



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA-407]

RIN 1117-AB40 and 1117-AB78

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Second 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: On March 1, 2023 the Drug Enforcement Administration (DEA), in concert with the Department of Health and Human Services (HHS), promulgated two notices of proposed rulemakings (NPRMs) soliciting comments on proposals to allow for prescribing of controlled medications pursuant to the practice of telemedicine in instances where the prescribing practitioner has never conducted an in-person medical evaluation of the patient. On May 10, 2023, following initial review of the comments received, DEA, jointly with HHS, issued a temporary rule (First Temporary Rule) extending certain exceptions granted to existing DEA regulations in March 2020 as a result of the COVID–19 Public Health Emergency (COVID–19 PHE). These exceptions were granted in order to avoid lapses in care for patients. In particular, with respect to practitioner-patient relationships formed after the May 11, 2023, expiration of the COVID-19 PHE, the First Temporary Rule extended the temporary exceptions until November 11, 2023. In this second temporary rule, as DEA and HHS continue to consider revisions to the proposed rules set forth in the March 1, 2023 NPRMs and in light of Telemedicine Listening

Sessions that DEA hosted on September 12 and 13, 2023, DEA and HHS are further extending such exceptions to existing DEA regulations for new practitioner-patient relationships through December 31, 2024.

DATES: As of November 11, 2023, the end of the effective period for the temporary rule published at 88 FR 30037 on May 10, 2023, is extended from November 11, 2024, to December 31, 2024. This rule is effective November 11, 2023.

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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 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 Rule) and "Expansion of Induction of Buprenorphine via Telemedicine Encounter"⁴ (the Buprenorphine Rule) – 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

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](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf).

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](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).

– 35,454 comments on the General Telemedicine Rule and 2,915 comments on the Buprenorphine Rule.

On May 10, 2023 DEA, jointly with HHS (with the Substance Abuse and Mental Health Services Administration (SAMHSA) acting on behalf of HHS), issued the First Temporary Rule, 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 have been or will be established on or before November 11, 2023. In other words, under the First Temporary Rule, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have 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 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. DEA is carefully evaluating the information and perspectives presented at the Telemedicine Listening Sessions, as well as the comments received in response to the NPRMs, as DEA and HHS develop regulations providing access to the practice of telemedicine when consistent with public health and safety, and that also effectively mitigate the risk of possible diversion.

In light of the need to further evaluate the best course of action given the comments received in response to the NPRMs and the presentations at the Telemedicine Listening Sessions, DEA, jointly with HHS, is issuing this second temporary rule (“Second Temporary Rule”) extending the full set of telemedicine flexibilities regarding prescription of controlled

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

medications as were in place during the COVID–19 PHE, through December 31, 2024. This extension authorizes 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 is effectively subsumed by this Second Temporary Rule, which continues 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 this Second Temporary Rule, like the one before it, is to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions, as well as allowing adequate time for providers to come into compliance with any new standards or safeguards. DEA is working to promulgate new standards or safeguards by the fall of 2024.

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.⁶ 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.⁷

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

⁶ 21 U.S.C. 829(e).

⁷ 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.

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.”⁸

Pursuant to this authority, DEA, jointly with HHS, is hereby promulgating this Second Temporary Rule specifying certain circumstances under which practitioners may prescribe controlled medications, for the time period described above, to patients whom the practitioner has never evaluated in person. This Second Temporary Rule, like the First Temporary Rule, covers the portions of the NPRM related to extensions of the telemedicine flexibilities in place during the COVID-19 PHE, and it extends, through December 31, 2024, 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/or HHS anticipate implementing a final set of regulations providing access to the practice of telemedicine when consistent with 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 First Temporary Rule and the additional consideration of the input received during the Telemedicine Listening Sessions, DEA, jointly with HHS, has elected to again extend those flexibilities to maintain access to care during a limited window of time as they 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, and because there are legitimate concerns regarding patient access to care following the expiration the practitioner-patient relationship aspect of the First Temporary Rule on November 11, 2023, DEA and HHS have determined that this Second Temporary Rule is consistent “with effective controls against diversion and

⁸ 21 U.S.C. 802(54)(G).

otherwise consistent with the public health and safety” as required under 21 U.S.C. 802(54)(G).

DEA, jointly with HHS, is promulgating this temporary rule pursuant to 21 U.S.C. 802(54)(G).

HHS also 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 shortly after, 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 the initiation of 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 and potentially HHS to thoroughly consider the presentations made at the Telemedicine Listening Sessions;
- Enable DEA, jointly with HHS, 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 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 second extension of flexibilities to a short, time-limited period.

IV. Summary of Second Temporary Rule Changes

This Second Temporary Rule amends portions of 21 CFR 1307.41 and 42 CFR 12.1 through December 31, 2024.

Paragraph (a) is amended to state that the authorization granted in the amended paragraph (c) expires at the end of *December 31, 2024*, instead of November 11, 2023.

Paragraph (c) is amended to extend the COVID-19 telemedicine prescribing flexibilities from May 12, 2023 through *December 31, 2024*, provided all of the conditions listed in paragraph (e) are met.

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."⁹

As discussed earlier, DEA, jointly with HHS, is publishing this second temporary extension of certain exceptions granted to existing DEA regulations in March 2020 as a result of the COVID-19 PHE in order to prevent a reduction in 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 first extension expires on November

⁹ 5 U.S.C. 553(b)(B).

11, 2023. Further, the reduction in access to care that patients would experience if the existing telemedicine flexibilities ended on November 11, 2023 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, earlier this year DEA received 38,369 comments on two proposed rules regarding the flexibilities to be extended by this rule. DEA considered those comments in publishing the First Temporary Rule.¹⁰ Moreover, any final rule or rules that DEA and/or HHS promulgate addressing telemedicine more generally would reflect viewpoints and information from comments received in response to the proposed rules, the Telemedicine Listening Sessions, and any further comments that may be collected during additional rounds of public comment. Because the public has so recently had the opportunity to comment on these flexibilities and because DEA and HHS continue to consider information that was provided in those comments 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 Second Temporary Rule was developed in accordance with the principles of Executive Orders (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).

¹⁰ 88 FR 30037, 30039-30041 (May 10, 2023).

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 proposed 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 the Office of Management and Budget (OMB) for review.

DEA, jointly with HHS, is publishing this Second 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 until December 31, 2024, of the COVID-19 flexibilities is necessary to thoroughly consider the presentations made at the Telemedicine Listening Sessions, as well as the comments made to the proposed rules set forth in the NPRMs.

Without this Second Temporary Rule, COVID-19 PHE telemedicine flexibilities are scheduled to expire on November 11, 2023, with respect to practitioner-patient relationships established after that date. This rule extends the expiration of those flexibilities for new practitioner-patient relationships through December 31, 2024. Because this rule does not create or remove any regulatory requirements, DEA and HHS estimate that there is no cost associated with this Second Temporary Rule. However, DEA and HHS believe this extension creates a benefit in form of cost savings to prescribers and patients and reduced transfer payments to the Federal Government, similar to those described in the General Telemedicine Rule.

However, due to the nature of this rule, differing policies between the flexibilities being extended with this Second Temporary Rule and the flexibilities still proposed in the General Telemedicine Rule, and any additional policy that may be addressed in one or more final rules, DEA is unable to quantify the cost savings and reduction in transfer payments.

Executive Order 12988, Civil Justice Reform

The Second Temporary Rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This Second 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 Second 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this Second Temporary Rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This Second 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 Second Temporary Rule, COVID-19 PHE telemedicine flexibilities would expire on November 11, 2023, with respect to practitioner-patient relationships established after that date. While this Second Temporary Rule does not create or remove any regulatory requirements, this Second Temporary Rule extends the expiration of those flexibilities through December 31, 2024. DEA and HHS believe this extension create a benefit in 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.

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.

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).¹¹ However, pursuant to the CRA, DEA is submitting a copy of this temporary rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration and the Department of Health and Human Services was signed on October 4, 2023, by DEA Administrator Anne Milgram. Those documents with the original signatures and dates 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.

List of Subjects

¹¹ 5 U.S.C. 804(2).

21 CFR Part 1307

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

42 CFR Part 12

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

21 CFR Chapter II

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. Amend § 1307.41 by revising paragraphs (a) and (c) 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, 2024. The authorization granted in paragraph (c) of this section expires at the end of December 31, 2024.

* * * * *

(c) During the period May 12, 2023, through December 31, 2024, 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 (e) of this section are met.

* * * * *

42 CFR Chapter I

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. Amend § 12.1 by revising the section heading and paragraphs (a) and (c) 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, 2024. The authorization granted in paragraph (c) of this section expires at the end of December 31, 2024.

* * * * *

(c) During the period May 12, 2023, through December 31, 2024, 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 (e) of this section are met.

* * * * *

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

[FR Doc. 2023-22406 Filed: 10/6/2023 8:45 am; Publication Date: 10/10/2023]