Services amends 42 CFR part 12 as follows:

PART 12—TELEMEDICINE FLEXIBILITIES

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

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

■ 5. Add subpart B to read as follows:

Subpart B—Telemedicine Prescribing

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

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

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

(1) *Prescription drug monitoring program review.* The prescribing practitioner must be authorized to access the applicable prescription drug monitoring program (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter. The prescribing practitioner shall review such data regarding any controlled medication prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The prescribing practitioner shall ensure the date and time of such a review is annotated in the patient's electronic health record (EHR) or paper record. This review, or attempted review, must be conducted prior to issuing a prescription in a manner authorized under this section.

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

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

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

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

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

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

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

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

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

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

[FR Doc. 2025–01049 Filed 1–15–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–407VA]

RIN 1117–AB40; 1117–AB88

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Continuity of Care via Telemedicine for Veterans Affairs Patients

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

ACTION: Final rule.

SUMMARY: This final rule authorizes Department of Veterans Affairs (VA) practitioners acting within the scope of their VA employment to prescribe controlled substances via telemedicine to a VA patient with whom they have not conducted an in-person medical evaluation. VA practitioners are permitted to prescribe controlled substances to VA patients if another VA practitioner has, at any time, previously conducted an in-person medical evaluation of the VA patient, subject to certain conditions.

DATES: This final rule is effective February 18, 2025.

FOR FURTHER INFORMATION CONTACT: Heather Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION: This rule is a final rule that finalizes portions of the proposed rule titled *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient have Not Had a Prior In-Person Medical Evaluation,* specifically those proposed regulations affecting VA practitioners prescribing controlled substances.[1] Under this final rule, a VA practitioner who is acting within their scope of employment with the VA may prescribe controlled substances while engaged in the practice of telemedicine with a VA patient with whom they have not conducted an in-person medical evaluation, if another VA practitioner has previously conducted an in-person medical evaluation with the VA patient. Additionally, prior to issuing a prescription via telemedicine for a

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

schedule II–V controlled substance, the prescribing practitioner must review both the patient's VA electronic health record (EHR) (to include the internal prescription database) and the prescription drug monitoring program (PDMP) data for the state in which the VA patient is located at the time of the telemedicine encounter (if the state has such a program) for prescriptions of controlled substances issued to the VA patient. Should either the VA EHR (to include the VA internal prescription database) or the state PDMP (if the state has a PDMP program) be unavailable or non-operational, the practitioner must limit the prescription to a 7-day supply and must later review both the VA patient's VA EHR (to include the internal prescription database) and the PDMP data for the state in which the patient is located at the time of the telemedicine encounter for prescriptions of controlled substances issued to the patient before continuing to prescribe controlled substances to the patient via telemedicine. If no PDMP program exists for the state in which the VA patient is located at the time of the telemedicine encounter the practitioner must review the VA EHR, to include the VA internal prescription database, prior to issuing a prescription for controlled substances for more than a 7-day supply. For reasons discussed more fully below, this final rule does not apply to contracted practitioners located outside a VA facility or clinic providing care via the community care network (CCN) or conducting disability compensation evaluations.

I. Legal Authority and Background

In March 2023, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPRM) titled *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* (the General Telemedicine NPRM).[2] DEA is now partially finalizing the rule, specifically the sections of that proposed rule that pertain to Department of Veterans Affairs (VA) practitioners.[3] DEA has modified the proposed provisions to address concerns brought forth by commenters that are specific to VA practitioners prescribing controlled substances through the practice of telemedicine under the statutory authority of 21 U.S.C. 802(54)(G). This final rule pertains only to VA practitioners prescribing controlled substances to VA patients in circumstances where the prescribing VA practitioner has not conducted an in-person medical evaluation of the VA patient prior to the issuance of the prescription.[4]

This final rule falls under the last category of the ''practice of telemedicine'' as defined in the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (Ryan Haight Act),[5] which authorizes the prescribing of controlled substances in specified circumstances where the prescribing practitioner has not conducted an in-person medical evaluation of the patient. The Administrator of the DEA (pursuant to delegation by the Attorney General)[6] and the Secretary of Health and Human Services (HHS) jointly issue this regulation and have both determined that this regulation is consistent with effective controls against diversion and with the public health and safety, as required under 21 U.S.C. 802(54)(G).

DEA implements and enforces the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 through 1399. 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, distributing, 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.[7] The CSA further authorizes the Attorney General (and the Administrator of DEA by delegation through 28 CFR part 0) to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA.[8]

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 Cosmetic Act may be . . . dispensed by means of the internet without a valid prescription,''[9] and which defines ''valid prescription'' in part 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 . . .''[10]

However, pursuant to 21 U.S.C. 829(e)(3)(A), there is an exception to this in-person medical evaluation requirement where the practitioner is ''engaged in the practice of telemedicine.''[11] 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)[12] who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42,'' and which also falls within

[2] 88 FR 12875 (Mar. 1, 2023).

[3] A ''VA practitioner'' refers to an individual authorized to prescribe, dispense, or administer controlled substances within the Department of Veterans Affairs, consistent with the definition of ''practitioner'' in 21 U.S.C. 802(21). This includes any licensed individual permitted by the VA to perform professional medical duties within the scope of VA healthcare practices.

[4] Pursuant to 21 CFR 1300.04(f), the term ''in-person-medical evaluation'' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner.

[5] Public Law 110–425, 122 Stat. 4820 (2008).

[6] The Attorney General has delegated this authority to the Administrator of DEA under 28 CFR 0.100(b).

[7] The term ''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).

[8] 21 U.S.C. 871(b), 958(f).

[9] 21 U.S.C. 829(e)(1).

[10] *Id.* 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 of a covering practitioner 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 DEA-registered 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.*

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

[12] This definition of telemedicine does not exclude a pharmacist functioning as a mid-level practitioner authorized to prescribe controlled substances.

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.[13]

As a general matter, those seven distinct categories include telemedicine encounters where: (1) patients are physically located at DEA-registered hospital or clinic, and the remote prescribing practitioner is DEA-registered in the state in which the patient is located at the time of the telemedicine encounter; (2) patients are being treated by a practitioner, and in the physical presence of a DEA-registered practitioner in the state in which the patient is located; (3) the practitioner is an employee or contractor of the Indian Health Service, acting within the scope of the practitioner's employment, who has been designated an *Internet Eligible Controlled Substances Provider* by HHS; (4) they take place during a public health emergency declared by HHS; (5) the practitioner has obtained a *Special Registration* with DEA; [14] (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.[15]

The seven distinct categories provided under the statutory definition of the practice of telemedicine involve circumstances in which the 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. 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.

As noted above, when a practitioner engages in the practice of telemedicine, the practitioner must use ''a telecommunications system referred to in section 1395m(m) of Title 42.'' The Centers for Medicare and Medicaid Services has defined telehealth for the Medicare program, in part, as ''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.'' [16]

COVID–19 Public Health Emergency

In response to the COVID–19 public health emergency (PHE), as declared by the Secretary of HHS on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), DEA granted temporary exceptions (listed below) to the Ryan Haight Act. To prevent lapses in care, these exceptions authorized the prescribing of controlled substances via telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient prior to prescribing. These telemedicine flexibilities authorized DEA-registered practitioners to prescribe schedule II–V controlled substances via audio-video telemedicine encounters, including schedule III–V narcotic controlled substances approved by FDA for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, provided that such controlled substance prescriptions otherwise comply with the requirements outlined in DEA guidance documents, 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; [17] and
- A March 31, 2020 ''Dear Registrant'' letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division.[18]

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), published 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) [19] and *Expansion of Induction of Buprenorphine via Telemedicine Encounter* (the Buprenorphine NPRM).[20] These NPRMs proposed to expand patient access to prescriptions for controlled substances via telemedicine encounters relative to the pre-COVID–19 PHE landscape. The intent 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 General Telemedicine NPRM proposed specific requirements for telemedicine prescribing of controlled substances by both VA and non-VA practitioners, addressing both the types of drugs permitted and the procedural safeguards necessary for prescribing via telemedicine without an in-person medical evaluation. For practitioners, the General Telemedicine NPRM proposed permitting prescribing schedule III–V non-narcotic controlled substances via telemedicine for up to a 30-day supply prior to conducting an in-person medical evaluation. However, for schedule II substances or narcotics, or any controlled substance prescription exceeding a 30-day supply, the General Telemedicine NPRM proposed that a ''qualifying telemedicine referral'' is necessary. As proposed in the General Telemedicine NPRM, the qualifying

[13] 21 U.S.C. 802(54).

[14] 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, 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.

[15] 21 U.S.C. 802(54).

[16] 42 CFR 410.78(a)(3).

[17] 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.*

[18] 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.*

[19] 88 FR 12875 (Mar. 1, 2023).

[20] 88 FR 12890 (Mar. 1, 2023).

referral would involve a physical evaluation conducted by another DEA-registered practitioner, who would then formally refer the patient to the prescribing practitioner. Additionally, practitioners would be required to conduct a review of the PDMP for the state where the patient is located at the time of the telemedicine encounter to monitor recent controlled substance prescriptions, as a safeguard against potential misuse. The General Telemedicine NPRM proposed that in instances where the PDMP is temporarily unavailable, the prescribing practitioner would be authorized to prescribe up to a 7-day supply until the prescribing practitioner is able to review the PDMP.

The General Telemedicine NPRM also proposed to mandate detailed recordkeeping, whereby the telemedicine practitioner would be required to thoroughly document each controlled substance prescribed via telemedicine, including the date, patient details, medication specifics, and locations of both the practitioner and the patient during the encounter. Moreover, each prescription issued via a telemedicine encounter would be required to bear a notation on its face indicating it was issued via a telemedicine encounter. These extra safeguards were intended to provide an additional layer of transparency for DEA audits and investigations.

The General Telemedicine NPRM proposed certain provisions for VA practitioners prescribing controlled substances via telemedicine. Specifically, VA practitioners prescribing controlled substances during telemedicine encounters with VA patients utilizing the VA healthcare system would be exempt from the 30-day supply limitation, allowing VA practitioners to prescribe controlled substances, including schedule II drugs, without a qualifying referral. This proposed exemption recognized the VA's integrated healthcare system, and the reliable, centralized patient data systems bridging all VA facilities, which ensures a continuity of patient care provided within its healthcare system. To mitigate risks related to diversion or misuse, the General Telemedicine NPRM proposed to require VA practitioners to consult not only the PDMP for the state the VA patient is located during the telemedicine encounter, but also the VA's internal prescription database, ensuring a comprehensive review of the VA patient's controlled substance prescription history.

These distinctions underscore DEA's intention in the General Telemedicine NPRM to balance access to care via telemedicine with the necessary safeguards against diversion or misuse of controlled substances. Specifically, the General Telemedicine NPRM emphasized the continuity and security of care for VA patients receiving healthcare services through the VA system. By structuring the requirements differently for VA and non-VA practitioners, the General Telemedicine NPRM sought to leverage the VA's established telemedicine infrastructure and patient monitoring capabilities to enhance safety without imposing excessive restrictions on the VA's healthcare delivery model. Unlike other healthcare providers, VA operates under Federal law and is a nationally integrated, closed healthcare system with rigorous internal policies and controls that ensure patient safety, continuity of care, and thorough monitoring of prescriptions. VA practitioners have access to shared information systems that enable continuity of care and veterans' data sharing across VA facilities. This includes access to VA's internal prescription database, allowing VA practitioners to monitor and manage controlled substance prescriptions. This infrastructure ensures the safety of telemedicine prescribing without necessitating an additional registration layer, as VA practitioners operate within a highly regulated and cohesive system tailored specifically to veterans' needs.

The comment period for the General Telemedicine NPRM and Buprenorphine NPRM closed on March 31, 2023. The General Telemedicine NPRM generated a total of 35,454 comments.

On May 10, 2023, DEA jointly with HHS (with the Substance Abuse and Mental Health Services Administration (SAMHSA) acting on behalf of HHS) issued a Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications (First Temporary Rule) pursuant to 21 U.S.C. 802(54)(G), which extended through November 11, 2023, the full set of telemedicine flexibilities regarding the prescribing of controlled substances, as had been in place under the COVID–19 PHE.[21] 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 live, in-person Telemedicine Listening Sessions to receive additional public input concerning the practice of telemedicine with regard 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 prescribing of certain controlled substances via telemedicine 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, 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 General Telemedicine and Buprenorphine NPRMs and the presentations at the Telemedicine Listening Sessions, DEA, jointly with HHS, issued the Second Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications (Second Temporary Rule), also pursuant to 21 U.S.C. 802(54)(G), thereby extending through December 31, 2024, the full set of telemedicine flexibilities regarding prescription of controlled substances as were in place during the COVID–19 PHE.[22] 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 DEA-registered practitioner had 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 the 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 DEA-registered

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

[22] 88 FR 30037 (May 10, 2023).

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.

On November 19, 2024, DEA and HHS issued a Third Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications (Third Temporary Rule) to again extend the temporary exceptions originally authorized under the COVID–19 PHE, through December 31, 2025. This extension allows telemedicine flexibilities for all practitioners, extending patient access to care until broader telemedicine rulemaking is complete. Additionally, these temporary exemptions, now extended through December 31, 2025, ensure that practitioners can continue to prescribe controlled substances without an in-person medical evaluation, maintaining continuity of care while DEA works to establish tailored regulations for both VA and non-VA practitioners. DEA's NPRM titled *Special Registrations for Telemedicine and Limited State Telemedicine Registrations* (RIN 1117–AB40) (Special Registrations NPRM), published elsewhere in this issue of the **Federal Register**, focuses on non-VA practitioners and allows for further opportunity for public comment and development of a framework suited to the diverse operational environments outside the VA's integrated healthcare system.

DEA is specifically tailoring this final rule to practitioners within the VA healthcare system to accommodate VA's unique healthcare infrastructure while safeguarding effective prescribing of controlled substances via telemedicine. This final rule is distinct from the broader Special Registrations NPRM to acknowledge the VA's unique structure and patient population, particularly VA patients in rural or underserved areas who benefit significantly from telemedicine services. This final rule reflects the VA's robust internal controls and centralized framework, which ensure continuity and quality of care across VA facilities and practitioners.

After careful consideration of the public comments and discussions with the VA, DEA and HHS have decided to promulgate this final rule only with respect to VA practitioners. Specifically, DEA and HHS have decided to extend telemedicine prescribing authority to VA practitioners to accommodate VA's unique healthcare infrastructure while safeguarding effective prescribing of controlled substances via telemedicine. Unlike non-VA practitioners, who operate in a variety of healthcare systems with diverse, non-integrated records management structures, VA practitioners are governed by a unified, closed-loop healthcare system, which offers comprehensive patient oversight, centralized health information and a dedicated internal prescription database, facilitating safe and effective telemedicine practices specific to VA patients and veterans' healthcare needs. Thus, DEA and HHS believe that promulgating this final rule would maintain critical patient access to necessary medications without creating an unreasonable risk of diversion. Although DEA and HHS are not extending this authority to non-VA practitioners at this time, DEA is committed to working with HHS to periodically evaluate whether extending telemedicine prescribing authority to non-VA practitioners under 21 U.S.C. 802(54)(G) would be appropriate in the future.

Additionally, DEA notes that the Special Registrations NPRM, proposes to create a special registration for telemedicine which would authorize telemedicine prescribing authority for non-VA practitioners. DEA encourages the public to review and comment on that proposed rule.

II. Need for Rulemaking Specific to the Department of Veteran Affairs

As a result of discussions held between DEA, HHS, and the VA, as well as the comments received in response to the General Telemedicine NPRM, DEA and HHS have determined that the best course of action to ensure continued access to care for patients receiving care from VA healthcare, while maintaining sufficient safeguards to detect and protect against the diversion of controlled substances, is to promulgate regulatory changes that enable a VA practitioner to prescribe controlled substances, via telemedicine, to a VA patient who has previously had an in-person medical evaluation with a different VA practitioner. The proposed expansion of authorized internet prescribing for VA practitioners responds directly to the evolving landscape of the healthcare needs of VA patients, advancements in telemedicine, and DEA's capacity to implement safeguards that protect against potential misuse. The need for comprehensive, accessible medical care for VA patients has been a consistent priority; however, recent factors underscore the necessity for regulatory updates. Notably, the COVID–19 pandemic accelerated the adoption and acceptance of telemedicine, demonstrating its effectiveness in maintaining continuity of care without in-person interactions, particularly for vulnerable populations as discussed below.[23] This shift has underscored the need for accessible controlled-substance prescribing via telemedicine, enabling VA practitioners to respond swiftly and safely to VA patients' healthcare needs. VA now has improved tools and data systems, including enhanced monitoring of telemedicine practices and centralized systems like the VA's internal prescription monitoring database, allowing for more effective oversight than what was available in the past.[24] These advances support a framework that meets current clinical and oversight needs.

Further, alternative telemedicine provisions, such as those outlined in 21 U.S.C. 802(54)(A)–(B), (F), are insufficient to address the unique policy goals of this rulemaking. For instance, the requirement for an in-person medical evaluation to establish a prescribing relationship fails to accommodate VA patients with limited mobility, access issues, or chronic health conditions that make travel difficult. While theoretically possible for some VA patients to attend an in-person medical evaluation with every provider, practical barriers mean that an in-person medical evaluation is often not feasible or results in delayed access to needed medications. VA's centralized healthcare model offers a unique opportunity to manage these challenges responsibly, with systems that allow for comprehensive patient oversight across facilities, secure data sharing, and a controlled, consistent telemedicine infrastructure. The rule thus leverages the VA's specific capabilities to meet VA patients' needs without over-relying on a one-size-fits-all approach to telemedicine, creating tailored, effective access to care for VA patients while maintaining appropriate oversight that ensures the continued protection of patient health through the mitigation of diversion and prevention of overprescribing.

This approach is based on several considerations:

A. Specialized Needs of Veterans

Upon separation from the military, many veterans face physical, mental,

[23] Aday, L.A. (2002). At Risk in America: The Health and Health Care Needs of Vulnerable Populations in the United States, 2 (13).

[24] Frequently Asked Questions—VA EHR Modernization. *https://digital.va.gov/ehr-modernization/frequently-asked-question/#:~:text=VA%27s%20Electronic%20Health%20Record%20Modernization%20(EHRM)%20program%20is%20managing%20the,)%2C%20to%20the%20Federal%20EHR.*

and social issues that categorize them as a vulnerable population. Due to the nature of their military service, the veteran population is comprised of individuals who may be diagnosed with serious medical conditions which require specialized care.[25] Some of these medical conditions include, but are not limited to, traumatic brain injury, Post-Traumatic Stress Disorder (PTSD), loss of limb(s), and medical conditions related to exposure to hazardous environments and materials (*e.g.,* medical conditions associated with the exposure to the herbicide ''Agent Orange'' during the Vietnam War).[26] To ensure that VA is able to accomplish its mission to provide comprehensive medical care to all veterans receiving care through its healthcare system, this final rule provides that VA practitioners are authorized to prescribe controlled substances via telemedicine, so long as the VA patient has an established medical relationship with any VA practitioner who has conducted at least one in-person medical evaluation of the patient, at any time, among other requirements. It is important to note, that within the scope of this final rule, ''VA patient'' refers to a veteran as defined in 38 CFR 3.1 as ''a person who served in the active military, naval, or space service and who was discharged or released under conditions other than dishonorable'' and is receiving medical care via the VA healthcare system. It also includes persons otherwise eligible under title 38, United States Code, or any other law authorizing the Secretary of Veterans Affairs to furnish health care.

1. *Vulnerable Population.* The veteran population is comprised of individuals from a cross-section of the American people, including the elderly, disabled, chronically ill, racial and ethnic minorities, individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ), and those who are economically disadvantaged.[27] These vulnerable groups face an increased risk of health-related problems, and due to a lack of access to health care, their mortality rates are higher, and their quality of life may be lower than that of the American population at-large.[28] [29]

2. *Geographic and Physical Barriers to Care.* Approximately 2.7 million veterans receive VA healthcare and live in rural or underserved areas where access to healthcare facilities is limited, particularly for the complex care needed by many veterans.[30] [31] Of these veterans, 54 percent are aged 65 or older, and 44 percent earn less than $35,000 per year.[32] Requiring frequent in-person medical evaluation for veterans who have already established a relationship with the VA healthcare system would create a significant barrier to care, potentially leading to undiagnosed or untreated conditions and worsening health outcomes.

Additionally, for veterans with significant mobility issues or chronic pain, traveling to in-person appointments can be daunting and may discourage them from seeking necessary medical attention.[33] One of the top five cited reasons that veterans cancel medical appointments is transportation issues.[34] Authorizing VA practitioners to prescribe controlled substance medications via telemedicine would facilitate access to medications that are crucial for managing patients' overall health and wellbeing.

3. *Mental Health Considerations.* Veterans have a higher risk for mental health disorders, traumatic brain injuries, and suicide when compared to their civilian counterparts.[35] One in three veterans experience some type of mental health issue, including but not limited to PTSD, depression, or anxiety.[36] In the 2023 VA Annual Benefits Report, 2,564,653 veterans were receiving disability compensation benefits for a mental health condition. Of these, 1.4 million were for PTSD and an additional 322,158 veterans were receiving benefits for major depressive disorder.[37] The stigma associated with seeking mental health help can deter veterans from attending in-person appointments, making telehealth an essential alternative path to receiving care.[38] By allowing VA practitioners to prescribe controlled substances without requiring more than one in-person medical evaluation with a VA practitioner, this final rule will support the mental health needs of the veteran community, making it easier for them to access treatments and controlled substance medications that can significantly improve their quality of life.

B. Unique Structure of VA Health Care

The VHA is one of the largest Federal health care systems in the United States, providing care at more than 1,300 facilities, including more than 150 VA Medical Centers and 1,100 VHA outpatient clinics to over 9 million veterans in the integrated VA health care program.[39] [40] As a Federal healthcare system, the VA establishes, maintains, and ensures compliance with standardized internal policies and procedures, including those to prevent and detect diversion of controlled substances, and engages in quality improvement and inspection activities.[41]

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[25] Moore MJ, Shawler E, Jordan CH, et al. Veteran and Military Mental Health Issues. Updated 2023 Aug 17. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK572092/.*

[26] The Department of Veterans Affairs, Annual Benefits Report 2023 (2023), *https://www.benefits.va.gov/REPORTS/abr/docs/2023-abr.pdf.*

[27] Ernstmeyer K, Christman E. (2022). Nursing: Mental Health and Community Concepts, Vulnerable Populations. *https://www.ncbi.nlm.nih.gov/books/NBK590046/#.*

[28] Aday, L.A. (2002). At Risk in America: The Health and Health Care Needs of Vulnerable Populations in the United States, 2 (13).

[29] Waisel, D.B. (2013). Vulnerable populations in healthcare, Current Opinion in Anesthesiology 26(2), 186–192.

[30] The Department of Veterans Affairs, Office of Rural Health Annual Report (2023), *https://www.va.gov/HEALTH/docs/annual-reports/ORH2842_2023_Thrive_051524_508c.pdf.*

[31] The Department of Veterans Affairs, Care of Complex Chronic Conditions (2024), *https://www.hsrd.research.va.gov/research/portfolio_description.cfm?Sulu=9.*

[32] The Department of Veterans Affairs, Office of Rural Health Annual Report (2023), *https://www.va.gov/HEALTH/docs/annual-reports/ORH2842_2023_Thrive_051524_508c.pdf.*

[33] Musich, S., et al. (2018). The impact of mobility limitations on health outcomes among older adults. Geriatric Nursing, 39(2), 162–169. *https://www.sciencedirect.com/science/article/pii/S0197457217302057?via%3Dihub.*

[34] VA's Veterans Engineering Research Council. *https://www.research.va.gov/.*

[35] Ernstmeyer K, Christman E. (2022). Nursing: Mental Health and Community Concepts, Vulnerable Populations. *https://www.ncbi.nlm.nih.gov/books/NBK590046/#.*

[36] Id.

[37] The Department of Veterans Affairs, Annual Benefits Report 2023 (2023), 103, *https://www.benefits.va.gov/REPORTS/abr/docs/2023-abr.pdf.*

[38] McGuffin, J.J., Riggs, S.A., Raiche, E.M., & Romero, D.H. (2021). Military and Veteran help-seeking behaviors: Role of mental health stigma and leadership. Military Psychology, 33(5), 332–340. *https://doi.org/10.1080/08995605.2021.1962181.*

[39] It is important to note that the VA is comprised of three entities that serve unique missions: (1) the Veteran Benefits Administration, which provides benefits and services, such as disability compensation and needs-based pension benefits; (2) the VHA, which provides healthcare to veterans; and (3) the National Cemetery Administration, which provides veterans with burial services and memorials. The scope of this final rule focuses solely on the VHA, as it is responsible for the administration of healthcare to the veteran population.

[40] About VHA—Veterans Health Administration (*va.gov*). As a general matter, integrated healthcare refers to ''coordinated care that addresses all aspects of patient health, focuses on a patient's individual needs, and involves a multidisciplinary team of health care professionals.'' *https://www.va.gov/health/aboutvha.asp#:~:text=The%20Veterans%20Health%20Administration%20(VHA,Veterans%20enrolled%20in%20the%20VA.*

[41] Readiness for the Patient-Centered Medical Home: Structural Capabilities of Massachusetts Primary Care Practices—PMC (*nih.gov*) *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2629002/*

1. *VA Oversight and Control.* The VA's continued commitment to patient safety is evidenced by its ongoing efforts to combat prescription drug misuse through education, monitoring, and intervention programs. These rigorous internal controls include regular audits, prescription monitoring programs, and adherence to established clinical guidelines, ensuring that controlled substances are prescribed ethically and as appropriate for the patient.[42] Additionally, the VA continues to collaborate closely with DEA and other regulatory bodies to ensure compliance with applicable Federal and state regulations related to prescribing controlled substances, including to ensure that VA practitioners acting in the usual course of their professional practice issue controlled substance prescriptions for legitimate medical purposes. This continued partnership enhances the VA's ability to maintain high standards of care while ensuring the safety of veterans receiving controlled substances.

2. *Movement Towards an Integrated EHR.* As a Federal health care system, VA delivers standardized medical care through multidisciplinary team(s) of health care professionals who share information regarding veteran patients through data systems that cross VA facilities.[43] VA's national, integrated health care system allows VA practitioners to access information on a VA patient's encounter history, prior prescriptions, and any relevant treatment plans. VA is transitioning from its current medical records system to a more robust Federal EHR which will share information among the VA, the Department of Defense, the U.S. Coast Guard, the National Oceanic and Atmospheric Administration, and participating community care providers.[44]

Id.; and Concerns of Primary Care Clinicians Practicing in an Integrated Health System: a Qualitative Study—PMC (*nih.gov*). *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7661604/.*

[42] VA healthcare regulations establish a range of protections and safeguards for veterans and VA patients. See 38 U.S.C. 1701 et seq; 38 CFR parts 17 through 80.

[43] Ten Key Principles for Successful Health Systems Integration—PMC (*nih.gov*). *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3004930/.*

[44] Frequently Asked Questions—VA EHR Modernization. *https://digital.va.gov/ehr-modernization/frequently-asked-question/#:~:text=VA%27s%20Electronic%20Health%20Record%20Modernization%20(EHRM)%20program%20is%20managing%20the,)%2C%20to%20the%20Federal%20EHR.*

III. Summary of the General Telemedicine NPRM's Veteran Affairs-Specific Provisions and Changes in This Final Rule

As noted above, safeguards within the regulations proposed in the General Telemedicine NPRM generally would have limited initial prescriptions of non-narcotic schedules III–V controlled substances to no more than a 30-day supply in instances where the patient had never had an in-person medical evaluation with the prescribing practitioner, and additional prescriptions beyond the initial 30-day prescription would have required that the patient undergo an in-person medical evaluation. The proposed General Telemedicine NPRM also would have generally prohibited the telemedicine prescribing of schedule II and narcotic controlled substances in schedules III through V, unless there had been a qualifying referral.

As also noted above, in the General Telemedicine NPRM, the provisions governing VA practitioners largely took the form of exemptions from these safeguards applicable to non-VA practitioners. Specifically, the General Telemedicine NPRM proposed that, subject to safeguards discussed below, a VA practitioner would be authorized to issue a prescription for controlled substances via telemedicine to a VA patient without a qualifying referral if that VA patient had previously been evaluated in-person by a VA practitioner. It additionally proposed that the VA practitioner would be authorized to prescribe a supply in addition to the 30-day supply if the in-person medical evaluation had been conducted by a VA practitioner. The NPRM proposed this would include controlled substances in schedules II–V.

In addition to these proposed exemptions from some of the safeguards in the General Telemedicine NPRM, VA practitioners would also be subject to certain additional safeguards relative to other telemedicine practitioners. Specifically, before prescribing controlled substances pursuant to the regulations proposed in the General Telemedicine NPRM, VA practitioners would be required to review not only the PDMP of the state in which the patient was located at the time of the telemedicine visit, but also the VA's internal prescription database when prescribing controlled substances via telemedicine.

After reviewing comments received in response to the General Telemedicine NPRM, as will be discussed in more detail below, DEA and HHS are adopting this final rule to treat VA practitioners as was proposed in the General Telemedicine NPRM. However, while the General Telemedicine NPRM proposed a generally applicable telemedicine scheme, and then created exemptions or additional requirements for VA practitioners relative to that generally applicable scheme, DEA and HHS are now finalizing only the proposed treatment of VA practitioners from the General Telemedicine NPRM, without finalizing the broader scheme. Most notably, when VA patients have had an in-person medical evaluation with a VA practitioner previously, this final rule authorizes a different VA practitioner, via the practice of telemedicine, to issue prescriptions for that patient for schedule II–V controlled substances, without being limited to a 30-day supply.

In this final rule, DEA and HHS are also finalizing, among other things, the General Telemedicine NPRM's proposed requirement for a VA practitioner to review the VA's internal prescription database and the PDMP data of the state in which the patient is located during the telemedicine encounter prior to issuing a prescription via telemedicine. It also finalizes the proposed requirement that a prescription for controlled substances be limited to a 7-day supply in situations when either the VA's internal prescription database or the PDMP data of the state in which the patient is located during the telemedicine encounter is unavailable or non-operational. It also requires that under circumstances where the VA patient is located in a state which does not have a PDMP program, the VA practitioner review the VA EHR prior to issuing a prescription for controlled substances in excess of a 7-day supply. DEA and HHS believe these changes will provide VA practitioners with necessary and appropriate flexibilities to provide care for our Nation's veterans, while still ensuring effective controls are in place to safeguard against diversion or misuse of controlled substances.

IV. Discussion of Veteran-Related Public Comments Received in Response to the March 1, 2023, General Telemedicine NPRM

DEA received a total of 233 veteran-related comments in response to the General Telemedicine NPRM.[45] Of those comments, 87 focused on non-VA healthcare or unrelated issues and therefore are outside the scope of this final rule, as this rulemaking focuses solely on the practice of telemedicine by VA practitioners within the VA

[45] 88 FR 12875 (Mar. 1, 2023).

healthcare system. As such, those comments will not be discussed further within this rulemaking. DEA and HHS thank all commenters for their input during the telemedicine rulemaking process.

In this final rule, DEA and HHS are only finalizing the proposals specific to the VA from the General Telemedicine NPRM. Therefore, in this final rule DEA will not be responding to comments deemed outside the scope of VA telemedicine. Moreover, the Special Registrations NPRM, focuses on non-VA practitioners and allows for further opportunity for public comment and additional development of a framework suited to the diverse operational environments outside the VA's integrated healthcare system. DEA has grouped the comments into several distinct categories below in order to effectively summarize and respond to the VA-related comments received in response to the General Telemedicine NPRM. Of the comments received, some comments pertained to only one issue while others encompassed several issues.

In-Person Medical Evaluation Requirement

Comment: DEA received the largest number of comments with concerns pertaining to the General Telemedicine NPRM's proposed requirement that, as a general matter, would require an in-person medical evaluation as a predicate to receiving a telemedicine prescription for either (1) a schedule II substance or a narcotic controlled substance in schedules III–V or (2) more than a 30-day supply of a non-narcotic controlled substance in schedules III–V. Specifically, commenters stated that requiring an in-person medical evaluation to receive such prescriptions would create an undue barrier for veterans seeking care within the VA healthcare system.

Response: DEA and HHS recognize the hardships an in-person medical evaluation requirement could cause to receive such prescriptions and why this requirement could be burdensome to VA patients.[46] Consequently, this final rule expands the telemedicine prescribing authority of VA practitioners so long as another VA practitioner has conducted an in-person medical evaluation with the VA patient. This expansion eliminates the need for a VA patient to undergo an in-person medical evaluation with the prescribing practitioner prior to receiving telemedicine services. For the reasons discussed above, DEA and HHS believe that this expansion reduces the burdens placed on VA patients receiving medical care from the VA and addresses these commenters' concerns, while at the same time providing sufficient safeguards against diversion.

Access to Care

Comment: DEA received 45 comments raising concerns about the challenges VA patients face, including disabilities that cause mobility issues and residency in rural areas, emphasizing that telemedicine is often their only viable option for accessing healthcare (particularly specialized care). Commenters asserted that the General Telemedicine NPRM posed practical barriers to care due to the burdens associated with conducting an in-person medical evaluation, such as long travel times and lack of available providers.

Response: DEA and HHS acknowledge that in-person medical evaluation requirements may be burdensome for patients with limited ability, either geographically or physically, to receive an in-person medical evaluation in order to be prescribed controlled substances either in the first instance or for additional duration. As noted above, this final rule authorizes indefinite prescribing via telemedicine so long as the VA patient has previously had at least one prior in-person medical evaluation with another VA practitioner. DEA and HHS believe that this will reduce the overall burden placed on VA patients living in rural areas and those with mobility issues, while still providing sufficient safeguards against diversion.

Negative Impact on VA Patients and VA Healthcare

Comment: DEA received 39 comments specifically highlighting potential adverse effects the General Telemedicine NPRM's in-person medical evaluation requirements would have on VA patients, including veterans, who rely on VA telemedicine services. Commenters stated that the VA's national telemedicine system, which is considered efficient and widely utilized, could be impacted by an in-person medical evaluation requirement. Many of these commenters urged for an exemption for VA practitioners due to the unique needs of the VA's patient population, which includes veterans.

Response: DEA and HHS agree that VA's use of telemedicine services has been effective and has taken under advisement the potential impact that any restrictions would impose on the VA healthcare system. Accordingly, this final rule authorizes indefinite prescribing via telemedicine so long as the VA patient has previously had at least one prior in-person medical evaluation with another VA practitioner, as noted above.

Mental Health Care

Comment: DEA received 28 comments from mental health professionals or patients within the VA healthcare system who emphasized the importance of telemedicine in providing continuous care for VA patients with mental health conditions. These commentors raised concerns that limiting telemedicine would have severe consequences for VA patient populations, including veterans.

Response: DEA and HHS recognize the unique challenges that mental health patients and providers face, particularly as it relates to veterans. DEA and HHS note that 1 in 3 veterans experience some type of mental health issue, including, but not limited to, PTSD, depression, and anxiety.[47] DEA and HHS believe that the changes incorporated within this final rule provide an environment where continuity of care can be maintained, while still helping to ensure VA patient safety and safeguard against diversion.

V. Scope of Final Rule

Once an in-person medical evaluation of a VA patient has been conducted by a VA practitioner, this practitioner-patient relationship is extended to all VA practitioners engaging in the practice of telemedicine (which is defined as ''telehealth'' in 38 CFR 17.417).[48] Under such circumstances, this rulemaking essentially avoids the need for VA practitioners to obtain a DEA Special Registration for telemedicine before issuing prescriptions for controlled substances; such Special Registrations are the subject of the Special Registrations NPRM. The VA-specific regulations discussed below align with DEA's core responsibilities of regulating controlled substances, while enabling the VA to leverage its existing integrated and standardized model of care to allow VA practitioners to prescribe controlled substances to VA patients when they have not conducted an in-person medical evaluation. It is important to

[46] DEA is proposing to address this issue more generally for individuals outside of the VA healthcare system under the Special Registrations NPRM.

[47] McGuffin, J. J., Riggs, S.A., Raiche, E.M., & Romero, D.H. (2021). Military and Veteran help-seeking behaviors: Role of mental health stigma and leadership. Military Psychology, 33(5), 332–340. *https://doi.org/10.1080/08995605.2021.1962181.*

[48] 38 CFR 17.417(a)(4) and (b) define a healthcare professional's scope while practicing telemedicine within the VA healthcare system.

emphasize that this final rule will only be applicable in situations where the VA patient has previously undergone an in-person medical evaluation with a VA practitioner, thus establishing a preexisting relationship of care with the VA healthcare system. A preexisting relationship of care between a VA patient and the VA healthcare system will be deemed to exist if, even prior to promulgation of this rule, the VA patient has undergone an in-person medical evaluation with a VA practitioner. The changes to DEA's regulations are consistent ''with effective controls against diversion and otherwise consistent with the public health and safety'' pursuant to 21 U.S.C. 802(54)(G). DEA is promulgating these regulatory changes in concert with HHS, and HHS was consulted in the creation of these regulatory provisions and concurs with this rulemaking. HHS also has advised DEA that no further rulemaking by HHS is necessary for the promulgation of this joint final rule. Moreover, these regulations, and DEA regulations generally, do not apply to telehealth encounters that do not result in a prescription for controlled substances.[49] Simply put, the regulations promulgated in this final rule do *not* apply unless a VA practitioner deems it necessary to prescribe controlled substances to a VA patient via telemedicine and that VA patient has previously had an in-person medical evaluation performed by a VA practitioner.

The following provides the criteria that must be met to allow a VA practitioner to engage in the practice of telemedicine under this final rule:

A. *Criteria for Practitioners.* To be eligible for the provisions within these regulations, the VA practitioner must meet each of the following criteria:

i. Be either employed by, or in contract with, the VA, and be operating within the scope of their employment as defined in 38 CFR 17.419.[50]

ii. For VA contracted practitioners, the prescribing practitioner conducting the telemedicine encounter must be practicing at either a VA facility or a VA community clinic. For the scope of this rule, practitioners providing medical care to VA patients as part of the Community Care Network (CCN) are not considered to be practicing within a VA facility or a VA community clinic.

iii. Be registered with DEA under 21 U.S.C 823(g) in any State or be utilizing the DEA registration of a hospital or clinic operated by the VA registered under section 823(g).

iv. Be prescribing within the usual course of their practice and ensure all prescribing practices are in accordance with applicable State and Federal law(s).

The above criteria are designed to ensure that a practitioner engaging in the practice of telemedicine is operating within their capacity as a VA practitioner and is acting in accordance with both applicable Federal and state law(s) and regulation(s).

B. *Requirements for Previous In-Person Medical Evaluation.* To be eligible for the provisions within these regulations, an in-person medical evaluation must have been conducted by a VA practitioner, who at the time of the evaluation:

i. Conducted the evaluation within their official capacity as an employee of the VA (as defined above), and

ii. The nature of the in-person medical evaluation falls within the scope of their practice of medicine as defined in 38 CFR 17.419.

The criteria in this section establish the circumstances when a previous in-person medical evaluation conducted by another VA practitioner would establish the necessary relationship of care between patient and the VA healthcare system so as to allow for use of the telemedicine flexibilities finalized in this final rule.

C. Requirements for the Review of the VA's Internal Prescription Database and Prescription Drug Monitoring Program. Before issuing a telemedicine-controlled substance prescription otherwise authorized by this final rule, the prescribing practitioner must:

i. Review both the VA patient's EHR (to include the VA's internal prescription database) and the PDMP data of the state in which the patient is located at the time of the telemedicine encounter for any prescriptions of controlled substances issued to the patient and annotate the date and time that such a review was conducted in the patient's EHR. If either the VA's internal prescription database or the PDMP for the state where the patient is located at the time of the telemedicine encounter is unavailable or inaccessible for any reason, the prescribing practitioner must annotate the date and time that such a review was attempted in the patient's EHR and provide a reason as to why a review was unable to be completed.

ii. The review of the VA patient's EHR (to include the VA's internal prescription database) and state PDMP must encompass the previous 12 calendar months, proceeding the controlled substance prescription, of the patient's record, or if less than a year of data is available, for the entire period of data availability.

iii. In instances where the VA patient's EHR (to include the VA's internal prescription database) or the state PDMP for the state the patient is located at the time of the telemedicine encounter (if the state has such a program) are either unavailable or non-operational, prescribing VA practitioners must limit the supply of the controlled substance prescription to 7-days. Once access is restored to the VA patient's EHR (to include the VA's internal prescription database) and the PDMP, if one exists for the state where the VA patient is located at the time of the telemedicine encounter, the prescribing practitioner must review the relevant data prior to prescribing an additional supply of the controlled substance, in accordance with the otherwise applicable requirements discussed above. Additionally, the prescribing VA practitioner must annotate the date and time that such a review was attempted in the patient's EHR and provide a reason as to why a review was unable to be completed. The VA practitioner may then issue a controlled substance prescription in excess of a 7-day supply limit.

iv. If the VA patient is located in a state which does not use a PDMP, the VA practitioner must review the patient's EHR before issuing a prescription for controlled substances for more than a 7-day supply.

The above criteria are designed to safeguard against the risk of diversion of controlled substances. The review of the patient's VA medical record (to include the internal prescription database) and the PDMP data for the state in which the patient is located gives the prescribing VA practitioner additional insight into the patient's prescription history of controlled substances, allowing for additional clarity on the medical appropriateness of an additional controlled substance prescription issued via telemedicine. Moreover, limiting the quantity of controlled substances that can be prescribed during periods when the either the VA patient's EHR (to

[49] 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 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 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.

[50] 38 CFR 17.419 provides the requirements for an individual to be considered a health care professional within the scope of the VA healthcare system.

include the VA's internal prescription database) or the PDMP for the state where the VA patient is located at the time of the telemedicine encounter is unavailable provides an additional safeguard to ensure that controlled substances are prescribed appropriately, while preventing a lapse in care.

VI. Regulatory Analyses

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

DEA and HHS have determined that this rulemaking is a ''significant regulatory action'' under section 3(f) of Executive Order (E.O.) 12866, Regulatory Planning and Review, but it is not a section 3(f)(1) significant action. Accordingly, this final rule has not been submitted to the Office of Management and Budget for review. This 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.

This final rule authorizes Department of Veterans Affairs practitioners acting within the scope of their VA employment to prescribe controlled substances via telemedicine to a VA patient with whom they have not conducted an in-person medical evaluation. VA practitioners are permitted to prescribe controlled substance medications to VA patients if, among other things, another VA practitioner has previously conducted an in-person medical evaluation of the VA patient. DEA and HHS estimate the total annual cost savings of this rule is $2.54 million due to patient travel time and cost savings. Two million three hundred ninety thousand dollars ($2.39 million) of the cost savings is realized by the patient and $0.15 million of the cost savings is realized by the VA in form of reduced transfers (travel reimbursements). Government benefit payments are considered as ''transfers.'' [51] Additionally, DEA and HHS estimate an additional annual cost to the VA of $1.76 million due to the required EHR and PDMP reviews. The full analysis of costs, cost savings, and transfer savings is provided below.

1. Baseline

For DEA and HHS's analysis of the economic impact of this final rule, the baseline 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. This final rule provides:

(1) *In-Person medical evaluation exemption:* exempts VA practitioners from the requirement of an in-person medical evaluation if the patient has had a prior in-person medical evaluation from any VA practitioner (21 CFR 1306.52(a)(3)).

(2) *PDMP review:* requires a PDMP review of the state in which the patient is located, if the state has such a program (21 CFR 1306.52(b)(1)).

The costs, cost savings, and benefits associated with exempting VA practitioners from the requirement of conducting an in-person medical evaluation under the circumstances permitted by this rule were evaluated from the perspective of the following impacted parties in the following areas: patients, the VA, and the risk of diversion. Those costs, cost savings, and benefits are discussed below.

2. Patient Costs, Cost Savings, and Benefits

This rule benefits VA patients by reducing transportation costs and travel time costs, and by expanding access to medical care. The cost savings associated with this rule predominantly stem from reductions in two categories of 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 in this final 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.[52]

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.[53]

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.[54] 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 relevant for this analysis.[55] 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.[56] 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.[57] The load of 45.3 percent, or $10.47 (0.453 × $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).

[51] Office of Management and Budget (OMB) Circular A–4.

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

[53] 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.

[54] 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).

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

[56] 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.*

[57] 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).

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 Net Cost of Travel per Practitioner Visit

DEA estimates there will be cost savings to VA patients as a result of not having to travel to a VA practitioner for a visit. The patient's net cost of travel is the cost of travel net of reimbursements received from the VA. 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.[58] Using the IRS travel reimbursement rate for businesses of 67 cents per mile as an estimate of travel cost,[59] the estimated patient's cost of travel to and from a practitioner's appointment is $13.27 ($0.67 \times 19.8$), as can be seen in table 3 below.

TABLE 3—PATIENT TRAVEL COST PER TRIP

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

The VA reimbursement rate is $0.415 per mile for approved, health-related travel, with a current deductible of $6 round-trip for each appointment, up to $18 total each month.[60] Assuming VA patients generally do not reach the $18 monthly deductible limit, the estimated VA mileage reimbursement is $8.22 ($0.415 \times 19.8$) per visit. After a $6 deductible, the net VA reimbursement after deductible is $2.22 ($8.22 − $6) and the patient's net cost of travel is $11.05 ($13.27 − $2.22). Table 4 summarizes the VA reimbursement and patient's net cost of travel.

TABLE 4—VA REIMBURSEMENT AND PATIENT NET TRAVEL COST PER TRIP

	Travel cost per mile ($)	Travel distance (miles)	Per appointment cost ($)
VA mileage reimbursement per trip	0.415	19.8	8.22
Deductible (paid by patient)	N/A	N/A	6.00
Net VA mileage reimbursement per trip	N/A	N/A	2.22
Patient net travel cost per trip	N/A	N/A	11.05

[58] 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)

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

[60] U.S. Department of Veterans Affairs, Reimbursed VA travel expenses and mileage rate, *https://www.va.gov/resources/reimbursed-va-travel-expenses-and-mileage-rate/* (accessed 11/12/2024).

c. Total Number of Telemedicine Visits

This final rule's patient cost savings results from eliminating the need for an 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 this rule, DEA needed to estimate the total number of first-time telemedicine visits resulting in prescriptions for controlled substances.[61] 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, the number of practitioner visits conducted via telemedicine was reduced to those that constituted first-time telemedicine visits. Second, DEA determined the proportion of the first-time telemedicine visits that would result in prescriptions. Third, it refined the total number of first-time telemedicine visits resulting in prescriptions of controlled substances. And lastly, DEA considered the impact of the rule's requirements and determined the total number of first-time telemedicine visits resulting in prescriptions of controlled substances under this rule. DEA performed this multi-step analysis to derive an estimate of *the number* of first-time telemedicine visits resulting in prescriptions for controlled substances, which resulted in an estimate of the current value for the total patient cost savings.

Step 1: First-Time Visits. Based on a VHA 2023 annual report there were over 9.4 million telehealth encounters to veterans in the home or other offsite locations.[62] 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 this 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 this rule, shows that the vast majority of practitioner visits are for returning patients, and approximately 10 percent of those practitioner visits are new visits.[63] This is in line with the Center for Disease Control and Prevention's (CDC) 2019 National Ambulatory Medical Care (NAMC) non-Federal 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.[64] Taking 10 percent of 9,400,000 practitioner visits conducted via telemedicine would provide a total of approximately 940,000 first-time, telemedicine practitioner visits, as can be seen in table 5.

TABLE 5—NUMBER OF FIRST-TIME TELEMEDICINE VISITS

Telemedicine visits	9,400,000
First-time telemedicine visit rate	0.1
First-time telemedicine visits	940,000

Step 2: 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, DEA determined, as reflected in table 6, 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 940,000 first-time, telemedicine visits resulting in approximately a total of 676,800 first-time telemedicine visits resulting in the issuance of prescriptions, as can be seen in table 7.

TABLE 6—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
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

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

[62] VHA. *VHA 2023 Annual Report. https://department.va.gov/vha-annual-report/* (accessed 10/12/2024).

[63] 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%).

[64] 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 6—ESTIMATE OF NUMBER OF PRESCRIPTIONS USING VISIT DATA—Continued

Number of prescriptions	Number of visits (thousands)	Total number of prescriptions (thousands)
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 7—ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS WITH PRESCRIPTIONS

First-time telemedicine visits		940,000
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		676,800

Step 3: 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.[65] 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.[66] Applying this 16 percent to the total number of 676,800 telemedicine visits resulting in the issuance of prescriptions, provides a value of approximately 108,288 first-time telemedicine visits resulting in prescriptions for controlled substances, as can be seen in table 8.

TABLE 8—CURRENT ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS RESULTING IN PRESCRIPTIONS OF CONTROLLED SUBSTANCES

First-time telemedicine visits with prescriptions	676,800
Controlled substance (CS) rate	0.16
First-time telemedicine visits with CS prescriptions	108,288

Step 4: Effect of this Rule. Lastly, DEA determined the total number of first-time telemedicine visits resulting in prescriptions of controlled substances under this rule. Under this final 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.[67] 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.[68] Because this rule is not limited to mental health, DEA applied the broader and lower 61 percent to the 108,288 first-time telemedicine visits resulting in prescriptions of controlled substances. The multi-step analysis ultimately derived a current estimate of 66,056 first-time telemedicine visits resulting in prescriptions of controlled substances under this rule, as can be seen in table 9.

[65] *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).

[66] 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).

[67] 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).

[68] 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 9—CURRENT ESTIMATE OF NUMBER OF FIRST-TIME TELEMEDICINE VISITS RESULTING IN PRESCRIPTIONS OF CONTROLLED SUBSTANCES UNDER THIS RULE

Telemedicine visits	9,400,000			
First time telemedicine visit rate	0.1			
First-time telemedicine visits	*940,000*		940,000	
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			*676,800*	676,800
Controlled substance (CS) rate				0.16
First-time telemedicine visits with CS prescriptions				*108,288*
First-time telemedicine visits that do not have an in-person follow up visit.				0.61
First-time telemedicine visits under this rule with CS prescriptions				66,056

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 total patient cost savings of $2,540,514 ($38.46 × 66,056) per year.

Additionally, from table 4, DEA estimates VA will reimburse the patient $2.22 per trip. Applying this reimbursement amount to the number of trips, the VA reimbursement amount (transfers to the patient) is $146,644 ($2.22 × 66,056). Subtracting the VA reimbursement amount from the total cost savings, DEA estimates a total patient net cost savings of $2,393,870 ($2,540,514 − $146,644) per year. Table 10 summarizes this calculation.

TABLE 10—TOTAL COST/TRANSFER SAVINGS

	Total cost savings ($)	VA reimbursement ($)	Patient net cost savings ($)
Patient cost savings (per visit)	38.46	2.22	N/A
Patient cost savings	2,540,514	146,644	2,393,870

e. Patient Benefit: Increased Access to Care

While DEA estimated the patient cost savings for the estimated 66,056 patient visits that would fall under this final rule, DEA is unable to quantify the number of patients that will be treated that would not have been treated absent this regulation. In recent years, telemedicine has emerged as a vital solution for enhancing healthcare accessibility for VA patients, especially in the face of healthcare shortages. Notably, telemedicine extends its benefits to patients in remote and other underserved areas, including by offering access to specialized care. While DEA is unable to quantify the number of patients that will be treated that would not have been treated absent this regulation, it is reasonable to assume there will be VA patients that will fall in this category and the benefits of increased access to care are not negligible.

3. VA Costs and Transfer Savings

Impact on the VA is primarily due to two primary factors, additional burden for VA patient EHR and PDMP reviews prior to prescribing and reduced travel reimbursements to VA patients.

Prior to prescribing, the practitioner must conduct a review of both the patient's VA medical record, to include in the VA's internal prescription database, and the PDMP of the state in which the patient is located at the time of the telemedicine encounter (if the State has such a program) for controlled substance prescription(s) for the patient's previous twelve (12) months preceding the controlled substance prescription(s), or if less than a year of data is available, for the entire prescription period. Additionally, the VA practitioner must annotate in the VA patient's EHR their attempts to obtain the PDMP of the state in which the patient is located and VA internal prescription database data. DEA estimated the cost of this requirement by estimating the cost per review and applying the cost to the number of patient visits.

Based on the BLS wage data, DEA estimated the cost per review for physicians, nurse practitioners (NPs), and physician's assistants (PAs), then calculated a weighted average cost per review based on the number of physicians, NPs, and PAs.[69]

The mean wage data for physicians is $129.71 and the median wage for PAs and NPs are $62.51 and $60.70, respectively.[70] 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.[71] The load of 45.3 percent is added to wages and salaries by multiplying the wages and salaries by 1.453 (1 + 0.453). The resulting loaded hourly rates are $188.47 ($129.71 × 1.453), $90.83 ($62.51 × 1.453), and $88.20 ($60.70 × 1.453), for physicians, PAs, and NPs, respectively.

Based on a 2018 study, it takes a practitioner 27 seconds to log in and 37 seconds to retrieve a report once logged

[69] 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.

[70] *Id.* (Weighted average of mean hourly wages for 29–1210 Physicians and 29–1240 Surgeons. Used ''mean'' hourly wages because ''median'' was not available.)

[71] Bureau of Labor Statistics, Employer Costs for Employee Compensation—March 2023, *https://www.bls.gov/news.release/archives/ecec_06162023.pdf* (accessed 9/24/2024).

in.[72] The total time it takes to retrieve a PDMP report is roughly a minute (27 + 37 = 64 seconds) or 0.017 (1/60) hours. Applying 0.017 hours to the loaded hourly rates, 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 11 summarizes the results.

TABLE 11—EHR AND 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 Assistant	62.51	28.32	90.83	0.017	1.54
Nurse Practitioners	60.70	27.50	88.20	0.017	1.50

As of October 19, 2024, DEA estimates there were 15,148 physicians, 5,351 NPs, and 1,513 PAs registered with DEA that meet the VA employment requirements of this final rule.[73] For simplicity, DEA calculated a single cost of a review based on the weighted average of the three occupations. The weighted average of the cost of review is $2.67. Table 12 details the calculation.

TABLE 12—EHR PDMP CHECK TIME COST

Occupation	VA registrants	VA registrant weights	Cost per PDMP check ($)	Weighted cost per PDMP check ($)
Physicians	15,148	0.6882	3.20	2.20
Physician Assistant	1,513	0.0687	1.54	0.11
Nurse Practitioners	5,351	0.2431	1.50	0.36
Total	22,012	N/A	N/A	2.67

As discussed earlier in table 9, DEA estimates that annually, there will be 66,056 first time telemedicine patient visits, which are patients visiting a specific practitioner for the first time, that result in a prescription for a controlled substances that fall under this final rule. However, unlike patient travel time and cost savings, since the EHR and PDMP reviews are required for all visits and not just first-time visits, there will not be a first-time visit adjustment. While EHR and PDMP reviews will be required for all prescriptions under this rule, DEA believes PDMP checks are already conducted in most cases, lowering the additional burden imposed by this rule. However, to be conservative, DEA applied the full cost of $2.67 to all telemedicine visits leading to a prescription by backing out the 0.1 factor applied for first-time visits (table 9), in other words, by multiplying the number of first-time telemedicine visits (66,056) by 10 for 660,560 total visits. Applying the cost of $2.67 to the total number of visits results in a total cost of $1,763,695 ($2.67 × 660,560) per year.

As discussed earlier in table 10, DEA estimates the VA will save $146,644 annually from reduced travel reimbursements to patients.

While there may be reduced costs to the VA as a result of fewer patient visits to its facilities, for the purposes of this analysis, DEA and HHS anticipate that there will be no significant net economic impact on the VA's healthcare systems due to the 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.[74]

However, evidence suggests that it does not routinely reduce the cost of care delivery for the health system as a whole.[75] 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.[76]

4. Risk of Diversion

Requiring an in-person medical evaluation serves as a safeguard against diversion, consistent with the Ryan Haight Act. Since the advancement of telemedicine technology, new diversion paradigms have emerged in telemedicine.[77] Therefore, to address new ways of delivering care, DEA believes that other anti-diversion safeguards—such as those in this final rule—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, Dea is

[72] 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.

[73] DEA estimate based on registrations.

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

[75] *Id.*

[76] 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. *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).

[77] 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.*

concerned that the intentionally concealed and frequently underreported nature of drug diversion makes these illicit activities inherently difficult to track.[78] 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.

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 this rule, DEA is requiring prescribers to review patient records and check PDMPs prior to prescribing controlled substances. DEA believes the requirements of this rule and the VA's internal safeguards will adequately manage the risk of diversion. DEA and HHS would like to protect and advance access to care for Veterans. Accordingly, this final rule will help to advance access to care while protecting against potential diversion risk.

[78] 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 rule and under the separate *Expansion of Buprenorphine Treatment via Telemedicine Encounter* final rule (RIN 1117–AB78), published elsewhere in this issue of the **Federal Register**. *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.*

5. Summary of Economic Impact

DEA and HHS estimate the total annual cost savings of this final rule is $2.54 million due to patient travel time and cost savings. $2.39 million of the cost savings is realized by the patient and $0.15 million of the cost savings is realized by the VA in form of reduced transfers (travel reimbursements). Additionally, DEA and HHS estimates an additional annual cost to the VA of $1.76 million due to the required EHR and PDMP reviews.

DEA believes that the benefits of increased availability for treatment outweigh the dangers of a potential increase in diversion, so long as VA practitioners adhere to the anticipated safeguards VA and/or DEA will implement or have already implemented with respect to the practice of telemedicine.

Regulatory Flexibility Act

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

This final rule affects the VA and its individual patients. The VA is not a small entity. Therefore, this rule will not have significant economic impact on a substantial number of small entities.

Paperwork Reduction Act of 1995

This action would not create or modify a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. PRA is not applicable when the information is being collected from Federal employees or contractors as a part of their job. In this final rule, all recordkeeping actions are taken by Federal employees as a part of their work-related duties with the VA.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Unfunded Mandates Reform Act of 1995

The estimated annual impact of this final 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.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), the Office of Information and Regulatory Affairs has determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2). DEA will submit a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1306

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

42 CFR Part 12

Administrative practice and procedure.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 13, 2025, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for

publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

Miriam E. Delphin-Rittmon,

Assistant Secretary for Mental Health and Substance Use, Department of Health and Human Services.

Drug Enforcement Administration

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

PART 1306—PRESCRIPTIONS

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

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

■ 2. Add § 1306.52 to read as follows:

§ 1306.52 Other circumstances where Department of Veterans Affairs practitioners may prescribe controlled substances via the practice of telemedicine.

A practitioner may prescribe controlled substance(s) to a patient via the practice of telemedicine under § 1300.04(i)(7) of this chapter if all the following conditions are met:

(a) The practitioner is:

(1) An employee or contractor of the Department of Veterans Affairs (VA) who is acting in the scope of such employment or contract, and registered under section 303(g) of the Act (21 U.S.C. 823(g)) (§ 1301.13 of this chapter) in any state or is utilizing the registration of a hospital or clinic operated by the VA registered under section 303(f);

(2) Prescribing to a VA patient who has previously received, at any time, an in-person medical evaluation by any VA practitioner who at the time of the in-person medical evaluation was acting within the scope of their VA employment or contract and had prescribing authority, or would reasonably be expected to have prescribing authority based on their credentials (*e.g.,* medical doctor) or organizational role (*e.g.,* primary care provider), as described in paragraph (a)(1) of this section;

(3) Not a contracted practitioner located outside a VA facility or clinic providing care via the community care network or conducting disability compensation evaluations; and

(4) Prescribing a controlled substance(s) for a legitimate medical purpose in the usual course of professional practice, and in accordance with applicable Federal and State law(s).

(b) Prior to prescribing, the practitioner must conduct a review of both the VA EHR, to include the VA's internal prescription database, and the PDMP data of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) for controlled substance prescription(s) for the patient's previous twelve (12) months preceding the controlled substance prescription(s), or if less than a year of data is available, for the entire prescription period.

(1) Should either the patient's VA electronic health record, to include the VA's internal prescription database, or the PDMP of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) be unavailable or non-operational, for any reason, the VA practitioner must limit the prescription to a 7-day supply. Once the VA's internal prescription database and the PDMP are available or operational, a review of the databases as outlined in this paragraph (b) must be completed to continue prescribing the controlled substance(s) to the VA patient.

(2) If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the VA practitioner must review the VA internal prescription database prior to issuing a controlled substance prescription. A prescription may extend beyond 7 days under this circumstance.

(3) The VA practitioner must annotate in the VA patient's EHR their attempts to access the PDMP data of the state in which the patient is located, and VA internal prescription database data. If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the prescribing practitioner must annotate that in the VA patient's EHR. If the prescribing VA practitioner fails to access the PDMP data of the state in which the patient is located or VA internal prescription database data as described in paragraph (b)(1) of this section, the VA practitioner must annotate in the VA patient's EHR the dates and times that the VA practitioner attempted to gain access, the reason why the VA practitioner was unable to gain access, and any follow-up attempts made to gain access to the system. The attempts must be recorded in accordance with the VA's internal policies and recordkeeping requirements.

(c) The controlled substance prescription(s) must be otherwise in conformity with the requirements of the Controlled Substances Act and this chapter.

Department of Health and Human Services

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

PART 12—TELEMEDICINE FLEXIBILITIES

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

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

■ 4. Add § 12.4 to read as follows:

§ 12.4 Telemedicine prescribing of schedule II–V medications by the Department of Veterans Affairs practitioners.

A practitioner may prescribe controlled substance(s) to a patient via the practice of telemedicine under 21 CFR 1300.04(i)(7) if all the following conditions are met:

(a) The practitioner is:

(1) An employee or contractor of the Department of Veterans Affairs (VA) who is acting in the scope of such employment or contract, and registered under section 303(g) of the Controlled Substances Act (Act) (21 U.S.C. 823(g)) (21 CFR 1301.13) in any state or is utilizing the registration of a hospital or clinic operated by the VA registered under section 303(f);

(2) Prescribing to a patient who has previously received, at any time, an in-person medical evaluation by any VA practitioner who at the time of the in-person medical evaluation was acting within the scope of their VA employment or contract and had prescribing authority, or would reasonably be expected to have prescribing authority based on their credentials (*e.g.,* medical doctor) or organizational role (*e.g.,* primary care provider), as described in paragraph (a)(1) of this section;

(3) Not a contracted practitioner located outside a VA facility or clinic providing care via the community care network or conducting disability compensation evaluations; and

(4) Prescribing a controlled substance(s) for a legitimate medical purpose in the usual course of professional practice, and in accordance with applicable Federal and State law(s).

(b) Prior to prescribing, the practitioner must conduct a review of both the VA EHR, to include the VA's internal prescription database, and the PDMP data of the state in which the patient is located at the time of the

telemedicine encounter (if the state has such a program) for controlled substance prescription(s) for the patient's previous twelve (12) months preceding the controlled substance prescription(s), or if less than a year of data is available, for the entire prescription period.

(1) Should either the patient's VA electronic health record, to include the VA's internal prescription database, or the PDMP data of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) be unavailable or non-operational, for any reason, the VA practitioner must limit the prescription to a 7-day supply. Once the VA's internal prescription database and the PDMP are available or operational, a review of the databases as outlined in this paragraph (b) must be completed to continue prescribing the controlled substance(s) to the VA patient.

(2) If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the VA practitioner must review the VA internal prescription database prior to issuing a controlled substance prescription. A prescription may extend beyond 7 days under this circumstance.

(3) The VA practitioner must annotate in the VA patient's EHR their attempts to access the PDMP data of the state in which the patient is located, and VA internal prescription database data. If the prescribing VA practitioner fails to access the PDMP data of the state in which the patient is located or VA internal prescription database data as described in paragraph (b)(1) of this section, the VA practitioner must annotate in the VA patient's EHR the dates and times that the VA practitioner attempted to gain access, the reason why the VA practitioner was unable to gain access, and any follow-up attempts made to gain access to the system. The attempts must be recorded in accordance with the VA's internal policies and recordkeeping requirements.

(c) The controlled substance prescription(s) is otherwise in conformity with the requirements of the Act and 21 CFR chapter II.

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