The technical amendments do not impose any new substantive regulatory requirements on any person and merely reflect the vacatur of the Private Fund Adviser Rules. For these reasons, for good cause, the Commission finds that notice and public comment are unnecessary.[4]

For similar reasons, although the APA generally requires publication of a rule at least 30 days before its effective date, the Commission finds there is good cause for the amendments to take effect on [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].[5]

Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs has designated these amendments as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 17 CFR Part 275

Administrative practice and procedure, Reporting and recordkeeping requirements, Securities.

Text of Amendments

For the reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The authority citation for part 275 continues to read in part as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, 80b–11, 1681w(a)(1), 6801–6809, and 6825, unless otherwise noted.

* * * * *

Section 275.204–2 is also issued under 15 U.S.C. 80b–6.

* * * * *

§ 275.204–2 [Amended]

■ 2. Amend § 275.204–2 by:
■ a. Removing the ''; and'' at the end of paragraph (a)(7)(iv)(B) and adding a period in its place;
■ b. Removing paragraph (a)(7)(v); and
■ c. Removing and reserving paragraphs (a)(20) through (24).

* * * * *

§ 275.206(4)–9, § 275.206(4)–10 [Removed]

■ 3. Remove §§ 275.206(4)–9 and 275.206(4)–10.

* * * * *

§ 275.206(4)–7 [Amended]

■ 4. Amend § 275.206(4)–7 by revising paragraph (b) to read as follows:

* * * * *

(b) *Annual review.* Review, no less frequently than annually, the adequacy of the policies and procedures established pursuant to this section and the effectiveness of their implementation; and

* * * * *

§ 275.211(h)(1)–1 through § 275.211(h)(2)–3 [Removed]

■ 5. Remove §§ 275.211(h)(1)–1, 275.211(h)(1)–2, 275.211(h)(2)–1, 275.211(h)(2)–2, and 275.211(h)(2)–3.

Dated: November 8, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–26524 Filed 11–18–24; 8:45 am]

BILLING CODE 8011–01–P

[4] This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the amendments to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a Federal agency finds that notice and public comment are impractical, unnecessary or contrary to the public interest, a rule shall take effect at such time as the Federal agency promulgating the rule determines). The amendments also do not require analysis under the Regulatory Flexibility Act. *See* 5 U.S.C. 604(a) (requiring a final regulatory flexibility analysis only for rules required by the APA or other law to undergo notice and comment).

[5] *See* 5 U.S.C. 553(d)(3).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA–407]

RIN 1117–AB40, 1117–AB78, and 1117–ZA06

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Third Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications

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

ACTION: Temporary rule.

SUMMARY: The Drug Enforcement Administration (DEA) in concert with the Department of Health and Human Services (HHS) is issuing a third extension of telemedicine flexibilities for the prescribing of controlled medications, through December 31, 2025.

DATES: This rule is effective January 1, 2025, through December 31, 2025.

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

SUPPLEMENTARY INFORMATION:

I. Background

Overview

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act), a prescribing practitioner—subject to certain exceptions—may prescribe controlled medications to a patient only after conducting an in-person evaluation of that patient. In response to the COVID–19 Public Health Emergency (COVID–19 PHE), as declared by the Secretary (the Secretary) of the Department of Health and Human Services (HHS) on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), the Drug Enforcement Administration (DEA) granted temporary exceptions to the Ryan Haight Act and DEA's implementing regulations under 21 U.S.C. 802(54)(D).

In order to prevent lapses in care, these exceptions allowed for the prescribing of controlled medications via telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient. These telemedicine flexibilities authorized practitioners to prescribe schedule II–V controlled medications via audio-video telemedicine encounters, including schedule III–V narcotic controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, provided that such prescriptions otherwise comply with the 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 (the McDermott Letter);[1] and
- A March 31, 2020 ''Dear Registrant'' letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant

[1] 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.*

Administrator, Diversion Control Division (the Prevoznik Letter).[2]

On March 1, 2023, DEA, in concert with HHS, promulgated two notices of proposed rulemaking (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'' [3] (the General Telemedicine NPRM) and ''Expansion of Induction of Buprenorphine via Telemedicine Encounter'' [4] (the Buprenorphine NPRM)—which proposed to expand patient access to prescriptions for controlled medications via telemedicine encounters relative to the pre-COVID–19 PHE landscape. The purpose of the two proposed rules was to make permanent some of the telemedicine flexibilities established during the COVID–19 PHE in order to facilitate patient access to controlled medications via telemedicine when consistent with public health and safety, while maintaining effective controls against diversion. The comment period for these two NPRMs closed on March 31, 2023. Those NPRMs generated a total of 38,369 public comments—35,454 comments on the General Telemedicine NPRM and 2,915 comments on the Buprenorphine NPRM. Many of those comments requested changes of varying degrees to the proposed regulations in the two March 2023 NPRMs.

On May 10, 2023 DEA, jointly with HHS (with the Substance Abuse and Mental Health Services Administration (SAMHSA) acting on behalf of HHS), issued the first temporary extension (First Temporary Rule), which extended the full set of telemedicine flexibilities regarding the prescribing of controlled medications, as had been in place under the COVID–19 PHE, through November 11, 2023.[5] 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. In other words, under the First Temporary Rule, if a patient and a practitioner had established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that had governed the relationship to that point would continue to apply through November 11, 2024.

On August 7, 2023, DEA announced that it would host Telemedicine Listening Sessions on September 12 and 13, 2023, in order to receive additional input concerning the practice of telemedicine with regards to prescribing controlled medications and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. On October 10, 2023, DEA, jointly with HHS, issued a second temporary extension (Second Temporary Rule) extending the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID–19 PHE, through December 31, 2024.[6] This extension authorized all DEA-registered practitioners to prescribe schedule II–V controlled medications via telemedicine through December 31, 2024, whether or not the patient and practitioner established a telemedicine relationship on or before November 11, 2023. In other words, the grace period provided in the First Temporary Rule was effectively subsumed by this Second Temporary Rule, which continued the extension of the current flexibilities for all practitioner-patient relationships—not just those established on or before November 11, 2023—until the end of 2024.

On June 13 and 27, 2024, DEA held virtual Tribal Consultations with numerous Tribal governments and organizations in order to elicit further comment from interested Tribal parties regarding the prescribing of controlled medications via telemedicine and its impact on Tribal persons. Additionally, in June 2024, DEA transmitted a new draft telemedicine NPRM to the Office of Management and Budget (OMB) for review under Executive Order (E.O.) 12866. Since then, DEA has also attended several meetings with interested parties coordinated by OMB pursuant to E.O. 12866, which have provided interested parties with the opportunity to provide further views to OMB.

With the deadline of December 31, 2024, granted by the Second Temporary Rule quickly approaching, DEA, jointly with HHS, is now issuing a third temporary extension (Third Temporary Rule) to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions. This additional time will allow DEA (and also HHS, for rules that must be issued jointly) to promulgate proposed and final regulations that are consistent with public health and safety, and that also effectively mitigate the risk of possible diversion. Furthermore, this Third Temporary Rule will allow adequate time for providers to come into compliance with any new standards or safeguards eventually adopted in a final set of regulations. DEA remains committed to carefully evaluating the comments received in response to the prior NPRMs, as well as the information and perspectives presented at the Telemedicine Listening Sessions, the Tribal Consultations, and the E.O. 12866 meetings.

II. Legal Authority

The Ryan Haight Act amended the Controlled Substances Act (CSA) to generally require that the dispensing of controlled medications by means of the internet be predicated on a valid prescription involving at least one in-person medical evaluation.[7] At the same time, it also established excepted categories of telemedicine pursuant to which a practitioner may prescribe controlled medications for a patient despite never having evaluated that patient in person, provided that, among other things, such practice is in accordance with applicable Federal and State laws.[8]

One of these categories authorizes the Attorney General and the Secretary to jointly promulgate rules that would allow practitioners to prescribe medications for patients via telemedicine without having had an in-person evaluation when such telemedicine practice is in accordance with applicable Federal and State laws, uses an approved telecommunications system, and is ''conducted under . . . circumstances that the[y have] . . . determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.'' [9]

Pursuant to this authority, DEA, jointly with HHS, is hereby promulgating this Third Temporary Rule specifying certain circumstances under which practitioners may

[2] 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.*

[3] 88 FR 12875 (Mar. 1, 2023).

[4] 88 FR 12890 (Mar. 1, 2023).

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

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

[7] 21 U.S.C. 829(e).

[8] 21 U.S.C. 802(54)(A)–(G). The Attorney General has delegated his rulemaking authority under this provision to the Administrator of DEA via 28 CFR 0.100. The Secretary delegated his rulemaking authority under 21 U.S.C. 802(54)(G) to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration on May 4, 2023.

[9] 21 U.S.C. 802(54)(G).

prescribe controlled medications, for the time period described above, to patients whom the practitioner has never evaluated in person. This Third Temporary Rule, like the First and Second Temporary Rules, covers the portions of the March 2023 NPRMs related to extensions of the telemedicine flexibilities in place during the COVID–19 PHE, and it extends, through December 31, 2025, the telemedicine flexibilities that have been in place since March 2020 for prescribing controlled medications via the practice of telemedicine.

As noted previously, DEA and, for rules that must be issued jointly, HHS anticipate implementing a final set of regulations that are consistent with the public health and safety and that also effectively mitigate the risk of possible diversion. However, given the impending expiration of the flexibilities provided in the Second Temporary Rule and the additional consideration of the input received during the Telemedicine Listening Sessions, the Tribal Consultations, and the E.O. 12866 meetings, DEA, jointly with HHS, has elected to again extend those flexibilities to maintain access to care during a limited window of time as the agencies consider the appropriate pathway forward.

As explained further below, because this is an extension of limited duration of flexibilities that existed during the COVID–19 PHE, DEA and HHS have determined that this Third Temporary Rule is consistent ''with effective controls against diversion and otherwise consistent with the public health and safety'' as required under 21 U.S.C. 802(54)(G). Thus, DEA, jointly with HHS, is promulgating this temporary rule pursuant to 21 U.S.C. 802(54)(G).

HHS has advised DEA that no additional rulemaking by HHS is necessary as it pertains to the promulgation of these provisions pursuant to 21 U.S.C. 802(54)(G).

III. Purpose and Need for Regulatory Changes

The purpose of this rulemaking is to further extend, for a limited period of time, the telemedicine flexibilities that existed during the COVID–19 PHE in order to:

- Prevent a reduction in access to care for patients who do not yet have an existing telemedicine relationship with their practitioners pending promulgation of a final rule or rules addressing telemedicine more generally;
- For relationships established both during the COVID–19 PHE and those established during the prior extensions, prevent backlogs with respect to in-person medical evaluations in the months shortly before and after the expiration of the telemedicine flexibilities and ensure the availability of telemedicine for practitioners and patients who have come to rely on it;
- Address the urgent public health need for continued access to buprenorphine as medication for opioid use disorder in the context of the continuing opioid public health crisis;
- Allow patients, practitioners, pharmacists, service providers, and other stakeholders sufficient time to prepare for the implementation of any future regulations that apply to prescribing of controlled medications via telemedicine;
- Enable DEA to continue considering the presentations made at the Telemedicine Listening Sessions, the Tribal Consultations, and the E.O. 12866 meetings;
- Enable DEA, with HHS for rules that must be issued jointly, to conduct a thorough evaluation of regulatory alternatives in order to promulgate regulations that most effectively expand access to telemedicine encounters in a manner that is consistent with the public health and safety, while also effectively mitigating against the risk of possible diversion; and
- Avoid incentivizing the investment necessary to develop new telemedicine companies that might encourage or enable problematic prescribing practices by limiting the third extension of flexibilities to a short, time-limited period.

IV. Summary of Third Temporary Rule Changes

This Third Temporary Rule amends portions of 21 CFR 1307.41 and 42 CFR 12.1 through December 31, 2025.

Paragraph (a) is amended to state that the authorization granted in the amended paragraph (c) expires at the end of December 31, 2025, instead of December 31, 2024.

Current paragraph (b) is deleted.

Current paragraph (c) is redesignated as paragraph (b) and is amended to reflect that current paragraph (d) has been deleted and to extend the COVID–19 telemedicine prescribing flexibilities through December 31, 2025, provided all the conditions listed in current paragraph (e) are met.

Current paragraph (d) is deleted.

Current paragraph (e) is redesignated as paragraph (c) and is amended to reflect that current paragraphs (b) and (d) have been deleted.

DEA and HHS are using the revise and republish instruction to reflect these changes as parts of newly redesignated paragraph (c) are not changing.

V. Regulatory Analyses

Administrative Procedure Act

DEA and HHS are issuing this rule without prior notice and an opportunity to comment pursuant to the Administrative Procedure Act's (APA's) ''good cause'' exception. In certain circumstances, agencies may forgo notice-and-comment rulemaking when a rulemaking is published in the **Federal Register** and the agency ''for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [10]

As discussed earlier, DEA, jointly with HHS, is publishing this third temporary extension of certain exceptions to existing DEA regulations, granted in March 2020 as a result of the COVID–19 PHE, in order to prevent reduced access to care for patients that do not yet have an existing telemedicine relationship with their practitioners pending promulgation of a final rule or rules addressing telemedicine more generally. It would be impracticable for DEA and HHS to publish a notice of proposed rulemaking; await, review, and respond to new comments; and issue a rule in the time remaining before the second extension expires on December 31, 2024. Further, the reduction in access to care that patients would experience if the existing telemedicine flexibilities ended on December 31, 2024 would be contrary to the public interest, as it could lead to potential patient harm—due to an inability to access appropriate care—in some instances.

As noted above, in March 2023, DEA received 38,369 comments on two proposed rules regarding the flexibilities that would be extended by this rule. DEA considered those comments in publishing the First Temporary Rule and Second Temporary Rule.[11] Moreover, any final rule or rules that DEA and, for rules that must be issued jointly, HHS promulgate addressing telemedicine more generally would reflect viewpoints and information from comments received in response to the proposed rules, the Telemedicine Listening Sessions, the Tribal Consultations, the E.O. 12866 meetings, and any further comments that may be collected during additional rounds of public comment. Because DEA and, for rules that must be issued jointly, HHS continue to consider information that

[10] 5 U.S.C. 553(b)(B).

[11] 88 FR 30037 (May 10, 2023) and 88 FR 69879 (October 10, 2023).

was provided in those comments and presentations, and that may be provided in the near future before issuing a final set of regulations, further opportunity for public comment on these flexibilities at this time would serve little, if any, purpose.

For these reasons, each of which individually constitutes good cause, DEA, jointly with HHS, finds that notice and public comment on this rule are impracticable, unnecessary, and contrary to the public interest.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This Third Temporary Rule was developed in accordance with the principles of E.O. 12866, as amended by E.O. 14094 and E.O. 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866.

The economic, interagency, budgetary, legal, and policy implications of this temporary rule have been examined, and DEA has determined that it is a significant regulatory action under E.O. 12866, but not a Section 3(f)(1) significant regulatory action. Accordingly, this rule has been submitted to OMB for review.

DEA, jointly with HHS, is publishing this Third Temporary Rule to further extend certain exceptions DEA granted to its existing regulations in March 2020 as a result of the COVID–19 PHE in order to avoid a lapse of care for patients. The additional extension of the COVID–19 flexibilities until December 31, 2025, is necessary to thoroughly consider the presentations made at the Telemedicine Listening Sessions, the Tribal Consultations, the E.O. 12866 meetings, as well as the comments made to the proposed rules set forth in the March 2023 NPRMs.

Without this Third Temporary Rule, the COVID–19 PHE telemedicine flexibilities are scheduled to expire on December 31, 2024. This rule extends the expiration of those flexibilities through December 31, 2025. Because this rule does not create or remove any regulatory requirements, DEA and HHS estimate that there is no cost associated with this Third Temporary Rule. However, DEA and HHS believe this extension creates a benefit in the form of cost savings to prescribers and patients and reduced transfer payments to the Federal Government, similar to those described in the General Telemedicine NPRM. However, DEA is unable to quantify the cost savings and reduction in transfer payments.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This Third Temporary Rule does not have substantial direct effects on the Tribes, on the relationship between the national government and the Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes. However, DEA has determined that there is a reasonable basis that the March 2023 NPRMs may have Tribal implications, consistent with the definition in E.O. 13175. As such, DEA engaged in virtual consultations with numerous Tribal governments and organizations on June 13 and 27, 2024. DEA plans to incorporate the concerns raised during those virtual consultations when a final set of regulations is promulgated.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this Third Temporary Rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This Third Temporary Rule, as discussed above, merely extends for a limited time the status quo with respect to the current flexibilities allowed during the COVID–19 PHE, in order to avoid lapses in coverage for patients.

Without this Third Temporary Rule, the COVID–19 PHE telemedicine flexibilities would expire on December 31, 2024. While this Third Temporary Rule does not create or remove any regulatory requirements, this Third Temporary Rule extends the expiration of those flexibilities through December 31, 2025. DEA and HHS believe this extension creates a benefit in the form of cost savings to prescribers and patients and reduced transfer payments to the Federal Government.

In accordance with the RFA, DEA will be evaluating the impact on small entities at the time the final rule or rules are issued as part of these rulemakings.

Unfunded Mandates Reform Act of 1995

The estimated annual impact of this 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

This temporary rule is not a major rule as defined by Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA).[12] However, pursuant to the CRA, DEA is submitting a copy of this temporary rule to both Houses of Congress and to the Comptroller General.

Paperwork Reduction Act of 1995

This temporary rule will not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Also, this temporary rule does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or other organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

[12] 5 U.S.C. 804(2).

List of Subjects

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

Administrative practice and procedure, Drug traffic control, Prescription drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Administrative practice and procedure, Drug traffic control, Prescription drugs.

Drug Enforcement Administration

For the reasons set out above, the Drug Enforcement Administration amends 21 CFR part 1307 as follows:

PART 1307—MISCELLANEOUS

■ 1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

■ 2. Revise and republish § 1307.41 to read as follows:

§ 1307.41 Temporary extension of certain COVID–19 telemedicine flexibilities for prescription of controlled medications.

(a) This section is in effect until the end of the day December 31, 2025. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2025.

(b) During the period May 12, 2023, through December 31, 2025, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (c) of this section are met.

(c) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraph (b) of this section if all of the following conditions are met:

(1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);

(3) The practitioner is:

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

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

(4) The prescription is consistent with all other requirements of 21 CFR part 1306.

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

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

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

■ 2. Revise and republish § 12.1 to read as follows:

§ 12.1 Temporary extension of certain COVID–19 telemedicine flexibilities for prescription of controlled medications.

(a) This section is in effect until the end of the day December 31, 2025. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2025.

(b) During the period May 12, 2023, through December 31, 2025, a Drug Enforcement Administration (DEA)-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (c) of this section are met.

(c) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraph (b) of this section if all of the following conditions are met:

(1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);

(3) The practitioner is:

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

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

(4) The prescription is consistent with all other requirements of 21 CFR part 1306.

Signing Authority

This document of the Drug Enforcement Administration and the Department of Health and Human Services was signed on November 14, 2024, by DEA Administrator Anne Milgram and the HHS Assistant Secretary for Mental Health and Substance Use. Those documents with the original signatures and dates are 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.

[FR Doc. 2024–27018 Filed 11–15–24; 4:15 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SATS No. MT–040–FOR; Docket No. OSM–2023–0001; S1D1S SS08011000 SX064A000 231S180110; S2D2S SS08011000 SX064A000 23XS501520]

Montana Regulatory Program/ Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approving, in part.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving, in part, an amendment to the Montana regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). During the 2019 legislative session, Montana updated its Montana Strip and Underground Mine Reclamation Act codified in the Montana Code Annotated. Accordingly, Montana submitted this amendment to OSMRE on its own initiative. The amendment requires a permit applicant's compliance information to be updated and approved if a bankruptcy or reorganization results in