DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1306

[Docket No. DEA–407]

RIN 1117–AB40

Special Registrations for Telemedicine and Limited State Telemedicine Registrations

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (the ''*Ryan Haight Act*'') generally requires an in-person medical evaluation prior to the issuance of a prescription of controlled substances but provides an exception to this in-person medical evaluation requirement where the practitioner is engaged in the ''practice of telemedicine'' within the meaning of the *Ryan Haight Act.* These proposed regulatory changes would establish a Special Registration framework and authorize three types of Special Registration. This proposed rulemaking also provides for heightened prescription, recordkeeping, and reporting requirements. DEA believes such changes are necessary to effectively expand patient access to controlled substance medications via telemedicine while mitigating the risks of diversion associated with such expansion. A summary of this rule may be found at *https://www.regulations.gov/docket/DEA-2023-0029.*

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before March 18, 2025. 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 (OMB) on or before March 18, 2025.

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

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type comments directly into the comment field on the web page or to attach a file containing 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 generated by *http://www.regulations.gov.* Please be aware that submitted comments are not instantaneously available for public view on *http://www.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 the electronic submission are discouraged. Should you wish to mail a paper comment *in lieu of* submitting a comment electronically, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. Hand-delivered comments will not be accepted.
- *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, OMB, 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: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received, including attachments and other supporting materials, in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make all comments available for public inspection online at *http://www.regulations.gov.* The *Freedom of Information Act* applies to all comments received. Confidential information or personal identifying information (PII), 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 *http://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.

Overview

I. Executive Summary

The *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (the ''*Ryan Haight Act*''), amended the Controlled Substances Act (CSA) by, among other things, requiring all prescription drugs which are dispensed by means of the *internet* [1] be issued as a ''valid prescription.'' [2] Generally, a valid prescription requires, at a minimum, at least one ''in-person medical evaluation,'' [3] which is issued for a legitimate medical purpose in the usual course of professional practice.[4] The *Ryan Haight Act* does, however, provide an exception to this in-person medical evaluation requirement, when the practitioner is ''engaged in the practice of telemedicine.'' [5]

The *Ryan Haight Act* provides seven (7) distinct categories of the *practice of telemedicine* in which a prescribing practitioner need not satisfy the *Ryan Haight Act's* in-person medical evaluation requirement, yet nonetheless may be able to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice.[6] In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the *practice of telemedicine* is able to conduct a *bona fide* medical evaluation of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the *Ryan Haight Act* contemplates that the practitioner will be permitted to prescribe controlled substances by means of the *internet* despite not having conducted an in-person medical evaluation.

Thus far, DEA has permitted, or promulgated regulations to permit, the *practice of telemedicine* pursuant to two of the seven categories of telemedicine authorized under the *Ryan Haight Act.* In March 2020, in response to the COVID–19 Public Health Emergency (''COVID–19 PHE'') declared by the Secretary (the ''Secretary'') of the Department of Health and Human Services (HHS) on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), DEA used its authority under 21 U.S.C. 802(54)(D) to grant temporary exceptions to the *Ryan Haight Act* and its implementing regulations, allowing authorized practitioners to generally prescribe controlled substances in Schedules II–V through telemedicine.

Three years later, in March 2023, DEA, in concert with HHS, promulgated two notices of proposed rulemakings (NPRMs) (the ''General Telemedicine NPRM,'' and ''Buprenorphine NPRM'') pursuant to 21 U.S.C. 802(54)(G), which collectively proposed to expand patient access to prescriptions via telemedicine relative to the pre-COVID–19 PHE landscape. On May 10, 2023, to prevent a lapse of care with the expiration of the COVID–19 PHE, DEA, jointly with HHS, promulgated a rule (the ''First Temporary Rule'') pursuant to 21 U.S.C.802(54)(G) to extend the temporary exceptions originally authorized under the COVID–19 PHE through November 11, 2023.

On September 12 and 13, 2023, DEA hosted live, in-person Telemedicine Listening Sessions to receive additional input concerning the *practice of telemedicine* with regards to controlled substances and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. DEA invited the public to express their views concerning the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation at all, the availability and types of data that would be useful in detecting diversion of controlled substances via telemedicine, and specific additional safeguards that could be placed around the prescribing of Schedule II controlled substances via telemedicine.

On October 10, 2023, in light of the need to further evaluate the best course of action given the comments received in response to the March 2023 NPRMs and the presentations at the September 2023 Telemedicine Listening Sessions, DEA, jointly with HHS, issued a second temporary rule (the ''Second Temporary Rule'') to further extend the temporary exceptions originally authorized under the COVID–19 PHE through December 31, 2024. On November 19, 2024, DEA and HHS issued a third temporary rule (the ''Third Temporary Rule'') to again extend the temporary exceptions originally authorized under the COVID–19 PHE through December 31, 2025, to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled substance prescriptions.

The Third Temporary Rule has also provided additional time for DEA to promulgate the *Special Registration* regulations proposed in this NPRM, and additional time for practitioners to come into compliance with any new standards or safeguards eventually found within a final rule establishing a *Special Registration* framework. DEA has determined that the best course of action to ensure patient access to care, while maintaining sufficient safeguards to prevent and detect diversion of controlled substances, is to establish and maintain a regulatory scheme including three separate *Special Registrations* pursuant to 21 U.S.C. 802(54)(E) and 21 U.S.C. 831(h).

These separate *Special Registrations* would allow more comprehensive prescribing, including prescribing of Schedule II and narcotic and non-narcotic controlled substances in limited circumstances, by properly registered physicians and *mid-level practitioners* (hereinafter collectively referred to as *clinician practitioners*), and dispensing by online telemedicine platforms that constitute *covered online telemedicine platforms,* in their capacity as *platform practitioners,* who have proven to have a legitimate need for such *Special Registrations* and where DEA has concluded that such registration is consistent with the public interest. Once properly registered under the *Special Registration* framework, *clinician practitioners* would be considered *clinician special registrants* and *covered online telemedicine platforms,* in their capacity as *platform practitioners,* would be considered *platform special registrants.*

This NPRM introduces the three types of *Special Registrations for Telemedicine:* (1) a *Telemedicine Prescribing Registration,* authorizing qualified *clinician practitioners* to prescribe Schedule III–V controlled substances via telemedicine, (2) an *Advanced Telemedicine Prescribing Registration,* authorizing qualified, specialized *clinician practitioners* (*e.g.,* psychiatrists, *hospice care* physicians) to prescribe Schedule II–V controlled substances via telemedicine, and (3) a *Telemedicine Platform Registration,* authorizing *covered online telemedicine platforms,* in their capacity as *platform practitioners,* to dispense Schedule II–V controlled substances.[7] To satisfy the

[1] Italicized terms indicate that it is a proposed term defined by the NPRM or a term currently defined in the CSA or DEA's regulations.

[2] 21 U.S.C. 829(e)(1).

[3] 21 U.S.C. 829(e)(2)(B)(i).

[4] 21 U.S.C. 829(e)(2)(A)(i).

[5] 21 U.S.C. 829(e)(3)(A).

[6] 21 U.S.C. 802(54).

[7] The term ''institutional practitioner'' is currently defined at 21 CFR 1300.01. Proposed changes to 21 CFR 1300.01 will explicitly exclude

statutory requirements under 21 U.S.C. 831(h), DEA would also require the *special registrant* to maintain a *State Telemedicine Registration* for every state in which a patient is treated by the *special registrant,* unless otherwise exempted. The *State Telemedicine Registration* would be issued by DEA, not the states, and operate as an ancillary credential, contingent on the *Special Registration* held by the *special registrant.*

To streamline the *Special Registration* application process, the NPRM would introduce a new registration application form, known as Form 224S. The three types of *Special Registrations* (*Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* and *Telemedicine Platform Registration*) and the *State Telemedicine Registration* (one type for *clinician special registrants* and one type for *platform special registrants*) would be on a three-year cycle. The NPRM also proposes heightened prescription requirements addressing the manner in which *special registration prescriptions* are issued, as well as additional elements required to be on a *special registration prescription* issued under a *Special Registration.*

Special registration prescriptions issued under the *Special Registration* would be required to be prescribed through electronic prescribing for controlled substances (EPCS), and after the *special registrant* has verified the identity of the patient and carried out a nationwide Prescription Drug Monitoring Program (PDMP) check of all 50 states and any U.S. district or territory that maintains its own PDMP (referred to as the ''nationwide PDMP check''). The nationwide PDMP check requirement, however, would have a delayed effective date of three years. In the interim, for all Schedule II–V controlled substances, *clinician special registrants* would be required to conduct a PDMP check of: (1) the state/territory where the patient is located; (2) the state/territory where the *clinician special registrant* is located; and (3) any state/territory that has a PDMP reciprocity agreement with the states/territories where the patient and *clinician special registrant* are located.

Furthermore, *special registration prescriptions* would require the inclusion of the *Special Registration* numbers of the *clinician special registrant* and the *platform special registrant* (if a *platform special registrant* facilitated the prescription), and the *State Telemedicine Registration* numbers of the *clinician special registrant* and *platform special registrant* (if a *platform special registrant* facilitated the prescription). To ensure clarity and easy identification of the type of registration, *Special Registration* numbers and *State Telemedicine Registration* numbers would be formatted distinctly. This would allow registrants and DEA to differentiate them from each other and from conventional DEA registration numbers issued under 21 U.S.C. 823(g). Additionally, pharmacies filling *special registration prescriptions* would be able to easily verify these registration numbers to confirm that the prescribing *clinician practitioner* is authorized to prescribe controlled substances within a given Schedule via a *Special Registration,* and that a *platform practitioner,* if one facilitated the *special registration prescription,* is authorized to dispense controlled substances under the *Special Registration* framework.

It is also important to note when the proposed regulations would not apply. The *Ryan Haight Act,* and the telemedicine regulations implementing it thereunder, apply only in limited circumstances, impacting only a subset of practitioner-patient relationships: those where the prescribing practitioner intends to prescribe controlled substances, and has never conducted an in-person medical evaluation of the patient prior to the issuance of the prescription. In other words, the regulations implemented under the *Ryan Haight Act* would not be applicable to practitioner-patient relationships in which there has ever been a prior in-person medical evaluation of the patient by the practitioner.

Moreover, the regulations proposed in this rule are further limited to telemedicine practiced under a *Special Registration,*[8] but would not apply to the other forms of the *practice of telemedicine* authorized under the *Ryan Haight Act.* The proposed regulations within this NPRM would not apply to the *practice of telemedicine* authorized under 21 U.S.C. 802(54)(A)–(D), (F), and (G). Therefore, these proposed regulations would not apply to the *practice of telemedicine* authorized under the *Expansion of Buprenorphine Treatment via Telemedicine Encounter* final rule (RIN 1117–AB78) or the *Continuity of Care via Telemedicine for Veterans Affairs Patients* final rule (RIN 1117–AB88) published elsewhere in this issue of the **Federal Register**. Under the authority of 21 U.S.C. 802(54)(G), these final rules permit, in limited circumstances, certain prescribing practitioners to issue prescriptions for controlled substances by telemedicine, without having personally performed an in-person medical evaluation or fulfilling the *Special Registration* requirements as proposed within this rule. At this stage, DEA remains committed to actively soliciting and considering feedback from the public and revising the *Special Registration* regulations as necessary and appropriate.[9]

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 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.[10] The CSA further authorizes the Attorney General (and the Administrator by delegation through 28 CFR part 0) to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA.[11]

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008. 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.* A central feature of the *Ryan Haight Act* is the in-person medical evaluation requirement. The in-person medical evaluation requirement is set forth in 21 U.S.C. 829(e), which provides that ''[n]o controlled substance that is a prescription drug as determined under the Federal Food, Drug, and

''covered online telemedicine platform'' to clarify that such an entity is not an ''institutional practitioner.''

[8] 21 U.S.C. 802(54)(E).

[9] *See* Appendix A for Chart: *Do I Need a Special Registration for Telemedicine?*

[10] ''Dispense'' in the context of this rulemaking means to deliver a controlled substance to an ultimate user, which includes the prescribing of a controlled substance. 21 U.S.C 802(10).

[11] 21 U.S.C. 871(b), 958(f).

Cosmetic Act may be . . . dispensed by means of the internet without a valid prescription,'' [12] and which defines ''valid prescription'' as ''a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' [13] Section 829(e), however, provides an exception to this in-person medical evaluation requirement where the practitioner is ''engaged in the practice of telemedicine.'' [14]

Pursuant to 21 U.S.C. 802(54) the *practice of telemedicine* means ''the practice of medicine in accordance with applicable Federal and state laws by a practitioner (other than a pharmacist) [15] who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system [16] referred to in section 1395m(m) of Title 42,'' and which also falls within one of seven distinct categories that Congress determined were appropriate to allow for the prescribing of controlled substances via telemedicine despite the practitioner never having conducted an in-person medical evaluation of the patient.

The seven distinct categories provided under the statutory definition of the *practice of telemedicine* generally involve either circumstances in which an in-person medical evaluation has been rendered impracticable due to temporary emergencies, or circumstances in which the prescribing practitioner might be unable to satisfy the *Ryan Haight Act's* in-person medical evaluation requirement, yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the *practice of telemedicine* is able to conduct a *bona fide* medical evaluation of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the *Ryan Haight Act* contemplates that the practitioner will be permitted to prescribe controlled substances by means of the *internet* despite not having conducted an in-person medical evaluation. The *Ryan Haight Act* defines these categories through the definition of ''practice of telemedicine,'' which is set forth in 21 U.S.C. 802(54).

As a general matter, those seven distinct categories include telemedicine encounters where: (1) a patient is physically located at a DEA-registered hospital or clinics, and the remote prescribing practitioner is DEA-registered in the state in which the patient is located; (2) a patient is being treated by a prescribing practitioner, and in the physical presence of a DEA-registered practitioner in the state in which the patient is located; (3) the prescribing practitioner is an employee or contractor of the Indian Health Service (IHS), acting within the scope of the practitioner's employment, who has been designated an *internet Eligible Controlled Substances Provider* by HHS; (4) it takes place during a public health emergency declared by HHS under section 247d of title 42; (5) the practitioner has obtained a *Special Registration* with DEA; [17] (6) there is a medical emergency that prevents the patient from being in the physical presence of an employee or contractor of the Veterans Health Administration (VHA) and one of its hospitals or clinics, and immediate intervention by the practitioner using controlled substances is required to prevent injury or death; and (7) any other circumstances that DEA and HHS have jointly determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.[18]

As noted above, the *Ryan Haight Act,* and the telemedicine regulations implementing it thereunder, apply only in limited circumstances, impacting only a subset of practitioner-patient relationships: where the prescribing practitioner wishes to prescribe controlled substances and has never conducted an in-person medical evaluation of the patient prior to the issuance of the prescription. In other words, the regulations proposed in this rule would not be applicable to practitioner-patient relationships in which there has been a prior in-person medical evaluation of the patient by the practitioner.

COVID–19 Public Health Emergency. In response to the COVID–19 PHE, as declared by the Secretary on January 31, 2020, pursuant to the authority under section 319 of the *Public Health Service Act* (42 U.S.C. 247), DEA granted temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations under 21 U.S.C. 802(54)(D), one of the seven distinct categories of telemedicine envisioned under the statutory definition of the *practice of telemedicine.* In order to prevent lapses in care, these exceptions allowed for the prescribing of controlled substances via

[12] 21 U.S.C. 829(e)(1).

[13] *Id.* at 829(e)(2)(A)(i). Under the Ryan Haight Act, the requirement of an in-person medical evaluation does not apply to a ''covering practitioner,'' *id.* 829(e)(2)(A)(ii), as defined by 829(e)(2)(C). A prescribing practitioner meeting this definition need not conduct an in-person medical evaluation as a prerequisite to prescribing a controlled substance to a given patient, provided that the practitioner for whom the practitioner is covering has provided an in-person medical evaluation of that patient and provided further that this covering arrangement is taking place on only a temporary basis. In addition, the covering practitioner—as with all practitioners who prescribe controlled substances—remains subject to the requirement that such prescriptions may be issued only for a legitimate medical purpose in the usual course of professional practice. *Id.*

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

[15] While this statutory definition of the *practice of telemedicine* explicitly excludes pharmacists, such exclusion does not apply to situations where a pharmacist is acting in their capacity as a *mid-level practitioner,* authorized to dispense controlled substances in accordance with their state licensure.

[16] 42 U.S.C. 1395m(m) references, but does not define, such *telecommunications systems.* The Center for Medicare and Medicaid Services (CMS) promulgated regulations implementing these statutory provisions and define the term *interactive telecommunications system.* 42 CFR 410.78(a)(3) defines *interactive telecommunications system* as ''. . . [the] multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. 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'' (emphases added). Though DEA's proposed regulatory definition for *audio-video telecommunications system* largely aligns with CMS's definition of *interactive telecommunications system,* DEA's proposed regulations would not authorize the use of audio-only communication technology for the diagnosis, evaluation, or treatment of mental health disorders, subject to one exception for opioid use disorder discussed in more depth later. These provisions reflect the heightened risks associated with prescribing controlled substances specifically.

[17] Congress enacted legislation in addition to the *Ryan Haight Act* which required DEA to ''promulgate final regulations specifying . . . the limited circumstances in which a special registration for telemedicine may be issued.'' 21 U.S.C. 831(h)(2). In particular, the SUPPORT for Patients and Communities Act (''SUPPORT Act''), signed into law on October 24, 2018, mandated that, in consultation with the Secretary [of Health and Human Services], the Attorney General shall promulgate final regulations specifying—(A) the limited circumstances in which a special registration for telemedicine . . . may be issued; and (B) the procedure for obtaining [a] special registration for telemedicine.'' *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (SUPPORT Act), Public Law 115–271, 3232, 132 Stat. 3894, 3950 (2018). The Attorney General has delegated this authority to the Administrator of DEA. *See* 28 CFR 0.100. As required by the SUPPORT Act, DEA has consulted with representatives of the Secretary of Health and Human Services regarding the substance of this proposed rule.

[18] 21 U.S.C. 802(54).

telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient. These telemedicine flexibilities authorized practitioners to prescribe Schedule II–V controlled substances via audio-video telemedicine encounters, including Schedule III–V opioid controlled substances approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, provided that such prescriptions otherwise comply with the recommendations outlined in DEA guidance documents, the requirements outlined in DEA regulations, and applicable Federal and State law. DEA granted those temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations via two letters published in March 2020:

- A March 25, 2020 ''Dear Registrant'' letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division (the McDermott Letter); [19] and
- A March 31, 2020 ''Dear Registrant'' letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division (the Prevoznik Letter).[20]

Prior NPRMs and Temporary Rules; Telemedicine Listening Sessions. On March 1, 2023, DEA, in concert with HHS and pursuant to 21 U.S.C. 802(54)(G), promulgated two NPRMs in the **Federal Register**, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* (the ''General Telemedicine NPRM'') [21] and *Expansion of Induction of Buprenorphine via Telemedicine Encounter* (the ''Buprenorphine NPRM''),[22] which proposed to expand patient access to prescriptions for controlled substances via telemedicine encounters relative to the pre-COVID–19 PHE landscape. The purpose of the two proposed rules was to make permanent some of the telemedicine flexibilities established during the COVID–19 PHE in order to facilitate patient access to controlled substance medications via telemedicine when consistent with public health and safety, while maintaining effective controls against diversion. The comment period for these two NPRMs closed on March 31, 2023. Those NPRMs generated a total of 38,369 public comments—35,454 comments on the General Telemedicine NPRM and 2,915 comments on the Buprenorphine NPRM.

On May 10, 2023 DEA, jointly with HHS (with the Substance Abuse and Mental Health Services Administration (SAMHSA) acting on behalf of HHS), issued the First Temporary Rule pursuant to 21 U.S.C. 802(54)(G), which extended the full set of telemedicine flexibilities regarding the prescribing of controlled substances, as had been in place under the COVID–19 PHE, through November 11, 2023.[23] The First Temporary Rule also provided a one-year grace period, through November 11, 2024, to any practitioner-patient telemedicine relationships that had been or would be established on or before November 11, 2023.

On September 12 and 13, 2023, DEA hosted the live, in-person Telemedicine Listening Sessions, to receive additional input concerning the practice of telemedicine with regards to prescribing controlled substances and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. DEA invited the public to express their views concerning the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation at all, the availability and types of data that would be useful in detecting diversion of controlled substances via telemedicine that are either already reported or could be reported, and specific additional safeguards that could be placed around the prescribing of Schedule II controlled substances via telemedicine. Approximately 58 stakeholders, including *institutional practitioners* and *clinician practitioners,* pharmacists, trade associations, state agencies, and other public interest groups, presented at the listening sessions.

On October 10, 2023, in light of the need to further evaluate the best course of action given the comments received in response to the March 2023 NPRMs and the presentations at the Telemedicine Listening Sessions, DEA, jointly with HHS, issued the Second Temporary Rule, also pursuant to 21 U.S.C. 802(54)(G), thereby extending the full set of telemedicine flexibilities regarding prescription of controlled substances as were in place during the COVID–19 PHE through December 31, 2024.[24] The extension authorized all DEA-registered practitioners to prescribe Schedule II–V controlled substances via telemedicine through December 31, 2024, whether or not the patient and practitioner established a telemedicine relationship on or before November 11, 2023. In other words, the grace period provided in the First Temporary Rule was effectively subsumed by this Second Temporary Rule, which continued the extension of the current flexibilities for all practitioner-patient relationships—not just those established on or before November 11, 2023—until the end of 2024. The purpose of the Second Temporary Rule, like the one before it, was to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled substance prescriptions, as well as to allow adequate time for providers to come into compliance with any new standards or safeguards that are promulgated as part of a final set of telemedicine regulations.

Tribal Consultations. On June 13 and 27, 2024, the Office of Tribal Justice, Department of Justice (OTJ) collaborated with DEA to host two virtual DOJ Government-to-Government Tribal Consultations to seek input from Tribal governments on the practice of telemedicine within American Indian/Alaskan Native (AI/AN) communities. OTJ and DEA invited the Tribal leaders of all federally recognized Tribes using the Bureau of Indian Affairs Tribal Leaders Directory, and provided a framing paper detailing the flexibilities, public engagement, and regulatory actions taken by DEA in recent years concerning telemedicine. OTJ and DEA invited Tribal input on any question or topic of interest related to the use of telemedicine by AI/AN communities, and specifically requested input on potential regulatory requirements and suggestions on what would help Tribal governments implement and comply with a future rule. OTJ and DEA also welcomed the submission of any written comments as well.

III. Need for Further Rulemaking: Special Registration for Telemedicine

In the process of reviewing and evaluating the comments to the

[19] 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.*

[20] 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.*

[21] 88 FR 12875 (Mar. 1, 2023).

[22] 88 FR 12890 (Mar. 1, 2023).

[23] Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 30037 (May 10, 2023).

[24] Second Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 69879 (October 10, 2023).

proposed 2023 General Telemedicine NPRM and Buprenorphine NPRM, as well as the presentations made by various stakeholders at the Telemedicine Listening Sessions, DEA has determined that the best course of action to ensure patient access to care, while maintaining sufficient safeguards to detect and protect against the diversion of controlled substances, is to establish and maintain a separate *Special Registration for Telemedicine* (also referred to as simply ''Special Registration''), *i.e.,* the regulatory scheme Congress specifically authorized in 21 U.S.C. 802(54)(E) and 21 U.S.C. 831(h). As compared to the pre-COVID–19 PHE landscape, the *Special Registration* proposed herein would allow more comprehensive prescribing, including prescribing of Schedule II narcotics and non-narcotic controlled substances in limited circumstances, by properly registered *clinician practitioners* and dispensing by *platform practitioners* with a legitimate need for the *Special Registration.*

In determining when a *Special Registration* should be issued under 21 U.S.C. 802(54)(E), DEA must consider the criteria set forth in 21 U.S.C. 831(h). First, DEA must evaluate a practitioner's legitimate need for such a *Special Registration,* as well as clearly define the limited circumstances under which a *Special Registration* is appropriate.[25] These statutory requirements emphasize the need for careful consideration when extending prescribing privileges through telemedicine. This evaluation is crucial in determining whether telemedicine serves a necessary role, especially given the heightened risks of diversion and inappropriate prescribing of controlled substances posed by remote services where a patient has never undergone an in-person medical evaluation with the prescribing practitioner.

While the COVID–19 PHE created a genuine need for increased use of telemedicine, it also highlighted the inherent risks associated with remote prescribing, particularly in the absence of in-person medical evaluations. In a 2021 *Harris Poll* online survey conducted on behalf of *Quest Diagnostics,* 67 percent of physicians expressed concerns about missing signs of drug use or use disorders during the COVID–19 PHE, and 75 percent of physicians felt that telemedicine constrained their ability to assess whether patients were at risk of, or already, misusing prescription drugs.[26] Although the telemedicine flexibilities during the PHE allowing practitioners to prescribe controlled substances without prior in-person medical evaluations were necessary to prevent lapses of care amid a global pandemic, it also facilitated the emergence of concerning business models engaged in the widespread diversion of controlled substances, taking advantage of the flexibilities established during the COVID–19 PHE.[27]

Second, DEA may only issue a *Special Registration* if the practitioner is ''registered under 21 U.S.C. 823(g) in the state which the patient will be located'' when receiving the telemedicine treatment, unless the *practitioner* is excepted from 823(g) registration.[28] Such 823(g) registration in the patient's state is a critical validation of the practitioner's qualifications and expertise in prescribing controlled substances within a given state. Moreover, the definition of ''practice of telemedicine'' under the *Ryan Haight Act* requires the practitioner to engage in the practice of medicine only ''in accordance with applicable Federal and state laws.'' A *special registrant* under this proposed framework would need to continue to comply with the laws and regulations of the state in which registered, and the laws and regulations of the state in which they are issuing *special registration prescriptions*[29] via a telemedicine encounter. Thus, where one state's law and regulations are more restrictive than the other state's law and regulations, the *special registrant* would be required to follow the more restrictive state law and regulations.[30]

Third, in all instances, *clinician practitioners* ''must establish and maintain a bonafide doctor-patient relationship in order to act 'in the usual course of . . . professional practice' and to issue a prescription for a 'legitimate medical purpose.' ''[31] The ''usual course of professional practice'' is defined by the state in which a registrant practices, because ''[c]onsistent with the CSA's recognition of the State's primary role in regulating the practice of medicine, the [CSA] generally looks to State law and standards of medical practice to determine whether a doctor and patient have established (and are maintaining) a bonafide doctor-patient relationship'' at the time of the prescription.[32]

Direct-to-Consumer Online Telemedicine Platforms. In today's rapidly evolving healthcare landscape, third-party online telemedicine platforms play a large and integral role, as intermediaries, in the delivery of remote healthcare to patients beyond traditional medical settings, with a shift towards predominantly virtual interactions. Many of these online telemedicine platforms employ a direct-to-consumer (''DTC'') business model in which they introduce or connect

[25] 21 U.S.C. 831(h)(1)(A).

[26] *Majority of Physicians Worry Signs of Addiction Were Missed During Pandemic, Finds New Quest Diagnostics Health Trends Report,* Quest Diagnostics (Nov. 15, 2021), *https://newsroom.questdiagnostics.com/2021-11-15-Majority-of-Physicians-Worry-Signs-of-Addiction-Were-Missed-During-Pandemic,-Finds-New-Quest-Diagnostics-Health-Trends-R-Report#assets_30649_137302-130:199.* While a survey conducted on behalf of a diagnostics services company, such as *Quest Diagnostics,* may carry the potential for bias—given the company's potential preference for traditional in-person healthcare models—it still offers valuable insights, even if interpreted with some caution. When considered in context, such information still provides a unique data point, that when weighted accordingly, can inform this analysis. The results of the *Harris Poll* survey are further reinforced by a 2024 National Center for Health Statistics (NCHS) Data Brief that shows the percentage of physicians who feel telemedicine *fully* provides the same care as in-person is 4.0 percent for primary care, 6.3 percent for surgical specialty, and 6.0 percent for medical specialty. Myrick K, Mahar M, DeFrances CJ. *Telemedicine Use Among Physicians by Physician Specialty: United States, 2021. NCHS Data Brief,* no 493. (Feb. 2024), *https://www.cdc.gov/nchs/data/databriefs/db493.pdf.*

[27] In June 2024, the founder and clinical president of a telehealth company were arrested for allegedly participating in a scheme to distribute *Adderall* and other stimulants online and conspiring to commit healthcare fraud. Specifically, they have been accused of arranging the prescription of over 40 million pills of *Adderall* and other stimulants, often with no legitimate medical purpose. The company allegedly provided easy access to controlled substances in exchange for a monthly subscription fee, leading to tragic consequences, including overdoses and deaths. These allegations underscore DEA's need to judiciously evaluate when a practitioner has a legitimate need for a *Special Registration,* and to ensure that any rule permanently authorizing telemedicine contains sufficient safeguards. *Founder/CEO and Clinical President of Digital Health Company Arrested for $100M Adderall Distribution and Health Care Fraud Scheme,* U.S. Department of Justice, Press Release Number: 24–752 (June 13, 2024), *https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-arrested-100m-adderall-distribution.*

[28] 21 U.S.C. 831(h)(1)(B).

[29] Proposed 21 CFR 1300.04 defines a *special registration prescription* to mean ''a prescription, defined under [21 CFR 1300.01], for controlled substances issued under a practitioner's Special Registration for Telemedicine for a legitimate medical purpose in the usual course of professional practice through the utilization of an audio-video telecommunications system defined in § 1300.04 of this chapter.

[30] Under some circumstances, a special registrant may operate under a state reciprocity agreement or other form of state permission that would authorize the special registrant to comply only with the normally applicable law or regulations of either the state in which they are registered or the state in which they are practicing. In other words, states may deem compliance with one state's normally applicable law and regulations as compliance with both states' laws and regulations. In this context, DEA would understand the special registrant to be complying with both states' laws and regulations, because the special registrant's prescribing of controlled substances would be authorized by both states.

[31] Dewey C. MacKay, 75 FR 49956, 49973 (2010), aff'd, *MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

[32] *Id.*

patients with a remote *clinician practitioner* enabling the patient to be ''seen'' anywhere using a computer or smart phone, forgoing the need for the patient to go to a medical facility to use the facility's telecommunications system.

Today's DTC online telemedicine platforms often engage in marketing to attract new patients, whom they then introduce or match with *clinician practitioners* under the platforms' direct employment or contract. The payment arrangements between the patient and the platform vary, but some platforms offer subscriptions, where patients pay a monthly fee for virtual consultations, sometimes up to and including an unlimited number of consultations, with a *clinician practitioner.* Often, but not always, the online telemedicine platform may own and operate the virtual environment, including the telecommunications system, where the patient and practitioner virtually ''meet,'' providing the technological infrastructure or support. Unlike traditional medical settings, the *clinician practitioner* conducts the medical evaluation remotely, after which they may prescribe medications, including controlled substances. While the DTC online telemedicine platforms are not entirely new, they proliferated in recent years, in large part due to the COVID–19 pandemic.

Dispensing by Practitioners under the CSA. Although these third-party, DTC online telemedicine platforms do not directly prescribe to patients or physically dispense controlled substances to patients, certain platforms' central involvement as intermediaries in the remote dispensing of controlled substances qualifies them as ''practitioners'' engaged in ''dispensing'' under the CSA. Under the CSA, to ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance.'' [33] This statutory definition encompasses not only the physical act of handing out medications, but the broader process of providing them to patients under the direction of a licensed healthcare provider.

The online telemedicine platforms serving as intermediaries for the prescribing of controlled substances fall squarely within the CSA's broad definition of ''practitioner.'' Under the CSA a ''practitioner'' means ''a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' [34] According to this statutory definition, a ''practitioner'' is not limited solely to individual healthcare providers, but also encompasses entities permitted by law to distribute or dispense controlled substances. Furthermore, considering the evolving nature of healthcare delivery, recognizing certain DTC online telemedicine platforms as practitioners engaged in dispensing under the CSA reflects the current landscape of telemedicine practice and ensures that DEA's regulations remain relevant and responsive to changes in healthcare technology.[35]

DEA Registration of Intermediaries. The registration of telemedicine intermediaries is not a novel concept. In fact, when Congress amended the CSA with the *Ryan Haight Act,* it recognized the integral role telepresenters, serving as intermediaries, played in certain telemedicine models. In 21 U.S.C. 802(54)(A)–(B), Congress specifically authorized two categories of telemedicine, both involving an intermediary healthcare provider facilitating a medical evaluation between a patient and a *clinician practitioner* located at a distance. Such intermediaries, in this context, are referred to as telepresenters. To uphold the integrity of the closed system, Congress required that such telepresenters, as intermediaries, be registered with DEA. Registration, the cornerstone of the closed system, helps to ensure that such intermediaries are qualified and accountable to DEA, reducing the risk of vulnerabilities or loopholes in this closed system that could lead to diversion and abuse of controlled substances.[36]

Special Registration of Certain DTC Online Telemedicine Platforms. Certain modern DTC online telemedicine platforms of today, which play a substantial and integral role as intermediaries in the remote dispensing of controlled substances, also require registration with DEA. These platforms are indispensable for delivering telemedicine services directly to patients through virtual platforms, in contrast to the other telemedicine models such as those that utilize telepresenters under 21 U.S.C. 802(54)(A)–(B). The necessity for oversight of these newer telemedicine intermediaries is heightened by concerns arising from business practices that have come to light during and after the COVID–19 pandemic. These practices include platforms that incentivize the prescription of controlled substances to patients by practitioners and the exertion of control over the medications prescribed to patients. DEA has been informed by some clinicians that there have been instances when they terminated their relationship with an online telemedicine platform and, in doing so, forfeited access to their patient's medical records stored by the platform. This renders such records non-compliant with DEA regulations, which mandate that the records be readily retrievable by the practitioner, because they become entirely inaccessible to the *clinician practitioner.*

As discussed in further detail below, DEA is proposing the *Special Registration* of these DTC online telemedicine platforms when they meet the proposed regulatory definition of a *covered online telemedicine platform.* DEA is proposing a definition for *covered online telemedicine platform,* delineating the criteria that indicate their substantial and integral role as intermediaries in the remote dispensing of controlled substances, qualifying them as practitioners engaged in dispensing under the CSA and subject to the requirements imposed upon non-

[33] 21 U.S.C. 802(10).

[34] Public Law 91–513 and 21 U.S.C. 802(21). The definition of *practitioner* has also remained unchanged since the enactment of the original CSA.

[35] *See* Senate Report 110–521, *Ryan Haight Online Pharmacy Consumer Protection Act of 2007,* accompanying S.980, November 17, 2008 (providing ''[c]ertain telemedicine practices are exempted from the in-person medical evaluation requirement. The Committee recognizes that telemedicine is a practice tool that can improve health outcomes and reduce costs. It is not the intent of the Committee to restrict the legitimate practice of telemedicine or the emerging practices of telemedicine which are consistent with medical practice guidelines of the State in which the practitioner is licensed, provided such practices do not contravene the goal of effectively controlling the diversion of controlled substances'').

[36] In addition to these two telepresenter categories, Congress created two additional regulatory categories (the *special registration* category and the joint rule category) to allow DEA to carry out its diversion control mission in light of future industry developments. *See* Senate Report 110–521, *Ryan Haight Online Pharmacy Consumer Protection Act of 2007,* accompanying S.980, November 17, 2008 (noting that the statute provides that the Attorney General and the Secretary of Health and Human Services may promulgate regulations that allow for the full practice of telemedicine consistent with medical practice guidelines, so long as these regulations continue to effectively control diversion).

pharmacist practitioners [37] under the *Controlled Substances Act* and its regulations.

When any one of the four outlined factors are present, it solidifies the platform's role as an integral intermediary in the remote dispensing of controlled substances.[38] The proposed definition and criteria are intended to provide a practical and clear framework for identifying when a DTC online telemedicine platform's conduct qualifies them as a *covered online telemedicine platform,* mandating registration as a dispenser with DEA.[39] As proposed, this definition is intended to limit the *Special Registration* requirements only to those DTC online telemedicine platforms that play a substantial and integral role as intermediaries in the remote dispensing of controlled substances.

The definition of *covered online telemedicine platform* also explicitly excludes certain types of entities, including hospitals, clinics, insurance providers, and *local in-person medical practices. Local in-person medical practice* is, in turn, defined by this rule to be a medical practice where all its offices are within 100 miles of each other, and where less than 50 percent of the total prescriptions for controlled substances collectively issued by the practice's physicians and *mid-level practitioners* are issued via telemedicine in any given calendar month, but is not a hospital, clinic, or insurance provider. The type of entities excluded from the definition of *covered online telemedicine platform* are entities that engage in conduct that could potentially fall under the definition's criteria but are not the types of entities whose primary business operations rely on, or center around, telemedicine services. Moreover, it should be noted that the proposed definition of *local in-person medical practice* uses the term ''telemedicine'' rather than ''*practice of telemedicine.*'' This distinction is significant, as ''telemedicine'' is used in its general, colloquial sense, whereas the ''*practice of telemedicine*'' carries the specific statutory meaning defined by the *Ryan Haight Act.*

Determining whether an entity dispenses controlled substances and meets the criteria of a *covered online telemedicine platform* is a fact-specific inquiry. If there is any uncertainty regarding the entity's role as a dispenser, particularly concerning its involvement in the practitioner-patient relationship, registering may be advisable to avert the risk of enforcement action based on potential unregistered, and thus illegal, dispensing of controlled substances.

IV. Section-by-Section Discussion of Proposed Rule

The proposed regulations discussed below are designed to satisfy the statutory mandates of 21 U.S.C. 831(h) and 21 U.S.C. 802(54)(E), while fulfilling DEA's core responsibilities of regulating controlled substances and adapting to the evolving landscape of telemedicine, including the rise of new types of DTC online telemedicine platforms engaged in dispensing of controlled substances. Before discussing the proposed regulations, it is important to once again highlight what they do not govern or permit. First, as emphasized previously, the proposed regulations do not affect practitioner-patient relationships in cases where an in-person medical evaluation has occurred at any point within the relationship. Once an in-person medical evaluation has taken place, the practitioner-patient relationship falls outside the scope of the *Ryan Haight Act* and the DEA regulations implementing the *Ryan Haight Act.* Second, these proposed regulations primarily focus on the *practice of telemedicine* under the *Special Registration* framework authorized by the *Ryan Haight Act.*[40] Other categories of telemedicine established by the *Ryan Haight Act,* such as telemedicine occurring during a public health emergency declared by HHS as authorized under 21 U.S.C. 802(54)(D), are not subject to the registration, prescription, and recordkeeping and reporting regulations proposed in this NPRM.

Third, these proposed regulations would not apply in the absence of a prescription for controlled substances.[41] In other words, practitioners would *not* be required to obtain a *Special Registration* unless they wish to prescribe or otherwise dispense controlled substances to patients via telemedicine encounters. And fourth, the proposed regulations would only permit the *prescribing* of controlled substances through telemedicine by *clinician practitioners.* Under the *Special Registration* framework, *clinician practitioners* would not be authorized to engage in other modes of ''dispensing,'' such as ''administering'' controlled substances to patients via telemedicine.[42]

A. Registration Requirements Under 21 CFR Part 1301

As discussed earlier, registration is the cornerstone of the closed system of control for manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA, unless otherwise exempted. Establishing a *Special Registration* for telemedicine would enhance patient access to care by allowing certain practitioners to prescribe controlled substances via telemedicine without the limitations of geographical barriers. At the same time, it would establish the appropriate circumstances and guardrails for telemedicine-based prescribing and dispensing of controlled substances where an in-person medical evaluation has never been performed by the prescribing practitioner. The rise of DTC online telemedicine platforms in recent years has further transformed healthcare delivery, but it has also introduced new challenges and heightened risks of diversion due to the remote nature of care delivery. The proposed registration requirements for telemedicine-based prescribing and dispensing create a new business activity within DEA's overarching registration framework, distinguishing it from the traditional modes of dispensing under a 21 U.S.C. 823(g) registration.

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[37] *See supra* footnote 15.

[38] The behaviors listed in these four factors are included solely to determine whether a platform is serving as an integral intermediary. Federal, state, or local laws and/or regulations may impose statutory or regulatory requirements related to these behaviors. The inclusion of these behaviors in the definition of *covered online telemedicine platform* does not indicate that such behaviors are permitted under any particular law or regulation.

[39] The definition of *covered online telemedicine platform* and the four criteria are discussed in further detail below in the NPRM's discussion of proposed regulatory definitions.

[40] *Ryan Haight Online Pharmacy Consumer Protection Act of 2008,* Public Law 110–425, 122 Stat. 4820, § 3(a) (2008) (codified as amended in 21 U.S.C. 802(54)(E)).

[41] This is an important distinction given potential conflation between colloquial use of the term ''telemedicine'' and the statutory definition of the ''practice of telemedicine'' in the CSA and these proposed regulations. To illustrate this point, the following scenarios are non-exhaustive examples in which ''telemedicine'' may occur in the colloquial sense but would not constitute the ''practice of telemedicine'' under the CSA or these proposed regulations: (1) a practitioner issues a prescription for a non-controlled substance; (2) a practitioner treats the patient through audio-visual means and, after doing so, determines the patient does not require controlled substances; or (3) a practitioner is a mental health counselor who treats patients using ''talk therapy'' exclusively, without prescribing controlled substances.

[42] 21 U.S.C. 802(2) defines ''administer'' to mean the ''direct application of a controlled substance to the body of a patient or research subject by a practitioner (or, in his presence, by his authorized agent), or the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.''

1. Three Types of Special Registration; Registrant Eligibility

The proposed requirements for the *Special Registration* [43] are devised to meet the statutory requirements of 21 U.S.C. 831(h). This provision authorizes DEA to issue a *Special Registration* if the practitioner demonstrates a legitimate need for a *Special Registration.*[44] Moreover, this statutory provision requires DEA to promulgate regulations specifying the limited circumstances under which a *Special Registration* may be issued and establish clear eligibility criteria for practitioners and the procedure for seeking a *Special Registration.*[45] To accommodate the varying legitimate needs of practitioners, including both *clinician practitioners* and *covered online telemedicine platforms,* in their capacity as *platform practitioners,* the proposed framework offers three distinct categories of *Special Registrations.*

The first category, the *Telemedicine Prescribing Registration,* would authorize the prescribing of Schedules III through V controlled substances by *clinician practitioners.*[46] The second category, the *Advanced Telemedicine Prescribing Registration,* would authorize certain specialized *clinician practitioners* the privilege to prescribe not only Schedule III through V controlled substances, but Schedule II controlled substances as well,[47] even though such substances have higher potential for abuse and dependence.[48] And lastly, the third category, the *Telemedicine Platform Registration,* would authorize *covered online telemedicine platforms* to dispense Schedules II through V controlled substances through a *clinician practitioner* possessing either a *Telemedicine Prescribing Registration* or an *Advanced Telemedicine Prescribing Registration.*[49]

Under proposed § 1301.11(c)(1)(A), an applicant for one of the three types of *Special Registration* would be required to already have one or more DEA registrations under 21 U.S.C. 823(g) to prescribe (if an *clinician practitioner*) or dispense (if a *platform practitioner*) controlled substances in a state in which they are licensed, registered, or otherwise permitted to prescribe or dispense controlled substances through telemedicine, unless they are otherwise exempted.

This requirement for *Special Registration* streamlines the review and approval process for applications for *Special Registrations* by building upon the checks and assessments already conducted for 21 U.S.C. 823(g) registrations. While the proposed framework allows for VA *practitioners* to seek and obtain a *Special Registration,* DEA and HHS have also jointly promulgated the *Continuity of Care via Telemedicine for Veterans Affairs Patients* final rule (RIN 1117–AB88), published elsewhere in this issue of the **Federal Register**, which specifically addresses the *practice of telemedicine* within the VA health care system. As discussed above, a DTC online telemedicine platform that qualifies as a *covered online telemedicine platform* dispenses controlled substances and must register with DEA in its capacity as a dispenser. It also bears emphasizing that proposed § 1301.11(c)(1) requires that *covered online telemedicine platforms,* like their *clinician practitioner* counterparts, already have one or more DEA registrations under 21 U.S.C. 823(g) to dispense controlled substances; DEA registrations under 21 U.S.C. 823(g) in turn require licensing of the activity by the state in which DEA registration under 21 U.S.C. 823(g) is sought.

Proposed § 1301.11(c)(1)(i) makes it clear that those officials for whom the requirement of registration to prescribe is generally waived under § 1301.23(a) of this chapter must still obtain a *Telemedicine Prescribing Registration* or *Advance Telemedicine Prescribing Registration* before issuing *special registration prescriptions.*[50] Such officials are, as described below, exempt from obtaining *State Telemedicine Registrations,* though they must identify all the states in which patients will be treated via telemedicine on their registration application.

a. Telemedicine Prescribing Registration (Schedules III–V) Clinician Practitioners Eligibility

To be eligible for the *Telemedicine Prescribing Registration* under proposed § 1301.11(c)(2), *clinician practitioners* would need to demonstrate that they have a legitimate need for a *Special Registration.* DEA has determined that physicians and board-certified *mid-level practitioners* (defined under 21 CFR 1300.01) have a legitimate need to prescribe Schedules III through V controlled substances when they anticipate that they will be treating patients for whom requiring in-person medical evaluations prior to prescribing Schedule III–V controlled substances could impose significant burdens on *bona fide* practitioner-patient relationships. For example, practitioners may have a legitimate need for the *Special Registration* when their patients face significant challenges in attending in-person medical evaluations, such as severe weather conditions, living in remote or distant areas, or having communicable diseases, which make in-person appointments difficult or even unadvisable.

b. Advanced Telemedicine Prescribing Registration (Schedules II–V) Clinician Practitioner Eligibility

To be eligible for the *Advanced Telemedicine Prescribing Registration* under proposed § 1301.11(c)(3), physicians and *mid-level practitioners,* as *clinician practitioners,* would not only need to demonstrate they have a legitimate need for the *Special Registration* but that such need warrants the authorization of prescribing of Schedule II controlled substances in addition to Schedules III through V controlled substances. DEA has determined that certain specialized physicians and board-certified *mid-level practitioners* have a legitimate need to prescribe Schedule II controlled substances via telemedicine when treating particularly vulnerable patient populations. Such authorization is reserved only for the most compelling use cases, ensuring that Schedule II prescribing via telemedicine is used only when necessary.

Consistent with these concerns regarding vulnerable patient populations, and cognizant of the high potential for abuse that exists for Schedule II controlled substances, DEA has determined that only certain specialized physicians and board-certified *mid-level practitioners* have a legitimate need for the *Advanced Telemedicine Prescribing Registration,* in the following limited circumstances or practice specialties:

(1) psychiatrists;
(2) *hospice care* physicians;
(3) *palliative care* physicians;
(4) physicians rendering treatment at *long term care facilities;*
(5) pediatricians; [51]

[43] Proposed 21 CFR 1301.11.
[44] 21 U.S.C. 831(h)(1)(A).
[45] *Id.;* 831(h)(2)(A).
[46] Proposed 21 CFR 1301.11(c)(2).
[47] Proposed 21 CFR 1301.11(c)(3).
[48] *See* 21 U.S.C. 812(b)(2), (3).
[49] Proposed 21 CFR 1301.11(c)(4).

[50] 21 CFR 1301.23(a) waives the requirement of registration ''for any official of the U.S. Army, Navy, Marine Corps, Air Force, Space Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties.''

[51] Proposed 21 CFR 1306.45(e) would also require that the parent or guardian of patients under the age of 18 be present in the room with the patients when the patients are being issued prescriptions for a Schedule II controlled substance.

(6) neurologists; and

(7) *mid-level practitioners* and physicians from other specialties who are board certified in the treatment of psychiatric or psychological disorders, *hospice care, palliative care,* pediatric care, or neurological disorders unrelated to the treatment and management of pain.

The type of specialized practitioners and board-certified *mid-level practitioners* eligible for the *Advanced Telemedicine Prescribing Registration* typically treat patients that face significant healthcare accessibility challenges, and, in some cases, who suffer from particularly debilitating or terminal illnesses. The hardships faced by such patients were discussed at length by certain speakers during the Telemedicine Listening Sessions. For example, some speakers discussed accessibility issues created by shortages of psychiatrists, and the need for qualified, perhaps board-certified, psychiatrists to diagnose and treat illnesses like ADHD.[52] Another group of speakers addressed the accessibility challenges faced by *palliative* and *hospice* patients, often homebound, who may need urgent pain treatment and symptom management.[53] The heightened specificity of these limited circumstances is intended to strike a balance between ensuring access to necessary medications for vulnerable patients while controlling the prescribing of Schedule II controlled substances that have a higher potential risk of abuse and dependence.

Furthermore, these eligible specialized physicians and board-certified *mid-level practitioners* are uniquely positioned to provide expert care for specific, vulnerable patient populations. These specialized physicians and *mid-level practitioners* have specialized training and in-depth knowledge to equip them to make informed decisions regarding the use of Schedule II controlled substances when prescribed remotely to particularly vulnerable patient groups. While DEA is not proposing regulations that delineate specific criteria for practitioners falling into the designated practice specialties, *clinician* practitioners are required to furnish information on their *Special Registration* applications that would demonstrate their specialized training. For example, the *clinician practitioner* could cite or provide information on board certification in a specialty, specialized training, or the percentage of the *clinician practitioner's* overall practice that falls within one of the specialized practices. *Mid-level practitioners* are, however, required to be board-certified under this proposed framework. DEA invites public comments on all facets of the proposed regulations, including this specific provision.[54] Particularly, DEA seeks input on whether other types of practitioners should be included if they can demonstrate specific training in expertise in managing conditions that are traditionally treated with Schedule II controlled substances. DEA also seeks input on alternative methods to ensure that practitioners seeking to prescribe Schedule II controlled substances pursuant to the *Advanced Telemedicine Prescribing Registration* have the appropriate training and expertise to do so safely.

c. Telemedicine Platform Registration (Schedules II–V) Platform Practitioner Eligibility

To be eligible for the *Telemedicine Platform Registration* under proposed § 1301.11(c)(4), *covered online telemedicine platforms* would need to demonstrate that they have a legitimate need for a *Special Registration.* DEA has determined that *covered online telemedicine platforms* (defined under 21 CFR 1300.04), in their capacity as *platform practitioners,* have a legitimate need to dispense Schedules II through V controlled substances when they anticipate providing necessary services to introduce or facilitate connections between patients and *clinician practitioners* via telemedicine for the diagnosis, treatment, and prescription of controlled substances, are compliant with federal and state regulations, provide oversight over *clinician practitioners'* prescribing practices, and take measures to prioritize patient safety and prevent diversion, abuse, or misuse of controlled substances. The *platform practitioner* would be required to attest to its legitimate need on their *special registration* application. If, however, it is later discovered that the practitioner provided false information to obtain the *special registration* or used it for unlawful or inappropriate purposes, the practitioner could be found in violation of 21 U.S.C. 824(a), which could lead to penalties such as revocation or suspension of the registration.

As discussed previously, the registration of *covered online telemedicine platforms* within the *Special Registration* framework is necessary given the pivotal role they sometimes play in the delivery of healthcare through telemedicine. While these *covered online telemedicine platforms* may improve healthcare accessibility by connecting patients with *clinician practitioners,* their emergence also brings more, and sometimes easier, avenues to divert or abuse controlled substances, particularly when such entities have financial incentives tied to prescriptions and/or do not adequately screen the *clinician practitioners* utilizing their system or platform. The lack of proper oversight and verification of *clinician practitioners'* credentials open the door to ''doctor shopping'' [55] on the systems or platforms, particularly when bad actors are aware of, and exploit, the lack of oversight and credential verification by *covered online telemedicine platforms.*

2. Ancillary Registration: State Telemedicine Registrations

Pursuant to 21 U.S.C. 802(54), the *practice of telemedicine,* including such practice authorized under a *Special Registration,* must be ''in accordance'' or consistent with Federal and *State* law. Section 831(h)(1)(B) authorizes DEA to issue a *Special Registration* to a practitioner if the practitioner is registered under 21 U.S.C. 823(g) in the *state* in which the patient is located when receiving a prescription for controlled substance via telemedicine (a ''823(g) patient state registration), subject to certain exceptions. While the proposed *Special Registration* framework must comply with these

[52] *See* Telemedicine Listening Sessions, Georgia Gaveras (Talkiatry), 21:6–22:4, 25:1–8 (Sept. 12, 2023); John Heaphy (NY State Dep. of Health, Mental Health), 76:10–77:14 (Sept. 13, 2023); and Caitlin Gilloley (American Hospital Association), 63:21–64:14 (Sept. 13, 2023).

[53] *See* Telemedicine Listening Sessions, David Hoffman (Columbia University), 44:17–44:23, 45:16–21, 46:19–21 (Sept. 12, 2023); Robin Plumer, M.D., 190:18–191:17 (Sept. 12, 2013); Kevin Duane, PharmD, 206:16–207:1 (Sept. 12, 2023); Joseph Rotella, M.D. (American Academy of Hospice and Palliative Medicine), 289:25–290:12 (Sept. 12, 2023); Alex Armitage, M.D. (Baylor Scott & White Health), 43:8–14, 43:24–44:10 (Sept. 13, 2023); and Caitlin Gilloley (American Hospital Association), 63:21–64:14 (Sept. 13, 2023).

[54] *See* Appendix B for Chart: *Which Special Registration for Telemedicine Do I Need as a Clinician Practitioner?*

[55] Bollmeier SG, Stevenson E, Finnegan P, Griggs SK. *Direct to Consumer Telemedicine: Is Healthcare from Home Best?* Mo Med. 2020 Jul–Aug;117(4):303–309. PMID: 32848261; PMCID: PMC7431063. *See also, Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications,* 88 FR 30037, 30040 (May 10, 2023). As discussed in the First Temporary Rule, while the conduct of certain online telemedicine platforms has raised concerns and such platforms may be subject to investigation for problematic prescribing practices, many others have acted in good faith to expand access to care. ''Doctor shopping is defined as seeing multiple treatment providers, either during a single illness episode or to procure prescription medications illicitly.'' Sansone RA, Sansone LA. Doctor shopping: a phenomenon of many themes. Innov Clin Neurosci. 2012 Nov;9(11–12):42–6. PMID: 23346518; PMCID: PMC3552465.

statutory provisions, DEA is mindful that telemedicine is largely designed to overcome geographical constraints. Therefore, to reduce the administrative burden and cost on *special registrants,* DEA is proposing a limited type of 21 U.S.C. 823(g) registration for a lower registration fee, the *State Telemedicine Registration.*

Pursuant to proposed § 1301.11(d), a *clinician special registrant* would be required to obtain a *State Telemedicine Registration,* which is a DEA-issued registration and not a registration issued by the individual states, for every state in which they intend to issue prescriptions for controlled substances to patients via telemedicine. Likewise, a *platform special registrant* would be required to obtain a *State Telemedicine Registration* for every state in which it dispenses Schedule II–V controlled substances to a patient. The *State Telemedicine Registration* would operate as an ancillary credential, contingent on the *Special Registration* held by the *clinician practitioner* or *platform practitioner.* In other words, a *State Telemedicine Registration* for a given state would allow the *special registrant* to prescribe only via telemedicine encounters as to that state, and only for the scheduled controlled substances authorized by their *Special Registration* (*i.e., Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration, or Telemedicine Platform Registration*).

Proposed 21 CFR 1301.11(d) stipulates that a practitioner's eligibility for the *State Telemedicine Registration* for a specific state depends on their authorization, such as state licensure or state-level registration, to prescribe or otherwise dispense controlled substances through telemedicine within that state. Consistent with the criteria for all 823(g) registrations, DEA will consider the public interest factors outlined in 21 U.S.C. 823(g)(1)(A)–(E) before granting a *State Telemedicine Registration.* The requirement of state authorization aligns with 21 U.S.C. 823(g)(1)(D), which assesses compliance with *state,* federal, and local laws regarding controlled substances.

Exemptions to the State Telemedicine Registration Requirement. Section 21 U.S.C. 831(h)(1)(B) does, however, provide two categories of exemptions to the state registration requirement. Generally, a *clinician special registrant* would not be required to obtain a section 823(g) registration in each patient state to prescribe via telemedicine, if the *clinician special registrant* is either: (1) subject to a regulatory exemption applicable to all states pursuant to 21 U.S.C. 822(d),[56] or (2) the *clinician special registrant* is an employee or contractor of the VA.[57]

As to the first category of exemptions, there is currently one regulatory exemption, promulgated pursuant to 21 U.S.C. 822(d), applicable to registration in all states. Specifically, 21 CFR 1301.23(a) waives registration ''for any official of the U.S. Army, Navy, Marine Corps, Air Force, Space Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties.'' The second category of exemptions is the one explicitly extended to VA employees or contractors by statute.[58] When an employee or contractor of the VA is acting in the scope of such employment or contract, and is registered under section 823(g) in *any state* or is utilizing the registration of a hospital or clinic operated by the VA registered under 21 U.S.C. 823(g), the prescriber would not need to possess a *State Telemedicine Registration* in each state in which a patient is located.[59]

While proposed § 1301.11(d) incorporates these exemptions, those *clinician practitioners* who are exempted from the *State Telemedicine Registration* requirement remain subject to other *Special Registration* eligibility requirements and are required to identify all the states in which patients will be treated via telemedicine on their registration application for the *Telemedicine Prescribing Registration* or the *Advanced Telemedicine Prescribing Registration.* DEA must have this information to coordinate oversight and verify that *State Telemedicine Registration*-exempted *clinician special registrants* are operating within the boundaries of their exemption while upholding regulatory standards. The *State Telemedicine Registration*-exempted *clinician special registrants* would also be exempted from the $50 fee per state under proposed 21 CFR 1301.13(e)(1)(xiii), further discussed below.[60]

[56] Pursuant to 21 U.S.C. 822(d), ''[t]he Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.''

[57] 21 U.S.C. 802(54)(A)(ii)(III).

[58] 21 U.S.C. 802(54)(A)(ii)(III)(bb).

[59] 21 U.S.C. 831(h)(1)(B)(i)–(ii).

[60] *See* Appendix C for Chart: *Which State Telemedicine Registrations Do I Need, If Any?*

3. Special Registration Application Process

The *Special Registration* application process for obtaining the proposed *Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* and the *Telemedicine Platform Registration* would differ from the standard 21 U.S.C. 823(g) registration application process. The proposed amendments to 21 CFR 1301.13 outline the new *Special Registration* application requirements.

a. Special Registration Application, Cycles, Fees, Generally

Proposed 21 CFR 1301.13(e)(1)(xi)–(xv) summarizes the *Special Registration* Application, Cycle, and Fees. DEA proposes issuing a new registration application, *Form 224S* (*Application for Special Registration for Telemedicine Under the Controlled Substances Act*), tailored for *Special Registrations. Special Registration* applicants would use the *Form 224S* to apply for one of the three types of the *Special Registration* (*i.e., Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* or *Telemedicine Platform Registration*), as well as the *State Telemedicine Registrations* for each state in which telemedicine patients will be located. The regulations propose a tiered fee structure to address the administrative demands specific to the new business activities. The regulations propose a three-year cycle for the *Special Registrations* (*i.e., Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* and *Telemedicine Platform Registration*), as well as the *State Telemedicine Registrations* (*i.e., Clinician Practitioner State Telemedicine Registration* and the *Platform Practitioner State Telemedicine Registration*).

For any one of the three types of *Special Registration,* the registration fee would be $888. The fee for the *Platform Practitioner State Telemedicine Registration* would be $888 for each state in which a *State Telemedicine Registration* is sought; however, the *Clinician Practitioner State Telemedicine Registration* would be discounted to $50 for each state in which the *clinician practitioner* sought a *State Telemedicine Registration.*[61] The fee for the *State Telemedicine Registration* for *clinician practitioners* is discounted to account for the expected

[61] 21 CFR 1301.21 exempts certain *clinician practitioner* applicants from payment of application fees for registration, including for *Special Registrations* and *State Telemedicine Registrations.*

lower volume of telemedicine that would be conducted by *clinician practitioners* compared to *covered online telemedicine platforms.* The $50 registration fee for the *Clinician Practitioner State Telemedicine Registration* would be waived for those exempted from registration pursuant to 21 U.S.C. 831(h)(1)(B) and proposed 21 CFR 1301.11(c)(3). In DEA's preliminary assessment, the registration fees are reasonable and are expected to account for the full operating costs associated with the heightened administrative and resource demands on the Diversion Control Program that will arise from regulating a new registration class; however, DEA may adjust these fees as it acquires additional information about the new registration classes to ensure appropriate funding for regulatory oversight.[62]

b. Supplemental Requirements on Special Registration Application (Form 224S)

Special Registered Location. Pursuant to proposed § 1301.13(k)(1), all *Special Registration* applicants would be required to designate one of their existing 21 U.S.C. 823(g) registered locations as the registered location/physical address (''*special registered location*'') of their *Special Registration.* The *special registered location* would serve as the physical point of contact for DEA telemedicine inquires and compliance actions. As will be further discussed below, the proposed rule would also mandate that the records arising from telemedicine encounters under the *Special Registration* be maintained at the *special registered location.*[63] Such centralized recordkeeping would allow DEA to more efficiently review records and ensure that prescriptions are being issued in accordance with DEA regulations. Proposed § 1301.13(k)(1) would provide an exemption for applicants who are exempted from the *State Telemedicine Registration* requirement under proposed § 1301.11(d); however, such exempted persons would be required to provide another physical address on the application to serve as their *special registered location.*

Form 224S Supplementary Disclosures and Attestations. Proposed 21 CFR 1301.13(k)(2) would require the *Special Registration* applicant to provide certain disclosures and attestations on the Form 224S. Such information would enhance transparency, patient safety, and anti-diversion efforts. First, proposed § 1301.13(k)(2)(i) would require *platform practitioners* applying for the *Telemedicine Platform Registration* to attest to all employment, contractual relationships, or professional affiliations with any *clinician special registrant* and Online Pharmacy and their respective registration numbers on the Form 224S. Likewise, proposed § 1301.13(k)(2)(ii) would require *clinician practitioners* applying for the *Telemedicine Prescribing Registration* or the *Advanced Telemedicine Prescribing Registration* to attest to all employment, contractual relationships, and professional affiliations, including but not limited to those with *covered online telemedicine platforms* (and the respective online telemedicine platform's *Telemedicine Platform Special Registration number,* if applicable) on the Form 224S. By understanding each prescriber's professional associations, DEA can more effectively evaluate the prescriber's qualifications, conflicts of interest, and compliance with DEA regulations.[64] Second, proposed § 1301.13(k)(2)(iii) would require that *clinician practitioners* and *platform practitioners* applying for a *Special Registration* to attest that they have devised, and are committed to maintaining, anti-diversion policies and procedures.

Third, proposed § 1301.13(k)(2)(iv) would require *clinician practitioners* applying for the *Advanced Telemedicine Prescribing Registration* to disclose their practice specialties, *e.g. hospice care* or *palliative care.* DEA would use this information in conjunction with other investigative information to help detect and prevent diversion of controlled substances via telemedicine. This would include circumstances where *clinician practitioners* appear to be prescribing medications for conditions unrelated to their practice specialties. DEA would also use this information as needed to check the applicant's eligibility for the *Advanced Telemedicine Prescribing Registration,* which is limited to certain specialized physicians and *mid-level practitioners* treating vulnerable patient populations who have a legitimate need to prescribe Schedule II controlled substances.

As discussed above, under the proposed 21 CFR 1301.11(c)(3), only psychiatrists, *hospice care* physicians, *palliative care* physicians, physicians rendering treatment at *long term care facilities,* pediatricians, neurologists, and *mid-level practitioners* board certified in the treatment of psychiatric or psychological disorders, *hospice care, palliative care,* pediatric care, or neurological disorders unrelated to the treatment and management of pain, would be eligible for the *Advanced Telemedicine Prescribing Registration.* Lastly, proposed § 1301.13(k)(2)(v) would require that, for each type of *Special Registration,* the applicant required to attest to their legitimate need on their *special registration* application. If, however, it is later discovered that practitioner provided false information to obtain the *Special Registration* or used it for unlawful or inappropriate purposes, they could be found in violation of 21 U.S.C. 824(a), which could lead to penalties such as revocation or suspension of registration.

c. Notification of Application Changes; Modifications (Form 224S–M)

Proposed 21 CFR 1301.13(l) would require *special registrants* to promptly notify DEA of any changes to the information provided in their original *Special Registration* application (Form 224S) within 14 business days on a Form 224S–M (*Application for Changes and Modifications to Special Registration*). For example, if a *clinician special registrant* began employment with, or otherwise entered an arrangement with, a new DTC online telemedicine platform not previously disclosed on their original Form 224S, the *clinician special registrant* would be required to submit a Form 224S–M to DEA within 14 business days of any such change. The Form 224S–M would also be used by *clinician special registrants* and *platform special registrants* to make modifications to their *Special Registration.* For example, the *special registrant* would submit a Form 224S–M to apply for additional *State Telemedicine Registrations* to engage in telemedicine in states for which the *special registrant* did not originally apply on their Form 224S.

[62] Pursuant to 21 U.S.C. 821, DEA is authorized to charge reasonable fees relating to registration and control of the dispensing (including prescribing) of controlled substances. Furthermore, 21 U.S.C. 886a(1)(C) requires those fees to be set at a level that ensures the recovery of the full costs of operating the various aspects of the Diversion Control. Program. For more information on fee scheduling, see Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants, 85 FR 44710–44734 (July 24, 2020).

[63] *See* Proposed 21 CFR 1304.04(j).

[64] *See* Telemedicine Listening Sessions, Dr. Shabana Khan (American Psychiatric Association and American Academy of Child and Adolescent Psychiatry), 38:16–19 (Sept. 12, 2023) (recommending that DEA could require the reporting of the prescriber's employer to hold the telemedicine employers accountable).

4. Special Registration for Telemedicine Actions

a. Approval and Denial of Special Registration Applications

Proposed amendments to 21 CFR 1301.35 address the approval and denial criteria that would be considered on an application for *Special Registration* under 21 U.S.C. 831(h). The proposed amendment to § 1301.35(a) states that the Administrator shall issue a Certificate of Registration (DEA Form 223) to a *Special Registration* applicant if: (1) the *Special Registration* applicant satisfies the eligibility requirements specified at proposed 21 CFR 1301.11(c)(2) (*Telemedicine Prescribing Registration*), proposed 21 CFR 1301.11(c)(3) (*Advanced Telemedicine Prescribing Registration*), proposed 21 CFR 1301.11(c)(4) (*Telemedicine Platform Registration*) or proposed 21 CFR 1301.11(d) (*State Telemedicine Registration*); and (2) after considering the public interest factors provided at 21 U.S.C. 823(g)(1)(A)–(E), the Administrator has determined that the *Special Registration* will be consistent with the public interest.

By evaluating *Special Registration* applicants on the eligibility requirements and considering the public interest factors under Section 823(g), DEA can ensure that only qualified practitioners, whether a *clinician practitioner* or a *platform practitioner,* who prioritize public safety and regulatory compliance are granted *Special Registrations for Telemedicine.* As is required for applications for other registrations (issued under 21 U.S.C. 823 and 21 U.S.C. 958), proposed 21 CFR 1301.35(a) requires the Administrator—if intending to deny an application—to issue an *Order to Show Cause* pursuant to 21 CFR 1301.37,[65] and, if requested by the applicant, hold a hearing on the application pursuant to 21 CFR 1301.31 for *Special Registration* Applications.

Proposed 21 CFR 1301.35(d) would specify what information a Certificate of Registration (DEA Form 223) issued for a *Special Registration* shall contain: name; *special registered location; Special Registration for Telemedicine* (*Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* or *Telemedicine Platform Registration*), and *State Telemedicine Registration(s);* the activity authorized by the *Special Registration,* the Schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle; the amount of fee paid (or exemption) for each registration, and the expiration date of each registration. Proposed 21 CFR 1301.35(d) would also require a special registrant to maintain the Certificate of Registration at the *special registered location* in a readily retrievable manner and to permit inspection of the certificate by any official, agent or employee of the DEA or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

b. Suspension and Revocation of Special Registrations

The proposed amendments to 21 CFR 1301.36 outline when *Special Registrations for Telemedicine* (*Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* and *Telemedicine Platform Registration*), and *State Telemedicine Registrations* may be suspended or revoked. Proposed 21 CFR 1301.36(c) would provide that such *Special Registrations for Telemedicine* can be suspended or revoked based on the grounds specified in 21 U.S.C. 824(a), which are fundamentally designed to authorize DEA to intervene when registrants jeopardize the responsible handling of controlled substances. A *Special Registration* is contingent on the good standing of the registrant's other DEA registrations; therefore, proposed 21 CFR 1301.36(k) stipulates that the suspension or revocation of any registration under 21 U.S.C. 823 will trigger an automatic suspension or revocation of any registration issued under 21 U.S.C. 831. These automatic suspensions and revocations are designed to prevent registrants who have had one registration suspended or revoked due to non-compliance or risk to patient safety, from exploiting alternate registrations.

B. Special Registration Prescriptions Issued by Clinician Special Registrants Under 21 CFR Part 1306

Proposed 21 CFR 1306.41 through 1306.47 provide heightened requirements for *clinician special registrants* when they issue *special registration prescriptions.* Along with these heightened *special registration prescription* requirements, *clinician special registrants* would remain obligated to comply with all prescription regulations required under their 21 U.S.C. 823(g) registration. The combination of heightened telemedicine standards and continued adherence to existing regulations ensures that the quality and integrity of medical practice are maintained, even in the evolving landscape of remote healthcare services. Generally, these proposed regulations address the manner in which prescriptions are issued by *clinician special registrants,* and certain elements required to be a part of *special registration prescriptions.*

1. Manner of Issuance of Special Registration Prescriptions

Prescription Origination within the United States. Proposed 21 CFR 1306.41 would require that the *clinician special registrant* be physically present in the United States when conducting a telemedicine encounter and issuing a *special registration prescription.* Additionally, proposed 21 CFR 1306.41 would require that the *clinician special registrant* hold the proper licensure and authorization within the state and territory where the practitioner is located when the telemedicine encounter takes place.[66] For the purposes of this proposed rule, the ''United States'' means the 50 states of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, America Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, and any other trust territory or possession of the United States. This proposed requirement ensures that DEA retains jurisdictional control over *special registration prescriptions* and maintains clear boundaries on where these prescriptions are issued, ensuring compliance with U.S. laws and regulations. Restricting *clinician special registrants* from operating outside the U.S. also minimizes the risk associated with international boundaries, such as different regulatory frameworks and potential challenges in oversight and accountability.

Electronic Prescribing for Controlled Substances (EPCS). Proposed 21 CFR 1306.42 requires all *special registration prescriptions* be issued through EPCS.[67] For the practice of telemedicine, in which physical practitioner-patient interactions do not exist, EPCS would be instrumental in securing the prescription process. It would establish a traceable and secure platform that reduces the risk of unauthorized access

[65] 28 CFR Pt. 0, Subpt. R., App., Sec. 7 delegates the authority to sign final orders connected with the suspension, denial, or revocation of registration to the Deputy Assistant Administrator of the DEA Office of Diversion Control.

[66] The practitioner would also be required to be licensed and authorized to practice telemedicine in the state where the patient is located pursuant to the relevant *State Telemedicine Registration. See* proposed 21 CFR 1301.11(d).

[67] *Electronic Prescriptions for Controlled Substances,* 75 FR 16236 (March 31, 2010).

and forgeries. Moreover, the majority of states have enacted EPCS mandates to combat the opioid crisis by focusing on opioid access and enhanced oversight of possible misuse.[68] According to one 2021 study of New York's e-prescribing mandate, the mandate reduced the rate of overdoses involving natural and semi-synthetic opioids by 22 percent.[69] EPCS offers a robust and accountable system that prevents misuse and diversion of controlled substances, helping to maintain the integrity of prescribing among *clinician special registrants.*

Nationwide Prescription Drug Monitoring Program (PDMP) Check. Proposed 21 CFR 1306.43 requires that *clinician special registrants* perform a check of relevant PDMPs. For a period of three (3) years from the date that a final rule becomes effective, before issuing any *special registration prescription* for controlled substance to a patient, the *individual special registrant* would be required to check the PDMPs for: (1) the state or territory where the patient is located; (2) state or territory where the *clinician practitioner* is located; and (3) any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the *clinician practitioner* is located. While the proposed regulation would require, at a minimum, that *clinician special registrants* check these three categories, DEA encourages *clinician special registrants* to check any other state PDMP that the registrant determines to be clinically appropriate.

After three years, however, the *individual special registrant* would be required, before issuing any *special registration prescription* for controlled substances to a patient, to check the PDMPs of all 50 states of the United States and any other U.S. district or territory that maintains its own PDMP. This requirement for a broader, nationwide PDMP check would not begin until three (3) years after the final rule's effective date, to allow registrants and industry sufficient time to comply with the new requirement. If, however, there is no mechanism to perform such a nationwide check after these three years, then *individual special registrants* would remain required to continue performing PDMPs checks of the states in the three categories described above, and *individual special registrants* would only be able to issue *special registration prescriptions* for Schedule II controlled substances to patients located within the same state as the *individual special registrant, i.e.,* where there is an intra-state practitioner-patient relationship. The proposed nationwide PDMP check requirement is intended to ensure that *clinician practitioners* and pharmacists have full visibility of a patient's controlled substance prescription history, not to proactively furnish DEA with access to this data. Accordingly, this rule does not propose that DEA would gain any new avenues, by means of this rule, to collect information from state PDMPs beyond what is otherwise authorized by federal and state laws.

This delayed nationwide PDMP check requirement also reflects that the fragmented nature of PDMPs across states and territories has created challenges for healthcare providers in obtaining comprehensive patient data, particularly in cases involving telemedicine. In the context of telemedicine, the extension of medical services across state boundaries increases the complexity of controlling diversion of controlled substances. Telemedicine allows patients to consult *clinician practitioners* located in different states, creating a scenario where patients might seek multiple prescriptions from different *clinician practitioners* practicing in different regions, *i.e.* ''doctor shop,'' by exploiting the current fragmented nature of PDMPs across the states. Moreover, the absence of in-person interaction with telemedicine patients may limit the practitioner's ability to gauge whether patients are being honest about their medical history, potentially enabling the concealment of pertinent information related to controlled substances. During the Telemedicine Listening Sessions, various speakers highlighted the challenges resulting from the fragmented nature of PDMPs across states and territories and called for enhanced interoperability of PDMPs nationwide; some speakers also advocated for a unified national or federal PDMP to address these concerns more effectively.[70]

To address these risks to public health and safety, it is imperative that *clinician special registrants* ultimately be required to perform this comprehensive PDMP check of all 50 states, and any other U.S. district or territory that maintains its own PDMP. This comprehensive nationwide PDMP check would provide the *clinician special registrants* a comprehensive view of the patient's prescription history, helping to prevent over-prescribing and mitigating the risk of patients engaging in ''doctor shopping'' to obtain multiple controlled substance prescriptions across state lines. DEA acknowledges that it is currently unlikely that any one healthcare provider has access to all PDMPs nationwide. However, DEA also recognizes that current efforts to standardize, centralize, and interconnect PDMP data are making headway. These initiatives, aimed at creating a more unified and accessible system, offer a feasible future solution to bridge the gap and improve the accessibility of vital prescription information.

Special Registration Prescriptions and Audio-Video Telecommunication Systems. Proposed 21 CFR 1306.44(a) mandates that a *clinician special registrant* utilize both audio and video components of an *audio-video telecommunications system* to prescribe under the *Special Registration* framework for every telemedicine encounter whether an initial visit or subsequent visit or follow-up. This requirement underscores the critical need to not only audibly, but visually, assess patients when prescribing controlled substances. Controlled substances, which often carry a substantial risk of misuse or diversion, require a more comprehensive evaluation. Visual observation of the patient is crucial for providers, because it communicates valuable information that cannot be obtained through other means and allows for more effective identity verification.[71] By observing a

[68] *EPCS Mandates: Ultimate Guide to 2023 Deadlines √ RXNT (Available: https://www.rxnt.com/epcs-mandates/).*

[69] Abouk R, Powell D. *Can Electronic Prescribing Mandates Reduce Opioid-Related Overdoses?* Econ Hum Biol. 2021 Aug;42:101000. doi: 10.1016/j.ehb.2021.101000. Epub 2021 Apr 9. PMID: 33865194; PMCID: PMC8222172 (Available: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8222172/*).

[70] Telemedicine Listening Sessions, Dr. Shabana Khan (American Psychiatric Association and American Academy of Child and Adolescent Psychiatry), 36:21–37:1, 38:6–10, 41:20–42:6 (Sept. 12, 2023); Dr. Helen Hughes (John Hopkins Medicine) 69:3–10 (Sept. 12, 2023); Jodi Sullivan (Investigations Medicare Drug Integrity Contractor), 197:5–13, 197:24–198:21 (Sept. 12, 2023); and Dr. Jeffrey Chester, 256:22–257:10 (Sept. 12, 2023); Telemedicine Listening Sessions, Dr. Felicia Bailey, 19:6–13 (Sept. 13, 2023); Dr. Connie Guille (Medical University of South Carolina), 52:11–20 (Sept. 13, 2023); Christa Natoli (CTel), 151:15–152:3 (Sept. 13, 2023); John Wells (Louisiana State University), 160:4–8 (Sept. 13, 2023); Dan Golden (East Coast Telepsychiatry), 215:6–216:23 (Sept. 13, 2023); Dr. Shirley Reddoch, 235:14–18 (Sept. 13, 2023); Dr. Stephen Martin (Boulder Care), 128:24–129:10 (Sept. 13, 2023); and Dr. Ujjal Ramtekkar (Quartet Health), 142:10–18 (Sept. 13, 2023).

[71] *See* Faustinella F. *The Power of Observation in Clinical Medicine.* Int J Med Educ. 2020 Nov 30;11:250–251. doi: 10.5116/ijme.5fb9.1c9b. PMID: 33254147; PMCID: PMC7883801 (Available: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7883801/*); and Bramstedt, Katrina, Ph.D., MA. *The Use of Visual Arts as a Window to Diagnosing Medical Pathologies.* AMA J Ethics. 2016;18(8):843–854. doi: 10.1001/journalofethics.2016.18.8.imhl1–1608 (Available: *https://journalofethics.ama-assn.org/article/use-visual-arts-window-diagnosing-medical-pathologies/2016-08*).

patient's physical appearance, demeanor, and body language, providers can gather important indications of misuse or diversion of controlled substances. Though DEA has permitted audio-only telemedicine on a temporary basis for patients during and immediately after the COVID–19 PHE, the current landscape calls for a reevaluation. The Department of Health and Human Services (HHS) declared an end to the Federal PHE for COVID–19 under section 319 of the Public Health Service Act on May 11, 2023,[72] and as pointed out by some researchers, the ''risk benefit calculation of audio-only visits has changed, and it is increasingly important to protect patients from potentially lower-quality audio-only visits,'' especially when visual observations are critical.[73] At the Telemedicine Listening Sessions, various speakers advocated for the use of audio-video telemedicine specifically.[74] Expressing their concerns about the use of audio-only telemedicine, one speaker said, ''we require video visits. On rare occasions we do the telephone. Just for the fact you can lay eyes on the people. They may tell you they're perfectly fine, but they may have tears coming down their face. They may have physical problems. They may have meth marks. You know, things that people need to see. So video's important.'' [75]

The utilization of *audio-video telecommunication systems*—as opposed to audio-only communication technology—not only offers advantages in helping prevent diversion, but it also allows the *clinician special registrant* to visually confirm the patient's identity in real time. This would be achieved by comparing the patient to their existing photo identification on file, which will exist in the vast majority of cases given the requirements under proposed 21 CFR 1304.04(i). This direct visual verification serves as a further safeguard against the diversion of controlled substances during telemedicine encounters.[76]

Schedule III–V Special Registration Prescriptions for Opioid Use Disorder. Proposed 21 CFR 1306.44(b) would allow *clinician special registrants* to issue *special registration prescriptions* for, and *platform special registrants* to dispense, Schedule III–V controlled substances approved by the FDA for the treatment of Opioid Use Disorder (''OUD'') through the use of an *audio-only telecommunications system* as described in 42 CFR 410.78(a)(3), provided that the treatment was initiated through the use of an *audio-video telecommunications system* as defined in the proposed 1300.04 of this chapter. According to one survey of 866 mental health (MH), primary care (PC), and specialty care (SC) clinicians in the Department of Veterans Affairs New England Healthcare System (VANEHS), less than one-third of the clinicians surveyed rated phone as equivalent to or higher in quality when treating new patients. However, the survey indicated that support for such audio-only telecommunications increased significantly when treating established patients. These results highlight the importance of visual assessments for new patients, while showing that audio-only telecommunications may be more acceptable or useful once a patient is established.[77]

Currently, the only Schedule III–V narcotic drug approved by the FDA for the treatment of OUD is buprenorphine.[78] DEA's proposed authorization for the use of *audio-only telecommunications systems* for the treatment of OUD is rooted in the unique nature of OUD treatment. The complex and long-term management of OUD often necessitates a continuum of care that might be best accommodated through flexibility in telecommunication methods. Expanding the circumstances under which *clinician practitioners* are authorized to prescribe buprenorphine via telemedicine encounters, including audio-only encounters, would increase access to treatment for those individuals with OUD who may not want to seek treatment, or are unable to seek treatment, due to various economic, geographical, sociological, and logistical reasons.

Many OUD patients may lack the financial means to obtain in-person treatment traditionally or through audio-video telemedicine encounters. OUD patients who are unhoused, unemployed, or facing other challenges may find it prohibitive to afford devices capable of audio-video telemedicine encounters or consistent access to wireless internet and/or data plans adequate to support bandwidth demands of telemedicine encounters.[79] The estimated number of deaths from opioid overdoses for the 12-month period ending in October 2023 were 79,695, with a peak of 83,985 opioid overdose deaths for the 12-month period ending in May 2023.[80] Access to buprenorphine decreases the risk of overdosing,[81] and increasing access to buprenorphine after a drug overdose has also been associated with a reduced risk of death.[82] This allowance acknowledges the specific challenges faced by OUD patients and the importance of ensuring consistent therapeutic relationships with limited interruptions.

It also important to highlight that the *Expansion of Buprenorphine Treatment via Telemedicine Encounter* final rule (RIN 1117–AB78), jointly promulgated with HHS elsewhere in this issue of the **Federal Register**, allows a DEA-registered practitioner without a *Special Registration* to issue a prescription for a Schedule III–V controlled substance approved by the FDA for the treatment of OUD via audio-only or audio-video telemedicine for an initial consecutive six-month supply. Following the initial six-month supply, practitioners may prescribe the controlled substance by other forms of the *practice of telemedicine* authorized under the CSA (such as pursuant to a *Special*

[72] *Fact Sheet: End of the COVID–19 Public Health Emergency,* Press Release, U.S. Dept. of Health and Human Services (HHS)(May 9, 2023), *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html*.

[73] *Rethinking the Impact of Audio-Only Visits on Health Equity,* RAND Corp. (Dec. 17, 2021),), *https://www.rand.org/blog/2021/12/rethinking-the-impact-of-audio-only-visits-on-health.html*.

[74] Telemedicine Listening Sessions, Melanie Melville (Legacy Community Health), 96:1–16 (Sept. 12, 2023); Bruce Bassi, M.D., 29:18–30:3 (Sept. 13, 2023); Connie Guille (Medical University of South Carolina), M.D., 53:21–54:1 (Sept. 13, 2023).

[75] Telemedicine Listening Sessions, Dan Golden, 218:15–219:6 (Sept. 13, 2023).

[76] *See* Telemedicine Listening Sessions, Kevin Duane. 202:21–203:9 (Sept. 12, 2023); and Bruce Bassi, M.D., 31:12–20 (Sept. 13, 2023).

[77] Connolly SL, Miller CJ, Gifford AL, Charness ME. Perceptions and Use of Telehealth Among Mental Health, Primary, and Specialty Care Clinicians During the COVID–19 Pandemic. *JAMA Netw Open*. 2022;5(6):e2216401. doi:10.1001/jamanetworkopen.2022.16401.

[78] 42 CFR 8.12(h)(2)(ii).

[79] DeLaCruz et al., *Telemental Health for the Homeless Population: Lessons Learned when Leveraging Care,* (Dec. 8, 2022) *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9734763/*.

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

[81] Dadiomov, *et al., Buprenorphine and naloxone access in pharmacies within high overdose areas of Los Angeles during the COVID–19 pandemic,* Harm Reduction Journal (June 29, 2022), *https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-022-00651-3*. Last accessed April 11, 2024.

[82] Larochelle, *et al., Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality,* Annals of Internal Medicine, (August 07, 2018), *https://www.acpjournals.org/doi/10.7326/M17-3107*. Last accessed April 11, 2024.

Registration) or after conducting an in-person medical evaluation.

This proposed Special Registration NPRM would not preclude a *clinician special registrant* from utilizing the authority under the *Expansion of Buprenorphine Treatment via Telemedicine Encounter* final rule (RIN 1117–AB78) for the prescription of buprenorphine for the treatment of OUD. However, after the six-month supply has been completed, a *clinician special registrant* would need to initiate further prescribing of the controlled substance through an *audio-video telecommunications system.* After this initial audio-video telemedicine encounter, the *clinician special registrant* may then use *audio-only telecommunications systems* to prescribe buprenorphine for the treatment of OUD to the patient for the duration of the practitioner-patient relationship.

DEA's proposed authorization of audio-only telemedicine follow-ups under the *Special Registration* framework does not or should not be taken to imply that buprenorphine cannot be or is not diverted. Some presenters spoke to these issues during the Telemedicine Listening Sessions. According to one presentation, there is a ''robust illicit market for buprenorphine,'' and anecdotal reports of patients are selling buprenorphine to fund abuse of other controlled substances.[83] Another presenter said that drugs like suboxone and buprenorphine, prescribed to treat OUD, are used as a ''currency'' to purchase other drugs like methamphetamine*s,* and that in his community, ''if methamphetamine is involved, you can pretty much be assured the diversion of buprenorphine is involved.'' [84]

Such anecdotal information, however, must be considered in the context of the nation's opioid crisis, as well as recent data showing a lower risk of diversion for buprenorphine relative to other controlled substances. In November 2023, a report by the Office of the Inspector General of HHS found that 97 percent of Part D enrollees received the recommended amounts or less of buprenorphine for OUD in 2022, suggesting that the risk of misuse or diversion of buprenorphine in Medicare Part D may be low.[85] Considering this data and the additional proposed safeguards in this rule for *special registration prescriptions,* including the initiation of buprenorphine through audio-video telemedicine encounters, DEA believes that expanding access to buprenorphine through audio-only follow-ups outweighs the relatively lower risk of misuse and diversion of buprenorphine.

Schedule II Controlled Substance Prescriptions. Proposed 21 CFR 1306.45 requires that every *special registration prescription* for a Schedule II controlled substance be issued by a *clinician special registrant* that maintains the *Advanced Telemedicine Prescribing Registration,* who is issuing the prescription while the *clinician special registrant* is practicing within their given medical specialty. Proposed 21 CFR 1306.45(a) imposes further conditions on *clinician special registrants* who are pediatricians or board-certified in pediatric care and requires the mandatory presence of the minor's parent or guardian when the *clinician special registrant* prescribes a Schedule II controlled substance to the minor. This proposed provision is rooted in DEA's commitment to safeguarding the well-being of minors, particularly given the substantial risks associated with Schedule II controlled substances, including opioids.

This safeguard aligns with the broader intent of the *Ryan Haight Act,* which was enacted following the death of Ryan Haight, who tragically died after obtaining prescription opioids online without a valid prescription and without having ever been seen by the prescribing physician. Ryan Haight was only 17 years old when he purchased the opioids, and 18 years old when he died.[86] The direct parental or guardian supervision would help to discourage any potential misuse or attempts to acquire a Schedule II controlled substance for non-medical reasons. While DEA acknowledges potential concerns of minors who may perceive this as an intrusion on their privacy, it is crucial to balance this consideration against the inherent risks associated with Schedule II controlled substances in particular. It should also be noted that this proposed requirement would not extend to cases where a pediatrician prescribes a Schedule III through V controlled substance under the *Special Registration* framework.

Given the higher potential for abuse and dependence of Schedule II controlled substances, 21 CFR 1306.45 proposes two additional requirements when issuing a *special registration prescription* for a Schedule II controlled substance; DEA anticipates imposing one or both of the proposed requirements based on the comments received by stakeholders. The first of the two proposed requirements, under proposed 21 CFR 1306.45(b), would require that the *clinician special registrant* be physically located in the same state as the patient when issuing a *special registration prescription* for a Schedule II controlled substance. Under this same-state limitation, when issuing a Schedule II *special registration prescription,* a *clinician special registrant* would not only have to have the *Advanced Telemedicine Prescribing Registration,* and a *State Telemedicine Registration* in the state in which the patient is located, but the *clinician special registrant* would also have to be physically located in the same state as the patient.[87] Requiring the *clinician special registrant* to be in the same state as the patient helps mitigate the risks associated with the prescribing of Schedule II controlled substances across state lines. Geographical proximity enables more effective oversight by state regulatory agencies to ensure compliance with state laws governing the prescription of these high-risk medications and will make it more likely that the *clinician special registrant* can see the patient in-person should any medical or diversion concerns arise.

The second of the two proposed requirements, under proposed 21 CFR 1306.45(c), would require that the average number of *special registration prescriptions* for Schedule II controlled substances constitutes less than 50 percent of the total number of Schedule II prescriptions issued by the *clinician special registrant* in their telemedicine and non-telemedicine practice in a calendar month. Limiting the proportion of Schedule II prescriptions issued through telemedicine would help to manage the risks associated with the prescribing of Schedule II controlled substances by ensuring that a significant portion of these prescriptions are issued following in-person medical evaluations, which can provide a more comprehensive assessment of the

[83] Telemedicine Listening Sessions, Daniel Reck (Matclinics), 104:3–9. (Sept. 12, 2023).

[84] Telemedicine Listening Sessions, Jerome Cohan (Catalyst Health Solutions), 268:2–20. (Sept. 12, 2023).

[85] U.S. Dept. of Health and Human Services, Office of Inspector General, OEI–02–24–00130, *Data in Brief: The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder in Medicare Part D Continues to Appear Low: 2022* (Nov. 2023) (Available: *https://oig.hhs.gov/oei/reports/OEI-02-24-00130.pdf*).

[86] U.S. Drug Enforcement Administration, Prescription for Disaster: How Teens Abuse Medicine (Accessed: Dec. 13, 2023) (Available: *https://www.dea.gov/sites/default/files/resource-center/Publications/DEA_Prescription-For-Disaster_508ver.pdf*).

[87] It should be noted, however, that the *Special Registered Location* associated with the *Advanced Telemedicine Prescribing Registration* would not have to be in the same state in which the patient was issued the Schedule II controlled substance.

patient's medical history and condition than can be done remotely.

State Laws Applicable to Special Registration Prescriptions. Proposed 21 CFR 1306.46 would require special registrants, when issuing a *special registration prescription,* to comply with the laws and regulations of the state in which the special registrant is located during the telemedicine encounter resulting in the *special registration prescription*; the state in which the patient is located during the telemedicine encounter resulting in the *special registration prescription*; and any state or states in which the special registrant maintains a DEA registration to dispense controlled substances or a medical license, to the extent that the law or regulation applies to telemedicine encounters between practitioners and patients located in the states in which the special registrant and the patient are each located during the telemedicine encounter resulting in the *special registration prescription.* This provision would require that the practice of telemedicine be conducted in accordance with applicable state laws set forth in 21 U.S.C. 802(54).

2. Additional Elements on a Special Registration Prescription

A prescription for controlled substances, whether issued via telemedicine or not, must contain the elements specified in 21 CFR 1306.05(a), which encompass the signature of the prescriber, issue date, patient's full name and address, drug details (name, strength, dosage form, and quantity), directions for use, and the practitioner's name, address, and registration number.[88] Proposed 21 CFR 1306.47 would require two additional elements for *special registration prescriptions:* (1) the *Special Registration* numbers of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner*; and (2) *State Telemedicine Registration* numbers of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner* (unless exempted from obtaining a *State Telemedicine Registration* under proposed 21 CFR 1301.11(d)).[89] Proposed 21 CFR 1306.47(c) would add a corresponding liability provision for these new requirements, to track the current provision in 21 CFR 1306.05(f) that imposes a corresponding liability on a pharmacist who fills a prescription not prepared in the form prescribed in 21 CFR 1306.05(a).

The inclusion of the *Special Registration* numbers of the *clinician practitioner* and the *platform practitioner* (if a platform practitioner facilitated the prescription) would provide the pharmacist the information necessary to determine whether the *clinician practitioner* has the authority to prescribe a Schedule II controlled substance under the *Special Registration* framework, and that the *platform practitioner* (if a *platform practitioner* facilitated the prescription) has the authority to dispense a Schedule II controlled substance. The inclusion of *State Telemedicine Registration* numbers would provide pharmacists the information necessary to verify that patients are only being prescribed *special registration prescriptions* by *special registrants* authorized to practice in the specific state where the patient is located; registered pharmacists would be able to verify these registration numbers on DEA's *CSA Registration Validation Tool*.

Pharmacists occasionally encounter what they may perceive as ''red flags'' for certain telemedicine prescriptions, which can stem from the nature of telemedicine itself, where patients may receive prescriptions from prescribers located at distances far away (both inside and outside the state where the patient is located). The geographical distance can raise doubts about the legitimacy of the prescription and could lead pharmacists to question its validity and refuse to fill the prescription. By verifying the *State Telemedicine Registration* numbers, pharmacists would be provided a level of assurance that a *special registration prescription* is legitimate when it originates from a prescriber located a significant distance from the patient. For *clinician special registrants* exempted from obtaining *State Telemedicine Registrations,* proposed 21 CFR 1306.47(a) would require them to instead provide a notation on the prescription identifying the state in which the patient is located.

C. Recordkeeping and Reporting Under 21 CFR Part 1304

Clinician special registrants would remain subject to their existing recordkeeping and reporting obligations under their 21 U.S.C. 823(g) registrations; however, they would also be subject to supplementary requirements within the *Special Registration* framework. *Clinician special registrants* would be required to establish and maintain photographic records for patient verification and maintain their *special registration prescription* records at their designated *special registered location. Platform special registrants,* on the other hand, would be required to maintain and update credential verification and documentation records. As to data reported to DEA, pharmacies dispensing *special registration prescriptions* would be required to report monthly aggregated *special registration prescription* data on Schedule II controlled substances and certain Schedule III–V controlled substances, and *special registrants* would be required to report annually aggregated information about their telemedicine practice, including the number of new patients they treat through telemedicine, and the total number of *special registration prescriptions* for Schedule II controlled substances, and certain Schedule III–V controlled substances, they dispensed for the preceding year.

1. Patient Verification Photographic Record

Proposed 21 CFR 1304.04(i) would generally require that a *clinician special registrant,* or a delegated employee or contractor under the direct supervision of the *clinician special registrant,* verify the identity of a patient seeking treatment via telemedicine by requiring that the patient present a state or federal government-issued photo identification card through the camera of the *audio-video telecommunications system.* At the first telemedicine encounter, the *clinician special registrant* would also be required to capture a photographic record of the patient presenting their federal or state-issued photo identification card or other acceptable documents and use the photographic records to confirm the patient's identity in subsequent telemedicine encounters.

If for some reason the patient does not consent to their photo being captured, proposed 21 CFR 1304.04 would allow the *clinician special registrant* (or their delegated employee or contractor under their direct supervision) to accept a copy of the patient's federal or state government-issued photo identification card or other forms of documentation provided by the patient. To ensure that patient privacy is protected, the patient verification photographic records would be securely stored in the patient's medical record or chart, separate from the *special registration prescription* records/data reported to DEA under proposed 21 CFR 1304.40.

Recognizing that not all persons may have a photo identification card,

[88] *https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information; https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.*

[89] Proposed 21 CFR 1306.47(b) would not require that the Special Registrant provide the registration number associated with their conventional registration under 21 U.S.C. 823(g).

proposed 21 CFR 1304.04(i)(1) would allow a *clinician special registrant,* or a delegated employee or contractor under the direct supervision of the *clinician special registrant,* to verify the identity of the patient with other forms of documentation, and would require the *clinician special registrant* to maintain a record of how they verified the patient's identity and what documents were used to verify the patient's identity. For example, a *clinician special registrant* (or their delegated employee or contractor under their direct supervision) might verify patient identity by observing a patient's pay stub and/or a bill with the patient's home address, a letter provided by a shelter employee if the patient is unhoused, or a patient's school identification card or report card if the patient is a minor.

This proposed requirement would ensure that the patient's identity is verified at each telemedicine encounter, reducing the risk of unauthorized individuals diverting controlled substances. Throughout the Telemedicine Listening Sessions, various presenters underscored the importance of implementing strong patient identification measures in the context of telemedicine.[90] According to some physicians who presented during the Telemedicine Listening Sessions, identity verification of telemedicine patients is currently a typical practice and constitutes a component of good care.[91] Furthermore, the photographic record provides a clear link between the patient's identity and the telemedicine encounter, supporting accurate recordkeeping under the *Special Registration* framework.[92]

2. Special Registration Telemedicine Encounter Record

For every telemedicine encounter resulting in a *special registration prescription,* proposed 21 CFR 1304.04(j) would require that *clinician special registrants* maintain a record of the date and time of the telemedicine encounter, the address of the patient during the telemedicine encounter, and the home address of the patient. Like patient verification photographic records, the *clinician special registrant* would be required to maintain *Special Registration* telemedicine encounter records for a minimum of two (2) years from the date of the telemedicine encounter. The proposed *Special Registration* telemedicine encounter record provides an additional layer of verification for the telemedicine encounter, detailed documentation that can be referenced by the *clinician special registrant* in the future and helps ensure that the patient is located in a state in which the *clinician special registrant* is authorized to prescribe controlled substances under the proposed *Special Registration* framework.

3. Credential Verification and Conduct-Related Documentation

Proposed 21 CFR 1304.04(k) would require *platform special registrants* to maintain records related to *clinician special registrants* with whom they enter and maintain a *covered platform relationship,* including:[93] (1) verification of the *clinician special registrant* credentials, including but not limited to records on education, training, board or specialty certifications, and their *Special Registration* number and *State Telemedicine Registration* number(s); (2) the employment contract and any other contract between the *platform special registrant* and the *clinician special registrant;* and (3) any disciplinary actions or sanctions, or documentation of complaints, disputes, or incidents involving the *practice of telemedicine*. The *platform special registrant* would be required to maintain and update the credential verification and conduct-related records for a minimum of every two (2) years, which should be readily available for inspection by DEA.

This proposed requirement is intended to address DEA's concerns regarding the adequacy of the screening of the prescribers utilizing the services of the *covered online telemedicine platforms* as discussed above. By mandating the verification and documentation of *clinician registrants'* qualifications and credentials, these records should serve as evidence of thorough screening processes by the *platform special registrants,* helping to ensure that only qualified and vetted *clinician practitioners* are practicing telemedicine under the *Special Registration* framework and reducing the risk of improper remote prescribing of controlled substances. Furthermore, by requiring that *platform special registrants* maintain such records, they are compelled to assume responsibility for the conduct and prescribing practices of the *clinician special registrants* whose telemedicine prescribing is facilitated by their platform.

4. Centralized Recordkeeping at the *Special Registered Location*

Proposed 21 CFR 1304.04(l) mandates that records arising from telemedicine encounters under the *Special Registration* framework be kept at the *special registered location.* Given the nationwide reach of telemedicine—where a *special registrant* could serve patients in any state—it would pose an unreasonable administrative burden to require the *special registrant* to maintain records in every state where telemedicine patients are located. By consolidating these records, DEA investigations are more efficient, enhancing the detection of diversion patterns, which is vital for preventing the diversion and misuse of controlled substances. This approach enhances public safety while ensuring a practical burden for practitioners. Furthermore, this proposed regulation keeps pace with modern recordkeeping practices, as the majority of healthcare providers already maintain electronic records, which can be easily centralized and accessed when required.

5. Pharmacy Reporting of *Special Registration Prescription* Data

Proposed 21 CFR 1304.60 would require that a pharmacy report aggregate data, within the first seven (7) days of the start of every month, for the *special registration prescriptions* filled during the preceding month for each Schedule II controlled substance and certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressants that constitute a benzodiazepine (including their salts, isomers, and salt of isomers).[94] For each

[90] Telemedicine Listening Sessions: Lori Uscher-Pines (RAND Corporation), 131:15–19 (Sept. 12, 2023); Bruce Bassi, M.D., 29:18–30:3 (Sept. 13, 2023); Dr. Phillip Moore (Gaudenzia), 85:10–16, 86:14–87:8 (Sept. 13, 2023); and Dan Golden (East Coast Telepsychiatry), 218:9–14 (Sept. 13, 2023).

[91] Telemedicine Listening Sessions: Dr. Shabana Khan (American Psychiatric Association and American Academy of Child and Adolescent Psychiatry), 33:20–34:5, 43:9–19 (Sept. 12, 2023); Dr. Brian Clear (Bicycle Health), 77:13–22 (Sept. 12, 2023); Telemedicine Listening Sessions: Lori Uscher-Pines (RAND Corporation), 131:15–19 (Sept. 12, 2023); Bruce Bassi, M.D., 29:18–30:3 (Sept. 13, 2023); Dr. Phillip Moore (Gaudenzia), 85:10–16, 86:14–87:8 (Sept. 13, 2023); and Dan Golden (East Coast Telepsychiatry), 218:9–14 (Sept. 13, 2023).

[92] *See* Telemedicine Listening Sessions, Bruce Bassi, M.D., 31:12–20 (Sept. 13, 2023).

[93] Proposed 21 CFR 1300.04 would define a *covered platform relationship* to mean ''the formal association between the online telemedicine platform, in its capacity as a *platform practitioner,* and the *clinician practitioner* it directly employs, contracts with, or is otherwise professionally affiliated with to introduce or facilitate connections between patients seeking remote medical consultations and the *clinician practitioner,* via an audio-video telecommunications system, for the diagnosis, treatment, and prescription of controlled substances.''

[94] DEA has identified 36 depressants that constitute a benzodiazepine Scheduled in 21 CFR 1308.14(c) at the time of this publication.

of these controlled substances, the pharmacy would provide the following information, organized by the different *State Telemedicine Registration numbers* of the *individual special registrants* who prescribed the controlled substance, and organized by the National Drug Code (NDC) for each formulation of the controlled substance dispensed: the number of prescriptions filled, the volume of the controlled substance dispensed, and the number of patients prescribed the controlled substance. A NDC is a unique, 10-digit three-segment number that serves as a universal product identifier for human drugs, including controlled substances. It is used by drug establishments, such as manufacturers and distributors, to report all drugs made, prepared, propagated, compounded or processed for sale in the U.S. to the Food and Drug Administration (FDA).[95] At this time, Schedule III–V controlled substances subject to this proposed requirement under 21 CFR 1304.60 are limited to those specifically identified. However, additional Schedule III–V controlled substances may be included in the future via regulation based on trends in diversion and misuse.

Requiring timely collection and reporting of aggregate patient-anonymized prescription data ensures that DEA has current information on the prescribing of controlled substances via telemedicine, vital for protecting public health and safety, especially amid the national opioid overdose epidemic. Following the COVID–19 PHE, the opioid overdose epidemic has only worsened. According to the Centers for Disease Control and Prevention (CDC), the ''number of people who died from a drug overdose in 2021 was over six times the number in 1999. The number of drug overdose deaths increased more than 16% from 2020 to 2021. Over 75% of the nearly 107,000 drug overdose deaths in 2021 involved an opioid.'' [96]

While the opioid overdose epidemic has, in recent years, been largely fueled by illicitly manufactured *fentanyl,* a synthetic opioid, the diversion of prescribed opioids exacerbates the opioid crisis by increasing the overall opioid supply available on the illicit market. Proposed 21 CFR 1304.60 would arm DEA with the data necessary to timely intervene in cases of diversion or other acts in violation of the law.

Recognizing the importance of data to combat diversion, various stakeholders speaking at the Telemedicine Listening Sessions—many of whom were practitioners—advocated for DEA to collect prescription data to help identify potential exploitative practices.[97] One physician said, ''I urge DEA to design any new process to improve [its] ability to oversee and audit prescribing patterns and to intervene when exploitative practice is identified. . . .'' [98]

The aggregation of prescription data would also allow DEA to employ advanced data analytics to further combat diversion. With such data, for example, DEA could detect outliers, irregular prescription volumes, and abnormal geographic concentrations of controlled substances. As identified by the Government Accountability Office (GAO) in its 2020 recommendations to DEA, which encouraged the enhanced utilization of data analytics to identify problematic patterns and trends to combat the opioid epidemic, ''data-analytics activities can include a variety of techniques to prevent and detect diversion, including data matching and data mining. Data matching is the largescale comparison of records and files to detect errors or incorrect information. It can be used to verify information provided by recipients or detect unreported changes. Data mining is the use of automated computer algorithms to detect patterns, including those that are otherwise not obvious, correlations, or anomalies within large data sets indicative of potential diversion.'' [99] At the Telemedicine Listening Sessions, similar recommendations to those of the GAO were echoed.[100] Various stakeholders advocated for the leveraging of data analytics as a tool to be used by DEA to address bad actors or exploitative practices.[101]

Data analytics could help recognize patterns in how controlled substances are combined to provide DEA with critical information about emerging trends in polysubstance abuse.[102] Recent examples highlight the dangers of such combinations, underscoring the need for proactive measures. Benzodiazepines, Schedule IV depressants, have been used to amplify the effect of opioids, especially when injected.[103] The combination of opioids and benzodiazepines can have dire consequences, as their use together increases the risk of overdose as both drugs cause sedation and suppress breathing.[104] According to one study, overdose death rates among patients taking both drugs was 10 times higher than among those only receiving opioids.[105] By staying informed about emerging drug use trends, particularly polysubstance abuse, DEA can take proactive measures to prevent these trends from evolving into widespread problems. This information not only aids in prevention but could also guide DEA in strategically directing resources and investigative efforts to ensure the most effective responses to emerging challenges.

Lastly, DEA could use the aggregated data to make more informed, evidence-based policy decisions. For instance, DEA could timely monitor controlled substance prescription patterns and demand indicators to make informed quota decisions to prevent or mitigate shortages and ensure a steady and reliable supply of controlled substances for legitimate medical purposes. The data could also be used to better retrospectively assess the impact of DEA's policy positions and promulgated

[95] National Drug Code Directory, U.S. Food & Drug Administration (FDA) (July 22,2022) (*https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory*).

[96] *Understanding the Opioid Overdose Epidemic,* Centers for Disease Control and Prevention (CDC) (Aug. 8, 2023), *https://www.cdc.gov/opioids/basics/epidemic.html.*

[97] Telemedicine Listening Sessions, Robert Krayn (Talkiatry), 26:4–21 (Sept. 12, 2023); Dr. Shabana Khan (American Psychiatric Association and American Academy of Child and Adolescent Psychiatry), 37:2–11 (Sept. 12, 2023); Dr. Brian Clear (Bicycle Health), 79:8–13, 87:3–8 (Sept. 12, 2023); Chris Adamec (Alliance for Connected Care), 143–18–144:11, 146:5–8 (Sept. 12, 2023); Kevin Duane, PharmD, 207:3–9, 213:13–214:9 (Sept. 12, 2023); Felicia Baily (Nurse Practitioner, Avaesen Healthcare), 17:25–18:21 (Sept. 13, 2023); and John Heaphy (New York Dept. of Health), 78:25–79:6 (Sept. 13, 2023).

[98] Telemedicine Listening Sessions, Dr. Brian Clear (Bicycle Health), 79:8–13 (Sept. 12, 2023).

[99] *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders,* U.S. Gen. Accounting Office, GAO–20–118, (Jan. 29, 2020),), *https://www.gao.gov/products/gao-20-118#summary_recommend.*

[100] Telemedicine Listening Sessions, Dr. Shabana Khan (American Psychiatric Association and American Academy of Child and Adolescent Psychiatry), 37:18–23 (Sept. 12, 2023); Dr. Brian Clear (Bicycle Health), 79:8–13 (Sept. 12, 2023); and Laura Jantos (Healthcare Technology and Digital Healthcare Management Consultant), 14:25–15:21 (Sept. 13, 2023).

[101] *Id.*

[102] Centers for Disease Control and Prevention (CDC). *What is Polysubstance Use?* (February 23, 2022) (Available: *https://www.cdc.gov/stopoverdose/polysubstance-use/index.html*).

[103] Jones JD, Mogali S, Comer SD. *Polydrug abuse: a review of opioid and benzodiazepine combination use.* Drug Alcohol Depend. 2012 Sep 1;125(1–2):8–18. doi: 10.1016/j.drugalcdep.2012.07.004. Epub 2012 Aug 2. PMID: 22857878; PMCID: PMC3454351 (Available: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/*).

[104] National Institute on Drug Abuse (NIDA). *Benzodiazepines and Opioids.* (November 7, 2022), Available: *https://nida.nih.gov/research-topics/opioids/benzodiazepines-opioids.*

[105] Dasgupta N, Funk MJ, Proescholdbell S, Hirsch A, Ribisl KM, Marshall S. *Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality.* Pain Med. 2016 Jan;17(1):85–98. doi: 10.1111/pme.12907. Erratum in: Pain Med. 2016 Apr;17(4):797–8. PMID: 26333030, *https://pubmed.ncbi.nlm.nih.gov/26333030/*).

regulations.[106] For example, DEA could use the prescription data to evaluate: patient outcomes associated with *special registration prescriptions*; the impact of the proposed *Special Registration* regulations on patient access to controlled substances (especially in remote or rural areas); the efficacy of the proposed *Special Registration* regulations on preventing and detecting diversion associated with remote prescribing; and trends or changes to telemedicine prescription practices that might necessitate regulatory reforms.

It should be emphasized that the prescription data reporting would be aggregated and patient-anonymized, and will not be shared with persons or entities outside of DEA. Like all data provided to, and handled by, DEA, the security and privacy of such data will be handled with the highest standards of security and privacy. All data transmitted to and stored by DEA is encrypted, including data transmitted between external systems and internal databases. Furthermore, all data transmitted from registrants to DEA is additionally protected by Department of Justice firewalls and network monitoring. Access to the data is limited to certain authorized persons, employed or contracted by DEA. External user access to applications receiving and providing data require a unique username and a strong, complex password, internal users of the data are vetted by DEA and its Diversion Control Division's security and privacy processes, and access is restricted according to a need-to-know-basis.

6. Annual Special Registrant Reporting of Special Registration Prescription Data

Proposed 21 CFR 1304.61 would require that *individual special registrants* and *platform special registrants* report annual data on the total number of new patients in each state for which they issued at least one *special registration prescription* for a Schedule II controlled substance or certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine; the total number of *special registration prescriptions* for Schedule II controlled substances issued by the *special registrant,* in aggregate and across all states; and the total number of *special registration prescriptions* for certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepines (including their salts, isomers, and salt of isomers), which were issued by the *special registrant,* in aggregate and across all states.

This proposed reporting requirement would provide DEA with necessary data to proactively monitor for concerning trends that may signal the existence of digital pill mills exploiting the proposed *special registration* framework to provide patients with medically unnecessary controlled substances.[107] Data on new patients and distribution of Schedule IIs and certain Schedule III–V controlled substances on an annual basis would allow DEA to assess prescribing behaviors of controlled substances, identify spikes and anomalies in prescription volume, and take timely action against suspicious activity. At this time, Schedule III–V controlled substances subject to this proposed requirement under 21 CFR 1304.61 are limited to those specifically identified. However, additional Schedule III–V controlled substances may be included in the future via regulation based on trends in diversion and misuse.

D. Regulatory Definitions Under 21 CFR part 1300

This last section provides an overview of proposed regulatory definitions and revisions to 21 CFR part 1300. These proposed definitions are intended to provide clarity as to the authorities and obligations of *special registrants* under the registration requirements (21 CFR 1301), prescription requirements (21 CFR 1306), and the recordkeeping and reporting requirements (21 CFR 1304). The proposed amendments offer definitions for the different, relevant registrations under the *Special Registration* framework, including the: *Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration, Telemedicine Platform Registration, State Telemedicine Registration,* and *special registered location*. The core aspects of these proposed definitions have largely been addressed in the preceding sections, requiring minimal discussion of many of them here.

That said, the proposed term and definition of a *covered online telemedicine platform* warrants further discussion. A *covered online telemedicine platform* means an entity that facilitates connections between patients and *clinician practitioners,* via an *audio-video telecommunications system,* for the diagnosis and treatment of patients that may result in the prescription of controlled substances, but is not a hospital, clinic, *local in-person medical practice,* or insurance provider, and meets one or more of the following criteria:

(1) the entity explicitly promotes or advertises the prescribing of controlled substances through the platform;

(2) the entity has financial interests, whether direct incentives or otherwise, tied to the volume or types of controlled substance prescriptions issued through the platform, including but not limited to, ownership interest in pharmacies used to fill patients' prescriptions, or rebates from those pharmacies;

(3) the entity exerts control or influence on clinical decision-making processes or prescribing related to controlled substances, including, but not limited to: prescribing guidelines or protocols for *clinician practitioners* employed or contracted by the platform; consideration of *clinician practitioner* prescribing rates in the entity's hiring, retention, or compensation decisions; imposing explicit or de facto prescribing quotas; directing patients to preferred pharmacies; and/or

(4) the entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

When any one of the four factors are present, it solidifies the platform's role as an integral intermediary in the remote dispensing of controlled substances. The proposed definition and criteria are intended to provide a practical and clear framework for identifying when a DTC online telemedicine platform's conduct qualifies them as a *covered online telemedicine platform,* mandating registration as a dispenser with DEA. As proposed, this definition is intended to limit the *Special Registration* requirements only to those DTC online telemedicine platforms that play a substantial and integral role as intermediaries in the remote dispensing of controlled substances.

Under the first criterion, when an entity explicitly promotes or advertises the prescribing of controlled substances through the platform, it is directly influencing patient behavior and decision-making. This targeted promotion guides patients to seek medical consultations and prescriptions for controlled substances through the platform, effectively influencing the

[106] *See* Administrative Conference of the United States (ACUS), *Administrative Conference Recommendation 2021–2: Periodic Retrospective Review* (June 17, 2021) (Available: *https://www.acus.gov/document/periodic-retrospective-review*).

[107] Stevens, Morgan. *Click Here for Adderall: Fixing Telehealth Advertising and Services to Prevent Stimulant Misuse,* Center for Data Innovation (Dec. 5, 2022), *https://www2.datainnovation.org/2022-telehealth-stimulant-abuse.pdf*.

demand and supply of this service. This active role in attracting and managing patient flow makes the platform more involved as an integral intermediary in the remote prescribing of controlled substances. Under the second criterion, when an entity has financial interests tied to the volume or types of controlled substances prescriptions issued through the platform, the platform's role extends beyond mere facilitation—it becomes a key player that directly affects the flow and distribution of controlled substances. The financial ties ensure that the platform's operations are closely linked to the outcome of prescription activities, making it an integral intermediary in the process of remote prescribing of controlled substances.

Under the third criterion, when an entity exerts control or influence on clinical decision-making processes or prescribing related to controlled substances, including but not limited to prescribing guidelines or protocols for *clinician practitioner*s employed or contracted by the platform, imposing explicit or de facto prescribing quotas, or directing patients to preferred pharmacies, it plays a direct and active role in the decision-making processes that affect patient care and the distribution of controlled substances. The platform becomes an essential link in the chain between the *clinician practitioner* and the patient, making it an integral intermediary in the process of remote prescribing of controlled substances. Under the fourth and last criterion, when an entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform, it has significant control over sensitive and regulated information, actively involving the platform in the handling and processing of controlled substances. Moreover, control or custody of such information allows a platform to influence patient treatment plans, underscoring their position as an intermediary, and thus dispenser, in the process of remote prescribing of controlled substances.

It is important to clarify that ownership and operation of the online or digital system or platform on which the virtual visit takes places are not mandatory criteria within the proposed definition of a *covered online telemedicine platform*. Similarly, an entity solely operating a platform or system that merely provides the technological service or conduit for a telemedicine encounter to occur, without the presence of one of the additional four factors, would not constitute a *covered online telemedicine platform*. As discussed above, the definition is also drafted to exclude entities that engage in conduct that could potentially fall under the definition's criteria but are not the types of entities whose primary business operations rely on, or center around, telemedicine services.

The definition of *covered online telemedicine platform* also explicitly excludes certain types of entities, including hospitals, clinics, insurance providers, and *local in-person medical practices. Local in-person medical practice* is, in turn, defined by this rule to be a medical practice where less than 50 percent of the total prescriptions for controlled substances collectively issued by the practice's physicians and *mid-level practitioners* are issued via telemedicine in any given calendar month, but is not a hospital, clinic, or insurance provider. The type of entities excluded from the definition of *covered online telemedicine platform* are entities that engage in conduct that could potentially fall under the definition's criteria but are not the types of entities whose primary business operations rely on, or center around, telemedicine services.

Determining whether an entity dispenses controlled substances and meets the criteria of a *covered online telemedicine platform* is a fact-specific inquiry. If there is any uncertainty regarding the entity's role as a dispenser, particularly concerning its involvement in the practitioner-patient relationship, registering may be advisable to avert the risk of enforcement action based on potential unregistered, and thus illegal, dispensing of controlled substances.

Turning elsewhere, DEA is incorporating CMS's current definitions and standards for the terms *hospice care* and *palliative care.*[108] DEA acknowledges that its core expertise and mission revolve around combating the diversion of controlled substances, and therefore is leveraging the medical expertise of CMS by adopting its healthcare standards as to these terms. Lastly, the rulemaking rule proposes to revise the DEA regulatory definition of ''practice of telemedicine'' to mean practice in accordance with applicable federal and state laws by a practitioner (other than a pharmacist) who is at a remote location from the patient and communicates with the patient, or health care professional who is treating the patient, using a telecommunications system defined in 42 CFR 410.78(a)(3), which practice falls within a category specified in the definition.[109]

E. Request for Comments

With respect to the proposed rule, DEA invites comments regarding the need for any clarifications or suggested modifications to the proposed regulations, which are consistent with the public health and safety. The public's input and insights are instrumental in achieving the appropriate balance between expanding access to care and implementing the necessary safeguards to prevent diversion of controlled substances effectively. In particular, DEA seeks the public's input on the newly introduced *Special Registrations* (*Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration,* and *Telemedicine Platform Registration*), and the *State Telemedicine Registrations.* Again, DEA recognizes the broad nature of the proposed requirements, and highly encourages the public to provide input on appropriate implementation timelines, or on-ramps for phased or gradual adoption, to help ensure a smoother transition when the final rule takes effect. Practitioners, pharmacies, and industry are encouraged to provide their input on the time necessary to operationalize the proposed requirements.

Furthermore, DEA is considering the inclusion of a severability clause in the final rule. Under such a clause, if any specific provision of the rule is found to be invalid or unenforceable by a court, the remaining provisions would continue to be operative and enforceable. We encourage public comments on the inclusion of such a clause, as well as whether any particular provisions of the proposed rule are especially integral to its overall implementation. All public insight, including responsive data, as to the effectiveness or appropriateness of the proposed safeguards is also encouraged. However, the public is asked to refrain from commenting on provisions that are simply republished existing regulatory definitions. These are included to provide context to the newly proposed definitions and to reduce editorial resources required for publishing the proposed rule.

[108] *See* 42 CFR 418.3.

[109] Proposed 21 CFR 1300.04. The current regulatory definition, 21 CFR 1300.04, initially implemented the *Ryan Haight Act's* statutory definition by repeating the statutory provision and requiring the use of a ''telecommunications system referred to in section 1834(m) of the Social Security Act'' [codified at 42 U.S.C. 1395m(m)].

Appendices:

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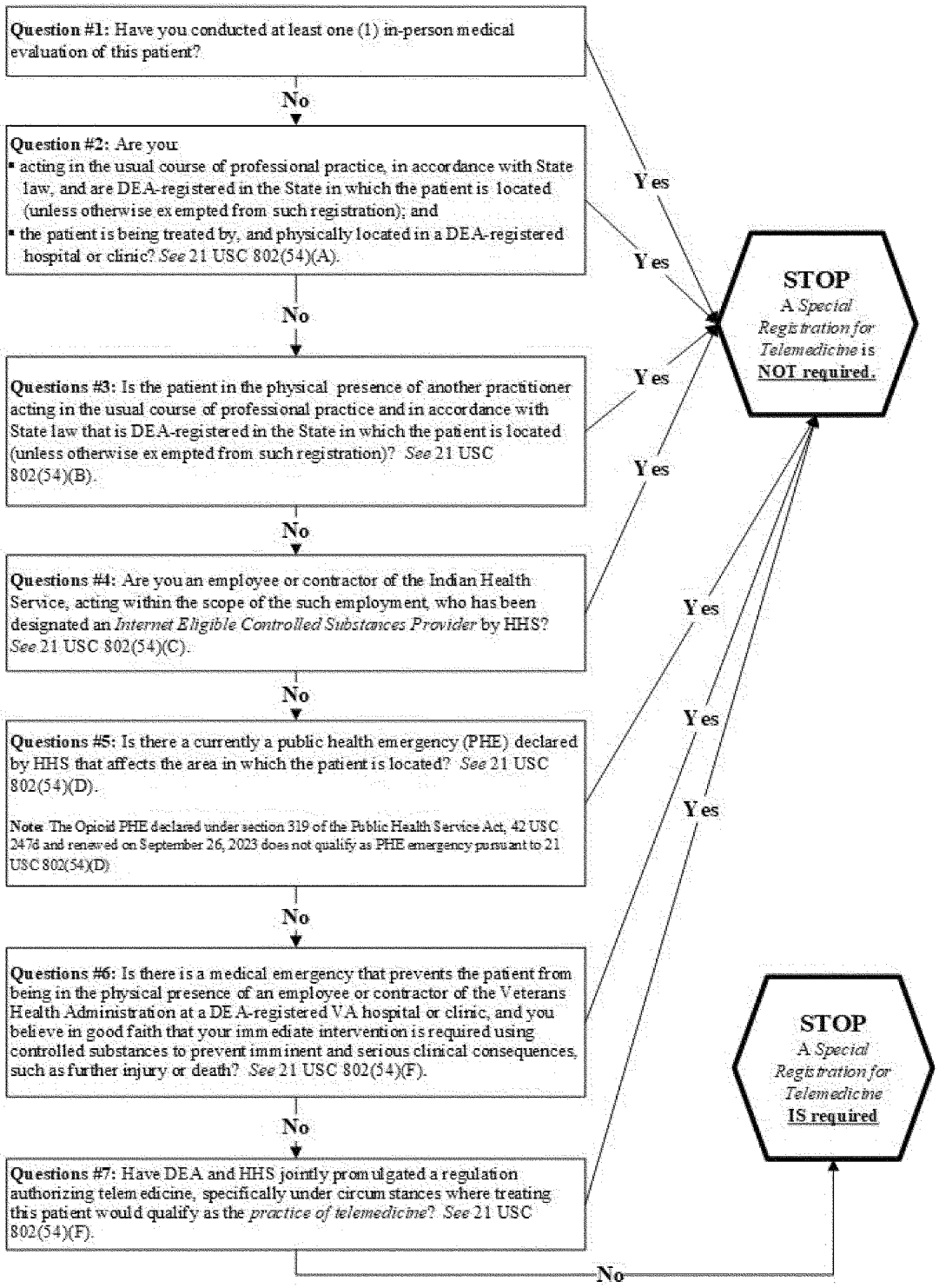
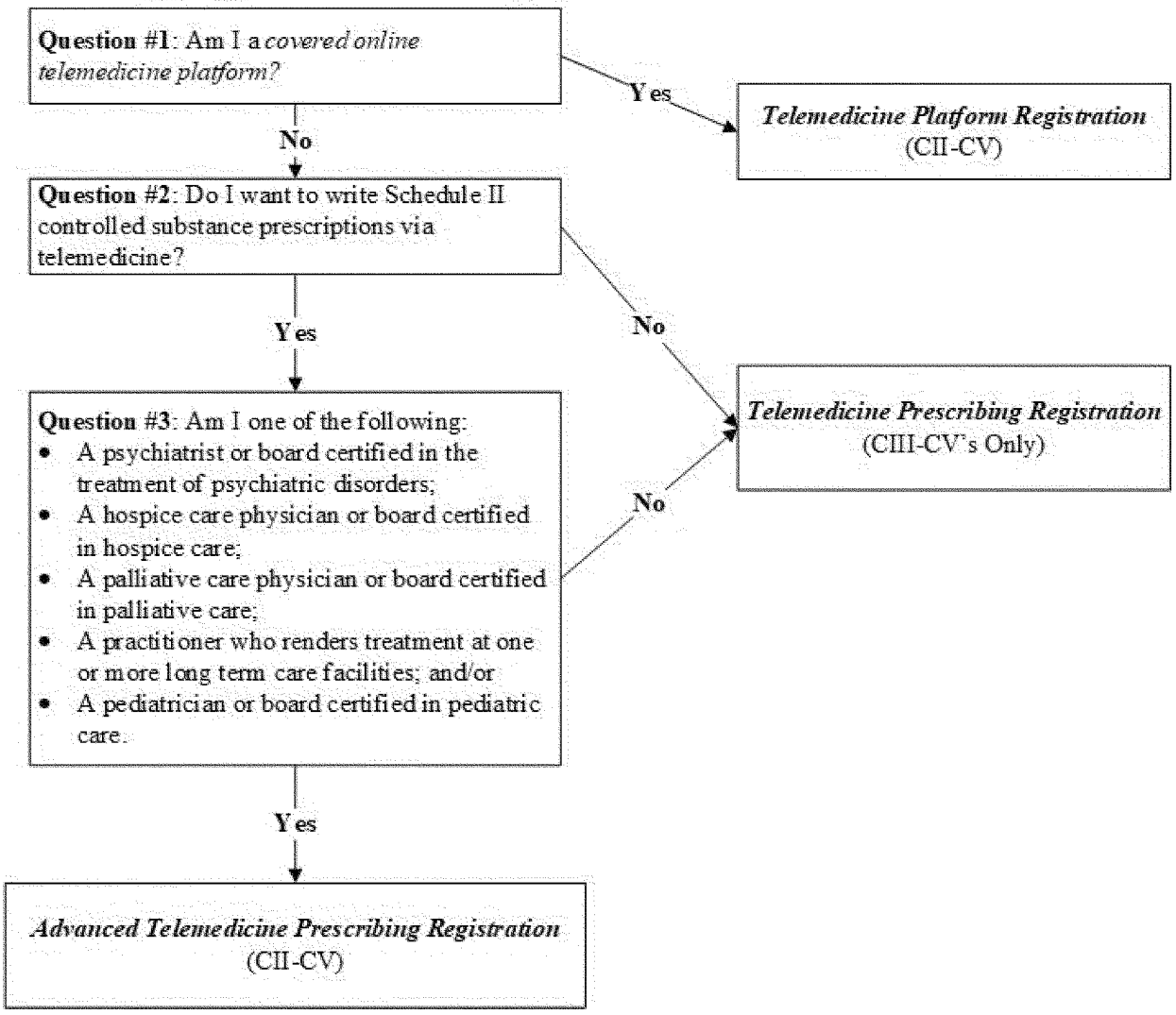
Appendix A

Chart: As a *Clinician Practitioner*, Is a *Special Registration for Telemedicine* Required to Treat This Patient?



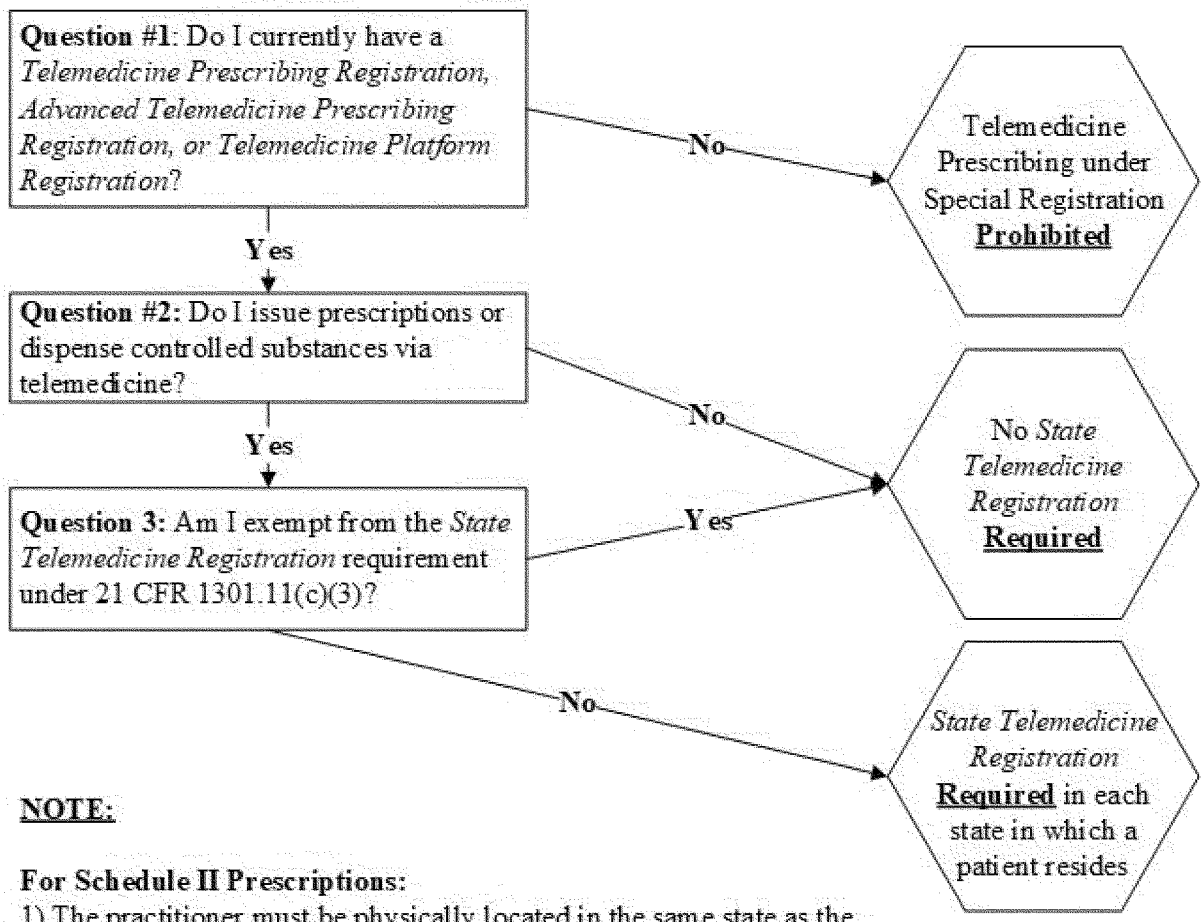
Appendix B

Chart: Which *Special Registration for Telemedicine* Do I Need?



Appendix C

Chart: Do I Need a *State Telemedicine Registration*?



NOTE:

For Schedule II Prescriptions:
1) The practitioner must be physically located in the same state as the patient; and
2) No more than 50% of the practitioners total telemedicine and non-telemedicine prescriptions for Schedule II controlled substances were prescribed under my *Advanced Telemedicine Prescribing Registration*.

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V. Regulatory Analyses

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

DEA has determined that this rulemaking is a ''significant regulatory action'' under section 3(f) of *Executive Order (E.O.) 12866, Regulatory Planning and Review* and is also a section 3(f)(1) significant action. Accordingly, this proposed rule has been submitted to the Office of Management and Budget (OMB) for review. This proposed rule has been drafted and reviewed in accordance with E.O. 12866, ''Regulatory Planning and Review,'' section 1(b), Principles of Regulation; E.O. 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation; and E.O. 14094, ''Modernizing Regulatory Review.''

Due to many uncertainties, DEA made a range of estimates: a low estimate, a moderate (primary) estimate, and a high estimate. Based on the moderate (primary) estimate, DEA projects that this proposed rule will result in a total annualized cost of $16 million, a total annualized cost savings of $23 million, for a net annualized cost savings of $7 million. The low estimate results in a total annualized cost of $0.60 million, a total annualized cost savings of $0.85 million, for a net annualized cost savings of $0.25 million. The high estimate results in a total annualized cost of $86 million, a total annualized cost savings of $122 million, for a net annualized cost savings of $36 million. Additionally, the proposed rule is estimated to increase annualized transfers (registration fees) to the federal government by $0.90 million, $24 million, and $128 million per year, for the low, moderate (primary), and high estimates, respectively. Fees paid to the federal government are considered transfer payments and not costs.[110] The full analysis of cost savings, costs, transfers, and benefits is provided below.

[110] OMB Circular A–4.

Overview

I. Regulatory Alternatives Considered

DEA considered three alternatives, including the selected alternative: (1) finalizing the proposed March 2023 General Telemedicine NPRM and Buprenorphine NPRM; (2) an alternative that would allow the prescribing of Schedules III–V controlled substances under a single *Special Registration for Telemedicine* pursuant to 21 U.S.C. 802(54)(E) and 831(h); and (3) the selected alternative.

First, DEA considered promulgating final rules based on the proposed March 2023 General Telemedicine NPRM and Buprenorphine NPRM pursuant to 21 U.S.C. 802(54)(G). The proposed General Telemedicine NPRM would have allowed for an initial prescription of non-narcotic Schedules III–V controlled substances for no more than a 30-day supply in instances where the patient has never had an in-person medical evaluation, and additional prescriptions beyond the initial 30-day prescription would require that the patient undergo an in-person medical evaluation. The proposed General Telemedicine NPRM generally would have required that a patient undergo an initial in-person medical evaluation prior to the prescription of Schedule II controlled substances, and Schedule III–V narcotic controlled substances (with the exception of buprenorphine for opioid use disorder (''OUD'') treatment), unless there was a *qualifying referral.*

Generally, the Buprenorphine NPRM would have allowed practitioners to prescribe buprenorphine for the induction of OUD treatment for no more than a 30-day supply through audio-only telemedicine. To obtain an additional supply of buprenorphine however, the patient would have to undergo an in-person medical evaluation within 30 days of the induction of the OUD treatment. Ultimately, DEA determined that final rules of the proposed regulations would have been potentially too burdensome on practitioners and patients, leading to reduced access to care.

The second alternative considered by DEA would have allowed practitioners—irrespective of their medical specialty or the patients they treat—to prescribe Schedule III–V controlled substances under a single *Special Registration for Telemedicine* pursuant to 21 U.S.C. 802(54)(E) and 831(h). Under this alternative, practitioners would not be authorized to prescribe Schedule II controlled substances. While this alternative could have established a more streamlined *Special Registration* framework, it would not take into consideration the diverse *legitimate needs* that practitioners may have to prescribe other controlled substances through telemedicine based on their medical specialties or the patients they serve. Additionally, it does not consider the fact that certain practitioners possess the necessary qualifications to prescribe Schedule II controlled substances through telemedicine, despite the heightened risk of abuse associated with Schedule II controlled substances. Consequently, DEA opted against this alternative.

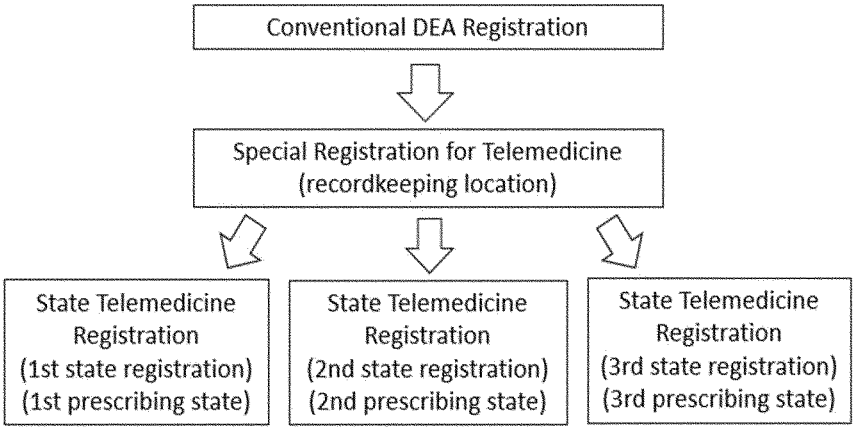
Finally, DEA is proposing the selected alternative, which would not require an in-person medical evaluation such as required under the first alternative and would allow certain qualified practitioners who demonstrate a *legitimate need* to prescribe Schedule II controlled substances through telemedicine unlike the second alternative. The selected, proposed alternative would establish a *Special Registration* framework pursuant to 21 U.S.C. 802(54)(E) and 21 U.S.C. 831(h), and authorize three types of *Special Registrations:* the (1) *Telemedicine Prescribing Registration* allowing qualified *clinician practitioners* to prescribe Schedule III–V controlled substances via telemedicine; the (2) *Advanced Telemedicine Prescribing Registration,* allowing qualified specialized *clinician practitioners* (*e.g.,* psychiatrists, *hospice care* physicians) and board-certified *mid-level practitioners* to prescribe Schedule II–V controlled substances via telemedicine, and (3) the *Telemedicine Platform Registration* for *covered online telemedicine platforms* in their capacity as *platform practitioners.*

Baseline. For our analysis of the economic impact of the selected alternative, the baseline for the selected alternative is the period before the temporary COVID–19 PHE exceptions to the *Ryan Haight Act.* During the baseline period, under 21 U.S.C. 829(e), the *Ryan Haight Act* has generally required an in-person medical evaluation prior to the prescription of controlled substances.

Proposed Requirements. The *Ryan Haight Act* does, however, provide an exception to this in-person medical evaluation requirement, where the practitioner is ''engaged in the practice of telemedicine.'' The *Ryan Haight Act* generally provides seven (7) distinct categories of the *practice of telemedicine* in which a prescribing practitioner might be unable to satisfy the *Ryan Haight Act's* in-person medical evaluation requirement, yet nonetheless may be able to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. The proposed requirements would allow a practitioner to obtain a *Special Registration for Telemedicine,* which is one of the seven categories of the *practice of telemedicine* as defined under the *Ryan Haight Act.* To engage in the *practice of telemedicine* under the proposed Special Registration framework, the practitioner must possess each of the following:

- An existing conventional DEA registration under 21 U.S.C. 823(g);
- One of the three types of *Special Registration for Telemedicine* authorizing the prescribing of controlled substances via telemedicine; and
- A *State Telemedicine Registration* allowing the prescribing of controlled substances via telemedicine for each state in which a patient is located.

Graphic 1: Necessary Registrations



As Graphic 1 shows, these types of DEA registrations are interconnected for the purposes of prescribing controlled substances under the Special Registration framework. To issue a *special registration prescription* to a patient located in a particular state, the practitioner must first obtain a *State Telemedicine Registration* for that state. However, a *State Telemedicine Registration* can only be obtained if the practitioner already holds or is simultaneously applying for a *Special Registration for Telemedicine.* In turn, the *Special Registration for Telemedicine* requires that the practitioner have an existing conventional DEA registration under 21 U.S.C. 823(g). The proposed rule has certain requirements for:

1. *The application process:* such as reporting professional affiliations with employers (21 CFR 1301.13(k)(2)(i)–(ii)), medical specialty (as mentioned above) (21 CFR 1301.13(k)(2)(iv)), that the practitioner will maintain anti-diversion policies (21 CFR 1301.13(k)(2)(iii)); and the facts and circumstances that form the basis for a legitimate need for a *Special Registration for Telemedicine* (21 CFR 1301.13(k)(2)(v)).

2. *The prescription process:* such as PDMP checks for the patient state, special registrant state, and any states with reciprocity agreement with either state (21 CFR 1306.43(a), a comprehensive nationwide PDMP check for all 50 states and any U.S. districts and territories that maintain a PDMP, if possible, starting three years from the effective date of the final rule (21 CFR 1306.43(b)), all prescriptions issued through EPCS (21 CFR 1306.42), telemedicine encounters being audio-visual with limited exception (21 CFR 1306.44), the inclusion of additional elements on special registration prescriptions (21 CFR 1306.47) and, for Schedule II controlled substances, prescriptions issued for care under an appropriate specialty and other safeguards (21 CFR 1306.45).

3. *Recordkeeping and reporting requirements:* such as patient verification using photographic records (21 CFR 1304.04(i)), *Special Registration* telemedicine encounter records (21 CFR 1304.04(j)), credential verifications of *clinician special registrants* (21 CFR 1304.04(k)), centralized recordkeeping at the *special registered location* (21 CFR 1304.04(l)), pharmacy reporting of telemedicine prescription data to DEA (21 CFR 1304.60) and special registrant reporting of the number of new telemedicine patients and prescription aggregated data to DEA (21 CFR 1304.61).

The costs, cost savings, benefits, and transfers associated with the proposed rule were evaluated from the perspective of the following impacted parties: patients, practitioners (including *mid-level practitioners*), pharmacies, healthcare systems, states, and society at large. The high and low ranges of economic impact are based on two factors: the rate of telemedicine visits resulting from this proposed rule and the level of participation by registrants under the proposed rule.

II. Patient Costs, Cost Savings, and Benefits

The proposed rule would benefit patients by reducing transportation costs, travel time costs, and expanding access to medical care. The cost savings associated with the proposed rule predominantly stem from reductions in two costs: (1) the cost of time, and (2) the cost of transportation.

A. Patient's Cost of Time per Practitioner Visit

To derive patients' cost of time, DEA needed to assess two factors: the *average length of time* to travel and wait for a practitioner's appointment, and the *average opportunity cost* (*i.e.,* forgone wages) to travel and wait for a practitioner's appointment. Simply put, (*average length of the time*) × (*opportunity cost*) = *patient's cost of time.* To determine an appropriate *average length of time,* DEA consulted relevant medical articles. While the *practice of telemedicine* proposed in this rule is a subset of telehealth that focuses on clinical services by practitioners, broader telehealth research can inform our understanding of telemedicine and provide a greater array of research to use in our analysis. It is also common for research to indicate it relates to ''telehealth,'' even when it may be more appropriate to call it a ''telemedicine'' study.[111]

To determine the *average length of time* to be used in this analysis, DEA consulted various studies. A 2023 study focused on cancer (non-elderly) telehealth patients treated between April 1, 2020, and June 30, 2021. This study found that telehealth patients saved about 2.9 hours of round-trip driving time and 1.2 hours of in-clinic time per visit, including time spent with a practitioner.[112] However, as this study focused on non-elderly cancer patients, it did not adequately represent the broader scope of telehealth patients considered in this analysis. In contrast, a 2019 study indicated that the *average length of time* (combining travel and waiting time) was 45 minutes (0.75 hours) per visit.[113] Given that 68.2 percent of all current telehealth claims are related to mental health, not non-elderly cancer patients, DEA believes that the 45-minute average is more

[111] Accordingly, in discussing such studies, DEA will use the word the word ''telehealth'' instead of telemedicine.

[112] Patel KB, Turner K, Alishahi Tabriz A, et al. Estimated Indirect Cost Savings of Using Telehealth Among Nonelderly Patients with Cancer. JAMA Netw Open. 2023;6(1):e2250211.

[113] Rhyan C. *Travel and Wait Times are Longest for Health Care Services and Result in an Annual Opportunity Cost of $89 Billion.* Altarum. (Feb. 22, 2019), *https://altarum.org/travel-and-wait* (accessed 9/5/2023).

relevant for this analysis.[114] DEA, however, acknowledges that there may be significant variability in the *average lengths of time* across different patient populations.

To determine an appropriate *average opportunity cost* (*i.e.,* forgone wages) to travel and wait for a practitioner's appointment, DEA consulted relevant data from the U.S. Bureau of Labor Statistics (BLS). DEA used median hourly wage data for all occupations ($23.11) as a proxy for the hourly *average opportunity cost* of travel and wait time for all patients, as can be seen in Table 1 below.[115] Additionally, BLS reports that average wages and salaries for civilians are 68.8 percent of total compensation. The 68.8 percent of total compensation equates to 45.3 percent (100 percent/68.8 percent—1) load on wages and salaries.[116] The load of 45.3 percent, or $10.47 (0.453 x $23.11), is added to the hourly rate to estimate the loaded hourly rates. As can be seen in Table 1, the loaded hourly wage for patients is $33.58 ($23.11 + $10.47). Therefore, the $33.58 loaded hourly wage represents the hourly *average opportunity cost* to travel and wait for a practitioner's appointment.

TABLE 1—PATIENTS LOADED HOURLY WAGE

Occupation	Hourly wage ($)	Load for benefits ($)	Loaded hourly wage ($)
All Occupations	23.11	10.47	33.58

Therefore, the patient's *cost of time* to travel and wait for a practitioner's visit—and thus the time cost savings achieved by telemedicine patients who could forego such a trip—equals $25.19 ($0.75 \times \$33.58$), as can be seen in Table 2 below.

TABLE 2—PATIENT COST OF TIME

[per Practitioner's Appointment]

Cost savings	Hourly opportunity cost ($)	Travel and wait time (hours)	Cost per appointment ($)
Time cost savings	33.58	0.75	25.19

B. Patient's Cost of Travel per Practitioner Visit

To determine the *cost of travel* to and from a practitioner's appointment, DEA used data from the *Southwest Rural Health Research Center* in the *Texas A&M School of Public Health,* and mileage reimbursement rates from the U.S. Internal Revenue Service (IRS). According to a 2017 survey by the *Southwest Rural Health Research Center,* the average national round-trip travel distance for a doctor's visit was 9.9 miles, or 19.8 miles round-trip.[117] The IRS travel reimbursement rate for businesses is 67 cents per mile.[118] Therefore, the patient's *cost of travel* to and from a practitioner's appointment—and thus the travel cost savings achieved by telemedicine patients who could forego such a trip—equals $13.27 (19.8 miles x $0.67 per mile), as can be seen in Table 3 below.

TABLE 3—PATIENT TRAVEL COST SAVINGS PER TRIP

Cost savings	Travel cost per mile ($)	Travel distance (miles)	Per appointment cost ($)
Travel cost savings	0.67	19.8	13.27

[114] Fair Health, ''Monthly Telehealth Regional Tracker.'' *https://www.fairhealth.org/fh-trackers/telehealth*. (accessed 8/4/2023 selecting Jan 2020, which had Jan 2019 data, and May 2023 using National Statistics data dropdown menu).

[115] Bureau of Labor Statistics, Occupational Employment and Wages, May 2023 National Occupational Employment and Wage Estimates, Occupation code: 00–0000 All Occupations, *https://www.bls.gov/oes/2023/may/oes_nat.htm.*

[116] Bureau of Labor Statistics, Employer Costs for Employee Compensation—June 2024, *https://www.bls.gov/news.release/archives/ecec_09102024.pdf.* (accessed 11/13/2024).

[117] Akinlotan, M., Khodakarami, N., Primm, K., Bolin, J., and Ferdinand, A.O. (Yen W. Rhyan C. Rural-Urban Variations in Travel Burdens for Care: Findings from the 2017 National Household Travel July 2021. *https://srhrc.tamu.edu/publications/travel-burdens-07.2021.pdf. https://ofm.wa.gov/sites/default/files/public/legacy/researchbriefs/2013/brief070.pdf* (accessed 9/24/2024).

[118] Internal Revenue Service. Standard Mileage Rates, Notice 2024–08, *https://www.irs.gov/pub/irs-drop/n-24-08.pdf.* (accessed 10/18/2024).

C. Total Number of Telemedicine Visits

The proposed rule's patient cost savings result from eliminating the need for an initial in-person medical evaluation or visit. Subsequent telemedicine visits are allowed after that initial in-person medical evaluation or visit, even without the COVID–19 PHE telemedicine flexibilities. So, to calculate the total patient cost savings under the proposed rule, DEA needed to estimate the *total number of first-time telemedicine visits resulting in prescriptions for controlled substances.*[119] Given the absence of direct information on this point, however, it was necessary for DEA to perform a multi-step analysis or derivation using different available data sources at each step to derive an estimate. First, DEA established the *total annual practitioner visits* using available data. Second, the total was further refined to those practitioner visits conducted *via telemedicine.* Third, the total was reduced to those that constituted *first-time* telemedicine visits. Fourth, DEA determined the proportion of the first-time telemedicine visits that would *result in prescriptions.* Fifth, it refined the total number of first-time telemedicine visits resulting in prescriptions of *controlled substances.* And lastly, DEA considered the impact of proposed requirements and determined the total number of first-time telemedicine visits resulting in prescriptions of controlled substances *under the proposed rule.* DEA performed this multi-step analysis to derive the low, moderate (primary), and high estimates of the *number of first-time telemedicine visits resulting in prescriptions for controlled substances,* which resulted in low, moderate (primary), and high values for the total patient cost savings.

i. Total Number of Telemedicine Visits Under the Current Telemedicine Rate

Step 1: Total Annual Practitioner Visits. As described above, DEA initially established the *total annual practitioner visits* using available data. According to the Centers' for Disease Control and Prevention (CDC) 2019 National Ambulatory Medical Care (NAMC) sample survey, it was estimated that there were a total of 1,036,484,000 practitioner visits that year, although not all of these visits resulted in prescriptions, as can be seen in Table 4.[120] An analysis of this survey revealed that a total of 3,476,239,000 prescriptions were issued during medical visits that year, as can be seen in Table 4.[121] This means that for every one practitioner visit, there were approximately 3.35 prescriptions, calculated as a coefficient of roughly 0.2982, which can be seen in Table 5.

TABLE 4—ESTIMATE OF NUMBER OF PRESCRIPTIONS USING VISIT DATA

Number of prescriptions	Number of visits (thousands)	Total number of prescriptions (thousands)
0	291,394	
1	192,488	192,488
2	129,561	259,122
3	84,898	254,694
4	60,766	243,064
5	52,613	263,065
6	34,041	204,246
And 7	28,900	202,300
8	29,043	232,344
9	23,393	210,537
10	15,320	153,200
11	17,034	187,374
12	14,744	176,928
13	13,419	174,447
14	10,635	148,890
15+	38,236	* 573,540
Total	** 1,036,485	3,476,239

* Used 15 as an approximation for 15+.
** The published total shows 1,036,484, so there is a rounding error of 1.

TABLE 5—ESTIMATE OF VISIT PER PRESCRIPTION COEFFICIENT

NAMC prescriptions	3,476,239,000
Prescriptions per visits ratio	3.35
Visit per prescription coefficient	0.2982

To estimate the total number of practitioner's visits, DEA did not use the NAMC survey because the survey results have been volatile year-to-year, and it only includes ''nonfederal office-based patient care physicians, excluding anesthesiologists, radiologists, and pathologists.'' [122] Instead, DEA used the derived coefficient in conjunction with IQVIA's more comprehensive 2019 prescription data to derive a more representative figure.[123] In 2019, IQVIA reported 4,386,834,000 prescriptions.[124] By multiplying this number by the coefficient 0.2982, DEA estimated that there were approximately *1,308,153,900 practitioner visits,* as can be seen in Table 6.

[119] Total Patient Cost Savings = (number of first-time telemedicine visits resulting in prescriptions for controlled substances) * (patient cost savings).

[120] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. (2019). *National Ambulatory Medical Care Survey: 2019 National Summary Tables.* Retrieved from *https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2019-namcs-web-tables-508.pdf.*

[121] *Id.*

[122] From the survey: ''Due to uncertainty regarding the true number of out-of-scope physicians in the 2018 NAMCS, the weighted frequency estimates for 2018 should be treated with caution. However, proportional estimates were not found to be significantly different between the 2018 NAMCS and 2019 NAMCS.''

[123] The IQVIA Institute. The Use of Medicines in the U.S. 2023. May 02, 2023. *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023* (accessed 4/23/2024) reports 4,437 million for 2019 unadjusted, but 6,218 million adjusted. A DEA IQVIA query of chain store prescriptions for 2019 was 4,386,834,000 but would be higher if food stores and independent were included. Ultimately, the 3,476,239,000 number from the survey appears low. However, even the number DEA used could be considered low, but DEA has chosen to be conservative.

[124] *Id.*

TABLE 6—ESTIMATE OF NUMBER OF PRACTITIONER VISITS

Coefficient	0.2982
IQVIA prescriptions	4,386,834,000
Visits—IQVIA prescriptions	1,308,153,900

Step 2: Rate of Telemedicine. DEA then further refined the total number of practitioner visits to those *conducted through telemedicine.* According to the *Fair Health Monthly Telehealth Regional Tracker,* as of July 2024, 4.7 percent of medical claims were conducted through telehealth.[125] As can be seen in Table 7, DEA then used this percentage to refine the total 1,308,153,900 practitioner visits to those likely to be conducted through telemedicine once a final rule is promulgated. Applying 4.7 percent, or the current telemedicine rate, to the 1,308,153,900 total practitioner's visits gives a total of *68,024,003 practitioner visits conducted via telemedicine,* as can be seen in Table 7.

TABLE 7—NUMBER OF TELEMEDICINE VISITS

Total practitioner visits	1,308,153,900
Telemedicine rate	0.047
Telemedicine visits	68,024,003

Step 3: First-Time Visits. DEA needed to further refine the total number of telemedicine practitioner visits to those that constituted *first-time* telemedicine visits. DEA's focus on first-time telemedicine practitioner visits, rather than all telemedicine visits, was to prevent an overestimation of the total patient cost savings. Under the status quo, after one bona fide in-person medical evaluation, patients are typically permitted to be seen via telehealth thereafter when receiving prescriptions for controlled substances. A potential overestimate of total patient cost savings arises from the fact that patient cost savings under the proposed rule primarily hinge on the bypassing of a first-time, in-person medical evaluation, but not subsequent telemedicine visits.

A 2022 study analyzing trends between 2017–2020 in interstate telehealth use by Medicare beneficiaries, a subset of the population impacted by the proposed rule, shows that the vast majority of practitioner visits are for returning patients, and approximately 10 percent of those practitioner visits are new visits.[126] This is in line with the CDC's 2019 NAMC nonfederal survey where 16.8 percent of office visits were for new patients. The CDC's 2019 NAMC survey, however, was not limited to telehealth visits, so DEA decided that the 10 percent estimate from the 2022 interstate telehealth study was more applicable to this analysis.[127] Taking 10 percent of 68,024,003 practitioner visits conducted via telemedicine would provide a total of approximately *6,802,400 first-time, telemedicine practitioner visits,* as can be seen in Table 8.

TABLE 8—NUMBER OF FIRST-TIME TELEMEDICINE VISITS

Telemedicine visits	68,024,003
First-time telemedicine visit rate	0.1
First-time telemedicine visits	6,802,400

Step 4: Visits Resulting in Prescriptions. DEA needed to determine the fraction of first-time telemedicine visits that would *result in prescriptions.* Looking again at CDC's 2019 NAMC survey (Table 4 above), DEA determined, as reflected in Table 4, that 291,394,000 visits did not include any prescribing, which means 745,090,000 of the 1,036,484,000 visits, or approximately 72 percent of the visits, did in fact result in the issuance of prescriptions. Because only 72 percent of visits resulted in a prescription, DEA applied the 72 percent to the calculated 6,802,400 first-time, telemedicine visits resulting in approximately a total of *4,889,996 first-time telemedicine visits resulting in the issuance of prescriptions,* as can be seen in Table 9.

[125] Fair Health, ''Monthly Telehealth Regional Tracker.'' *https://www.fairhealth.org/fh-trackers/telehealth.* (accessed 10/19/2024 selecting July 2024 using National Statistics data dropdown menu).

[126] Andino, J. J., Zhu, Z., Surapaneni, M., Dunn, R. L., & Ellimoottil, C. (2022). Interstate Telehealth Use by Medicare Beneficiaries Before and After COVID–19 Licensure Waivers, 2017–20. Health Affairs, 41(6). Appendix Exhibit 1 show that in person level 3 and level 4 new visits are 6.8% (3.5% + 3.3%) and out-of-state new visits are 10.7% (5.6% + 5.1%).

[127] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. (2019). National Ambulatory Medical Care Survey: 2019 National Summary Tables. Retrieved from *https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2019-namcs-web-tables-508.pdf.*

TABLE 9—ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS WITH PRESCRIPTIONS

First-time telemedicine visits	.....	6,802,400
NAMC survey visits—total	1,036,484,000	.....
NAMC survey visits—0 prescriptions	291,394,000	.....
NAMC survey rate—0 prescriptions	0.28	.....
NAMC survey rate—with prescriptions	0.72	* 0.72
First-time telemedicine visits with prescriptions	.....	4,889,996

* Rounded.

Step 5: Prescriptions for Controlled Substances. DEA then refined the total number of first-time telemedicine visits resulting in prescriptions for *controlled substances.* According to the Federal Trade Commission (FTC), *Surescripts* has 95% market share in e-prescribing services as of 2023.[128] DEA was able to use 2021 data from the *Surescripts National Progress Report* to determine that approximately 16 percent of all prescriptions (paper and electronic) are for controlled substances.[129] Applying this 16 percent to the total number of 4,889,996 telemedicine visits resulting in the issuance of prescriptions, provides a value of approximately *782,399 first-time telemedicine visits resulting in prescriptions for controlled substances,* as can be seen in Table 10.

TABLE 10—CURRENT ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS RESULTING IN PRESCRIPTIONS OF CONTROLLED SUBSTANCES

First-time telemedicine visits with prescriptions	4,889,995.73
Controlled substance (CS) rate	0.16
First-time telemedicine visits with CS prescriptions	782,399

Step 6: Effect of the Proposed Rule. Lastly, DEA determined the total number of first-time telemedicine visits resulting in prescriptions of controlled substances *under the proposed rule.* Under the proposed rule, patients would not have an in-person follow-up visit after the first-time telemedicine visit; they would never have to see the prescribing practitioner in person. Based on a study by *Epic Research* of primary care visits between March 1, 2020, and October 15, 2022, 61 percent of telehealth visits did not require an in-person follow-up.[130] A similar study by *Epic Research* on specialty visits provided that 85 percent of mental health and psychiatry telehealth visits did not have an in-person follow-up visit.[131] Because this proposed rule is not limited to mental health, DEA applied the broader and lower 61 percent to the 782,399 first-time telemedicine visits resulting in prescriptions of *controlled substances.* The multi-step analysis ultimately derived a current estimate of *477,264 first-time telemedicine visits resulting in prescriptions of controlled substances under the proposed rule,* as can be seen in Table 11.

TABLE 11—CURRENT ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS RESULTING IN PRESCRIPTIONS OF CONTROLLED SUBSTANCES UNDER THE PROPOSED RULE

NAMC visits	1,036,484,000	.....	.....	.....	.....
NAMC prescriptions	3,476,239,000	.....	.....	.....	.....
Prescriptions per visits ratio	3.35	.....	.....	.....	.....
Visit per prescription coefficient	*0.2982*	0.2982	.....	.....	.....
IQVIA prescriptions	.....	4,386,834,000	.....	.....	.....
Visits—IQVIA prescriptions	.....	*1,308,153,900*	1,308,153,900	.....	.....
Telemedicine rate	.....	.....	0.047	.....	.....
Telemedicine visits	.....	.....	*68,024,003*	68,024,003	.....
First time telemedicine visit rate	.....	.....	.....	0.1	.....
First-time telemedicine visits	.....	.....	.....	*6,802,400*	.....
NAMC survey visits—total	1,036,484,000	.....	.....	.....	.....
NAMC survey visits—0 prescriptions	291,394,000	.....	.....	.....	.....
NAMC survey rate—0 prescriptions	*0.28*	.....	.....	.....	.....
NAMC survey rate—with prescriptions	*0.72*	.....	.....	0.72	.....
First-time telemedicine visits with prescriptions	.....	.....	.....	*4,889,996*	4,889,996
Controlled substance (CS) rate	.....	.....	.....	.....	0.16
First-time telemedicine visits with CS prescriptions	.....	.....	.....	.....	*782,399*
First-time telemedicine visits that do not have an in-person follow up visit.	.....	.....	.....	.....	0.61

[128] *FTC Reaches Proposed Settlement with Surescripts in Illegal Monopolization Case Federal Trade Commission.* (July 27, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-reaches-proposed-settlement-surescripts-illegal-monopolization-case* (accessed 9/24/2024).

[129] According to the Surescripts National Progress Report, there were 256.9 million prescriptions of controlled substances prescribed through EPCS, accounting for 73 percent of the total number of prescriptions of controlled substances. Using these figures, DEA derived the total number of prescriptions of controlled substances to be 351.9 million ((256.9 million) * (100)/(73) = 351.9 million). There were 2.12 billion prescriptions of controlled substances and non-controlled substances prescribed electronically, accounting for 94 percent of the total number of all prescriptions paper or electronic for controlled substances or non-controlled substances. DEA derived the total number of all prescriptions paper or electronic for controlled substances or non-controlled substances to be 2.26 billion ((2.12 billion) * (100)/(94) = 2.26 billion). Using the total of all controlled substances prescriptions (351.9 million) and the total of all prescriptions (2.26 billion), DEA determined that 16% of all prescriptions are for controlled substances ((256.9 million) * (100)/2.26 billion = 16 percent).

[130] Gerhart J, Piff A, Bartelt K, Barkley E. *Most Primary Care Telehealth Visits Unlikely to Need In-Person Follow-Up. Epic Research. https://www.epicresearch.org/articles/most-primary-care-telehealth-visits-unlikely-to-need-in-person-follow-up* (accessed 10/20/2024).

[131] Gerhart J, Piff A, Bartelt K, Barkley E. *Telehealth Visits Unlikely to Require In-Person Follow-Up Within 90 Days.* Epic Research. *https://epicresearch.org/articles/telehealth-visits-unlikely-to-require-in-person-follow-up-within-90-days.* (accessed 10/20/2024).

TABLE 11—CURRENT ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS RESULTING IN PRESCRIPTIONS OF CONTROLLED SUBSTANCES UNDER THE PROPOSED RULE—Continued

First-time telemedicine visits under the proposed rule with CS prescriptions					477,264

ii. Forecasted Total Number of Telemedicine Visits

To project the future level of telemedicine visits, a forecast is required, utilizing the usage rate of telemedicine.[132] A forecast has two critical elements:

1. Baseline (or starting) value, and the
2. Growth rate from that baseline value.

A typical forecast relies on the existing value and the historic data to extrapolate an expected growth rate. However, this process becomes more complex with volatile historical data, as fluctuations make it challenging to determine a stable baseline and reliable growth trend.[133] In the case of telemedicine, the past five years have seen significant volatility in usage rates, resulting in baseline level and growth rates that have been significantly distorted, with the rate both increasing and decreasing depending on the time interval, as can be seen in Table 12. Specifically, the rate of telemedicine usage surged from 0.2 percent in 2019 to 13 percent in the April 2020 peak according to Fair Health's analysis of medical claims and to 31.2 percent in the second quarter of 2020 based on an analysis of doctor visits by *Epic Research.* [134] However, this trend reversed in subsequent years, with rates gradually declining. By the third quarter of 2023, the telemedicine usage rate had dropped to 5.8%, and as of July 2024, it stood at 4.7 percent, based on data from Epic Research.[135]

TABLE 12—HISTORICAL TELEMEDICINE RATE

Year	Month	Fair health (claims) (%)	YOY change (%)	Quarter	Epic research (doctor visits) (%)	YOY change (%)
2019	April	0.15		2Q	0.2	
2020	April	13.0	8566.7	2Q	31.2	15500.0
2021				2Q	9.1	−70.8
2022				2Q	7.1	−22.0
2023	May	5.4		2Q	6.0	−15.5
2024	May	4.8	−11.1			
2024	July	4.7				

Uncertainty and Factors that May Affect Future Telemedicine Usage. The future of telemedicine is difficult to predict. Patients may start to embrace telemedicine again, or they may continue to return to in-person visits as pandemic habits recede, especially given the lack of in-person exams and vital sign measurements in telehealth.[136] This uncertainty is reflected in corporate behavior. In March 2023, Walmart announced plans to further expand its telehealth services by opening 28 additional health centers.[137] However, less than a year later, in May 2024, the company reversed course, announcing the closure of all 51 of their health centers and its telehealth service as it no longer believed it a sustainable business model.

Even if the rule proposed in this NPRM were finalized, it remains unclear how state-level regulations will evolve and impact the telemedicine market. While 43 states and the District of Columbia (DC) may require commercial insurers to cover telehealth services (coverage parity), only a handful of states mandate equal reimbursement rates for telehealth and in-person care (payment parity).[138] Further, some states have rolled back telemedicine flexibilities introduced during the pandemic and reverted to pre-pandemic restrictions. As of December 2023, 30 states have banned or heavily restricted telehealth appointments with out-of-state doctors.[139]

Technology could also play a critical role in shaping the telemedicine market.

[132] The usage rate of telemedicine is the percent of medical visits conducted via telemedicine.

[133] For instance, for those who want to understand the potential of an economy, recessions may distort Gross Domestic Product (GDP) data. To counter that distortion interested parties may think in terms of the GDP at full employment and think how that full employment GDP grows every year. For some background see Universities-National Bureau Committee for Economic Research. *The Measurement and Behavior of Unemployment.* 1957. *https://www.nber.org/system/files/chapters/c2638/c2638.pdf* (accessed 10/20/2024).

[134] *Monthly Telehealth Regional Tracker,* Fair Health, *https://www.fairhealth.org/fh-trackers/telehealth.* (accessed 8/4/2023 selecting April 2020, which had April 2019 data, using National Statistics data dropdown menu); Bartelt K, Piff A, Allen S, Barkley E. *Telehealth Utilization Higher Than Pre-Pandemic Levels, but Down from Pandemic Highs.* Epic Research. *https://www.epicresearch.org/articles/telehealth-utilization-higher-than-pre-pandemic-levels-but-down-from-pandemic-highs* (accessed 10/19/2024), S&P Global. Telehealth finds mental health, provider niche as usage drops from pandemic peak. September 9, 2021. *https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/telehealth-finds-mental-health-provider-niche-as-usage-drops-from-pandemic-peak-66229670* (accessed 10/1/2024); The difference in the peak levels of demand could be due to Fair Health looking at claims that include filling prescription drugs and other non-visit related claims. However, Fair Health does look at a much larger volume of claims, possibly over 3 billion each year (*https://www.fairhealth.org/data*), than the Epic Research study, which only studied 475 million claims throughout the entire study period.

[135] *Monthly Telehealth Regional Tracker,* Fair Health, *https://www.fairhealth.org/fh-trackers/telehealth.* (accessed 10/19/2024 selecting July 2024 using National Statistics data dropdown menu).

[136] SteelFisher GK, McMurtry CL, Caporello H, Lubell KM, Koonin LM, Neri AJ, Ben-Porath EN, Mehrotra A, McGowan E, Espino LC, Barnett ML. *Video Telemedicine Experiences In COVID–19 Were Positive, But Physicians and Patients Prefer In-Person Care for The Future.* Health Aff (Millwood). April 2023.

[137] The Associated Press. *Walmart says it will close its 51 health centers and virtual care service.* NPR. May 1, 2024. *https://www.npr.org/2024/05/01/1248397756/walmart-close-health-centers-virtual-care#:~:text=the%20asset%27s%20value.-,Sponsor%20Message,vision%20centers%20in%20the%20U.S.* (accessed 10/31/2024).

[138] Ellimoottil C. *Understanding the Case for Telehealth Payment Parity.* Health Affairs. May 10, 2021. *https://www.healthaffairs.org/content/forefront/understanding-case-telehealth-payment-parity* (accessed 10/31/2024).

[139] Trotter C. In 30 states, you cannot use telehealth with out-of-state doctors. Pacific Legal Foundation. December 13, 2023. *https://pacificlegal.org/30-states-telehealth-rules/* (accessed 10/24/2024).

For example, technological advances could reduce the cost of remote patient monitoring devices, further driving the demand of telemedicine.[140] On the other hand, some communities may still not be able to utilize telemedicine in their homes, because they continue to lack the broadband internet to support the technology either because such broadband service is unavailable or unaffordable.[141] Ultimately, the telemedicine market has been shaped by a shifting landscape of factors, making it difficult to pinpoint any one baseline value or rate of growth with any certainty.

Low, Moderate (Primary), and High Estimates. Given these uncertainties, DEA analyzed a range of possible baseline values and growth rates for telemedicine usage (*i.e.,* rates of telemedicine) to demonstrate a range of possible outcomes. This approach allows for the derivation of a low, moderate, and high estimate of the total number of telemedicine visits over the next 10 years.

- For the low estimate, DEA selected a baseline telemedicine usage rate of 0.2 percent, reflecting the lower levels of use observed in 2019, prior to the COVID–19 pandemic. A growth rate of 2 percent was chosen, corresponding to the projected growth rate of primary care between 2022 and 2026.[142]
- For the moderate (primary) estimate, DEA used a baseline telemedicine usage rate of 4.7 percent, mirroring the current rate of telemedicine. A growth rate of 4.95% was derived by taking the average of two different projections: a robust growth rate of 19 percent and a negative rate of –9.1 percent.[143]
- For the high estimate, DEA selected a baseline telemedicine usage rate of 13 percent, reflecting the usage observed at the April 2020 peak by Fair Health's more comprehensive claims data during the pandemic. A growth rate of 19 percent was chosen based on estimates from one source, *Fortune Business Insights,* which projected that growth rate per year between 2024 and 2032.[144]

The scenarios provided are informed projections, based on factors that could influence telemedicine usage and growth. While these projections draw on available data and insights from healthcare, they are ultimately speculative. The scenarios are summarized in Table 13 below.

TABLE 13—SUMMARY OF THE THREE SCENARIOS

Scenario	Telemedicine Rate (%)	Growth (%)	Demand
Low	0.20	2	Telemedicine usage returns to pre-pandemic level with low growth, corresponding to demand for healthcare services.
Moderate (Primary)	4.70	4.95	Telemedicine usage remains at current level with moderate growth.
High	*13	19	Telemedicine usage surges to the pandemic peak level and grows at high growth rate.

As seen in Table 11, ''telemedicine rate'' of ''0.047'' (4.7 percent) is a key factor in estimating ''first-time telemedicine visits under the proposed rule with [controlled substance] prescriptions'' of 477,264. Varying the ''telemedicine rate'' to 0.2 percent and 13 percent would result in ''first-time telemedicine visits under the proposed rule with [controlled substance] prescriptions'' to 20,309 (477,264 × (0.2/4.7)) and 1,320,092 (477,264 × (13/4.7)), respectively. DEA estimates the number of first-time telemedicine visits under the proposed rule with controlled substance prescriptions would reach these levels in the first year of implementation of this proposed rule. Table 14 below summarizes the first-year numbers and growth rates of first-time telemedicine visits under the proposed rule with controlled substance prescriptions for the low, moderate (primary), and high estimates.

TABLE 14—''YEAR 1'' VISITS AND GROWTH RATES

	Low	Moderate (primary)	High
(Year 1) First-time telemedicine visits under the proposed rule with CS prescriptions	20,309	477,264	1,320,092
Annual Growth Rate	2.00%	4.95%	19.00%

[140] Serrano LP, Maita KC, Avila FR, Torres-Guzman RA, Garcia JP, Eldaly AS, Haider CR, Felton CL, Paulson MR, Maniaci MJ, Forte AJ. *Benefits and Challenges of Remote Patient Monitoring as Perceived by Health Care Practitioners: A Systematic Review.* Perm J. Dec 2023.

[141] U.S. Government Accountability Office. *Closing the Digital Divide for the Millions of Americans without Broadband.* WatchBlog. February 01, 2023. *https://www.gao.gov/blog/closing-digital-divide-millions-americans-without-broadband#:~:text=Closing%20the%20digital%20divide%20is,and%20Information%20Administration%20(NTIA)*(accessed 10/31/2024).

[142] Jain S. *Projected Growth in Demand for Healthcare Services is Tepid. Trilliant Health: The Compass.* 11/6/2022, *https://www.trilliant health.com/market-research/studies/projected-growth-in-demand-for-healthcare-services-is-tepid* (accessed 10/24/2024).

[143] Adjusting the recent decline in the rate of telemedicine of 11.1 percent by the 2.0 percent growth of overall doctor visits means telemedicine visits may have fallen 9.1%. The 19 percent was taken from Fortune Business Insight. Telemedicine Market Size, Share & Industry Analysis, By Type (Products and Services), By Modality (Store-and-forward (Asynchronous), Real-time (Synchronous), and Others), By Application (Teleradiology, Telepathology, Teledermatology, Telecardiology, Telepsychiatry, and Others), By End-User (Healthcare Facilities, Homecare, and Others), and Regional Forecast, 2024–2032 *https://www.fortune businessinsights.com/industry-reports/telemedicine-market-101067* (Accessed 10/20/24); For simplicity a single growth rate was assumed. However, an alternative measure could project the gradual slowing of the annual decline of −22 percent, −15.5 percent, and −11.1 percent from Table 12. Just using the change in decline in latest data of 4.4 percent (15.5 − 11.1) would give −6.7 percent in year 1, −2.3 percent in year 2, 2.1 percent in year 3, 6.5 percent in year 4, 10.9 percent in year 5, 15.3 percent in year 6, and 19.7 percent in year 7. This is probably more in line with the expected course of telemedicine but is still uncertain.

[144] Fortune Business Insight. Telemedicine Market Size, Share & Industry Analysis, By Type (Products and Services), By Modality (Store-and-forward (Asynchronous), Real-time (Synchronous), and Others), By Application (Teleradiology, Telepathology, Teledermatology, Telecardiology, Telepsychiatry, and Others), By End-User (Healthcare Facilities, Homecare, and Others), and Regional Forecast, 2024–2032 *https://www.fortune businessinsights.com/industry-reports/telemedicine-market-101067* (Accessed 10/20/24).

Applying the growth rates to the 'Year 1' patient visit figures, DEA generated a 10-year forecast as shown in Table 15 below.

TABLE 15—NUMBER OF VISITS FORECAST

Year	Low		Moderate (primary)		High	
	Growth rate (%)	Patient visits	Growth rate (%)	Patient visits	Growth rate (%)	Patient visits
1	.....	20,309	.....	477,264	.....	1,320,092
2	2	20,715	4.95	500,889	19	1,570,909
3	2	21,129	4.95	525,683	19	1,869,382
4	2	21,552	4.95	551,704	19	2,224,565
5	2	21,983	4.95	579,013	19	2,647,232
6	2	22,423	4.95	607,674	19	3,150,206
7	2	22,871	4.95	637,754	19	3,748,745
8	2	23,328	4.95	669,323	19	4,461,007
9	2	23,795	4.95	702,454	19	5,308,598
10	2	24,271	4.95	737,225	19	6,317,232

D. Total Patient Cost Savings

Each telemedicine visit saves patients time and travel costs of $25.19 and $13.27, respectively, for a total savings of $38.46. Applying the cost savings of $38.46 to the estimated number of first-time telemedicine visits under the proposed rule with controlled substance prescriptions results in a 10-year forecast of patient cost savings for low, moderate (primary), and high scenarios as shown in Table 16 below.

TABLE 16—PATIENT ANNUAL TOTAL COST SAVINGS

Year	Low ($)	Moderate (primary) ($)	High ($)
1	781,084	18,355,573	50,770,738
2	796,699	19,264,191	60,417,160
3	812,621	20,217,768	71,896,432
4	828,890	21,218,536	85,556,770
5	845,466	22,268,840	101,812,543
6	862,389	23,371,142	121,156,923
7	879,619	24,528,019	144,176,733
8	897,195	25,742,163	171,570,329
9	915,156	27,016,381	204,168,679
10	933,463	28,353,674	242,960,743
Present Value*	7,657,624	205,278,372	1,096,535,599
Annualized Cost*	852,497	22,852,928	122,073,501

* Present value and annualized values are based on a two percent (2%) discount rate.

E. Patient Benefit: Increased Access to Care

DEA believes this proposed rule may improve patient access to care. However, DEA maintains that telemedicine is not as effective as in-person visits. According to a NCHS Data Brief from February 2024, only 4.0 percent of primary care physicians, 6.3 percent of surgical specialty physicians, and 6.0 percent of medical special physicians believe telemedicine is as effective as in-person visits.[145]

Telemedicine has emerged as a vital solution for enhancing healthcare accessibility, especially in the face of healthcare shortages. Notably, it extends its benefits to patients in remote and other underserved areas, including by providing access to specialized care. As of July 2024, telehealth utilization is 4.7 percent of medical claims (Table 12), a significant leap from the 0.17 percent recorded in January 2019, before the COVID–19 pandemic, demonstrating its growing importance.[146] Most notably, mental health claims using telehealth had risen from 39.6 percent to 68.2 percent during this period, demonstrating that the utilization of telemedicine for mental healthcare experienced a significant surge during the pandemic.[147]

The importance of telemedicine becomes even more apparent when considering the acute shortage of mental health professionals. Over 75 percent of all U.S. counties are classified as having mental health shortage areas, with 50 percent lacking any mental health professionals. Long-distance travel for treatment remains a major accessibility barrier for individuals in rural areas with limited transportation options.[148] As of June 2023, there were 6,546 designated ''Mental Health—Health Professional Shortage Areas'' covering a total population of 163,355,252

[145] Myrick K, Mahar M, DeFrances CJ. *Telemedicine Use Among Physicians by Physician Specialty: United States,* 2021. NCHS Data Brief, no 493. February 2024. *https://www.cdc.gov/nchs/data/databriefs/db493.pdf.*

[146] *Monthly Telehealth Regional Tracker,* Fair Health, *https://www.fairhealth.org/fh-trackers/telehealth.* (accessed 8/4/2023 selecting Jan 2020, which had Jan 2019 data, and May 2023 using National Statistics data dropdown menu).

[147] *Id.*

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

people.[149] However, it is crucial to note that the healthcare shortage issue extends beyond mental health professionals. A September 2022 report revealed that 97.6 million Americans live in areas with a primary health professional shortage, highlighting a broad need for enhanced access to a range of specialties.[150]

The utilization of telehealth is more prevalent among urban Americans and Americans between the ages of 31 to 50 with respect to non-hospital-based provider-to-patient telehealth claims, which is the largest category of telehealth.[151] However, when examining discharge-related provider-to-patient telehealth claims, rural Americans and those over age 50 are the most prevalent.[152] DEA is not certain as to why these disparities exist, but they could suggest that limited access to routine and preventative care in rural areas and for older patients result in higher rates of hospitalizations, leading to more discharge-related provider-to-patient telehealth claims. With greater access, rural Americans and older patients may increase their non-hospital-based provider-to-patient telemedicine. With the potential for a broader range of telemedicine practices enabled by the proposed *Special Registration* framework, qualified practitioners and MLPs could effectively reach a larger patient population, ultimately resulting in improved healthcare outcomes and reduced costs for patients across the nation.

As discussed further below, healthcare systems may, instead of lowering costs, be able to provide increased care at a similar cost based on an evaluation of health care systems.[153] While practitioners may be able to reduce travel to and from the office, this time saving is likely much less than patients' since practitioners may still go to the office and may see many patients. However, this travel time savings may allow practitioners to become more available to patients, increasing access to care. While DEA is unable to quantify all the benefits to increased patient access to care, DEA believes it is not negligible.

III. Practitioner and MLP Costs, Cost Savings, and Transfers

The proposed rule would impact qualified practitioners (limited to physicians, *mid-level practitioners,* and *covered online telemedicine platforms*) by imposing registration costs, imposing recordkeeping costs, creating transfer payments, allowing for travel cost savings, and allowing for greater demand for their services. Costs of the proposed rule are specific to the cost of applying for the *conventional registration* (for *covered online telemedicine platforms*), *Special Registration for Telemedicine, State Telemedicine Registration,* and for PDMP checks due to the increased risk of diversion from more practitioners having the authority to prescribe Schedule II–V controlled substances. DEA estimates that there will be no additional infrastructure cost for patients or providers with the *Special Registration for Telemedicine,* as DEA has concluded that most patients and providers will already possess or have ready access to a telecommunications system meeting the requirements of the proposed rule. An analysis of all costs is detailed below.

A. Number of Conventional Registrations, Special Registrations, and State Telemedicine Registrations

When it comes to analyzing the costs, cost savings, benefits, and transfers of practitioners, DEA has to consider that qualified practitioners will need to apply for two new types of registrations, with *covered online telemedicine platforms* needing to first ensure that they have a conventional registration with DEA pursuant to 21 U.S.C. 823(g) in their capacity as a *platform practitioner.* As discussed above, practitioners will have to apply for a *Special Registration* (either the *Telemedicine Prescribing Registration,* the *Advanced Telemedicine Prescribing Registration, or the Telemedicine Platform Registration*), as well as *State Telemedicine Registrations (either State Telemedicine Registration for Clinician Special Registrants* or *State Telemedicine Registration for Platform Special Registrants),* an ancillary type of registration required for each state in which patients are located that will be treated by the practitioner.

The number of conventional registrations under 21 U.S.C. 823(g) will be equal to the number of *Telemedicine Platform Registrations,* because one conventional registration is required to obtain a *Telemedicine Platform Registration;* currently, no online telemedicine platforms have a conventional registration. As a starting point to determine the number of conventional registrations, *Special Registrations* and *State Telemedicine Registrations* to be expected under the proposed rule, DEA first looked at current registrations held by practitioners. For the number of *covered online telemedicine platforms,* DEA used the number of telemedicine companies as a proxy.

As of October 19, 2024, there were 2,153,900 DEA registrants.[154] Among them, 1,122,940 were physicians who fall under this proposed rule (medical doctors and doctors of osteopathy), 403,748 were nurse practitioners (''NPs''), and 168,201 were physician assistants (''PAs''), as shown in Table 17 below.[155] These numbers exceed the actual employment figures in these fields. Specifically, there are 770,850 physicians, 280,140 nurse practitioners, and 145,740 physician assistants according to BLS.[156] This variation can be attributed to the fact that some registrants maintain registrations in multiple states or locations.[157] The number of employed can serve as a proxy for primary registrations, *i.e.* the 823(g) registration predominantly used by a practitioner, while the difference between these two sets of numbers (number of registrants and employment numbers) provides an estimate of non-primary registrations.

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

[149] Health Resources and Services Administration, *Designated Health Professional Shortage Area Statistics, Third Quarter of Fiscal Year 2023 Designated HRSA Quarterly Summary* (2023).

[150] KFF, ''Primary Care Health Professional Shortage Areas (HPSAs),'' September 30, 2022, *https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.* (accessed 8/4/2023).

[151] Fair Health ''A Multilayered Analysis of Telehealth,'' July 2019.

[152] *Id.*

[153] *Id.*

[154] DEA estimate based on registrations.

[155] *Id.*

[156] Bureau of Labor Statistics, Occupational Employment and Wages, May 2023 National Occupational Employment and Wage Estimates, *https://www.bls.gov/oes/2023/may/oes_nat.htm.* (accessed 10/18/2024). The following occupation codes were used: 29–1210 Physicians and 29–1240 Surgeons (for ''physician''), 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants.

[157] IBISWorld. Telehealth Services in the US—Number of Businesses. February 15, 2024. *https://www.ibisworld.com/industry-statistics/number-of-businesses/telehealth-services-united-states/* (accessed 4/20/2024).

TABLE 17—REGISTRATIONS BY OCCUPATION

Occupation	Number of employed	Number of registrants	Registrations per employed	Primary registrations	Non-primary registrations
Physicians	770,850	1,122,940	1.46	770,850	352,090
Nurse Practitioner	280,140	403,748	1.44	280,140	123,608
Physician Assistant	145,740	168,201	1.15	145,740	22,461
Total	1,196,730	1,694,889	1.42	1,196,730	498,159

* Non-Primary Registrations figures are the differences between the Number of Registrants and Number of Employed.

DEA believes *covered online telemedicine platforms* are best represented by telemedicine companies. IBISWorld estimates that as of 2023 there were 1,306 such companies in the United States.[158]

Current Telemedicine Rate Estimate of Number of Registrations. According to the Fair Health Monthly Telehealth Regional Tracker, as of July 2024, 4.7 percent of medical claims were conducted through telehealth.[159] There may be some variation in how Physicians, Nurse Practitioners, and Physician Assistants prescribe.[160] Telemedicine prescribing also may not be at the exact same rate as in-person.[161] However, given the uncertainty in the exact difference and for simplicity, DEA has assumed that each practitioner type prescribes at the same rate and uses telemedicine to prescribe at the same rate as in-person. DEA applied the 'telemedicine rates' in Table 13 to the total number of employed physicians, nurse practitioners, and physician assistants to estimate the number of individual practitioner *Special Registrations* there will be under the proposed rule. Applying the 'telemedicine rates' of 0.2 percent, 4.7 percent, and 13 percent to the total number of physicians, nurse practitioners, and physician assistants of 1,196,730, the estimated number of individual telemedicine prescribing registrations are 2,393, 56,246, and 155,575 for low, moderate (primary), and high estimates, respectively.[162] Using the 2023 IBISWorld estimate of telemedicine companies of 1,306 provides an estimate of 1,306 *Telemedicine Platform Registrations*.[163] The number of conventional registrations would then also be 1,306, in line with *Telemedicine Platform Registrations.* Applying the relationship between the low (0.2 percent), moderate (primary) (4.7 percent), and high (13 percent) ''telemedicine rates'' to the moderate (primary) estimate of 1,306 *Telemedicine Platform Registrations* from IBISWorld, results in a low estimate of 56 ($1{,}306 \times (0.2/4.7)$) and a high estimate of 3,612 ($1{,}306 \times (13/4.7)$).

Assuming the rate of registrants obtaining DEA registrations are in line with the rate of those that will obtain clinician *State Telemedicine Registrations,* DEA used 0.2 percent, 4.7 percent, and 13 percent of the total number of registrations to provide the low, moderate (primary), and high estimates of how many clinician *State Telemedicine Registrations* there will be under the proposed rule. Multiplying the total number of registrations of 1,694,889 (from Table 17) by 0.2 percent, 4.7 percent, and 13 percent, results in 3,390, 79,660, and 220,336 clinician *State Telemedicine Registrations* for low, moderate (primary), and high estimates, respectively. Assuming a similar relationship holds for platforms, the number of platform *State Telemedicine Registrations* are estimated to be 42 percent (from Table 17, 1.42 registrations per employed minus 1) higher than the level of *Telemedicine Platform Registrations.* However, platforms are expected to be registered in more states than *clinician practitioners.* Based on a DEA analysis of the distributions of other national registrant types, a rate of 10 times the *clinician practitioner* rate was chosen.[164] The number of platform *State Telemedicine Registrations* is then estimated to be 420% ($42\% \times 10$) higher than the level of *Telemedicine Platform Registrations,* or 291 (56×5.20), 6,791 ($1{,}306 \times 5.20$), and 18,782 ($3{,}612 \times 5.20$) for low, moderate (primary), and high estimates respectively. DEA estimates the number of special registrations would reach these levels in the first year of implementation of this proposed rule. Table 18 below summarizes the first-year numbers and growth rates of special registrations for the low, moderate (primary), and high estimates.

TABLE 18—''YEAR 1'' SPECIAL REGISTRATIONS AND GROWTH RATES

	Low	Moderate (primary)	High
''Telemedicine rate''	0.20%	4.70%	13.00%
Year 1 Patient Visits	20,309	477,264	1,320,092
Year 1 Telemedicine Prescribing-Individual	2,393	56,246	155,575
Year 1 State Telemedicine-Individual	3,390	79,660	220,336
Year 1 Conventional-Platform	56	1,306	3,612

[158] IBISWorld. Telehealth Services in the US—Number of Businesses. February 15, 2024. *https://www.ibisworld.com/industry-statistics/number-of-businesses/telehealth-services-united-states/* (accessed 4/20/2024).

[159] Fair Health, ''Monthly Telehealth Regional Tracker.'' *https://www.fairhealth.org/fh-trackers/telehealth.* (accessed 10/19/2024 selecting July 2024 using National Statistics data dropdown menu).

[160] Cipher DJ, Hooker RS, Guerra P. *Prescribing trends by nurse practitioners and physician assistants in the United States.* J Am Acad Nurse Pract. 2006 June. *https://pubmed.ncbi.nlm.nih.gov/16719848/.*

[161] Wabe N, Thomas J, Sezgin G, Sheikh MK, Gault E, Georgiou A. *Medication prescribing in face-to-face versus telehealth consultations during the COVID–19 pandemic in Australian general practice: a retrospective observational study.* BJGP Open. 2022 March, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8958736/pdf/bjgpopen-6-0132.pdf.*

[162] Employment was used because practitioner commonly have multiple conventional registrations to cover each practice location, but only need one special registration.

[163] IBISWorld. *Telehealth Services in the US—Number of Businesses.* Feb. 15, 2024. *https://www.ibisworld.com/industry-statistics/number-of-businesses/telehealth-services-united-states/* (accessed 4/20/2024).

[164] DEA manufacturers and distributors with the most registrations have ten, with the median being one. Assuming platforms have a similar distribution, but have a max of 50, it would imply a median of five. This is approximately 10 times the *clinician practitioner* rate of 0.42.

TABLE 18—"YEAR 1" SPECIAL REGISTRATIONS AND GROWTH RATES—Continued

	Low	Moderate (primary)	High
Year 1 Telemedicine Platform	56	1,306	3,612
Year 1 State Telemedicine-Platform	291	6,791	18,782
Year 1 Total Registrations	6,186	145,309	401,917
Annual Growth Rate	2.00%	4.95%	19.00%

Applying the growth rates to the 'Year 1' registration figures, DEA generated 10-year forecasts for the low, moderate (primary), and high estimates as shown in Tables 19, 20, and 21 below.

TABLE 19—REGISTRATIONS FORECAST (LOW, 0.2 PERCENT "TELEMEDICINE RATE")

Year	Growth rate (%)	Telemedicine prescribing-individual	State telemedicine-individual	Conventional-platform	Telemedicine platform	State telemedicine-platform
1		2,393	3,390	56	56	291
2	2	2,441	3,458	57	57	297
3	2	2,490	3,527	58	58	303
4	2	2,540	3,598	59	59	309
5	2	2,591	3,670	60	60	315
6	2	2,643	3,743	61	61	321
7	2	2,696	3,818	62	62	327
8	2	2,750	3,894	63	63	334
9	2	2,805	3,972	64	64	341
10	2	2,861	4,051	65	65	348

TABLE 20—REGISTRATIONS FORECAST (MODERATE (PRIMARY), 4.7 PERCENT "TELEMEDICINE RATE")

Year	Growth rate (%)	Telemedicine prescribing-individual	State telemedicine-individual	Conventional-platform	Telemedicine platform	State telemedicine-platform
1		56,246	79,660	1,306	1,306	6,791
2	4.95	59,030	83,603	1,371	1,371	7,127
3	4.95	61,952	87,741	1,439	1,439	7,480
4	4.95	65,019	92,084	1,510	1,510	7,850
5	4.95	68,237	96,642	1,585	1,585	8,239
6	4.95	71,615	101,426	1,663	1,663	8,647
7	4.95	75,160	106,447	1,745	1,745	9,075
8	4.95	78,880	111,716	1,831	1,831	9,524
9	4.95	82,785	117,246	1,922	1,922	9,995
10	4.95	86,883	123,050	2,017	2,017	10,490

TABLE 21—REGISTRATIONS FORECAST (HIGH, 13.0 PERCENT "TELEMEDICINE RATE")

Year	Growth rate (%)	Telemedicine prescribing-individual	State telemedicine-individual	Conventional-platform	Telemedicine platform	State telemedicine-platform
1		155,575	220,336	3,612	3,612	18,782
2	19	185,134	262,200	4,298	4,298	22,351
3	19	220,309	312,018	5,115	5,115	26,598
4	19	262,168	371,301	6,087	6,087	31,652
5	19	311,980	441,848	7,244	7,244	37,666
6	19	371,256	525,799	8,620	8,620	44,823
7	19	441,795	625,701	10,258	10,258	53,339
8	19	525,736	744,584	12,207	12,207	63,473
9	19	625,626	886,055	14,526	14,526	75,533
10	19	744,495	1,054,405	17,286	17,286	89,884

DEA also expects that *State Telemedicine Registrations* could potentially be much greater than this estimate given the fact that *State Telemedicine Registrations* will not require a physical location. However, based on an analysis done on Medicare beneficiaries using 2020 data, only 5 percent of telemedicine takes place across state lines and most of this out-of-state care was for established patient care.[165] To the extent established patient care was a practitioner-patient relationship established following an in-person medical evaluation it would also not be considered telemedicine per the proposed rule. Further, out of state telehealth represented only 0.8 percent of all visits.[166] It is unclear how willing practitioners will be to register in multiple states to handle a very limited number of their patients who need telemedicine across state lines, and which represents such a small share of their total patient load. However, DEA believes these numbers could grow substantially based on having permanent telemedicine flexibilities in place around which practitioners can restructure their practices without comparable worry of future removal or expiration. This would be in line with an increasing number of practitioners working for platforms that serve a much broader geographical region compared to a typical physician office.

B. Practitioner and MLP Cost to Apply for Special Registration

In order to estimate the time cost for applying for the conventional registration, *Special Registration* (*Telemedicine Prescribing Registration* and the *Advanced Telemedicine Prescribing Registration,* or the *Telemedicine Platform Registration*) and the *State Telemedicine Registration* (*State Telemedicine for Individual Special Registrants* or *State Telemedicine for Platform Special Registrants*), DEA used an estimate of the amount of time and the value of that time for a practitioner to apply for the registration. To calculate the labor cost of applying for either the conventional registration, *Special Registration* or the *State Telemedicine Registration,* DEA estimates that on average it will take ten minutes (0.17 hours) to complete the registration application.[167] Should the application for a *Special Registration* or the *State Telemedicine Registration* be completed at the same time, the extra cost would be minimal. However, erring on the side of caution, DEA has assumed applications will be done separately and therefore has not made such a reduction.

Typically, practitioners delegate the task of completing DEA registration applications to their medical office administration or secretarial staff, or they may opt to use a credentialing company. For this reason, DEA has used the BLS median hourly wages for Medical Secretaries and Administrative Assistants, occupational code 43–6013, of $19.54.[168] Additionally, BLS reports that average wages and salaries for civilians are 69 percent of total compensation. The 68.8 percent of total compensation equates to 45.3 percent (100 percent/68.8 percent—1) load on wages and salaries.[169] The load of 45.3 percent, or $8.85 ($0.453 \times \$19.54$), is added to the hourly rate to estimate the loaded hourly rates. As can be seen in Table 22, the loaded hourly wage for completing DEA registration applications is $28.39 ($19.54 + $8.85).

To calculate the labor cost of applying for either the *Special Registration* or the *State Telemedicine Registration,* DEA estimates that on average it will take ten minutes (0.17 hours) for an applicant to apply for any of them.[170] The estimated labor cost to complete the application is $4.83 ($\$28.39 \times 0.17$). These registrations are for three years, so the annualized labor cost of registration is $1.61 ($4.83/3). This calculation is shown in Table 22 below.

TABLE 22—PER APPLICATION COST

Occupation	Hourly wage ($)	Load for benefits ($)	Loaded hourly wage ($)	Application time (hours)	Cost per application ($)	Annualized cost per application ($)
Medical Secretaries and Administrative Assistants	19.54	8.85	28.39	0.17	4.83	1.61

[165] Andino, J., Zhu, Z., Surapaneni, M., Dunn, R. L., & Ellimoottil, C. (2022). *Interstate Telehealth Use by Medicare Beneficiaries Before and After COVID–19 Licensure Waivers,* 2017–20. Health Affairs, 41(6).

[166] *Id.*

[167] This estimate is based on the time required to complete the new DEA Form 224S and DEA Form 224S–M, which will be used as the application for a Special Registration for Telemedicine and State Telemedicine Registration.

[168] Bureau of Labor Statistics, Occupational Employment and Wages, May 2023 National Occupational Employment and Wage Estimates, *https://www.bls.gov/oes/2023/may/oes_nat.htm.* (Accessed 10/18/2024).

[169] Bureau of Labor Statistics, Employer Costs for Employee Compensation –June 2024, *https://www.bls.gov/news.release/archives/ecec_09102024.pdf.* (accessed 10/18/2024).

[170] This estimate is based on the time required to complete DEA Form 224A, which would be modified to also be used as the application for the *Special Registration for Telemedicine* and *State Telemedicine Registration.*

C. Practitioner and MLP Cost to Report to DEA

The proposed rule requires special registrants to report to DEA, on an annual basis, the total number of new patients in each state treated under their *Special Registration for Telemedicine,* the total number of prescriptions for Schedule II controlled substances issued by the special registrant, and the total number of prescriptions for qualified Schedule III–V controlled substances issued by the special registrant for the preceding year. The special registrant would be required to electronically report this data through the DEA Office of Diversion Control's secure network application.

DEA believes the creation of this report by the registrant's electronic prescription controlled substance (EPCS) system will be a minimal one-time expense. EPCS systems already are required by CFR 1311.120(b)(27)(i) to track controlled substance transactions. The new piece of data that will be needed for this to be fully automated is tracking which patients fall under the proposed rule's telemedicine requirements. DEA believes this can be added to these existing systems during routine operation and maintenance and tracked with minimal cost and effort.

DEA believes the annual running of this report and submitting electronically to DEA can be done in six minutes (0.10 hours). Using the previously calculated loaded hourly wage for Medical Secretaries and Administrative Assistants of $28.39, the cost per report is $2.84 ($28.39 × 0.1), as can be seen in Table 23 below.

TABLE 23—PER REPORT COST

Occupation	Hourly wage ($)	Load for benefits ($)	Loaded hourly wage ($)	Reporting time (hours)	Cost per report ($)
Medical Secretaries and Administrative Assistants	19.54	8.85	28.39	0.10	2.84

D. Practitioner and MLP Cost to Check PDMP per Visit

The proposed rule immediately requires practitioners to complete a PDMP check of (1) the state/territory where the patient is located; (2) the state/territory where the practitioner is located; and (3) any state/territory with PDMP reciprocity agreements with either the state/territory where the patient is located or the state/territory where the practitioner is located. With a delayed effective date of three years, it requires a PDMP review of all 50 states and any U.S. districts and territories that maintain a PDMP prior to issuing a telemedicine prescription under the *Special Registration.* While a single comprehensive system that can check all 50 states and any U.S. districts and territories that maintain a PDMP is not currently available, once that system is in place, DEA believes it will perform similarly to existing PDMP checks. Based on a 2018 study, it takes a practitioner 27 seconds to log in and 37 seconds to retrieve a report once logged in.[171] The total time it takes to retrieve a PDMP report is roughly a minute (27 + 37 = 64 seconds) or 0.017 of an hour (1/60).

From BLS data, DEA used the weighted average of the mean hourly wages for Physicians (occupation code 29–1210) and Surgeons (occupation code 29–1240) to represent the wages for all practitioners. For Physicians, the mean hourly wage and employment are $126.85 and 716,950, and for Surgeons, the mean hourly wage and employment are $167.74 and 53,900; the weighted average of the median hourly wages is $129.71.[172] DEA also used the average of the median hourly wages for Physician Assistants (occupation code 29–1071) of $62.51 and Nurse Practitioners (occupation code 29–1171) of $60.70 to represent the hourly wages of MLPs. As calculated earlier, a load of 45.3 for benefits is added to these wages to calculate loaded wages. The loaded wages for physicians, PAs, and NPs are $188.47 ($129.71 × 1.453), $90.83 ($62.51 × 1.453), and $88.20 ($60.70 × 1.453), respectively. The estimated labor cost to complete the review for physicians is $3.20 ($188.47 × 0.017), for physician assistants is $1.54 ($90.83 × 0.017), and for nurse practitioners is $1.50 ($88.20 × 0.017).

TABLE 24—PDMP CHECK TIME COST

Occupation	Hourly wage ($)	Load for benefits ($)	Loaded hourly wage ($)	PDMP check time (hours)	Cost per PDMP check ($)
Physicians	129.71	58.76	188.47	0.017	3.20
Physician Assistants	62.51	28.32	90.83	0.017	1.54
Nurse Practitioners	60.70	27.50	88.20	0.017	1.50

For simplicity, DEA calculated a single cost of a PDMP check based on the weighted average of the three occupations. Using the 'Number of Registrants' from Table 17 to calculate weights, the weighted average of the PDMP check is $2.63.[173]

Recordkeeping and Infrastructure Costs. This proposed rule requires practitioners to maintain records relating to the *Special Registration for Telemedicine*. DEA believes that the recordkeeping requirements related to the *Special Registration for Telemedicine* will not impose major

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

[172] Bureau of Labor Statistics, Occupational Employment and Wages, May 2023 National Occupational Employment and Wage Estimates, *https://www.bls.gov/oes/2023/may/oes_nat.htm*. (accessed 10/18/2024). Employment figures for Physicians and Surgeons are 716,950 and 53,900, respectively, for a total of 770,850. Weighted average = $126.85 × (716,950/770,850) + $167.74 × (53,900/770,850) = $129.71.

[173] The number of physician, physician assistant, and nurse practitioner registrants are 1,122,940, 168,201, and 403,748, respectively, for a total of 1,694,889. The weighted average is $3.20 × (1,122,940/1,694,889) + $1.54 × (168,201/1,694,889) + $1.50 × (403,748/1,694,889) = $2.63.

additional costs on registrants. Practitioners who prescribe using a *Special Registration* would face additional recordkeeping requirements; but, given that the photographic record, *Special Registration* telemedicine encounter record, credential verification and conduct-related recordkeeping, and centralized recordkeeping required by proposed 21 CFR 1304.04(i)–(l) is not extensive, DEA does not anticipate it imposes a major burden on registrants. DEA also examined the cost of technology for telemedicine, both capital investment and operational expenses, in order to operate under the proposed *Special Registration for Telemedicine* framework. DEA believes that these initial investments have already been made by the practitioners most likely to apply for the *Special Registration for Telemedicine* and that there will be no additional technology or infrastructure cost to these practitioners to use the *Special Registration for Telemedicine*.

E. Practitioner and MLP Total Costs; Cost Savings

Total Cost. As mentioned previously, the three types of costs to practitioners are: (1) registration time costs, (2) reporting time costs, and (3) PDMP check costs. In summary, these costs are listed in Table 25 below.

TABLE 25—UNIT COST SUMMARY

	Unit costs
Registration application labor cost, annualized (applies to all registrations)	1.61
Reporting cost (applies to the number of primary special registration)	2.84
PDMP check cost (applies to all visit)	2.63

Unlike patient travel time and cost savings, since the PDMP check is required for all visits and not just first-time visits, there will not be a first-time visit adjustment. While PDMP checks will be required for all *special registration prescriptions* under this proposed rule, many practitioners already conduct PDMP checks. Due to a combination of the following factors, this would lower the additional burden imposed by this proposed rule:

(1) 45 out of 50 states require PDMP checks in some form,[174]

(2) Some states, such as California and New York, require PDMP checks for Schedule II–IV drugs (excluding Schedule V),[175]

(3) Other states have requirements that focus on the initial visit and do not always require checks for all follow-up visits.[176]

(4) Compliance with existing state laws is not 100 percent and the proposed rule may have an impact, but there will also be instances of non-compliance.[177]

However, to be conservative, DEA applied the full cost of $2.63 to all telemedicine visits leading to a *special registration prescription* by backing out the 0.1 factor applied for first-time visits in Table 8, in other words by multiplying the number of first-time telemedicine visits (Table 11) under the proposed rule with controlled substance prescriptions by 10. The proposed rule intends for there to be a nationwide PDMP that would allow for one PDMP check per visit. However, until such a system is put in place, for the first three years practitioners will only be required under the proposed rule to check the state location of the patient, the state location of the practitioner, and all states with reciprocity agreements with either of those two states. This could increase the number of checks per visit to two for some practitioners.

However, patients and practitioners may be in the same state. Also, based on a September 2023 analysis done by DEA of state PDMP participation, the average state, including the District of Columbia, only shares PDMP data with 30 other states.[178] Both factors could substantially reduce the number of PDMP checks from two to something much closer to one. For simplicity, DEA will assume there will be only one PDMP check required, in line with its long-term expectation.

Applying the annualized registration application labor cost of $1.61 to the number of registrations in Table 19, 20, and 21, the reporting cost of $2.84 to the number of primary (non-state) special registrations in Table 19, 20, and 21, and the PDMP check cost of $2.63 to all telemedicine visits that result in a controlled substances prescription (10 times the number of first-time visits from Table 15), the 10-year cost forecast is shown in Tables 26, 27, and 28 below for the low, moderate (primary), and high estimates.

TABLE 26—TOTAL PRACTITIONER AND MLP COST (LOW)

Year	Registration application labor cost ($)	Reporting cost ($)	PDMP check cost ($)
1	9,959	6,955	534,127
2	10,159	7,094	544,805
3	10,362	7,236	555,693
4	10,570	7,381	566,818
5	10,781	7,529	578,153
6	10,995	7,679	589,725
7	11,214	7,833	601,507
8	11,437	7,989	613,526
9	11,666	8,148	625,809
10	11,898	8,310	638,327
Present Value *	97,631	68,185	5,236,494

[174] DrFirst. *State Mandates Driving EPCS and PDMP Utilization*. *https://drfirst.com/resources/regulatory-mandates/* (Accessed 11/2/2023).

[175] New York State Department of Health. *Frequently Asked Questions for the NYS PMP*. June 2017. *https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/docs/pmp_registry_faq.pdf* (Accessed 11/2/2023), and Health Services Advisory Group. California's Prescription Drug Monitoring Program (PDMP). *https://hsag.com/contentassets/d1483fc74ad34b60b14cc1116e8cb14c/surscapdmpworkflow2020508.pdf* (Accessed 11/2/2023).

[176] *Id.*

[177] Delcher C, Pauly N, Moyo P. *Advances in prescription drug monitoring program research: a literature synthesis* (June 2018 to December 2019). Curr Opin Psychiatry. 2020 Jul.

[178] Data from Pdmpassist.org (Accessed September 2023).

TABLE 26—TOTAL PRACTITIONER AND MLP COST (LOW)—Continued

Year	Registration application labor cost ($)	Reporting cost ($)	PDMP check cost ($)
Annualized Cost*	10,869	7,591	582,961

*Present value and annualized values are based on a two percent (2%) discount rate.

TABLE 27—TOTAL PRACTITIONER AND MLP COST (MODERATE—PRIMARY)

Year	Registration application labor cost ($)	Reporting cost ($)	PDMP check cost ($)
1	233,947	163,448	12,552,043
2	245,528	171,539	13,173,381
3	257,682	180,030	13,825,463
4	270,437	188,942	14,509,815
5	283,824	198,294	15,228,042
6	297,873	208,110	15,981,826
7	312,617	218,410	16,772,930
8	328,089	229,219	17,603,195
9	344,331	240,568	18,474,540
10	361,376	252,476	19,389,018
Present Value*	2,616,334	1,827,907	140,374,966
Annualized Cost*	291,267	203,495	15,627,458

*Present value and annualized values are based on a two percent (2%) discount rate.

TABLE 28—TOTAL PRACTITIONER AND MLP COST (HIGH)

Year	Registration application labor cost ($)	Reporting cost ($)	PDMP check cost ($)
1	647,086	452,091	34,718,420
2	770,032	537,987	41,314,907
3	916,340	640,204	49,164,747
4	1,090,445	761,844	58,506,060
5	1,297,631	906,596	69,622,202
6	1,544,180	1,078,848	82,850,418
7	1,837,575	1,283,831	98,591,994
8	2,186,713	1,527,758	117,324,484
9	2,602,188	1,818,032	139,616,127
10	3,096,603	2,163,458	166,143,202
Present Value*.	13,975,657	9,764,161	749,841,038
Annualized Cost*.	1,555,861	1,087,010	83,477,199

*Present value and annualized values are based on a two percent (2%) discount rate.

Cost Savings. The following sections summarize the expected cost savings related to the *Special Registration for Telemedicine* and *State Telemedicine Registration* that are realized by practitioners. As discussed in the healthcare system section, there may not be a cost savings on the healthcare system side based on an evaluation of health care systems.[179] While practitioners may be able to reduce travel to and from the office, this time savings is likely much less than patients since practitioners may still go to the office and may see many patients, each of whom would be saving travel time. Practitioners may also become more available to patients which may offset any travel time and cost savings. In line with this, DEA believes the net cost savings for practitioners will be $0.

F. Practitioner and MLP Transfers

The following sections summarize the changes in transfers related to the expected new conventional registrations, the *Special Registration for Telemedicine* (*Telemedicine Prescribing Registration,* the *Advanced Telemedicine Prescribing Registration* and *Telemedicine Platform Registration*) and the *State Telemedicine Registration* (*State Telemedicine for Individual Special Registrants* and *State Telemedicine for Platform Special Registrants*) realized by practitioners. As discussed earlier, registrations fees paid to DEA are considered to be ''transfers.''

DEA proposes to set Special Registration fees to recover the cost of administering the registrations and operating the diversion control aspect of the proposed new business activities. Due to a myriad of unknowns, DEA is unable to calculate a cost that would need to be recovered. Therefore, DEA proposed to set the *State Telemedicine*

[179] Snoswell CL, Taylor ML, Comans TA, Smith AC, Gray LC, Caffery LJ. *Determining if Telehealth Can Reduce Health System Costs: Scoping Review.* J Med internet Res. Oct 19, 2020.

for Individual Special Registration fee at $50 per three years and other *Special Registration* fees at the same rate as the ''dispensing or instructing'' business activity (currently $888 per three years) as discussed further below. 21 CFR 1301.13(e)(1)(iv). Other than the *State Telemedicine for Individual Special Registration,* the *Special Registration* provides authority to dispense controlled substances similar to the various registrants in the ''dispensing or instructing'' business activity. DEA's cost of administering the registrations and operating the diversion control aspect of the Special Registrations are expected to be similar to that of registrations in the ''dispensing or instructing'' business activity.

Conventional Registration Transfers. In order to prescribe controlled substances using a *Special Registration for Telemedicine,* practitioners generally must have three registrations. First, a practitioner must be registered under 21 U.S.C. 823(g), *i.e.* a conventional registration, unless exempt from requirement of registration pursuant to 21 CFR 1301.23(a). The fee for such 823(g) registrations, ''dispensing or instructing'' business activity, is currently $888 for a three-year cycle ($296/year) pursuant to 21 CFR 1301.13(e)(1)(iv), unless exempt from fees pursuant to 21 CFR 1301.21(a). Unless subject to an exemption, all *clinician practitioners* that prescribe or dispense controlled substances must have this registration; therefore, the proposed rule does not impact this registration category or fee for *clinician practitioners*.

Covered online telemedicine platforms must also be registered as practitioners. DEA applied the annualized registration fee calculated previously of $296 to the number of conventional registrations from Tables 19, 20, and 21 to estimate the conventional registration transfers for low, moderate (primary), and high estimates.

Special Registration Transfers. The proposed rule adds two new DEA registrations (and fees) that practitioners must obtain: a *Special Registration for Telemedicine* (either the *Telemedicine Prescribing Registration,* the *Advanced Telemedicine Prescribing Registration* and *Telemedicine Platform Registration*), and *State Telemedicine Registrations* (*State Telemedicine for Individual Special Registrants* and *State Telemedicine for Platform Special Registrants*).[180]

As discussed earlier, DEA proposes to set the fee for the individual *Special Registration for Telemedicine* (*Telemedicine Prescribing Registration* and *Advanced Telemedicine Prescribing Registration*) at the same fee as the ''dispensing or instructing'' business activity, currently $888 per three years pursuant to 21 CFR 1301.13(e)(1)(iv). For now, DEA proposes to set the registration fee for *Platform Special Registrants* at the same fee as the *Individual Special Registrants* and registrants under the conventional registration of institutions, such as hospitals and clinics. As DEA gathers more data (such as pharmacy and practitioner reports included in this proposed rule) on the burden DEA incurs from *Platform Special Registrants,* this fee will be reevaluated. DEA applied the annualized registration fee of $296 to the number of Special Registrations, labeled ''Telemedicine Prescribing-Individual'' (which includes ''Telemedicine Prescribing'' and ''Advanced Telemedicine Prescribing'' registrations) and ''Telemedicine Platform'' in Tables 19, 20, and 21, to estimate the primary special registration transfers for low, moderate (primary), and high estimates.

State Telemedicine Registration Transfers. It is also statutorily required that a practitioner ''is registered under section 823(g) of this title in the State in which the patient will be located when receiving the telemedicine treatment. . . .'' 21 U.S.C. 831(h)(B). Therefore, the proposed rule would create the *State Telemedicine Registration* (*State Telemedicine for Individual Special Registrants* and *State Telemedicine for Platform Special Registrants*) to satisfy this requirement.

Registration fees generally cover two primary costs: (1) costs associated with processing and administering registrations, and (2) costs associated with general oversight and enforcement of controlled substance laws and regulations. The *State Telemedicine for Individual Special Registration* is an ancillary registration to the Special Registration and DEA proposes to set the fee at a level to recover DEA's cost of processing and administering the registration only. Based on an internal DEA 2021 study, as can be seen in Table 29 below, the total annual registration cost to DEA was $28,930,063.[181] This equates to a registration cost per registration of $45.[182]

TABLE 29—HISTORICAL REGISTRATION COST OF CONVENTIONAL DEA REGISTRATION

Annual cost categories	Annual cost ($)	Registrations per year	Cost per registration ($)
Labor cost of processing registrations	17,107,968	645,734	26.49
Labor cost of pre-registration investigations	2,955,422	645,734	4.58
Cost to maintain the registration IT system	8,866,672	645,734	13.73
Total	28,930,062	.....	45

Adjusting the $45 cost for inflation, from 2020 to current (end of 2023) dollars, the current estimated cost to process and administer a registration is $50.[183] Since the registration is a three-year registration, the annualized registration fee is $17 ($50/3).

The cost to DEA of administering the platform *State Telemedicine Registration* (*State Telemedicine for Platform Special Registrants*) is not

[180] A non-VA practitioner would not be required to have a 21 U.S.C. 823(g)registration in his or her own State or a State Telemedicine Registration in the patient's state if exempt from registration in all States under DEA regulations. *See* 21 U.S.C. 831(h)(1)(B)(i), *proposed* 21 CFR 1301.61(b)(4).

[181] This includes the annual cost of labor to process registrations ($17,107,968), the annual cost of labor to conduct liability pre-registration investigations ($2,955,422), and the annual cost to maintain the registration IT system ($8,866,672). Figures are rounded as shown.

[182] Dividing the total annual cost of $28,930,063 by the average number of new registrations and registration renewals processed annually from FY2018 to FY2020 of 645,734 yields a per registration cost of $45 (rounded). Practitioners pay this registration fee on a triennial basis.

[183] Office of Management and Budget, Historical Tables, Table 10.1-Gross Domestic Product and Deflators Used in the Historical Tables: 1940–2029. *https://www.whitehouse.gov/omb/budget/historical-tables.* (*https://www.whitehouse.gov/wp-content/uploads/2024/03/hist10z1_fy2025.xlsx*). (Accessed November 1, 2024). Using the ''GDP (Chained) Price Index'' of 1.05547 for 2020 and 1.2207 for 2023, $45 in 2020 is adjusted for inflation to $52 ($45 × 1.2207/1.0547) in 2023. $52 is rounded down to $50.

limited to the marginal registration cost. An individual doctor's time is finite, whether they are serving patients in one state or multiple states. However, for a platform there can be a much greater number of patients, number of doctors, and risk of diversion given the broader scope of practice as compared to an individual practitioner. Each additional state creates access to a new pool of patients and a diversion risk that cannot be fully covered from the fees from the *Telemedicine Platform Registration* and other *State Telemedicine for Platform Special Registrations*. DEA is proposing a $888 platform *State Telemedicine Registration* (*State Telemedicine for Platform Special Registrants*) fee with an annual rate over three years of $296 (888/3). Three-year registration fees and annualized fees are summarized in Table 30 below.

TABLE 30—REGISTRATION FEES AND ANNUALIZED REGISTRATION FEES

	Registration fee/transfer ($)	Annualized registration fee/transfer ($)
Telemedicine Prescribing-Individual	888	296
State Telemedicine-Individual	50	17
Conventional-Platform	888	296
Telemedicine Platform	888	296
State Telemedicine-Platform	888	296

As with the *Telemedicine Platform Registration* fee, as DEA gathers more data (such as from pharmacy and practitioner reporting included in this proposed rule) on the burden from these registrants this fee may be adjusted in the future. DEA applied the annualized registration fee of $17 to the number of individual state registrations and the annualized registration fee of $296 to the number of platform state registrations from Tables 19, 20, and 21 to estimate the state registration transfers for low, moderate (primary), and high estimates.

Furthermore, based on review of DEA's registration data, approximately 8.2 percent of physicians, nurse practitioners, and physician assistants are exempt from paying registration fees. Therefore, a factor of 91.8 percent (100 − 8.2) was applied to the number of individual primary and state registrations to estimate the number of fee-paying registrations. The annualized fees and fee-paying percentages for the various registrations are summarized in Table 31 below.

TABLE 31—ANNUALIZED REGISTRATION FEES AND FEE-PAYING PERCENTAGES

	Annualized registration fee/transfer ($)	Fee paying
Telemedicine Prescribing-Individual	296	91.8%
State Telemedicine-Individual	17	91.8%
Conventional-Platform	296	100%
Telemedicine Platform	296	100%
State Telemedicine-Platform	296	100%

Summary of Practitioner Transfers. Applying the annualized registration fees and fee-paying percentages (Table 31) to the number of registrations from Table 19, 20, and 21, results in registration fee transfers as shown in Tables 32, 33, and 34 for low, moderate (primary), and high estimates respectively.

TABLE 32—TOTAL TRANSFER PAYMENTS BY REGISTRATION

[Low]

Year	Telemedicine prescribing-individual ($)	State telemedicine-individual ($)	Conventional-platform ($)	Telemedicine platform ($)	State telemedicine-platform ($)
1	650,245	51,867	16,576	16,576	86,136
2	663,288	52,907	16,872	16,872	87,912
3	676,603	53,963	17,168	17,168	89,688
4	690,189	55,049	17,464	17,464	91,464
5	704,047	56,151	17,760	17,760	93,240
6	718,177	57,268	18,056	18,056	95,016
7	732,579	58,415	18,352	18,352	96,792
8	747,252	59,578	18,648	18,648	98,864
9	762,197	60,772	18,944	18,944	100,936
10	777,414	61,980	19,240	19,240	103,008
Present Value *	6,376,680	508,519	160,426	160,426	844,385

TABLE 32—TOTAL TRANSFER PAYMENTS BY REGISTRATION—Continued

[Low]

Year	Telemedicine prescribing-individual ($)	State telemedicine-individual ($)	Conventional-platform ($)	Telemedicine platform ($)	State telemedicine-platform ($)
Annualized Cost*	709,894	56,612	17,860	17,860	94,002

*Present value and annualized values are based on a two percent (2%) discount rate.

TABLE 33—TOTAL TRANSFER PAYMENTS BY REGISTRATION

[Moderate—Primary]

Year	Telemedicine prescribing-individual ($)	State Telemedicine-Individual ($)	Conventional-platform ($)	Telemedicine platform ($)	State telemedicine-platform ($)
1	15,283,613	1,218,798	386,576	386,576	2,010,136
2	16,040,104	1,279,126	405,816	405,816	2,109,592
3	16,834,093	1,342,437	425,944	425,944	2,214,080
4	17,667,483	1,408,885	446,960	446,960	2,323,600
5	18,541,904	1,478,623	469,160	469,160	2,438,744
6	19,459,801	1,551,818	492,248	492,248	2,559,512
7	20,423,076	1,628,639	516,520	516,520	2,686,200
8	21,433,905	1,709,255	541,976	541,976	2,819,104
9	22,495,002	1,793,864	568,912	568,912	2,958,520
10	23,608,544	1,882,665	597,032	597,032	3,105,040
Present Value*	170,923,255	13,630,288	4,323,434	4,323,434	22,480,387
Annualized Cost*	19,028,293	1,517,413	481,313	481,313	2,502,663

*Present value and annualized values are based on a two percent (2%) discount rate.

TABLE 34—TOTAL TRANSFER PAYMENTS BY REGISTRATION

[High]

Year	Telemedicine prescribing-individual ($)	State telemedicine-individual ($)	Conventional-platform ($)	Telemedicine platform ($)	State telemedicine-platform ($)
1	42,274,084	3,371,141	1,069,152	1,069,152	5,559,472
2	50,306,092	4,011,660	1,272,208	1,272,208	6,615,896
3	59,864,124	4,773,875	1,514,040	1,514,040	7,873,008
4	71,238,386	5,680,905	1,801,752	1,801,752	9,368,992
5	84,773,701	6,760,274	2,144,224	2,144,224	11,149,136
6	100,880,650	8,044,725	2,551,520	2,551,520	13,267,608
7	120,048,072	9,573,225	3,036,368	3,036,368	15,788,344
8	142,857,192	11,392,135	3,613,272	3,613,272	18,788,008
9	170,000,102	13,556,642	4,299,696	4,299,696	22,357,768
10	202,300,137	16,132,397	5,116,656	5,116,656	26,605,664
Present Value*	913,025,030	72,809,126	23,092,483	23,092,483	120,077,218
Annualized Cost*	101,643,906	8,105,587	2,570,806	2,570,806	13,367,780

*Present value and annualized values are based on a two percent (2%) discount rate.

G. Summary of Practitioner Costs, Cost Savings, Benefits, and Transfers

The costs to practitioners and MLPs and registration fees (transfers) are summarized in Table 35 below.

TABLE 35—SUMMARY OF PRACTITIONER AND MLP COSTS AND TRANSFERS

Year	Low		Moderate (primary)		High	
	Cost to practitioners and MLPS ($ million)	Transfers ($ million)	Cost to practitioners and MLPs ($ million)	Transfers ($ million)	Cost to practitioners and MLPs ($ million)	Transfers ($ million)
1	0.55	0.82	13	19	36	53
2	0.56	0.84	14	20	43	63
3	0.57	0.85	14	21	51	76
4	0.58	0.87	15	22	60	90
5	0.60	0.89	16	23	72	107
6	0.61	0.91	16	25	85	127
7	0.62	0.92	17	26	102	151
8	0.63	0.94	18	27	121	180
9	0.65	0.96	19	28	144	215
10	0.66	0.98	20	30	171	255
Present Value*	5.40	8.05	145	216	774	1,152
Annualized Cost**	0.60	0.90	16	24	86	128

* Present value and annualized values are based on a two percent (2%) discount rate.
** Figures are rounded as shown.

IV. Pharmacy Costs

Under the proposed rule, pharmacies would be required to submit monthly reports in accordance with proposed § 1304.60. DEA assumes similar reports are already being submitted to state PDMPs electronically and pharmacies would be able to submit reports as required by § 1304.60 with minimal additional costs.

V. Healthcare System Costs and Cost Savings

Based on the available research, DEA anticipates that there will be no significant net economic impact on healthcare systems due to the proposed rule. According to one peer-reviewed medical journal article from 2020, telehealth is expected to reduce costs in health systems between 32 percent to 53 percent of the time. However, evidence suggests that it does not routinely reduce the cost of care delivery for the health system as a whole.[184] A more recent 2023 study, focused on payment analysis for telehealth and in-person care, comes to a similar conclusion, noting the lack of cost differential and concluding that the primary benefit of telehealth is increased access and convenience, not cost savings.[185]

VI. State Costs

The proposed rule immediately requires practitioners to complete a PDMP check of: (1) the state/territory where the patient is located; (2) the state/territory where the practitioner is located; and (3) any state/territory with PDMP reciprocity agreements with either the state/territory where the patient is located or the state/territory where the practitioner is located. However, three years after the proposed rule's effective date, in order for Schedule II prescribing to continue across state lines, DEA is requiring that practitioners conduct PDMP checks for patients in all 50 states and any U.S. districts and territories that maintain a PDMP. Based on a September 2023 analysis conducted by DEA of State PDMP participation, the average state, including the District of Columbia, only shares PDMP data with 30 other states, as can be seen in Table 36.[186] Based on that study, California was the only state that does not share data with any other state or a U.S. district and territory. However, California now does share PDMP data with Oregon. Guam and Northern Mariana Islands both share with Nebraska and each other. Puerto Rico shares with 30 states plus the District of Columbia.

TABLE 36—PDMP SHARING AMONG 50 STATES AND THE DISTRICT OF COLUMBIA

	Number of states sharing with
Minimum	1
Minimum*	10
Average	30
Median	32
Maximum	45

* Excluding California.

This is a significant improvement since practitioners first gained access to PDMPs in 1990 and electronic sharing of PDMP data was started in 2010.[187] Further, most states use the same PDMP interconnectivity hub, with the two primary ones being PMP InterConnect and RxCheck.[188] However, even with these improvements and similarities, ''there are some variances when it comes to data sharing and integration (*i.e.,* assigned user roles, patient matching methods, percentage of provider population integrated, retention of PDMP data or reports) that pose challenges'' according to a report by the Prescription Drug Monitoring Program Training and Technical Assistance Center.[189]

[184] Snoswell CL, Taylor ML, et al. *Determining if Telehealth Can Reduce Health System Costs: Scoping Review.* J Med internet Res. October 2020.

[185] Amin K, Rae M, et al. *Early in the pandemic, private insurer payments for telehealth and in-person claims were similar.* Peterson-KFF Health System Tracker. January 18, 2023; and *https://www.healthsystemtracker.org/brief/telehealth-payments-similar-early-in-the-pandemic/#Average%20payment%20for%20evaluation%20and%20management%20professional%20claims%20by%20telehealth%20and%20in-person,%20among%20privately%20insured,%202020* (Accessed 9/5/2023).

[186] Data from Pdmpassist.org (Accessed September 2023).

[187] *Interstate PDMP Access and Data Sharing Alignment,* Prescription Drug Monitoring Program Training and Technical Assistance Center (Jan. 2021), *https://www.pdmpassist.org/pdf/resources/Interstate_PDMP_Access_and_Data_Sharing_Alignment_20210125.pdf* (Accessed October 23, 2023).

[188] Data from Pdmpassist.org (Accessed October 2023).

[189] *Interstate PDMP Access and Data Sharing Alignment,* Prescription Drug Monitoring Program Training and Technical Assistance Center (Jan. 2021), *https://www.pdmpassist.org/pdf/resources/*

DEA does not have a basis to determine what the cost and coordination hurdles are in trying to implement 50-state sharing of PDMP data or how much more PDMP data sharing would have happened without this rule. Based on a 2016 study, there is evidence that states who have implemented PDMPs had a decline in the rate of opioid-related deaths in the year after their inauguration and that those declines were strongest in states whose PDMPs had the most comprehensive and efficient features, such as more frequently updated data.[190] DEA believes increased state sharing will produce similar results and that any costs associated with implementation will be surpassed by the benefit of lower opioid-related deaths.

From 2012 to 2016, SAMHSA funded projects across nine states to, among other things, increase PDMP access across states.[191] Based on a report from the CDC, these projects were successful in increasing interstate PDMP data sharing, and this sharing brought about a decrease in prescription opioid abuse. Accordingly, there is reason for optimism that states can implement sharing and that outside groups can have a positive impact as well. This proposed rule would not create any mandate for states. Any costs incurred in PDMP data sharing among states are incurred outside of this rule. Therefore, any cost to states as a result of this rule would be minimal.

VII. Diversion

Requiring an in-person medical evaluation serves as a safeguard against diversion, consistent with the *Ryan Haight Act*. Certain signs of diversion or misuse of controlled substances may go undetected without an in-person assessment, as some indicators are either essential to observe personally or are more reliably detected when face-to-face. Without this safeguard, new diversion paradigms have emerged in telemedicine.[192] Therefore, in the absence of an in-person medical evaluation requirement, DEA believes that other anti-diversion safeguards—such as those proposed in this NPRM—are necessary, beyond the measures that have been in place since March 2020, to address the ongoing risks of diversion.

Admittedly, there is little quantified data on diversion since the onset of the COVID–19 pandemic. However, the intentionally concealed and frequently underreported nature of drug diversion makes these illicit activities inherently difficult to track.[193] By design, illegal activities like diversion are meant to evade detection, which complicates the collection of comprehensive and reliable quantitative data. Furthermore, diversion of controlled substances can take on many forms, from theft and fraud to improper prescribing making it difficult to quantify in a standardized method. Arguably, data shedding more light on diversion rates could be pulled from state PDMPs; however, as discussed above, the fragmented nature of PDMPs across the states fails to provide a comprehensive set of standardized data.

Given the dearth of comprehensive standardized data on diversion, DEA has had to rely on qualitative information and insights, such as anecdotal information, expert testimony from industry, and the specialized experience and knowledge of DEA's diversion investigators to identify emerging trends and inform enforcement strategies. Under the proposed NPRM, DEA would be implementing a system requiring pharmacies to inform DEA monthly about practitioner *special registration prescriptions* in accordance with proposed § 1304.60, which will allow DEA to collect more uniform and comprehensive data in order to carry out more quantitative analyses to evaluate the diversion of controlled substances via telemedicine.

VIII. Summary of Economic Impact

DEA estimates a cost savings to patients of $38.46 per first-time telemedicine visit that results in a controlled substance prescription. DEA estimates an annualized cost to practitioners, MLPs, and platforms of $1.61 for the labor cost of a registration application. DEA estimates a cost to practitioners and MLPs of $2.84 for annual reporting. DEA estimates a cost to practitioners and MLPs of $2.63 for PDMP checks. These unit costs were applied to the 10-year forecast of visits and registrations to develop a 10-year forecast of the cost savings, costs, and transfers. Furthermore, the annualized registration fees (transfers) were applied to the 10-year forecast of registrations to develop a 10-year forecast of transfers. The resulting cost savings, costs, and transfers for low, moderate (primary), and high estimates are shown in Table 37 below.

TABLE 37—SUMMARY OF ECONOMIC IMPACT ($ MILLIONS)

Year	1	2	3	4	5	6	7	8	9	10
Low Estimate										
Patient cost savings	0.78	0.80	0.81	0.83	0.85	0.86	0.88	0.90	0.92	0.93
Costs	0.55	0.56	0.57	0.58	0.60	0.61	0.62	0.63	0.65	0.66
Net Cost Savings	0.23	0.23	0.24	0.24	0.25	0.25	0.26	0.26	0.27	0.27

Interstate_PDMP_Access_and_Data_Sharing_Alignment_20210125.pdf (Accessed October 23, 2023).

[190] Patrick, S.W., Fry, C.E., Jones, T.F., & Buntin, M.B. (2016). *Implementation of prescription drug monitoring programs associated with reductions in opioid-related death rates.* Health Affairs, 35(7), 1324–1332.

[191] *Integration & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States,* CDC (Feb. 2017), *https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf* (Accessed 10/23/2023).

[192] *See, e.g., Founder/CEO and Clinical President of Digital Health Company Arrested for $100M Adderall Distribution and Health Care Fraud Scheme,* U.S. Department of Justice, Press Release Number: 24–752 (June 13, 2024), *https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-arrested-100m-adderall-distribution.*

[193] In some comments to the March 2023 NPRMs and during some of the presentations during the Telemedicine Listening Sessions, individuals cited studies demonstrating a lack of increased proportion of overdose deaths involving buprenorphine during the initial months of the pandemic, when the telemedicine flexibilities were first put in place, as evidence of a lack of diversion of controlled substances more generally. However, it is important to note that these studies focused solely on buprenorphine, and it would be inappropriate to extrapolate their findings to all controlled substances given the unique characteristics of buprenorphine, particularly the combination buprenorphine product (*Suboxone*), which adds naloxone designed to deter diversion and misuse. Consistent with this data, buprenorphine has been provided unique treatment under this proposed NPRM and under the separate *Expansion of Buprenorphine Treatment via Telemedicine Encounter* final rule (RIN 1117–AB78). *See, e.g.,* Tanz LJ, Jones CM, Davis NL, Compton WM, Baldwin GT, Han B, Volkow ND. *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID–19 Pandemic.* JAMA Netw Open. 2023 Jan 3;6(1): e2251856. doi: 10.1001/jamanetworkopen.2022.51856. PMID: 36662523; PMCID: PMC9860517; and Sade E. Johns, Mary Bowman, F. Gerard Moeller, *Utilizing Buprenorphine in the Emergency Department after Overdose,* Trends in Pharmacological Sciences, Volume 39, Issue 12, (2018), *https://doi.org/10.1016/j.tips.2018.10.002* (Available: *https://www.sciencedirect.com/science/article/pii/S0165614718301809.*

TABLE 37—SUMMARY OF ECONOMIC IMPACT ($ MILLIONS)—Continued

Year	1	2	3	4	5	6	7	8	9	10
Transfers	0.82	0.84	0.85	0.87	0.89	0.91	0.92	0.94	0.96	0.98
Moderate (Primary) Estimate										
Patient cost savings	18	19	20	21	22	23	25	26	27	28
Costs	13	14	14	15	16	16	17	18	19	20
Net Cost Savings	5	6	6	6	7	7	7	8	8	8
Transfers	19	20	21	22	23	25	26	27	28	30
High Estimate										
Patient cost savings	51	60	72	86	102	121	144	172	204	243
Costs	36	43	51	60	72	85	102	121	144	171
Net Cost Savings	15	18	21	25	30	36	42	51	60	72
Transfers	53	63	76	90	107	127	151	180	215	255

* Figures are rounded as shown, Net Cost Savings may not add exactly in the table.

DEA calculated the present value and annualized figures for the cost savings, costs and transfers shown in Table 37. The resulting present value and annualized figures are shown in Table 38 below.

TABLE 38—NET PRESENT VALUE AND ANNUALIZED COST SAVINGS/COSTS ($ MILLIONS)

	Low	Moderate (Primary)	High			
			h	PV*	A*	PV*
Patient—Cost Savings	7.7	0.85	205	23	1,097	122
Practitioner cost	5.4	0.60	145	16	774	86
NPV (Cost Savings)	2.3	0.25	60	7	323	36
Registration fee (Transfers)	8.1	0.90	216	24	1,152	128

* Present value (PV) and annualized (A) values are based on a two percent (2%) discount rate.

While DEA believes that the benefits of increased availability for treatment outweigh the dangers of a potential increase in diversion—so long as prescribers using the *Special Registration for Telemedicine* adhere to the safeguards inherent in the requirements of the proposed rule—the data system DEA is implementing will allow DEA to monitor the actual impact of the rule and be able to proactively make any necessary changes, either on the enforcement side or the regulatory side.

Regulatory Flexibility Act

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

In accordance with the RFA, DEA evaluated the impact of this proposed rule on small entities. The proposed rule allows for DEA-registered physicians and MLPs, or practitioners, to apply for three types of *Special Registrations:* the (1) *Telemedicine Prescribing Registration* authorizing qualified practitioners to prescribe Schedule III–V controlled substances via telemedicine; (2) the *Advanced Telemedicine Prescribing Registration,* authorizing qualified specialized practitioners (*e.g.,* psychiatrists, *hospice care* physicians) to prescribe Schedule II–V controlled substances via telemedicine, and (3) a *Telemedicine Platform Registration,* authorizing *covered online telemedicine platforms,* in their capacity as *platform practitioners,* to dispense Schedule II–V controlled substances.

The proposed rule immediately requires practitioners to complete a PDMP check of (1) the state/territory where the patient is located; (2) the state/territory where the practitioner is located; and (3) any state/territory with PDMP reciprocity agreements with either the state/territory where the patient is located or the state/territory where the practitioner is located. With a delayed effective date of three years, it requires a PDMP review of all 50 states and any U.S. districts and territories that maintain a PDMP prior to issuing a telemedicine prescription under the *Special Registration.*

A significant number of 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 the potential applicants for the Special Registrations for Telemedicine. 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'').[194] The following business NAICS codes are estimated to represent businesses that employ the affected persons (potential applicants):

- 621111—Offices of Physicians, Except Mental Health Specialists
- 621112—Offices of Physicians, Mental Health Specialists
- 621420—Outpatient Mental Health and Substance Abuse Centers
- 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

[194] 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.

of firms in various firm size ranges with SBA size standards for each of the representative NAICS codes. The SBA size standard is the firm size based on the number of employees or annual receipts depending on industry. The SBA size standards for NAICS codes 621111, 621112, 621420, and 622210 are annual receipts of $16.0 million, $13.5 million, $19.0 million, and $47.0 million, respectively.[195]

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 175,503 entities are affected by this proposed rule, of which 172,436 (98.25 percent) are small entities. The analysis is summarized in Table 39 below.[196]

TABLE 39—NUMBER OF AFFECTED ENTITIES AND SMALL ENTITIES

NAICS Code	Number of firms	SBA size standard ($)	Number of small firms
621111—Offices of Physicians, Except Mental Health Specialists	161,286	16,000,000	157,563
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	200
Total	178,766		174,012
Percent of Total			97.3 percent

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

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

In this analysis DEA has assumed a practitioner falls under the platform registration even though that registration is designed for telemedicine companies who are serving as intermediaries between patients and *clinician practitioners,* which is expected to exclude physician offices that have only one physician. If the cost is not burdensome for a single physician office, then it would not, presumably, be a burden for larger offices as well.

As covered above, DEA estimates the cost to apply at $4.83 per application and that each registrant would apply for 2.5 individual Special Registrations (1 initial and 1.5 state) and 3.5 platform registrations (1 conventional, 1 initial telemedicine, and 1.5 state) for a total of 6 (2.5 + 3.5), at an annual rate of 2 Special Registrations per year (6/3), giving a total cost of $9.66 ($4.83 × 2). This would also mean there would be fees of $888 for the platform conventional registration, $1,776 (888 × 2) for both the individual and platform initial *Special Registration* and $150 ($50 × 3) for 3 special state registrations, for a total of $2,814 ($888 + $1,776 + $150), or $938 per year ($2,814/3).

DEA estimates the cost for reporting to DEA would be $2.84 per report. With one report per year, that would be an annual cost of $2.84. DEA estimates the cost per PDMP check for physicians, physician assistants, and nurse practitioners is $3.20, $1.54, and $1.50, respectively. DEA estimates the number of new PDMP checks per year by taking the total number of new PDMP checks and dividing by the number of Special Registrations. For the high estimate, the number of new PDMP checks per year is 83 (63,172,320/761,781). Being conservative, DEA used the year 10 figures. The total annual cost of the new PDMP checks per year is $266 (84 × $3.20), $128 (83 × $1.54), and $125 (83 × 1.50), respectively for physicians, physician assistants, and nurse practitioners.

The average annual total economic impact for each registrant who prescribes under this proposed rule is then the combination of the PDMP check cost, registration time cost, reporting cost, and annualized registration fee. For physicians, physician assistants, and nurse practitioners, this is $1,210 ($266 + $3.22 + $2.84 + $938), $1,072 ($128 + $3.22 + $2.84 + $938), and $1,069 ($125 + $3.22 + $2.84 + $938), respectively.

The average annual total economic impacts are compared to the loaded annual mean wages for physicians and MLPs (physician assistants and nurse practitioners). Based on the Bureau of Labor Statistics' (BLS) Occupational Employment and Wages data, DEA estimates an annual mean wage of $263,840 for physicians (occupation code 29–1210),[197] $130,490 for physician assistants (occupation code 29–1071),[198] and $128,490 for nurse practitioners (occupation code 29–1171).[199] Based on the previously calculated load of 45.3 percent, the loaded annual mean wages are then $383,360 ($263,840 × 1.453), $189,602 ($130,490 × 1.453), and $186,696 ($128,490 × 1.453), respectively.

The total annual fees and costs are then 0.32 percent ($1,210/$383,360),

[195] U.S. Small Business Administration, Table of size standards, Effective March 17, 2023, *https://www.sba.gov/document/support-table-size-standards* (*https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023_.xlsx*) (Accessed October 18, 2024).

[196] SUSB, 2017 SUSB Annual Data Tables by Establishment Industry, U.S., Data by Enterprise Receipts Size, 6-digit NAICS, *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html* (*https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_rcptsize_2017.xlsx*) (Accessed October 20, 2024).

[197] Bureau of Labor Statistics, *Occupational Employment and Wages, May 2023* (29–1210 Physicians), annual mean wage, *https://www.bls.gov/oes/2023/may/oes_nat.htm* (Accessed 10/18/2024). While the weighted average of the 29–1210 Physicians and 29–1240 Surgeons is used to calculate costs earlier in the document, here, the total costs and fees is compared to the loaded median annual wages for 29–1210 Physicians only. 29–1210 is the large majority and this analysis examines the impact on this occupation with the lower wage.

[198] Bureau of Labor Statistics, *Occupational Employment and Wages, May 2023, 29–1071 Physician Assistants,* median hourly wage *https://www.bls.gov/oes/2023/may/oes_nat.htm.* (Accessed 10/18/2024).

[199] Bureau of Labor Statistics, *Occupational Employment and Wages, May 2023, 29–1171 Nurse Practitioners,* annual mean wage, *https://www.bls.gov/oes/2023/may/oes_nat.htm.* (Accessed 10/18/2024).

0.57 percent ($1,072/$189,602), and 0.57 percent ($1,069/$186,696) of loaded annual wages for physicians, physician assistants, and nurse practitioners, respectively. Table 40 presents the details of the calculation.

TABLE 40—COSTS AND FEES AS PERCENT OF WAGES

	Registration cost ($)	Reporting cost ($)	PDMP check cost ($)	Annualized registration fee cost ($)	Total cost and fees ($)	Loaded annual mean wage ($)	Costs and fees as percent of wage (percent)
Physicians	3.22	2.84	266	938	1,210	383,360	0.32
Physician Assistants	3.22	2.84	128	938	1,072	189,602	0.57
Nurse Practitioners	3.22	2.84	125	938	1,069	186,696	0.57

The economic impact of applying for the *Special Registration for Telemedicine* represents a small fraction (0.32 percent, 0.57 percent, and 0.57 percent) of annual wages. DEA estimates the proposed rule will not have a significant economic impact on individual physicians and MLPs. The small entities that employ the potentially affected physicians and MLPs are expected to generate enough revenue to pay their wages. Therefore, DEA concludes the proposed rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

DEA has determined that this proposed rule may have Tribal implications, as defined by Executive Order 13175. The determination that this proposed rule will have Tribal implications is, in part, based off the several public comments made by Tribal organizations on the 2023 General Telemedicine NPRM and the Buprenorphine NPRM, stating that the requirements in those two proposed rules would have a substantial impact on Tribal communities. The most prominent concerns of the Tribal organizations involved the extreme remoteness and practitioner shortages faced by some Tribal communities. Specifically, as a result of these obstacles to care, the Tribal communities noted the challenges posed by, as proposed in the 2023 NPRMs, necessitating an in-person medical examination to obtain prescriptions for certain substances, as well as the 30-day telemedicine prescription supply limit. On June 13 and 27, 2024, OTJ and DEA hosted two Tribal consultations to have broad discussions regarding the practice of telemedicine with Tribal communities. Many of the Tribal organizations that participated in the two Tribal consultations reiterated their concerns about any telemedicine rule that would require an in-person medical examination to obtain prescriptions for certain substances and a 30-day telemedicine prescription supply limit.

After carefully considering the information and insights shared in the public comments to the two 2023 NPRMs, during the Telemedicine Listening Sessions, and during the June 2024 Tribal Consultations, DEA reevaluated its approach and determined that the best course of action was to proceed with the promulgation of a *Special Registration* rule. Notably, this proposed *Special Registration* rule no longer contains an in-person medical examination requirement for certain substances and no longer contains a 30-day telemedicine prescription supply limit requirement; DEA believes these changes have largely addressed the prominent concerns raised by Tribes. DEA encourages Tribal members and entities to submit public comments on this *Special Registration* NPRM. Furthermore, it intends to continue Tribal consultations on Telemedicine, including the proposed requirements of the *Special Registration* NPRM, to ensure meaningful collaboration with Tribal governments impacted by DEA's telemedicine policies.

Paperwork Reduction Act of 1995

This proposed rule would impose new collections and modify existing collections 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. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Proposed Rule

1. Title: Application for Registration, Registration Renewal, *Special Registration for Telemedicine,* and Changes and Modifications to *Special Registration for Telemedicine,* Forms DEA–224/224A/224S/224S–M
OMB Control Number: 1117–0014
Form Number: DEA–224/DEA–224A/DEA–224S/224S–M

DEA is proposing to amend its regulations by creating two new forms for all *Special Registration* applicants to use when applying for or modifying a *Special Registration for Telemedicine* and a *State Telemedicine Registration.* DEA Form 224S (*Application for Special Registration for Telemedicine Under the Controlled Substances Act*) will allow *Special Registration* applicants to use one form to apply for the *Telemedicine Prescribing Registration* (CS III–V), the *Advanced Telemedicine Prescribing Registration* (CS II–V), the *Telemedicine Platform Registration* (CS II–V), and the *State Telemedicine Registration* for each state in which a patient will be located. *Special Registration* applicants will be required to provide one *Special Registered Location. Platform practitioners* will be required to disclose all employment, contractual relationships, or professional affiliations with any *clinician special registrant* and Online Pharmacy and their respective registration numbers. *Clinician practitioners* will be required to disclose all employment, contractual relationships, and professional affiliations, including with any *covered online telemedicine platforms* and the respective *covered online telemedicine platform's Telemedicine Platform Special Registration* number; their practice specialties; and attest to their ability and intention to check relevant state PDMPs prior to issuing a *special registration prescription.* All *Special Registration* applicants will also be required to attest to having devised, and committing to maintain, anti-diversion

policies and procedures and to the facts and circumstances that form the basis for their legitimate need for a *Special Registration for Telemedicine.* Additionally, those practitioners that are exempt from obtaining *State Telemedicine Registrations* will be required to identify all states in which patients will be located when being treated via telemedicine.

DEA Form 224S–M (*Application for Changes and Modifications to Special Registration*) provides *special registrants* with a means to comply with the proposed requirement of notifying DEA, within 14 business days, of any changes to the information provided in the *Special Registration* application (Form 224S); such changes include if a *clinician special registrant* becomes employed by, contracts with, or otherwise becomes professionally affiliated with a new DTC online telemedicine platform not previously disclosed on the original Form 224S or if any *clinician special registrant* or *platform special registrant* needs to make modifications to their *Special Registration.* The information submitted on these two forms will enhance transparency, patient safety, and anti-diversion efforts.

The below estimates are based on the ''moderate (primary)'' estimates made in the E.O. 12866 section above. DEA estimates the following number of respondents and burden associated with this collection of information:

- Number of respondents: 670,916
- Frequency of response: 1 per year
- Number of responses: 718,917
- Burden per response: 0.20 hours (calculated)
- Total annual hour burden: 144,200 hours

2. Title: Special Registration Recordkeeping and Prescribing Requirements

OMB Control Number: 1117–New

Form Number: N/A

Clinician special registrants will remain subject to existing recordkeeping and prescribing requirements. However, under this rule, DEA is proposing additional requirements under the *Special Registration* framework.

Clinician special registrants would be required to maintain all records arising from telemedicine encounters under the *Special Registration* framework at the *special registered location* for a minimum of two (2) years. The *clinician special registrant* will be required to maintain a record of the date and time of the telemedicine encounter, the address of the patient during the telemedicine encounter, and the home address of the patient. This proposed requirement enhances public safety by making detection of diversion patterns and illegitimate prescribing practices easier to spot during DEA investigations. It will also alleviate the practical burden for *special registrants* by centralizing recordkeeping at the *special registered location* rather than requiring *special registrants* to maintain records in every state where telemedicine patients are located. Additionally, this proposed rule will require, in addition to the requirements of a prescription found in 21 CFR 1306.05(a), two additional elements for *special registration prescriptions* to include: (1) the *Special Registration* numbers of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner;* and (2) *State Telemedicine Registration* number of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner.* If a *clinician special registrant* is exempt from obtaining a *State Telemedicine Registration,* the *clinician special registrant* will be required to instead provide a notation on the prescription identifying the state in which the patient is located. This information will provide the pharmacist with the necessary information to determine whether the *clinician practitioner* has the authority to prescribe, and the *platform practitioner* has the authority to dispense, Schedule II controlled substances, and provide the pharmacist with the information necessary to verify that *special registration prescriptions* are prescribed and dispensed by *special registrants* authorized within the appropriate state.

This proposed rule requires that *clinician special registrants,* or a delegated employee or contractor under the direct supervision of the *clinician special registrant,* verify the identity of patients seeking treatment via telemedicine by requiring that the patient present a state or federal government-issued photo identification card or acceptable alternative forms of identification through the camera of the *audio-video telecommunications system.* The *clinician special registrant* will be required to photograph the patient presenting their photo identification card or other acceptable documents during an initial telemedicine encounter or accept a copy of such identification card or document and will be required to maintain this photographic record for a minimum of two (2) years. The photographic records, or copies of such, will be securely stored in the patient's medical record or chart to ensure patient privacy. This requirement ensures that patients' identities are verified, and the photographic record establishes a clear link between the patient's identity and the *special registration prescription.*

Platform special registrants will be required to maintain certain *clinician special registrant* records insomuch as that *platform special registrant* has a *covered platform relationship* with the *clinician special registrant.* Such records include documents related to verification of the *clinical special registrant's* credentials; employment contracts and any other contract between the *platform special registrant* and *clinician special registrant;* and any disciplinary actions or sanctions, or documentation of complaints, disputes, or incidents involving the *practice of telemedicine.* The *platform special registrant* will be required to maintain and update the credential verification and conduct-related records for a minimum of two (2) years. This requirement will help to address any potential issues of diversion, misconduct, or inadequate screening procedures and provides additional regulatory oversight over remote prescribing.

This proposed rule will require, in addition to the requirements of a prescription found in 21 CFR 1306.05(a), two additional elements for *special registration prescriptions* to include: (1) the *Special Registration* numbers of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner;* and (2) *State Telemedicine Registration* number of the *clinician practitioner* and, if a *platform practitioner* facilitated the prescription, the *platform practitioner.* If a *clinician special registrant* is exempt from obtaining a *State Telemedicine Registration,* the *clinician special registrant* will be required to instead provide a notation on the prescription identifying the state in which the patient is located. This information will provide the pharmacist with the necessary information to determine whether the *clinician practitioner* has the authority to prescribe, and the *platform practitioner* has the authority to dispense, Schedule II controlled substances, and provide the pharmacist with the information necessary to verify that *special registration prescriptions* are prescribed and dispensed by *special registrants* authorized within the appropriate state.

The below estimates are based on the ''moderate (primary)'' estimates made in the E.O. 12866 section above. DEA estimates the following number of

respondents and burden associated with this collection of information:

- Number of respondents: 57,552
- Frequency of response: 174.26562 (as needed, calculated)
- Number of responses: 10,029,335
- Burden per response: 0.0008602 (calculated)
- Total annual hour burden: 8,627 hours

3. Title: Special Registration Reporting Requirements
OMB Control Number: 1117-New
Form Number: N/A

This proposed rule will require both *individual special registrants* and *platform special registrants* to electronically report to DEA under 21 CFR 1304.61, on an annual basis, the total number of new patients in each state where at least one *special registration prescription* for a Schedule II controlled substance and certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine, has been issued; the total number of *special registration prescriptions* for Schedule II controlled substances issued by the *special registrant* in aggregate and across all states; and the total number of *special registration prescriptions* for certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressants constituting a benzodiazepines, which were issued by the *special registrant,* in aggregate and across all states. Amid the ongoing opioid epidemic, this vital information will provide DEA with accurate and up to date data on the prescribing of controlled substances via telemedicine.

This proposed rule will also require pharmacies to electronically report, within the first seven (7) days of the start of every month, aggregate data for the *special registration prescriptions* filled during the preceding month for each Schedule II controlled substance and certain Schedule III–V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine. For each of these controlled substances, the pharmacy will be required to report the number of prescriptions filled, the volume of the controlled substance dispensed, and the number of patients prescribed the controlled substance. These requirements provide valuable oversight of telemedicine prescriptions under the *Special Registration,* enable the detection of irregularities or suspicious prescribing and dispensing practices, and will help DEA understand any shifts in demand for medications via telemedicine.

The below estimates are based on the ''moderate (primary)'' estimates made in the E.O. 12866 section above. DEA estimates the following number of respondents and burden associated with this collection of information:

- Number of respondents: 69,134
- Frequency of response: 6.950774 (calculated)
- Number of responses: 871,488
- Burden per response: 0.006863 hours (calculated)
- Total annual hour burden: 5,981 hours

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the notice of proposed rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), 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 will 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 18, 2025. [''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) 776–3882.

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.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Prescription drugs, Security measures.

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, 1301, 1304, and 1306 as follows:

PART 1300—DEFINITIONS

■ 1. Revise the authority citation for part 1300 to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 831(h), 871(b), 951, 958(f).

■ 2. In § 1300.01(b) the add the term ''Clinician practitioner'' and revise the term ''Institutional practitioner'' shall be revised, as follows:

§ 1300.01 Definitions related to controlled substances

* * * * *

Clinician practitioner is an individual practitioner who provides direct patient care or assesses, diagnoses, or treats medical conditions.

* * * * *

Institutional practitioner means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it

practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy or covered online telemedicine platform.

* * * * *

■ 3. Revise and republish § 1300.04 to read as follows:

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

Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in sections 102 and 309 of the Act (21 U.S.C. 802, 829).

Advanced Telemedicine Prescribing Registration means a type of *Special Registration for Telemedicine* in which the registered practitioner is authorized to prescribe Schedules II through V controlled substances through the practice of telemedicine under 21 U.S.C. 802(54)(E).

Audio-video telecommunications system means the multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and practitioner, mid-level practitioner, or pharmacist.

Clinician special registrant means a special registrant issued either the Telemedicine Prescribing Registration or the Advanced Telemedicine Prescribing Registration under 1301.11(c)(2) and (3) of this chapter, respectively.

Covered online telemedicine platform means an entity that facilitates connections between patients and clinician practitioners, via an *audio-video telecommunications system,* for the diagnosis and treatment of patients that may result in the prescription of controlled substances, but is not a hospital, clinic, local in-person medical practice, or insurance provider, and meets one or more of the following criteria:

(1) The entity explicitly promotes or advertises the prescribing of controlled substances through the platform;

(2) The entity has financial interests, whether direct incentives or otherwise, tied to the volume or types of controlled substance prescriptions issued through the platform, including but not limited to, ownership interest in pharmacies used to fill patients' prescriptions, or rebates from those pharmacies;

(3) The entity exerts control or influence on clinical decision-making processes or prescribing related to controlled substances, including, but not limited to: prescribing guidelines or protocols for clinician practitioners employed or contracted by the platform; consideration of clinician practitioner prescribing rates in the entity's hiring, retention, or compensation decisions; imposing explicit or de facto prescribing quotas; directing patients to preferred pharmacies; and/or

(4) The entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

Covered platform relationship means the formal association between a covered online telemedicine platform and a clinician practitioner it directly employs, contracts with, or is otherwise professionally affiliated with to introduce or facilitate connections between patients seeking remote medical consultations and the individual practitioner, via an audio-video telecommunications system, for the diagnosis of patients and the treatment of those patients via prescription of controlled substances.

Covering practitioner means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

(1) Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(2) Is temporarily unavailable to conduct the evaluation of the patient.

Deliver, distribute, or dispense by means of the internet refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the internet.

Filling new prescriptions for controlled substances in Schedule III, IV, or V means filling a prescription for an individual for a controlled substance in Schedule III, IV, or V, if:

(1) The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter (for purposes of this definition, such a prescription shall be referred to as the ''original prescription'');

(2) The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in paragraph (d)(1) of this section (*i.e.,* the same controlled substance as described in paragraph (d)(1)); and

(3) The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Homepage means the opening or main page or screen of the website of an online pharmacy that is viewable on the internet.

Hospice care means a set of special services that are provided to individuals who are terminally ill. The focus is on comfort, not on curing an illness. Hospice programs can be delivered in a person's home or in a hospice center.

In-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. Nothing in this paragraph shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

Internet means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

Local in-person medical practice means a medical practice where all its offices are within 100 miles of each other, and where less than 50 percent of the total prescriptions for controlled substances collectively issued by the practice's physicians and mid-level practitioners are issued via telemedicine, in any given calendar month, but is not a hospital, clinic, or insurance provider.

Online pharmacy means a person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the internet. The term includes, but is not limited to, a pharmacy that has obtained a modification of its registration pursuant to §§ 1301.13 and 1301.19 of this chapter that currently authorizes it to dispense controlled substances by means of the internet, regardless of whether the pharmacy is currently dispensing controlled substances by

means of the internet. The term does not include:

(1) Manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 of the Act (21 U.S.C. 823(a), (b), (d), or (e)) (§ 1301.13 of this chapter) who do not dispense controlled substances to an unregistered individual or entity;

(2) Nonpharmacy practitioners who are registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) and whose activities are authorized by that registration;

(3) Any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter);

(4) A health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self–Determination and Education Assistance Act;

(5) Any agent or employee of any hospital or facility referred to in paragraph (h)(3) or (h)(4) of this section, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in paragraph (h)(4) of this section, only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such paragraph;

(6) Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(7) A person, entity, or internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the internet to any person in the United States;

(8) A pharmacy registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) whose dispensing of controlled substances via the internet consists solely of:

(i) Refilling prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (k) of this section; or

(ii) Filling new prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (d) of this section;

(9)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by this chapter and otherwise in compliance with the Act.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(9)(i) of this section, it would fall outside the definition of an online pharmacy;

(10)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a long term care facility when the registration of the automated dispensing system is held by that pharmacy as described in §§ 1301.17 and 1301.27 and the pharmacy is otherwise complying with this chapter.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(10)(i) of this section, it would fall outside the definition of an online pharmacy; or

(11) A covered online telemedicine platform as defined in this section.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. *Palliative care* throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Platform practitioner means a covered online telemedicine platform that dispenses controlled substances by virtue of its central involvement as an intermediary in the remote prescribing of controlled substances by an individual practitioner. Platform practitioners are subject to the requirements imposed upon non-pharmacist practitioners under the Controlled Substances Act, 21 U.S.C. 801–904, and its regulations.

Platform special registrant means a special registrant issued the Telemedicine Platform Registration under 1301.11(c)(4) of this chapter.

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 a telecommunications system defined in 42 CFR 410.78(a)(3), which practice falls within a category listed in paragraphs (1) through (7) of this definition:

(1) *Treatment in a hospital or clinic.* The practice of telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) *Treatment in the physical presence of a practitioner.* The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) *Indian Health Service or Tribal organization.* The practice of telemedicine is being conducted by a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian Tribe or Tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act; who is acting within the scope of the employment, contract, or compact; and who is designated as an internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. 831(g)(2));

(4) *Public health emergency declared by the Secretary of Health and Human Services.* The practice of telemedicine is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. 551–559 and 701–706);

(5) *Special registration.* The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) *Department of Veterans Affairs medical emergency.* The practice of telemedicine is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. 823(f)) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. 823(f));

(C) During which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) By a practitioner that:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) *Other circumstances specified by regulation.* The practice of telemedicine is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

Refilling prescriptions for controlled substances in Schedule III, IV, or V: (1) Means the dispensing of a controlled substance in Schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter, as appropriate; and

(2) Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

Special registered location means the physical address of record for a Special Registration for Telemedicine. The special registered location shall be the same address as one of the special registrant's 1301.13(e)(1)(iv) registered locations, unless exempted by § 1301.13(k)(1) of this chapter, in which case the *special registered location* shall be the physical address provided on the special registrant's Form 224S.

Special registrant means a practitioner who has been issued a Special Registration for Telemedicine (either a Telemedicine Prescribing Registration, an Advanced Telemedicine Prescribing Registration, or a Telemedicine Platform Registration).

Special Registration for Telemedicine means a registration issued by the Administrator pursuant to section 311(h) of the Act (21 U.S.C. 831(h)) to a practitioner who seeks to engage in the practice of telemedicine pursuant to section 102(54)(E) of the Act (21 U.S.C. 802(54)(E)) and 1300.04 of this chapter, which may be used to prescribe controlled substances by means of the internet (within the meaning of section 102(51) of the Act (21 U.S.C. 802(51)) without having first conducted an in-person medical evaluation with patients to whom such prescriptions are being issued. The three types of *Special Registration for Telemedicine* are the Telemedicine Prescribing Registration, the Advanced Telemedicine Prescribing Registration, and the Telemedicine Platform Registration.

Special registration prescription means a prescription, defined under § 1300.01 of this chapter, for controlled substances issued under a practitioner's Special Registration for Telemedicine for a legitimate medical purpose in the usual course of professional practice through the utilization of an audio-video telecommunications system defined in this section. A special registration prescription is facilitated if:

(1) The prescription is issued to a patient who was introduced to the prescribing practitioner through a covered platform relationship; or

(2) A covered online telemedicine platform facilitated the telemedicine encounter that resulted in the prescription, including by providing audio-visual communication services.

State Telemedicine Registration means a limited type of 21 U.S.C. 823(g) registration authorizing an individual special registrant to prescribe special registration prescriptions to patients located within the state or a platform special registrant to dispense Schedule II–V controlled substances to patients located within the state, as required by section 311(h)(1)(B) of the Act (21 U.S.C. 831(h)(1)(B)).

Telemedicine Platform Registration means a type of Special Registration for Telemedicine in which the registered covered online telemedicine platform is authorized to dispense Schedules II through V controlled substances through the practice of telemedicine under 21 U.S.C. 802(54)(E).

Telemedicine Prescribing Registration means a type of Special Registration for Telemedicine in which the registered practitioner is authorized to prescribe Schedules III through V controlled substances through the practice of telemedicine under 21 U.S.C. 802(54)(E).

Valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by:

(1) A practitioner who has conducted at least one in-person medical evaluation of the patient; or

(2) A covering practitioner.

(3) The definition of *valid prescription* shall not be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 4. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 5. In § 1301.11, revise the section heading and add paragraphs (c) and (d) to read as follows:

§ 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy; Eligibility Requirements for Special Registration for Telemedicine; State Telemedicine Registrations.

* * * * *

(c) *Eligibility for Special Registration for Telemedicine.* Clinician practitioners and covered online telemedicine platforms are eligible for the Special Registration for Telemedicine under § 1300.04 of this chapter. Clinician practitioners are eligible for either the Telemedicine Prescribing Registration or Advanced Telemedicine Prescribing Registration, and platform practitioners are eligible for the Telemedicine Platform Registration pursuant to 21 U.S.C. 802(54)(E) and 21 U.S.C. 831(h) subject to the following:

(1) *In general.* (i) A clinician practitioner applicant or a covered online telemedicine platform applicant shall be required to hold one or more registrations under § 1301.13(e)(1)(iv) of this chapter in a state in which they are licensed, registered, or otherwise permitted to prescribe or dispense controlled substances through telemedicine. Clinician practitioners exempted from obtaining a State Telemedicine Registration for every state in which patients to whom they will issue special registration prescriptions are located under § 1301.11(d) of this chapter are exempted from this requirement.

(ii) Notwithstanding § 1301.23(a) of this chapter, all clinician practitioners must apply for and obtain a Telemedicine Prescribing Registration or Advanced Telemedicine Prescribing Registration before issuing special registration prescriptions.

(2) *Telemedicine Prescribing Registration (Schedules III–V).* If the condition required in paragraph (c)(1) of this section is satisfied, a Practitioner or Mid-Level Practitioner, as defined under § 1300.01(b) of this chapter, may have a legitimate need under 21 U.S.C. 831(h) for the Telemedicine Prescribing Registration and may apply for the registration to prescribe Schedules III–V controlled substances when they anticipate that they will be treating patients for whom requiring in-person medical evaluations could impose significant burdens on the patients to maintain a bona fide practitioner-patient relationships.

(3) *Advanced Telemedicine Prescribing Registration (Schedules II–V).* If the condition required in paragraph (c)(1) of this section is satisfied, a Practitioner or Mid-Level Practitioner may have a legitimate need under 21 U.S.C. 831(h) for the Advanced Telemedicine Prescribing Registration, and may apply for the registration to prescribe Schedules II–V controlled substances, when they anticipate that they will be treating patients for whom requiring in-person medical evaluations could impose significant burdens on the patient to maintain bona fide practitioner-patient relationships, and the practitioner or Mid-Level Practitioner is one or more of the following:

(i) The practitioner is a psychiatrist or is board certified in the treatment of psychiatric or psychological disorders;

(ii) The practitioner is a hospice care physician or is board certified in hospice care;

(iii) The practitioner is a palliative care physician or is board certified in palliative care;

(iv) The practitioner renders treatment at one or more long term care facilities;

(v) The practitioner is a pediatrician or is board certified in pediatric care; and/or

(vi) The practitioner is a neurologist or is board certified in the treatment of neurological disorders unrelated to the treatment and management of pain.

(4) *Telemedicine Platform Registration (Schedules II–V).* A covered online telemedicine platform, as defined under § 1300.04 of this chapter, may have a legitimate need under 21 U.S.C. 831(h) for the Telemedicine Platform Registration, and shall apply for the registration to dispense Schedules II–V controlled substances, when the covered online telemedicine platform:

(i) Anticipates being compensated for introducing or facilitating connections between patients seeking remote medical consultations and practitioners, via an audio-video telecommunications system, for the diagnosis of patients and the treatment of those patients via prescription of controlled substances;

(ii) Is compliant with federal and state regulations;

(iii) Provides oversight over *clinician practitioners'* prescribing practices; and

(iv) Takes measures to prioritize patient safety and prevent diversion, abuse, or misuse of controlled substances.

(d) *State Telemedicine Registrations.* Practitioners issued any of the three types of Special Registration for Telemedicine shall obtain a State Telemedicine Registration defined under § 1300.04 of this chapter, for every state in which patients to whom special registration prescriptions will be issued are located. As a limited type of 21 U.S.C. 823(g) registration, the Administrator shall issue the State Telemedicine Registration when it is consistent with the public interest pursuant 21 U.S.C. 823(g)(1). The following clinician practitioners are exempted from obtaining a State Telemedicine Registration for every state:

(1) Officials of the U.S. Army, Navy, Marine Corps, Air Force, Space Force, Coast Guard, Public Health Service, or Bureau of Prisons who are authorized to prescribe via telemedicine in the course of their official duties;

(2) Veterans Health Administration (VHA) covered health care professionals under 38 U.S.C. 1730C(b), acting within the scope of their employment who are utilizing the registration of a hospital or clinic operated by the VHA registered under 21 U.S.C. 823(g) after having obtained the approval of the Secretary of the Veterans Affairs (VA) to utilize the 823(g) registration of a VHA-operated hospital or clinic; and

(3) Health care professionals acting within the scope of their contract with VHA and who have access to, and chart patient records within, the VHA's electronic health records, are subject to all policies of the VHA, and are utilizing the registration of a hospital or clinic operated by the VHA registered under 21 U.S.C. 823(g) after having obtained the approval of the Secretary of the Veterans Affairs (VA) to utilize the 823(g) registration of a VA-operated hospital or clinic; and

(4) Any practitioner otherwise exempted from registration under 21 U.S.C. 822(d).

■ 6. In § 1301.13, add paragraphs (e)(1)(xi), (xii), (xiii), (xiv), and (xv), (k), (l) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1)

Business activity	Controlled substances	DEA application forms	Application fees ($)	Registration period (years)	Coincident activities allowed
*	* *	*	*	*	*
(xi) Telemedicine Prescribing (Special Registration).	Schedules III–V	New—224S Renewal—224S Modification—224S(M).	888	3	
(xii) Advanced Telemedicine Prescribing (Special Registration).	Schedules II–V	New—224S Renewal—224S Modification—224S(M).	888	3	
(xiii) Telemedicine Platform (Special Registration).	Schedules II–V	New—224S Renewal—224S Modification—224S(M).	888	3	
(xiv) State Telemedicine for Individual Special Registrants (Ancillary Registration to a Special Registration).	(Determined by the Special Registration held).	New—224S Renewal—224S Modification—224S(M).	50	3	
(xv) State Telemedicine for Platform Special Registrants (Ancillary Registration to a Special Registration).	(Determined by the Special Registration held).	New—224S Renewal—224S Modification—224S(M).	888	3	

* * * * *

(k) *Special Registration application (Form 224S) requirements.* Form 224S will require the following:

(1) *Special registered location.* Special Registration applicants shall designate one of their existing registered locations under paragraph (e)(1)(iv) of this section as the registered location/physical address of their Special Registration. Special Registration applicants that would be exempted under § 1301.11(d) are exempted from this requirement however, such exempted persons shall be required to provide another physical address.

(2) *Required disclosures and attestations.* Special Registration applicants shall provide the following specific disclosures and attestations on the Form 224S:

(i) If the applicant is a platform practitioner applying for the Telemedicine Platform Registration, it shall disclose all employment, contractual relationships, or professional affiliations with any clinician special registrant and Online Pharmacy and their respective registration numbers.

(ii) If the applicant is a clinician practitioner applying for the Telemedicine Prescribing Registration or the Advanced Telemedicine Prescribing Registration, the applicant shall disclose all employment, contractual relationships, or professional affiliations, including with any covered online telemedicine platform and the respective covered online telemedicine platform's Telemedicine Platform Special Registration number, if applicable; and the applicant's practice specialties (*e.g.,* hospice care or palliative care);

(iii) The applicant for a Special Registration for Telemedicine, whether a clinician practitioner or a covered online telemedicine platform, shall attest that they have devised and are committed to maintaining anti-diversion policies and procedures;

(iv) The applicant for an Advanced Telemedicine Prescribing Registration shall disclose their practice specialties; and

(v) The applicant for any type of Special Registration for Telemedicine shall attest that they have a legitimate need for a Special Registration for Telemedicine and to the facts and circumstances that form the basis for their legitimate need.

(3) *State Telemedicine Registration-exempted practitioner disclosures.* Practitioners exempted from State Telemedicine Registration under § 1301.11(d) are required to identify all the states in which patients will be located when being treated via telemedicine on the practitioners' registration applications for the Telemedicine Prescribing Registration, the Advanced Telemedicine Prescribing Registration, and the Telemedicine Platform Registration.

(l) *Notification of application changes; Modifications (Form 224S–M).* The special registrant shall use Form 224S–M for the following purposes:

(1) To promptly notify DEA of any changes to the information provided on their Special Registration Application (Form 224S) within 14 business days on the Form 224S–M (*e.g.,* the special registrant becomes employed by, contracts with, or otherwise professionally affiliated with a new entity); and

(2) To make any modifications to their Special Registration (*e.g.,* applying for additional State Telemedicine Registrations to practice telemedicine in additional states).

■ 7. In § 1301.35, revise paragraph (a) and add paragraph (d) to read as follows:

§ 1301.35 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant under the applicable provisions of sections 102(54)(E) or 311(h) of the Act (21 U.S.C. 802(54)(E) and 831(h)) when:

(1) The applicant for the Special Registration for Telemedicine meets the eligibility requirements outlined in § 1301.11(c) of this subpart; and

(2) The Administrator has determined that the Special Registration is consistent with the public interest pursuant to the factors stipulated in 21 U.S.C. 823(g)(1).

* * * * *

(d) The Certificate of Registration (DEA Form 223) issued for a Special Registration shall contain the following information: name; Special Registered Location; Special Registration for Telemedicine (either a Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration, or Telemedicine Platform Registration), and State Telemedicine Registration(s);

the activity authorized by the Special Registration, the Schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle; the amount of fee paid (or exemption) for each registration, and the expiration date of each registration. The special registrant shall maintain the Certificate of Registration at the Special Registered Location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

■ 8. In § 1301.36:

■ a. Redesignate paragraphs (c) through (i) as paragraphs (d) through (j), respectively; and

■ b. Add paragraphs (c) and (k).

The additions read as follows:

§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

* * * * *

(c) For any registration issued under sections 102(54)(E) or 311(h) of the Act (21 U.S.C. 802(54)(E) and 831(h)), the Administrator may:

(1) Suspend the registration under the grounds stipulated in section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time; and

(2) Revoke the registration under the grounds stipulated in section 304(a) of the Act (21 U.S.C. 824(a)).

* * * * *

(k) The suspension or revocation of any registration issued under 21 U.S.C. 823(g) shall result in the automatic suspension or revocation of all registrations issued under 21 U.S.C. 831(h), including all Special Registrations for Telemedicine and State Telemedicine Registrations.

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, 831, 871(b), 958(e)–(g), and 965, unless otherwise noted.

■ 10. In § 1304.04, add paragraphs (i), (j), (k), and (l) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(i) For patient verification photographic records, an individual special registrant, with a Special Registration for Telemedicine pursuant to 1301.11(c)(2) or (3) of this chapter, or a delegated employee or contractor under the direct supervision of the individual special registrant, shall verify the identity of patients prior to issuing a special registration prescription via an audio-video telecommunications system, as defined under § 1300.04 of this chapter. At the first telemedicine encounter, the individual special registrant, or a delegated employee or contractor under the direct supervision of the individual special registrant, shall confirm the identity of the patient, and capture a photographic record of the patient presenting their federal or state-issued photo identification card or other acceptable documents as described in paragraph (i)(1) of this section; or verify, accept and maintain a copy of the patient's federal or state government-issued photo identification card or a document described in paragraph (i)(1) of this section provided by the patient. The photographic record shall be maintained by the individual special registrant and renewed a minimum of every two (2) years. After the first telemedicine encounter, the individual special registrant, or the individual special registrant's delegee, shall confirm the patient's identity against the initial or renewed photographic record at every telemedicine encounter that results in a special telemedicine prescription.

(1) If the individual special registrant or a delegated employee or contractor under the direct supervision of the individual special registrant reasonably determines that a patient lacks a federal or state-issued photo identification card, the individual special registrant or their delegee must verify the identity of the patients in the manner described in this paragraph (i) using other forms of documentation to verify the identity of the patient, and maintain a photographic record of what documents were used to verify the patient's identity.

(2) The photographic records must be securely stored within the patient's medical record or chart, separate from the special registration prescription data reported to DEA under § 1304.60 of this subpart to ensure that patient privacy is protected.

(j) For the purpose of maintaining special registration telemedicine encounter record, every telemedicine encounter that results in a special registration prescription, the prescribing individual special registrant shall maintain a record of the date and time of the telemedicine encounter, the address of the patient during the telemedicine encounter, and the home address of the patient. The individual special registrant must maintain the special registration telemedicine encounter record for a minimum of two (2) years from the date of the telemedicine encounter.

(k) For credential verification and conduct-related records, a platform special registrant, with a Special Registration for Telemedicine pursuant to 1301.11(c)(4) of this chapter, shall maintain the following records related to individual special registrants with whom they enter and maintain a covered platform relationship:

(1) Verification of the individual practitioner's credentials, including but not limited to records on education, training, board or specialty certifications;

(2) The employment contract and any other contract between the platform practitioner and the individual practitioner; and

(3) Any disciplinary actions or sanctions, or documentation of complaints, disputes, or incidents involving the practice of telemedicine engaged in by the individual practitioner. The platform practitioner must maintain and update the credential verification and conduct-related records for a minimum of two (2) years.

(l) For the purpose of maintaining centralized recordkeeping at the special registered location, a special registrant, with a Special Registration for Telemedicine pursuant to 1301.11(c)(2)–(4) shall maintain all records arising from telemedicine encounters at the special registrant's Special Registered Location.

■ 10. Add § 1304.60 under the undesignated center heading ''Prescription Reporting'' to read as follows:

§ 1304.60 Pharmacy reporting of special registration prescription data.

(a) A pharmacy shall, within seven (7) days of the start of every month, report aggregate data for the special registration prescriptions filled during the preceding month for each Schedule II controlled substance and each Schedule III–V controlled substance identified in paragraph (b). For each of these controlled substances, the pharmacy shall provide the following information, organized by the different State Telemedicine Registration numbers of the individual special registrants who prescribed the controlled substance, and organized by the National Drug Code (NDC) for each formulation of the controlled substance dispensed: the number of prescriptions filled, the volume of the controlled substance dispensed, and the number of

patients prescribed the controlled substance. If the individual special registrant is exempted from State Telemedicine Registration under § 1301.11(d) of this chapter, the pharmacy shall instead provide the Special Registration number for either the Telemedicine Prescribing Registration or Advanced Telemedicine Prescribing Registration of the individual special registrant in lieu of a State Telemedicine Registration number. The pharmacy shall electronically report this data through DEA Office of Diversion Control's secure network application.

(b) The Schedule III–V controlled substances subject to the reporting requirement in paragraph (a) of this section are:

(1) Ketamine, its salts, isomers, and salts of isomers (DEA Controlled Substances Code Number (CSCN) 7285);

(2) 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol) (CSCN 9752); and

(3) The following depressants as described in 1308.14(c) of this chapter, and their salts, isomers, and salt of isomers: Alprazolam (CSCN 2882); Bromazepam (CSCN 2748); Camazepam (CSCN 2749; Chlordiazepxide (CSCN 2744); Clobazam (CSCN 2751); Clonazepam (CSCN 2737); Clorazepate (CSCN 2768); Clotiazepam (CSCN 2752); Cloxazolam (CSCN 2753); Delorazepam (CSCN 2754); Diazepam (CSCN 2765); Estazolam (CSCN 2756); Ethyl loflazepate (CSCN 2758); Fludiazepam (CSCN 2759); Flunitrazepam (CSCN 2763); Flurazepam (CSCN 2767); Halazepam (CSCN 2762); Haloxazolam (CSCN 2771); Ketazolam (CSCN 2772); Loprazolam (CSCN 2773); Lorazepam (CSCN 2885); Lormetazepam (CSCN 2774); Medazepam (CSCN 2836); Midazolam (CSCN 2884); Nimetazepam (CSCN 2837); Nitrazepam (CSCN 2834); Nordiazepam (CSCN 2838); Oxazepam (CSCN 2835); Oxazolam (CSCN 2839); Pinazepam (CSCN 2883); Prazepam (CSCN 2764); Quazepam (CSCN 2881); Remimazolam (CSCN 2846); Temazepam (CSCN 2925); Tetrazepam (CSCN 2886); and Triazolam (CSCN 2887).

■ 12. Add § 1304.61 to read as follows:

§ 1304.61 Special registrant reporting of special registration prescription data.

A special registrant, either an individual special registrant or a platform special registrant, shall report to DEA on an annual basis within the seven (7) days of the start of every year the following information for the preceding year: the total number of new patients in each state where at least one special registration prescription for a Schedule II controlled substance, or a Schedule III–V controlled substance identified in § 1304.60(b) has been issued; the total number of special registration prescriptions for Schedule II controlled substances issued by the special registrant, in aggregate and across all states; and the total number of special registration prescriptions for Schedule III–V controlled substances identified in § 1304.60(b) issued by the special registrant, in aggregate and across all states. The individual special registrant shall electronically report this data through DEA Office of Diversion Control's secure network application.

PART 1306—PRESCRIPTIONS AND DISPENSING

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

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

■ 15. Add an undesignated center heading ''Special Registration Prescriptions Prescribed by Individual Special Registrants'' and §§ 1306.41 through 1306.47 to read as follows:

Special Registration Prescriptions Prescribed by Individual Special Registrants

§ 1306.41 Prescription origination within the United States.

The individual special registrant shall be physically located within the United States when conducting a telemedicine encounter and issuing a special registration prescription; and have any necessary licensure and authorization within the U.S. state or territory where the practitioner is located when the telemedicine encounter takes place. For the purposes of this chapter, the United States shall mean the 50 states of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, America Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

§ 1306.42 Electronic Prescribing for Controlled Substances (EPCS) of Special Registration Prescriptions.

The individual special registrant shall issue special registration prescriptions for controlled substances through Electronic Prescribing for Controlled Substances (EPCS).

§ 1306.43 Nationwide Prescription Drug Monitoring Program (PDMP) Check

(a) Effective immediately, on [EFFECTIVE DATE OF FINAL RULE], prior to issuing a special registration prescription for controlled substances, including Schedules II through V controlled substances, the individual special registrant shall perform a check of the state Prescription Drug Monitoring Program(s) (PDMPS) in:

(1) The state or territory where the patient is located;

(2) The state or territory where the individual special registrant is located; and

(3) Any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the individual special registrant is located, 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, prior to issuing a special registration prescription for controlled substances.

(b) Effective three (3) years from [EFFECTIVE DATE OF FINAL RULE], the individual special registrant shall perform a comprehensive nationwide check of all 50 state Prescription Drug Monitoring Programs (PDMPs) and PDMPs in any U.S. district and territory that maintains its own PDMP 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, prior to issuing a special registration prescription for controlled substances. If there is no means to perform this comprehensive nationwide check three (3) years from [the date of the promulgation of the final rule], then the individual special registrant shall continue to perform the PDMPs checks as described in paragraph (a) if this section, and special registration prescriptions for Schedule II controlled substances shall only be issued to patients located within the same state as the individual special registrant, *i.e.,* where there is an intra-state practitioner-patient relationship.

§ 1306.44 Required Use of Audio-Video Telecommunication System

(a) Every special registration prescription, as defined in § 1300.04 of this chapter, shall be issued through the use of an audio-video telecommunication system defined in § 1300.04 of this chapter.

(b) Notwithstanding paragraph (a) of this section and § 1300.04 of this chapter, special registrants may issue special registration prescriptions for

Schedule III–V narcotic controlled substances approved by the Food and Drug Administration for the treatment of Opioid Use Disorder through the use of an audio-only telecommunications system as described in 42 CFR 410.78(a)(3), provided that the treatment was initiated through the use of an audio-video telecommunications system as defined in § 1300.04 of this chapter, the practitioner has conducted at least one medical evaluation of the patient through the use of an audio-video telecommunication system defined in § 1300.04 of this chapter, and the prescription is being issued for the treatment of Opioid Use Disorder.

§ 1306.45 Requirements for Issuing a Special Registration Prescription for Schedule II Controlled Substances

(a) A special registration prescription may not be issued for a controlled substance listed in Schedule II unless the individual special registrant has an Advanced Telemedicine Prescribing Registration and the individual special registrant is: a psychiatrist or board certified in the treatment of psychiatric and psychological disorders, and issuing the prescription for the treatment of mental health; a hospice care physician or board certified in hospice care, and issuing the prescription for hospice care; a palliative care physician or board certified in palliative care, and issuing the prescription for palliative care; a physician rendering treatment to a patient who resides and is present in a long term care facility at the time the prescription is issued; a pediatrician or board certified in pediatric care, and is issuing the prescription to a patient under the age of 18 while the parent or guardian of the patient is present in the room with the patient at the time the prescription is issued; or a neurologist or board certified in the treatment of neurological disorders unrelated to the treatment and management of pain

(b) A special registration prescription may not be issued for a controlled substance listed in Schedule II unless the individual special registrant is physically located in the same state in which the patient was located at the time of the telemedicine encounter that resulted in the issuance of the prescription when issuing the prescription for the Schedule II controlled substance.

(c) The number of special registration prescriptions issued by the individual special registrant in a calendar month for Schedule II controlled substances shall constitute less than 50 percent of the total number of Schedule II prescriptions issued in that calendar month by the individual special registrant in their telemedicine and non-telemedicine practice. The average number of special registration prescriptions shall be calculated from the first day of the month through the last day of the month.

§ 1306.46 State Laws Applicable to Special Registration Prescriptions

When issuing a special registration prescription, a special registrant must comply with the laws and regulations of:

(a) The state in which the special registrant is located during the telemedicine encounter resulting in the special registration prescription;

(b) The state in which the patient is located during the telemedicine encounter resulting in the special registration prescription; and

(c) Any state or states in which the special registrant maintains a DEA registration to dispense controlled substances or a medical license, to the extent that the law or regulation applies to telemedicine encounters between practitioners and patients located in the states described in paragraphs (a) and (b) of this section.

§ 1306.47 Additional Elements on a Special Registration Prescription

(a) A special registration prescription shall contain: the individual special registrant's Special Registration for Telemedicine number and State Telemedicine Registration number, unless exempted from State Telemedicine Registration under § 1301.11(d) of this chapter; and, if the prescription is facilitated by a platform registrant, the covered online telemedicine platform's Special Registration for Telemedicine number and State Telemedicine Registration number. If exempted from State Telemedicine Registration, the special registrant shall notate on the prescription the state in which the patient was located at the time of the telemedicine encounter that resulted in the issuance of the prescription.

(b) A special registration prescription shall contain all the information required on a prescription under § 1306.05(a) of this chapter, with the exception that the number associated with a registration under 1301.13(e)(1)(iv) of this chapter shall not be required.

(c) A corresponding liability rests upon the pharmacist who fills a special registration prescription that is not prepared in the form required by this regulation.

Signing Authority

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

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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