing flexibilities established during the COVID–19 public health emergency to the use of the prescribing authority set forth in this proposed rule.

Finally, DEA proposes a technical amendment to remove from its regulations the ''[t]emporary definition of the practice of telemedicine'' found at 21 CFR 1300.04(j).

B. Part 1304: Records of Registrants

As the Ryan Haight Act recognized, the remote prescribing of controlled medications through the internet to patients who have not been seen in person by the prescriber presents a heightened risk of diversion. Thus, DEA is proposing to amend 21 CFR part 1304 to impose certain additional recordkeeping requirements for controlled substance prescriptions issued pursuant to telemedicine encounters.[37] These proposed requirements would significantly enhance DEA's ability to both detect and investigate the potential misuse of telemedicine to prescribe controlled substances for other than legitimate medical purposes.

In particular, proposed § 1304.03(i) would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating the date the prescription was issued; the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; the address at which the practitioner, and the city and State in which the patient, is located during the telemedicine encounter; if issued through a qualifying telemedicine referral, the name and National Provider Identifier (''NPI'') of the referring practitioner, a copy of the referral and any communications shared pursuant to § 1306.31(d)(3)(i)–(iii); and all efforts to comply to access the PDMP system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database). Proposed § 1304.03(j) would require practitioners to maintain copies of all qualifying telemedicine referrals they issue.

Proposed § 1304.03(k) would set requirements for maintaining records related to medical evaluations conducted by a prescribing practitioner with the patient and another DEA practitioner physically together at the other end of an audio-video link pursuant to § 1306.31(d)(2). Paragraph (1) would require an individual practitioner who participates in such a medical evaluation as the prescribing practitioner to maintain, for each such medical evaluation, the data and time of

[33] *Id.* at 65060.

[34] *Proposed* 21 CFR 1300.04().

[35] 21 CFR 1300.04(i). The CSA and DEA's regulations only define the ''practice of telemedicine'' for their own purposes. DEA is not attempting to define what constitutes appropriate telemedicine in other contexts. Thus, the proposed rule would not determine when substances that are not controlled may be appropriately prescribed via telemedicine or the nature of appropriate remote medical treatment more generally. Moreover, the proposed rule would not create any additional regulatory requirements for the other categories of telemedicine authorized by the CSA under 21 U.S.C. 802(54).

[36] *See* Xavier Becerra, Renewal of Determination That a Public Health Emergency Exists; William T. McDermott, *DEA Dear Registrant letter,* Drug Enforcement Administration (March 25, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf; see also* Thomas W. Prevoznik, *DEA Dear Registrant letter,* Drug Enforcement Administration (March 31, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.*

[37] DEA notes that practitioners who are authorized to engage in the practice of telemedicine under other statutory authority in 21 U.S.C. 802(54), such as IHS practitioners authorized under 21 U.S.C. 802(54)(C), would not be subject to these proposed additional recordkeeping requirements.

the evaluation; the NPI of the DEA-registered healthcare worker physically present with the patient; the address at which the prescribing practitioner is located during the telemedicine encounter; and the address at which the DEA-registered healthcare worker is physically present with the patient during the medical evaluation. Likewise, paragraph (2) requires an individual practitioner who participates in such a medical evaluation as the DEA-registered healthcare worker physically present with the patient to maintain, for each such medical evaluation, the data and time of the evaluation; the address at which the prescribing practitioner is located during the telemedicine encounter; the NPI of the prescribing practitioner; and the address at which the DEA-registered healthcare worker is physically present with the patient during the medical evaluation.

Proposed 1304.04(i) would require all such records to be maintained at the registered location of the practitioner's 21 CFR 1301.13(e)(1)(iv) dispensing registration. Put differently, a practitioner using telemedicine to prescribe controlled medications may operate out of multiple locations. Thus, to avoid any confusion and ensure that DEA investigators are able to locate the records when necessary, proposed § 1304.04(i) would specify that the required records must be maintained at the registered location of the practitioner's registration under 21 CFR 1301.13(e)(1)(iv) in digital or paper form that is readily accessible.

If DEA instead were to require records to be maintained in the State(s) where telemedicine patients are located, practitioners could theoretically have to maintain telemedicine records in over 50 different locations (if they had a nationwide practice), including states in which they may not retain a physical office location. This would be burdensome for both the practitioner and DEA investigators. In particular, the consolidation of the records under this provision is necessary for DEA investigators because the detection of patterns of diversion is often contingent upon looking comprehensively at a practitioner's prescribing habits and recordkeeping. This process would become impracticable if investigators had to obtain records from 50 different locations across the country, resulting in significant administrative waste. Ensuring ready access to this information in a consolidated manner in a central location during investigations would facilitate DEA's ability to detect patterns of potential illegitimate prescribing and thus enhance its ability to prevent further diversion of controlled medications. Practically, DEA does not anticipate that the consolidation of the records would be overly burdensome for practitioners as the majority of practitioners now maintain electronic records.

Requiring this recordkeeping would also serve to reinforce the obligation of practitioners who practice telemedicine to prescribe within the limited circumstances set forth in the proposed rule. Moreover, medical records that include the name of any DEA-registered healthcare worker in the physical presence of the patient during a telemedicine encounter would be an important tool in subsequent investigations as that information is often not otherwise recorded by the prescribing practitioner. Requiring the NPI would ensure physically present DEA-registered healthcare workers are properly identified, as many States may have several practitioners with the same name. Investigations can often occur years after the telemedicine encounter, and these recordkeeping provisions would reduce the risk of investigators missing crucial information because of fading memories or faulty/incomplete records.

C. Part 1306: Prescriptions

DEA proposes to amend part 1306 by adding § 1306.05(i), which would require all telemedicine prescriptions issued pursuant to § 1306.31 to include on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription was issued via a telemedicine encounter.

The proposed rule would also amend part 1306 by adding § 1306.31, which would provide a number of requirements that a practitioner would have to satisfy to issue a prescription for a controlled substance as a result of a telemedicine encounter. Consistent with the text of the Ryan Haight Act and other parts of the CSA, controlled substances only may be prescribed for legitimate medical purposes by practitioners acting in the usual course of professional practice. Proposed § 1306.31(a)(1) is one way the proposed rule fulfills that mandate.

First, proposed § 1306.31(a)(1) would make clear that telemedicine may only be used to issue a prescription if that prescription is issued pursuant to a telemedicine encounter and is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. As discussed above, the proposed rule would define ''telemedicine encounter'' as a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3), while the practitioner is engaged in the practice of medicine as defined in proposed § 1300.04(j).[38] Thus, under proposed § 1306.31(a)(1), for a prescription to be issued to a patient using telemedicine, among other things, the prescription would need to arise out of a telemedicine communication directly between the prescribing practitioner and that patient.[39]

Proposed § 1306.31(a)(2) would require all practitioners who wish to engage in the practice of telemedicine to be located in a State, Territory, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico at the time the relevant telemedicine encounter occurs. In other words, a practitioner cannot use telemedicine to prescribe controlled medications while that practitioner is located outside the United States.

Proposed § 1306.31(a)(3)(i) would require that a practitioner using telemedicine to prescribe a controlled substance be authorized to prescribe that basic class of controlled substance under registrations in the State where the practitioner is located, as well as the State where the patient is located.

Proposed § 1306.31(a)(4), like proposed § 1306.05(i) described above, would require the practitioner to include on a prescription issued pursuant to a telemedicine encounter that the prescription has been issued based on a telemedicine encounter. Thus, when reviewing pharmacy prescription records, DEA investigators could readily distinguish prescriptions issued pursuant to telemedicine encounters from those issued using their dispensing registrations for non-telemedicine prescriptions—giving investigators greater ability to detect abusive patterns in the use of telemedicine.

As discussed above, and as stated in proposed § 1306.31(c)(1)(i), the proposed rule would only authorize practitioners to use telemedicine to prescribe non-narcotic controlled substances in schedules III–V. Excluding schedule II controlled substances and all narcotic controlled substances [40] is consistent with the limitations Congress placed on the use

[38] *Proposed* 1300.04(o).

[39] *Proposed* 1306.31(a)(6) also broadly requires that a practitioner comply with the requirements of State law when prescribing pursuant to a telemedicine encounter.

[40] As noted above, DEA is addressing the prescribing of certain narcotic substances via telemedicine for the treatment of opioid use disorder in a separate rulemaking.

of telemedicine. Congress directed DEA and HHS to authorize the use of telemedicine only when doing so is ''consistent with effective controls against diversion and otherwise consistent with the public health and safety'' 21 U.S.C. 802(54)(G), but permitted DEA and HHS to determine the precise circumstances that were most appropriate. Given the ongoing opioid epidemic at the time of publishing, DEA believes that allowing for the prescription of any schedule II substances or the general prescription of narcotic controlled substances [41] as a result of telemedicine encounters would pose too great a risk to the public health and safety. However, if the prescribing practitioner has received a qualifying telemedicine referral under proposed § 1300.04(k) for that patient from a referring practitioner who has conducted a medical evaluation as described in paragraph proposed § 1306.31(d)(3), the prescription may be issued for any controlled substance that they are otherwise authorized to prescribe under applicable laws and regulations.

Proposed § 1306.31(c)(2) would also combat diversion by requiring that the prescribing of controlled substances as a result of a telemedicine encounter be initially time-limited for each patient (unless conducted by VA practitioners). Practitioners could prescribe controlled medications to a patient using telemedicine only for a period of 30 days before a medical evaluation of the nature described below would be required, starting from the date of issuance of the first prescription pursuant to a telemedicine encounter. The prescribing practitioner would be permitted to issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a 30-day supply of the controlled medication. Once that prescribing period ends, if the patient does not receive a medical evaluation as described below, the practitioner would no longer be able to prescribe any controlled medication to that patient as a result of a telemedicine encounter until the medical evaluation has taken place.

To continue prescribing beyond the 30-day window, the prescribing practitioner would have to either see the patient for an in-person medical evaluation provided in § 1306.31(d)(1)—removing the prescription from the bounds of the Ryan Haight Act's telemedicine restrictions—or receive a medical evaluation under one of the schemes provided in § 1306.31(d)(2) and (d)(3). Under the scheme provided in (d)(2), the patient would not be in the physical presence of the prescribing practitioner, but the patient would have to be being treated by, and in the physical presence of, another DEA-registered practitioner. This other non-prescribing practitioner would have to be acting in the usual course of professional practice. Also, the prescribing practitioner, the DEA-registered practitioner on site with the patient, and the patient would have to participate in an audio-video conference simultaneously (*i.e.,* these individuals must participate in a two-way, simultaneous interactive communication with both audio and video for this medical evaluation even if audio-only communication had been authorized under the standard of 42 CFR 410.78(a)(3) for prior communications between the prescribing practitioner and the patient). Thus, even though the prescribing practitioner would not be conducting an in-person evaluation themselves, they could rely on the in-person evaluation of the on-site practitioner—and remotely observe this evaluation via video and audio—when determining whether to continue prescribing to the patient.

Alternatively, the requirement of a medical evaluation is satisfied when the prescribing practitioner receives a qualifying telemedicine referral from a DEA registered practitioner under § 1306.31(d)(3). Under this scheme, the patient must have received a face-to-face evaluation from a DEA registered practitioner, referred to as the referring practitioner. The referring practitioner may then issue a written qualifying telemedicine referral to the prescribing practitioner based on the diagnosis, evaluation, or treatment that was provided for the medical issue upon which the medical evaluation was predicated pursuant to paragraphs (i) and (iii). Moreover, under paragraph (ii), the referring practitioner must communicate the results of the medical evaluation which include any diagnosis, evaluation, or treatment to the prescribing practitioner, prior to the prescribing practitioner issuing a prescription. If the prescribing practitioner issues the prescription to the patient prior to receiving the information provided in (ii), this does not qualify as a medical evaluation for the purposes of § 1306.31(d) and the patient must receive a medical evaluation in the manner described in paragraph (d)(1) or (d)(2).

For example, the following scenarios illustrate procedurally how this qualifying telemedicine referral would operate:

Example 1

A patient travels to receive a medical evaluation in the presence of their family physician. The physically present practitioner conducts a medical evaluation and provides a diagnosis, an evaluation, or treatment to the patient. The physically present practitioner determines that the patient would benefit from specialized care provided by a practitioner across the country (prescribing practitioner). The physically present practitioner issues a written referral to the prescribing practitioner via an appropriately secured electronic communication, and includes in the communication the reason for the referral, a copy of the medical record, as well as a description of the diagnosis, evaluation, and treatment of the patient prior to the prescribing practitioner. The prescribing practitioner reviews this information, engages in a telemedicine encounter with the patient, and issues a prescription for a controlled medication to the patient.

Example 2

A patient who is insured with, and receives treatment from, a medical group (such as Kaiser Permanente) travels to a local medical office to receive a medical evaluation in the physical presence of a practitioner. The physically present practitioner conducts a medical evaluation and provides a diagnosis, an evaluation, or treatment to the patient. The physically present practitioner determines that the patient would benefit from specialized care provided by a practitioner in the same medical group (prescribing practitioner). The physically present practitioner issues a written referral to the prescribing practitioner via an appropriately secured electronic communication, and includes in the communication the reason for the referral, a copy of or link to the medical record, as well as a description of the diagnosis, evaluation, and treatment of the patient prior to the prescribing practitioner. The prescribing practitioner reviews this information, engages in a telemedicine encounter with the patient, and issues a prescription for a controlled medication to the patient.

In both examples, the physically present practitioner issued a qualifying telemedicine referral to the prescribing

[41] As noted above, DEA is addressing the prescribing of certain narcotic substances via telemedicine for the treatment of opioid use disorder in a separate rulemaking.

practitioner. The physically present practitioners issued a written referral, based on the medical evaluation that was conducted by the physically present practitioner, and shared all pertinent medical information as required under proposed § 1306.31(d)(3) with the prescribing practitioner. The prescription issued by the prescribing practitioner may be for any controlled medication that they are otherwise authorized to prescribe under applicable laws and regulations under proposed § 1306.31(c)(1). These examples are not intended to be exhaustive, and represent only some of the possible scenarios upon which a qualifying telemedicine referral may be issued.

Once a medical evaluation meeting the specified criteria is performed, the proposed rule would allow a practitioner to continue prescribing a controlled medication to a patient without additional evaluations, so long as doing so was consistent with legitimate medical purposes and a subsequent evaluation was not required by law.

Proposed paragraph (e) would require practitioners to review available information about past prescriptions to a particular patient. Proposed paragraph (e)(1) would require the practitioner, if employed by the Department of Veterans Affairs, to review the Department of Veterans Affairs' internal prescription database for data regarding any controlled medication prescriptions issued to the patient in the last year, or, if less than a year of data is available, in the entire available period. Proposed paragraph (e)(1) would require all practitioners prescribing pursuant to § 1306.31 to review the PDMP data for the State in which the patient is located, where available, for the last year. PDMPs have proven to be an invaluable tool in preventing diversion, allowing practitioners to identity patients whose prescription history suggests that they are seeking controlled medications for other than legitimate medical needs—either because they misuse controlled medications or may be selling them to others. Given the heightened risk of diversion in the telemedicine context, DEA believes it is appropriate to require practitioners to review PDMP data and, for VA practitioners, the VA's own centralized health information system, before issuing a telemedicine prescription.

Proposed paragraph (e)(2)(i) would require, in those circumstances where the PDMP system is non-operational, practitioners to limit their prescriptions to patients to no more than a 7-day supply until they are able to access the PDMP system again. This limit applies until the practitioners are able to access the PDMP system, complete their review of the patient's prior prescription history, and verify the nature of prescriptions when applicable. Paragraph (e)(2)(ii) would require the practitioner to gain access to the PDMP system and conduct appropriate reviews within 7 days of the telemedicine encounter, and paragraph (e)(2)(iii) would require the practitioner to record the attempts to access the PDMP and (if applicable) the Department of Veterans Affairs internal prescription database pursuant to § 1304.03(i). If the practitioner failed to obtain the PDMP (or, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data, the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system. The 7-day prescription can be refilled upon successful review of the PDMP by the practitioner, as long as the prescriptions together do not exceed a 30-day supply.

If the practitioner otherwise completes their review of the PDMP system pursuant to paragraph (e)(2)(ii), or is otherwise able to comply with all relevant requirements in paragraph (e)(1), proposed paragraph (e)(3) would authorize practitioners to prescribe ''no more than a 30-day supply across all such prescriptions'' until the practitioner has conducted the required medical evaluation. Put another way, this provision would allow the doctor to provide up to a thirty-day supply in any combination of prescriptions and prohibits the doctor from going beyond that until the medical evaluation is conducted. This supply may include dosages that are titrated up or down depending on the patient's response to the medication and the practitioner's medical judgment, however, it may not exceed a supply sufficient to treat the patient for more than 30 days.

If the prescribing practitioner does not conduct a medical evaluation as described in proposed paragraphs (d)(1) or (d)(2) within a period of 30 calendar days, the practitioner would not be authorized to issue any subsequent prescriptions to that patient under proposed paragraph (f). This requirement would not apply to a practitioner who has a telemedicine relationship established during the COVID–19 public health emergency with the patient, as defined in § 1300.04(g), or to a practitioner employed by the Department of Veterans Affairs when prescribing to a patient of the Department of Veterans Affairs health system.

Proposed § 1306.31(g) would require all prescriptions issued as a result of telemedicine encounters to be consistent with all other requirements of this part. This provision would clarify that unless otherwise specified, practitioners authorized to prescribe controlled substances in the manner described in this rulemaking would nevertheless be subject to the regulatory requirements imposed by § 1306.31 and DEA registrations generally.

D. Request for Comments

With respect to the proposed rule, DEA invites comments concerning whether any clarifications or other regulatory provisions are warranted to ensure appropriate access to care, consistent with effective controls against diversion and otherwise consistent with the public health and safety. To that end, DEA is requesting comments on whether the rule should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications. DEA invites comments on the proposed practitioner recordkeeping obligations. Additionally, based on the available information, in order to balance benefits and risks to individual and public safety, DEA is proposing a 30-day maximum supply under proposed § 1306.31(c)(2) for the controlled substance being prescribed via telemedicine prior to an in-person evaluation being conducted. DEA seeks comment, including data from research and clinical practice, that provides evidence that an alternate maximum day supply would be more appropriate than the one proposed in this rulemaking. DEA also seeks comments about additional safeguards or flexibilities that should be considered with respect to this rule.

Moreover, DEA invites comments on whether the Notice of Proposed Rulemaking, entitled ''Expansion of Induction of Buprenorphine via Telemedicine Encounters'' (RIN 1117–AB78), published elsewhere in this issue of the **Federal Register**, should be combined with this rulemaking when publishing the Final Rule as both documents refer to prescribing via telemedicine pursuant to 21 U.S.C. 802(54)(G).

This rule is designed to ensure that patients do not experience lapses in care. It is also deigned to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID–19 public health emergency. The COVID–19 public

health emergency is set to expire on May 11, 2023. DEA and HHS have provided for a notice-and-comment period of 30 days so that they have an opportunity to fully review and respond to any submissions.

IV. Regulatory Analyses

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

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (''OMB''), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined that it is a significant regulatory action, but not an economically significant regulatory action having an annual effect on the economy of $100 million or more, under E.O. 12866. Accordingly, this rule has been submitted to the OMB for review.

DEA expects that this proposed rule would result in a cost savings of $3,762,089 per year. Additionally, the proposed rule is estimated to decrease transfers to the federal government by $11,628 per year. Fees paid to the federal government are considered transfer payments and not costs.[42] The analysis of cost savings, costs, transfers, and benefits is provided below.

Regulatory Alternatives Considered

DEA considered four alternatives, including the selected alternative: (1) an alternative only allowing the practice of telemedicine pursuant to an application and issuance of a ''special registration'' allowing such practice; (2) an alternative only allowing the practice of telemedicine pursuant to a special registration allowing such practice and limiting special registration to the prescribing of non-narcotic controlled substances to patients located in rural areas, (3) an alternative only allowing the practice of telemedicine pursuant to a special registration allowing such practice but requiring patients to be located at a qualified originating site, and (4) the selected alternative.

First, DEA considered allowing the practice of telemedicine pursuant to an application and issuance of a ''special registration'' allowing such practice. Upon further consideration, this alternative was deemed potentially burdensome for both prospective telemedicine providers and patients. Therefore, DEA decided against this alternative.

Second, DEA considered placing an additional geographic limitation on the circumstances under which controlled substances can be prescribed pursuant to a special registration for telemedicine. Under this alternative, a telemedicine encounter that gives rise to the issuance of a prescription under a special registration for telemedicine would have to be with a patient in a rural location based on the CMS definition of ''rural area'' [43] (unless the patient is being treated by the Department of Veterans Affairs (''VA'')). More specifically, under this alternative, prescriptions would have to be issued to patients who reside in such ''rural areas.'' Patients residing in rural areas were believed to face higher burdens when obtaining in-person medical evaluations and thus have a legitimate need for increased access to controlled medication prescriptions issued via telemedicine. If this alternative were implemented, the patients served would be limited to those residing in rural areas. However, upon further evaluation of the need for telemedicine and the risk of diversion, DEA decided not to propose this ''rural area'' requirement. DEA understands patients in non-rural areas can also be underserved and have a legitimate need for increased access to prescriptions issued via telemedicine. Therefore, DEA decided to include patients in non-rural areas in the proposed rulemaking.

Third, DEA considered requiring patients be located at a qualifying ''originating site'' during the relevant telemedicine encounter. Under this alternative, patients (except patients being treated by VA practitioners) would be required to be located at one of a defined set of ''originating sites'' when receiving treatment leading to a controlled substance prescription as a result of a telemedicine encounter. CMS regulations at 42 CFR 410.78(b)(3) list twelve types of locations described as ''originating sites'' for purposes of Medicare Part B payment. DEA considered including a subset of those locations as qualifying originating sites for the special registration for telemedicine. Specifically, this alternative would include the locations listed in section 410.78(b)(3)(i)–(ix): offices of physicians or practitioners,[44] critical access hospitals, rural health clinics, federally qualified health centers, hospitals, hospital-based or critical access hospital-based renal dialysis centers (including satellites), skilled nursing facilities, community mental health centers, and renal dialysis facilities.[45] The intent of this alternative was to expand the range of telemedicine treatment that practitioners may engage in under the CSA, while also mitigating,

[42] OMB Circular A–4.

[43] In its regulations, CMS defines a *rural area* as an area located outside an urban area, or a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration. *See* 42 CFR 414.605.

[44] The term ''practitioner,'' as used in this section of CMS regulations, differs from the definition of that term given in the CSA, and includes the following: physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, clinical social workers, registered dietitians or nutrition professionals, and certified registered nurse anesthetists. 42 CFR 410.78(b)(2). To be clear, under this alternative, these are persons whose offices would qualify as originating sites for a special registration for telemedicine, but not all of these persons would be eligible to obtain and treat patients under a special registration for telemedicine.

[45] Section 410.78 requires that in addition to qualifying as one of these types of facilities, the originating site must meet certain geographic requirements over and above the geographic restrictions that are part of the definition of some types of facilities. This alternative would not require that a facility meet these additional geographic requirements in order to qualify as an originating site under a special registration for telemedicine, but would require that it meet the restrictions imposed in the underlying definition of the facility. So, for example, to qualify as a rural health clinic and be an originating site for patients treated under a special registration for telemedicine, a facility would have to meet the requirements of 42 U.S.C. 1395x(aa)(2), but not the requirements of 21 CFR 410.78(b)(4).

to the extent practicable, the risk of diversion posed by this expansion in controlled substance prescribing. With this in mind, this alternative would stipulate that the originating site at which patients must be located during treatment must be a clinical setting, be capable of handling standard intake processing of patients, and have appropriate medical personnel available to provide support to the distant prescribing practitioner, as necessary. However, upon further consideration, this alternative was deemed too restrictive, with the potential of creating a substantial burden on prospective patients. Therefore, DEA decided against this alternative.

Finally, DEA is proposing the selected alternative, which would not limit prescriptions issued as a result of a telemedicine encounter to prescriptions issued pursuant to a special registration regime, to patients who reside in ''rural areas,'' or to patients located at a qualifying originating site. The selected (proposed) alternative is less restrictive and likely to benefit more patients. Below is a detailed analysis of the selected alternative.

Analysis of Costs, Cost Savings, Benefits, and Transfers

There are minimal costs and substantial cost savings, other benefits, and transfers associated with this proposed rulemaking. As discussed above, this proposed rule describes the circumstances under which, pursuant to 21 U.S.C. 802(54)(G), a practitioner may prescribe controlled substances to patients whom the practitioner has not evaluated in person. This rulemaking would not impose any new requirements on practitioners authorized to practice telemedicine under other statutory exceptions in 21 U.S.C. 802(54), such as IHS, who are authorized to engage in the practice of telemedicine under a different statutory paragraph, 802(54)(C).

Under this proposed rule, practitioners would be allowed to issue prescriptions via telemedicine for schedule III–V non-narcotic controlled medications to the extent otherwise authorized by their DEA registration(s).[46]

As also discussed earlier, the proposed rule specifies the circumstances under which practitioners may prescribe controlled substances, pursuant to 21 U.S.C. 802(54)(G), to patients whom the practitioner has never evaluated in person, including that:

- Such prescriptions be in accordance with applicable Federal and State laws; and
- Such practitioners possess an active DEA dispensing registration issued pursuant to 21 CFR 1301.13(e)(1)(iv) in the State in which the practitioner is located (unless exempted).

Consistent with effective controls against diversion and otherwise consistent with the public health and safety, the proposed rule also specifies requirements related to recordkeeping and prescriptions. DEA estimates that there would be no additional infrastructure cost for patients or providers associated with this proposed rule, as DEA has concluded that most patients and providers already possess or have ready access to a telecommunications system meeting the requirements of the proposed rule. In addition, there is potential for an added risk of diversion from more practitioners having the authority to prescribe schedule III–V non-narcotic controlled substances. An analysis of all costs is detailed below.

1. Recordkeeping

This proposed rule would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating the date the prescription was issued; the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; the address at which the practitioner, and the city and State in which the patient, are located during the telemedicine encounter; if issued through a qualifying telemedicine referral, the name and NPI of the referring practitioner, a copy of the referral and any communications shared pursuant to § 1306.31(d)(3)(i)–(iii); and all efforts to comply to access the PDMP system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database).

DEA believes that these recordkeeping requirements may result in additional recordkeeping costs; but, given that the recordkeeping required by proposed 21 CFR 1304.03(i) is not extensive and this information is expected to be readily available, DEA does not anticipate it imposes a major burden on registrants.

2. Prescriptions

First, this proposed rule would require all prescriptions issued pursuant to a telemedicine encounter to note on the face of any prescription, or within the prescription order if prescribed electronically, issued pursuant to § 1306.31 that the prescription was issued via a telemedicine encounter. DEA anticipates any added cost associated with this requirement would be minimal, as minimal additional time would be required to make this notation.

Second, as discussed above, this proposed rule would generally limit practitioners to use telemedicine to prescribe non-narcotic controlled substances in schedules III–V only for a period of 30 days, unless such a medical evaluation for the purposes of this section is conducted pursuant to § 1306.31 paragraph (d)(1), (d)(2), or (d)(3). As DEA is proposing to amend its regulations to specify circumstances under which practitioners may prescribe controlled substances, pursuant to 21 U.S.C. 802(54)(G), where there is no existing regulation, there is no cost associated with this provision.

Finally, this proposed rule would require all practitioners prescribing pursuant to § 1306.31 to review the PDMP data for the State in which the patient is located, where available, for the last year. DEA estimates many practitioners already check PDMP prior to issuing a prescription for a controlled substance for a variety of reasons, and therefore, any additional cost is minimal. However, DEA welcomes any comment on this estimate, including specific burden estimates, if any.

3. Risk of Diversion

This proposed rulemaking allows practitioners to issue prescriptions for schedule III–V non-narcotic controlled substances to the extent otherwise authorized by their DEA registration(s).[47]

Such substances are subject to diversion and misuse, and allowing practitioners an increased ability to prescribe these substances via telemedicine presents the potential for the increased diversion and misuse of these substances. DEA believes that the benefits of increased availability for treatment outweigh the dangers of a potential increase in diversion—so long as prescribers using telemedicine adhere to the safeguards inherent in the requirements of the proposed rule.

4. Other Potential Costs

DEA also examined the cost of technology for telemedicine, both capital investment and operational expenses, in order to use the proposed telemedicine authority. DEA believes

[46] As noted above, DEA is addressing the prescribing of certain narcotic substances via telemedicine for the treatment of opioid use disorder in a separate rulemaking.

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that these initial investments have already been made by the practitioners most likely to engage in telemedicine pursuant to 21 U.S.C. 802(54)(G), and that there would be no additional technology or infrastructure cost to these practitioners. For example, VA practitioners already make significant use of telehealth services under existing authorities. Thus, VA practitioners are already expected to have the necessary technology and broadband access in order to prescribe controlled medications utilizing telehealth services in a manner consistent with the proposed rule. Therefore, DEA believes that there are no additional technology or infrastructure costs associated with this proposed rulemaking because all stakeholders would be leveraging current resources.

5. Summary of Costs

In summary, DEA estimates any cost associated with this rule is minimal.

B. Cost Savings, Transfers, and Benefits

The following sections summarize the expected cost savings and change in transfers related to telemedicine, pursuant to 21 U.S.C. 802(54)(G), that are realized by both VA and non-VA practitioners.

1. Cost Savings for VA Practitioners

To quantify the expected cost savings, DEA used data provided by the VA regarding the number of VA health care professionals in FY2018 who have seen a patient via telehealth under existing telemedicine authorities, prescribed a controlled medication, and had not completed an in-person appointment with that patient. There were 21,046 encounters identified in FY2018 where a provider prescribed a schedule III–V controlled medication via telemedicine without having previously completed an in-person appointment under existing CSA telemedicine authorities.[48] These encounters were completed by 1,222 VA health care professionals. Because this proposed rule would authorize VA providers to prescribe schedule III–V non-narcotic controlled substances without requiring the veteran to be physically located in a VA clinic, these 21,046 appointments have the potential to be conducted in the veteran's home after promulgation of this rule. The VA provided DEA with further data on the various cost savings associated with conducting these 21,046 appointments via telehealth rather than in a VA clinic, including beneficiary travel reimbursement ($143,357); clinic staff, space, and equipment cost savings ($6,888,345).[49] The beneficiary travel reimbursement cost saving does not include the opportunity cost of the time required to travel to and from appointments at a clinic. DEA estimates this cost savings to be $492,476 annually.[50] DEA used these cost savings estimates to calculate the impact if 0–100% of those visits were conducted in the veteran's home, resulting in a cost savings of between $0 and $7,524,178 ($143,357 + $6,888,345 + $492,476) per year. DEA also considered whether or not there would be an increase in the number of patients that would be treated by VA practitioners pursuant to this proposed rule. As mentioned in the economic analysis accompanying the VA's 2018 telemedicine preemption rule,[51] when providers can use more of their appointment slots for telehealth care, it expands the accessibility of the provider's services without requiring additional clinical resources.[52] Telehealth visits are used in place of in-person visits but do not, in general, change the number of overall visits, supply, or demand. Because DEA does not have a basis to determine how many annual clinic appointments would transition to telehealth appointments after promulgation of this proposed rule, DEA chose to take the mid-point (the scenario in which 50% of the 21,046 clinic appointments become telehealth visits) of the cost savings estimated previously. Therefore, the total annual estimated cost savings is $3,762,089.

2. Transfers for VA Patients

Transfers borne by VA patients in the form of treatment co-pays are expected to be reduced. VA stated that patient co-pays would be reduced by $23,255 if the 21,046 appointments were conducted via telehealth rather than in VA clinics. Because DEA does not have a basis to determine how many annual clinic appointments would transition to telehealth appointments after promulgation of this proposed rule, DEA chose to take the mid-point (the scenario in which 50% of the 21,046 clinic appointments become telehealth visits), which results in a reduction of transfers from VA patients of $11,628.

3. Benefits of Increased Access to Telemedicine

Telemedicine has the potential to help address accessibility issues and improve access to care, including specialty care, for patients in remote and other underserved areas. More than 75 percent of all counties in the U.S. are classified as mental health shortage areas, and 50 percent do not have any mental health professionals.[53] The need to travel long distances to receive treatment is a common barrier to accessibility facing individuals in rural areas without reliable transportation options.[54] As of December 2018, there were 5,124 designated Mental Health—Health Professional Shortage Areas covering a total population of 115,383,074 people.[55] The greater range of telemedicine practice that would be possible under this proposed rule would allow practitioners to reach a greater number of patients, improving health care outcomes and reducing costs for patients throughout the country.

In addition to the benefits mentioned above, there are many benefits specifically for VA patients. A 2018 survey conducted by the VA indicated that about 14 percent of veterans with a need for mental health services self-reported living more than an hour from

[48] There is not a breakdown of whether the prescribed scheduled III–V controlled substance was a narcotic or non-narcotic. For the purposes of this analysis DEA assumes all 21,046 encounters forms the basis for cost savings.

[49] VA's Allocation Resource Center and Revenue Operations Business Information Office calculated these figures on behalf of DEA.

[50] DEA used hourly median wage data for All Occupations ($22.00) to represent the hourly opportunity cost of travel time for all patients. Bureau of Labor Statistics, *May 2021 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm* (last accessed January 7, 2023). Loaded for benefits, the hourly opportunity cost is $31.20 ($22.00 × 1.418). Bureau of Labor Statistics, *Employer Costs for Employee Compensation—September 2022, https://www.bls.gov/news.release/pdf/ecec.pdf* (last accessed January 7, 2023). Next, DEA estimated the miles travelled per appointment by first dividing the VA-provided travel reimbursement cost of $143,357 by the number of appointments (21,046), which results in a per-appointment travel reimbursement rate of $6.81. To convert the VA's per-appointment reimbursement rate into miles driven per appointment, $6.81 is then divided by the IRS medical mileage rate of $0.18 (*https://www.irs.gov/newsroom/standard-mileage-rates-for-2018-up-from-rates-for-2017*), resulting in 37.84 miles. DEA conservatively assumes that it would take the average patient 45 minutes (0.75 hours) to travel 37.84 miles, round-trip. Multiplying the per-hour opportunity cost of $31.20 by 0.75 results in an opportunity cost of $23.40 per appointment. This results in a total opportunity cost savings of $492,476 ($23.40 × 21,046) for patients.

[51] 83 FR 21897 (May 11, 2018).

[52] Department of Veterans Affairs, *Impact Analysis for RIN 2900–AQ06* (2018), *https://www.regulations.gov/document?D=VA-2017-VHA-0021-0083.*

[53] Substance Abuse and Mental Health Services Administration, *Rural Behavioral Health: Telehealth Challenges and Opportunities,* at 4 (2016), *https://store.samhsa.gov/system/files/sma16-4989.pdf.*

[54] *Id.*

[55] Health Resources and Services Administration, *Designated Health Professional Shortage Area Statistics, First Quarter of FY 2019 Designated HPSA Quarterly Summary* (2019), *https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false.*

the nearest VA facility.[56] Among all the VA users with a need for services, 10 percent reported they live more than one hour away from the nearest VA facility offering mental health services.[57] According to the survey, living a long distance from a VA facility with mental health services significantly decreased the odds of using VA mental health care over non-VA mental health care, suggesting that further expanding telemedicine options to rural veterans may improve access for those who see the distance to the nearest VA mental health facility as a barrier to choosing the VA for their care.[58] Moreover, rural veterans with mental health conditions are known to use VA services at a lower rate and to have a higher rate of unmet mental health needs than veterans living in urban communities.[59] Increasing access to care through telemedicine has the potential to address these issues.

4. Summary of Cost Savings and Transfers

In conclusion, DEA estimates that the annual cost savings of this proposed rule is $3,762,089, while annual transfer payments to the federal government are decreased by $11,628. It should be noted that this estimate of cost savings assumes that the practitioners who engage in telemedicine pursuant to 21 U.S.C. 802(54)(G) would adhere to the requirements of the proposed rule designed to reduce the risk of diversion. If such requirements were not followed, the risk of diversion would increase, and any resulting increase in diversion would drive up the societal costs associated with the misuse of controlled substances.

C. Summary of Economic Impact

As described above, DEA estimates the total annual cost savings of this proposed rule is $3,762,089. Additionally, transfers are estimated to decrease by $11,628 annually.

[56] Department of Veterans Affairs, Z. Joan Wang et al., *2018 Survey of Veteran Enrollees' Health and Use of Health Care* (2019), *https://www.va.gov/healthpolicyplanning/soe2018/2018enrolleedatafindingsreport_9january2019final508compliant.pdf.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

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

In accordance with the RFA, DEA evaluated the impact of this proposed rule on small entities. The proposed rule describes the circumstances under which, pursuant to 21 U.S.C. 802(54)(G), a practitioner may prescribe controlled substances to patients whom the practitioner has not evaluated in person.

A significant number of practitioners, physicians and MLPs, work in offices and institutions that meet the RFA's definition of small entities. To estimate the number of affected entities, DEA first determined the North American Industry Classification System (''NAICS'') codes that most closely represent businesses that employ practitioners that may engage in telemedicine pursuant to this regulation. Then, DEA researched economic data for those codes. The source of the economic data is the Small Business Administration (''SBA''), Office of Advocacy, and is based on data provided by the U.S. Census Bureau, Statistics of U.S. Businesses (''SUSB'').[60] The following business NAICS codes are estimated to represent businesses that employ the affected practitioners:

- 621112—Offices of Physicians, Mental Health Specialists
- 621420—Outpatient Mental Health and Substance Abuse Centers
- 622210—Psychiatric and Substance Abuse Hospitals

SUSB data contains the number of firms by size ranges for each of the NAICS codes. For the purposes of this analysis, the term ''firm'' as defined in the SUSB is used interchangeably with ''entity'' as defined in the RFA.

To estimate the number of affected entities that are small entities, DEA compared the SUSB data for the number of firms in various firm size ranges with SBA size standards for each of the representative NAICS codes. The SBA size standard is the firm size based on the number of employees or annual receipts depending on industry. The SBA size standards for NAICS codes 621112, 621420, and 622210 are annual receipts of $13.5 million, $19 million, and $47 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 estimates that a total of 17,480 entities are affected by this proposed rule, of which 16,453 (94.1 percent) are small entities. The analysis is summarized in table 1 below.

[60] 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. Table of size standards, effective December 19, 2022. *https://www.sba.gov/document/support-table-size-standards* (last visited January 7, 2023). SUSB, 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipts Size. *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.* The data table is available at *https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_rcptsize_2017.xlsx* (last visited January 7, 2023).

TABLE 1—NUMBER OF AFFECTED ENTITIES AND SMALL ENTITIES

NAICS Code	Number of firms	SBA size standard ($)	Number of small firms
621112—Offices of Physicians, Mental Health Specialists	10,561	13,500,000	10,400
621420—Outpatient Mental Health and Substance Abuse Centers	6,523	19,000,000	5,849
622210—Psychiatric and Substance Abuse Hospitals	396	47,000,000	204
Total	17,480		16,453
Percent of Total			94.1

While this proposed rule may affect a substantial number of small entities in the affected industries, as discussed in the E.O. 12866 section above, DEA estimates that the cost of this rule is minimal for all affected entities, including small entities. Therefore, DEA concludes the proposed rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

This proposed rule would impose a new collection of information under the Paperwork Reduction Act (''PRA''), 44 U.S.C 3501–3521. DEA has identified the following collection(s) of information related to this proposed rule. The collections of information contained in the proposed rule, and identified as such, have been submitted to OMB for review under section 3507(d). 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 *https://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Proposed Rule

1. *Title:* Reporting Requirements for Practitioners Conducting Telemedicine.

OMB control number: 1117–NEW.

Form numbers: N/A.

DEA is proposing this rule to describe the circumstances under which, pursuant to 21 U.S.C. 802(54)(G), a practitioner may prescribe controlled substances to patients whom the practitioner has not evaluated in person.

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

- *Number of respondents:* 31,451.
- *Frequency of response:* 12 per respondent per year.
- *Number of responses:* 377,412.
- *Burden per response:* 0.25 hours (rounded).
- *Total annual hour burden:* 94,353.

B. Request for Comments Regarding the Proposed Collections of Information

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

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

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB40/Docket No. DEA–407. All comments must be submitted to OMB on or before March 31, 2023. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

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

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

PART 1300—DEFINITIONS

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

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

■ 2. Amend § 1300.04 by:
■ a. Revising the introductory text of paragraph (i).
■ b. Removing and reserving paragraph (j).
■ c. Redesignating paragraphs (k) and (l), as paragraphs (l) and (p).
■ d. Adding paragraphs (k), (m), (n), and (o).

The revisions and additions read as follows:

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

* * * * *

(i) The term *practice of telemedicine* means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is

communicating with the patient, or health care professional who is treating the patient, using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3), which practice falls within a category listed in paragraphs (i)(1) through (7) of this section:

* * * * *

(j) [Reserved]

(k) A *qualifying telemedicine referral* means a referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral must note the name and National Provider Identifier of the practitioner to whom the patient is being referred.

* * * * *

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

(n) The term *telemedicine prescription* means a prescription issued pursuant to § 1306.31 by a physician, or a ''mid-level practitioner'' as defined in § 1300.01(b), engaging in the practice of telemedicine as defined in § 1300.04(j).

(o) An individual practitioner and a patient have a *telemedicine relationship established during the COVID–19 public health emergency* if:

(1) The practitioner has not conducted an in-person medical evaluation of the patient;

(2) The practitioner has prescribed one or more controlled substances based on telemedicine encounters during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 and pursuant to the designation pursuant to that public health emergency on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under section 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States; and

(3) No more than 180 days have elapsed since [EFFECTIVE DATE OF RULE] or the end of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019, whichever is later.

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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

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

■ 10. In § 1304.03, revise paragraph (c) and add new paragraphs (i), (j), and (k), to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(c) Except as provided in paragraph (i) of this section and § 1304.06, a registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

* * * * *

(i) An individual practitioner shall maintain, for each telemedicine prescription they issue, records indicating the date the prescription was issued; the full name and address of the patient; and the drug name, strength, dosage form, quantity prescribed, and directions for use; the address at which the practitioner, and the city and State in which the patient, are located during the telemedicine encounter; if issued a qualifying telemedicine referral, the name, and National Provider Identifier of the referring practitioner, a copy of the referral and any communications shared pursuant to § 1306.31(d)(3); and all efforts to comply to access the PDMP system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database).

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

(k)(1) An individual practitioner who participates in a medical evaluation conducted pursuant to § 1306.31(d)(2) as the prescribing practitioner shall maintain, for each such medical evaluation, the data and time of the evaluation; the National Provider Identifier (NPI) of the DEA-registered healthcare worker physically present with the patient; the address at which the prescribing practitioner is located during the telemedicine encounter; and the address at which the DEA-registered healthcare worker is physically present with the patient during the medical evaluation.

(2) An individual practitioner who participates in a medical evaluation conducted pursuant to § 1306.31(d)(2) as the DEA-registered healthcare worker physically present with the patient shall maintain, for each such medical evaluation, the data and time of the evaluation; the address at which the prescribing practitioner is located during the telemedicine encounter; the National Provider Identifier (NPI) of the prescribing practitioner; and the address at which the DEA-registered healthcare worker is physically present with the patient during the medical evaluation.

* * * * *

■ 11. In § 1304.04, add paragraph (i) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(i)(1) An individual practitioner shall maintain all records related to telemedicine prescriptions and qualifying telemedicine referrals required by this part at the registered location on the certificate of registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)). If the practitioner holds more than one registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)), the practitioner shall designate the location on one such certificate of registration at which to maintain all such records. If the individual practitioner is exempt from registration to dispense controlled substances pursuant to 21 U.S.C. 822(d), the practitioner shall maintain all records related to telemedicine prescriptions and qualifying telemedicine referrals required by this part at the location where they maintain other records related to controlled substances.

(2) If a prescribing practitioner conducts an evaluation during which the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner) pursuant to section 1306.31(d)(2), both the prescribing practitioner and the DEA-registered practitioner shall maintain records required by this part at the registered location on the practitioners' respective certificates of registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)).

* * * * *

PART 1306—PRESCRIPTIONS

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

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

■ 13. Amend § 1306.05 by adding paragraph (i), to read as follows.

§ 1306.05 Manner of issuance of prescriptions.

* * * * *

(i) In addition to the requirements of this section, the practitioner shall note on the face of any telemedicine prescription, or within the prescription order if prescribed electronically, that the prescription has been issued based on a telemedicine encounter.

■ 14. After § 1306.27, add an undesignated center header and § 1306.31 to read as follows:

* * * * *

Other Provisions

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

(a) An individual practitioner may issue telemedicine prescriptions if all of the following conditions are met:

(1) The telemedicine prescription is pursuant to a telemedicine encounter and is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

(2) At the time of the telemedicine encounter that gives rise to the issuance of the telemedicine prescription, the practitioner is located in a State, Territory, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico.

(3) The practitioner is:

(i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) 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).

(4) The prescription includes the information required by § 1306.05.

(b) In addition to the conditions outlined in paragraph (a), practitioners are also subject to the limitations in paragraphs (c), (d), (e), and (f) of this section when prescribing controlled substances pursuant to this section.

(c) Characteristics of telemedicine prescriptions:

(1) A telemedicine prescription may only be for a:

(i) A schedule III, IV, or V non-narcotic controlled substance; or

(ii) Any controlled substance that the practitioner is otherwise authorized to prescribe, provided that one or more of the following criteria are met:

(A) The prescribing practitioner has received a qualifying telemedicine referral as defined in § 1300.04(k) for that patient from a referring practitioner who has conducted a medical evaluation as described in paragraph (d)(3) of this section;

(B) The prescribing practitioner is employed by the Department of Veterans Affairs and the prescription is issued for a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination was employed by the Department of Veterans Affairs; or

(C) The prescribing practitioner has a telemedicine relationship established during the COVID–19 public health emergency with the patient, as defined in § 1300.04(o).

(2) The prescribing practitioner may issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a 30 day supply of the controlled substance. This 30-day limitation shall not apply to prescriptions issued by a practitioner who has a telemedicine relationship established during the COVID–19 public health emergency with the patient, as defined in § 1300.04(o), or to a practitioner employed by the Department of Veterans Affairs when prescribing to a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination, was employed by the Department of Veterans Affairs. The prescribing practitioner may prescribe a supply in addition to the 30 day supply if a medical evaluation is conducted pursuant to paragraph (d)(1), (2), or (3) of this section.

(d) Such a medical evaluation for the purposes of this section may be one of the following:

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

(2) An evaluation during which:

(i) The patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner);

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

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

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

(3) An evaluation during which the patient is treated by, and in the physical presence of, an individual DEA registered practitioner, or individual practitioner exempt from registration under 21 U.S.C. 822(d), who:

(i) Issued a written qualifying telemedicine referral as defined in § 1300.04(k) for the patient to the prescribing practitioner;

(ii) Communicated the results of the evaluation by sharing the relevant information in the medical record which includes, at a minimum, the diagnosis, evaluation, and treatment of the patient prior to the prescribing practitioner issuing the prescription; and

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

(e)(1) Prior to issuing the prescription, the practitioner, including a practitioner employed by the Department of Veterans Affairs, must review and consider the prescription drug monitoring program in the State where the patient is located (if the State has such a program) for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The practitioner, if employed by the Department of Veterans Affairs, must also review the Department of Veterans Affairs internal prescription database for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than a year of data is available, in the entire available period.

(2) If the practitioner is unable to obtain the PDMP (or, if employed by the Department of Veterans Affairs, the Department of Veterans Affairs internal prescription database) data due to the PDMP (or Department of Veterans Affairs internal prescription database) system being non-operational or otherwise inaccessible as a result of a temporary technological or electrical failure, then:

(i) The practitioner may issue the prescription for no more than a 7-day supply;

(ii) The practitioner must obtain the PDMP (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data and conduct the review described in paragraph (e)(1) of this section within 7 days of the telemedicine encounter; and

(iii) The practitioner must record the attempts to obtain the PDMP and (if

applicable) the Department of Veterans Affairs internal prescription database data. If the practitioner fails to obtain the PDMP (or, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data as described in paragraph (e)(1) of this section, the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system.

(3) Upon completing the review described in paragraph (e)(1) of this section, the practitioner may issue prescriptions authorizing the dispensing of no more than a 30-day supply across all such prescriptions, unless otherwise exempted from the 30-day supply limitation.

(f) If the prescribing practitioner does not conduct a medical evaluation meeting the requirements of clause (d)(1), (2), or (3) of this section within a period of 30 calendar days of first issuing the prescription, the practitioner may not issue any subsequent telemedicine prescriptions to that patient until such a medical evaluation has been conducted. This restriction shall not apply to a practitioner who has a telemedicine relationship established during the COVID–19 public health emergency with the patient, as defined in § 1300.04(o), or to a practitioner employed by the Department of Veterans Affairs when prescribing to a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination, was employed by the Department of Veterans Affairs.

(g) Except as provided in this section, telemedicine prescriptions must be consistent with all other requirements of this part.

Signing Authority

This document of the Drug Enforcement Administration was signed on February 24, 2023, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–04248 Filed 2–27–23; 2:30 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306

[Docket No. DEA–948]

RIN 1117–AB78

Expansion of Induction of Buprenorphine via Telemedicine Encounter

AGENCY: Drug Enforcement Administration.

ACTION: Notice of proposed rulemaking.

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

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before March 31, 2023. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget on or before March 31, 2023.

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

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

Paper Comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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