



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA-407]

RIN 1117-AB40, 1117-AB78, and 1117-ZA07

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Fourth 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) jointly with the Department of Health and Human Services (HHS) is issuing a fourth extension of telemedicine flexibilities for the prescribing of controlled medications through December 31, 2026.

DATES: This rule is effective January 1, 2026 through December 31, 2026.

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

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

Under the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (the *Ryan Haight Act*), a prescribing practitioner – subject to certain exceptions – may remotely prescribe

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controlled substances to a patient (colloquially referred to as “telemedicine”)¹ only after conducting at least one in-person medical evaluation of that patient in the course of their practitioner-patient relationship. Once a practitioner has conducted at least one in-person medical evaluation of a particular patient, the specific requirements of the *Ryan Haight Act* related to remote prescribing of controlled substances no longer apply to that specific practitioner-patient relationship. This permits the practitioner to remotely prescribe controlled substances to that patient indefinitely, regardless of how much time has passed since the initial in-person medical evaluation or whether that evaluation was for a separate medical concern, so long as such prescriptions are issued for a legitimate medical purpose while acting in the usual course of professional practice and in compliance with other relevant federal and state statutes and regulations. Regardless of whether a practitioner-patient relationship is subject to the specific remote prescribing rules of the *Ryan Haight Act*, however, the practitioner must still comply with all other applicable DEA regulations.

In response to the COVID-19 Public Health Emergency (COVID-19 PHE), as declared by the Secretary of HHS (the “Secretary”) on January 31, 2020, pursuant to the authority under section 319 of the *Public Health Service Act* (42 U.S.C. 247), DEA granted temporary exceptions to the remote prescribing requirements of the *Ryan Haight Act* and DEA’s implementing regulations under the authority granted by 21 U.S.C. 802(54)(D). These exceptions, often referred to as the “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

¹ It is important to distinguish the colloquial understanding of "telemedicine" in this context from its statutory definition in the *Ryan Haight Act*, 21 U.S.C. 802(54). The statutory term refers to the remote practice of medicine, via certain telecommunication systems, where a practitioner (other than a pharmacist) prescribes a controlled substance to a patient whom the practitioner has never conducted an in-person medical evaluation. This is permissible only under one of seven specific, congressionally approved circumstances as detailed in 21 U.S.C. 802(54)(A)-(G).

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);² 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).³

The 2023 Telemedicine NPRMs

On March 1, 2023, DEA, jointly 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”⁴ (the “General Telemedicine NPRM”) and “Expansion of Induction of Buprenorphine via Telemedicine Encounter”⁵ (the “Buprenorphine NPRM”) – which proposed to expand patient access to prescriptions for controlled medications via telemedicine encounters relative to the pre-COVID-19 Public Health Emergency (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

² 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).

³ 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).

⁴ 88 FR 12875 (Mar. 1, 2023).

⁵ 88 FR 12890 (Mar. 1, 2023).

Telemedicine NPRM and 2,915 comments on the Buprenorphine NPRM. Many of those comments requested changes of varying degrees.

The First Temporary 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 extension (the “First Temporary Rule”), which extended the full set of the telemedicine flexibilities that had been in place under the COVID-19 PHE, through November 11, 2023.⁶ The First Temporary Rule also provided a one-year grace period, through November 11, 2024, to any practitioner-patient 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 remotely established a practitioner-patient relationship by 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.

The Second Temporary Rule

On August 7, 2023, DEA announced that it would host Telemedicine Listening Sessions on September 12 and 13, 2023, for the purpose of obtaining additional input on the practice of telemedicine 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 (the “Second Temporary Rule”) again extending the full set of telemedicine flexibilities through December 31, 2024.⁷ The Second Temporary Rule, like the preceding extension, authorized all DEA-registered practitioners to remotely prescribe Schedules II-V controlled substances through December 31, 2024, without an in-person medical evaluation. This rule superseded the grace period from the First Temporary Rule by applying the

⁶ Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 30037 (May 10, 2023).

⁷ Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 FR 69879 (October 10, 2023).

telemedicine flexibilities to all practitioner-patient relationships until the end of 2024, not just those established by November 11, 2023.

Third Temporary Rule

On November 19, 2024, DEA, jointly with SAMHSA/HHS, issued a third temporary extension (the “Third Temporary Rule”) extending the full set of telemedicine flexibilities through December 31, 2025.⁸ Like the two preceding extensions, the Third Temporary Rule authorized all DEA-registered practitioners to remotely prescribe Schedules II-V controlled substances through December 31, 2025, so as to prevent lapses in patient care by allowing DEA more time to develop permanent regulations for prescribing controlled substances via telemedicine. The extension ensured and provided time for stakeholders to prepare for new rules.

The Special Registration for Telemedicine NPRM

On January 17, 2025, DEA published the “Special Registrations for Telemedicine and Limited State Telemedicine Registrations” Notice of Proposed Rulemaking (NPRM), which proposed a framework for a Special Registration for Telemedicine, pursuant to 21 U.S.C. 802(54)(E), authorizing physicians and mid-level practitioners with the Special Registration to prescribe controlled substances via audio-video telemedicine (and in limited instances, audio-only telemedicine) without having ever conducted an in-person medical evaluation of the patient, provided they adhere to the proposed prescription, recordkeeping, and reporting requirements. The NPRM further proposed the registration of certain direct-to-consumer (DTC) telemedicine platforms that function as intermediaries and are integral to the practitioner-patient relationship.⁹ In response to the Special Registration NPRM, DEA received over 6,475 comments.

Fourth Temporary Rule

⁸ Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FR 91253 (November 19, 2024).

⁹ See Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 FR 6541 (January 17, 2025).

With the December 31, 2025 expiration date of the Third Temporary Rule quickly approaching, **DEA**, jointly with HHS, is now issuing a fourth temporary extension (“Fourth Temporary Rule”) to prevent what has been commonly referred to as the “telemedicine cliff:” the reinstatement of the pre-pandemic restrictions imposed by the CSA, which could potentially and abruptly limit patients’ access to care until promulgation of a final set of regulations. Collaterally, the extension will provide time for **DEA** to promulgate a final set of regulations, to ensure a smooth transition for patients and providers that have come to rely on the availability of telemedicine to prescribe controlled substances to patients for whom they have never had an in-person medical evaluation, and allow sufficient time for providers to come into compliance with any new **DEA registration, record keeping, or security requirements** eventually adopted in a final set of regulations.

II. LEGAL AUTHORITY

The **Ryan Haight Act** amended the **Controlled Substances Act** (CSA) to generally require that the dispensing of controlled substances by means of the *Internet* is predicated on a valid prescription involving at least one in-person medical evaluation.¹⁰ At the same time, **it also established seven excepted categories of telemedicine pursuant to which a practitioner may prescribe controlled substances for a patient despite having never evaluated that patient in-person, provided that, among other things, such practice is in accordance with applicable Federal and State laws.**¹¹ 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 medical 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] . . .

¹⁰ 21 U.S.C. 829(e).

¹¹ 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.

determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.”¹² Pursuant to this authority, **DEA, jointly with HHS, is hereby promulgating this Fourth Temporary Rule specifying certain circumstances under which practitioners may prescribe controlled substances, for the time period described above, to patients whom the practitioner has never evaluated in person.**

This Fourth Temporary Rule, like the first three 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, 2026, the telemedicine flexibilities that have been in place since March 2020 for prescribing controlled substances via the practice of telemedicine. Due to the impending expiration of the flexibilities provided in the Third Temporary Rule, DEA, jointly with HHS, has elected to again extend those flexibilities to maintain access to care during a limited window of time. As explained further below, because this is an extension of limited duration of the telemedicine flexibilities that existed during the COVID-19 PHE, DEA and HHS have determined that this Fourth 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). 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 disruption of care and other problems that would arise should the Third Extension expire before DEA can finalize, and stakeholders can implement changes to comply with, regulations that balance access to care with the necessary safeguards against diversion.

The Impending Telemedicine Cliff

¹² 21 U.S.C. 802(54)(G).

DEA has received numerous communications from patients, providers, and other stakeholders warning that expiration of the current telemedicine flexibilities, without further regulation, could potentially and abruptly limit patients' access to care until promulgation of a final set of regulations. The abrupt end to the ability to prescribe controlled substances to patients who have not had an in-person medical evaluation is often referred to as the "telemedicine cliff." The potential harms are widespread. To put it into context, one stakeholder summarized unpublished data reviewed by *Epic*, Johns Hopkins, and Stanford: of an estimated 44.6 million prescriptions for controlled substances prescribed across 258 organizations in 2024, more than 7 million, approximately 16 percent, were issued without a prior in-person medical evaluation.

We need only examine the recent sunsetting of COVID-era, congressionally-granted Medicare telemedicine flexibilities to observe the negative impact a telemedicine cliff has on patients' access to care when no permanent laws or regulations are in place. The effects of the abrupt cessation of Medicare's telemedicine flexibilities on September 30, 2025 were quickly seen in the days following their expiration. In an analysis of national data of electronic medical records, there was a 24 percent reduction of fee-for-service telemedicine visits in the first 17 days following the September 30, 2025 expiration of Medicare's telemedicine flexibilities. In a wide range of states, including Florida, Louisiana, Washington, Tennessee, Maryland, Oklahoma, and New York, the reduction was nearly 40 percent or more.¹³ Until Congress extended Medicare's telemedicine flexibilities,¹⁴ beneficiaries and providers faced disruption in access to care and loss of timely critical services for patients.¹⁵ Telemedicine removes barriers to

¹³ Ateev Mehrotra, Michael L. Barnett, Andrew Wilcock, and Jared Perkins, *Medicare Telehealth Flexibilities at Risk with Government Shutdown*, Brown University School of Public Health, Center for Advancing Health Policy Through Research (CAHPR), https://cahpr.sph.brown.edu/sites/default/files/documents/Policy%20Briefs/2025/Research%20Brief_%20Medicare%20Telehealth%20Flexibilities%20at%20Risk%20of%20Expiration%20%281%29.pdf (last visited Dec. 2, 2025).

¹⁴ Julia Ivanova, PhD, MA, Senate Passes CR Extending Medicare Telehealth Flexibilities Through January 2026, *Telehealth.org*, Nov. 11, 2025, <https://telehealth.org/blog/senate-passes-cr-extending-medicare-telehealth-f flexibilities-through-january-2026/>.

¹⁵ Mehrotra, *supra* note 13.

care for patients with transportation and mobility challenges.¹⁶ The end of the telemedicine flexibilities, without further regulation, would reimpose those barriers, which could lead to lack of access to lifesaving care for some patients.

Purpose of Regulatory Changes

This extension will postpone the telemedicine cliff and provide the following benefits:

- **Prevent disruption of care:** Abruptly ending the current telemedicine flexibilities could significantly disrupt access to care for patients who rely on telemedicine, particularly those in rural or underserved areas, the elderly, or individuals with mobility limitations as well as for patients who do not yet have an existing telemedicine relationship with their practitioners;
- **Prevent a backlog of patients needing in-person appointments:** 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;
- **Allow for a smooth transition:** Extending the flexibilities provides the DEA with additional time to finalize and implement effective regulations that balance access to care with the necessary safeguards against diversion;
- **Provide adequate time for implementation:** Allow patients, practitioners, pharmacists, service providers, and other stakeholders sufficient time to prepare for the implementation of future regulations that would apply to the prescribing of controlled substances via telemedicine in cases where the prescribing provider has never conducted an in-person medical evaluation of the patient.

IV. SUMMARY OF FOURTH TEMPORARY RULE CHANGES

This Fourth Temporary Rule amends portions of 21 CFR 1307.41 and 42 CFR 12.1 through December 31, 2026.

¹⁶ Mehrotra, *supra* note 13.

Paragraph (a) is amended to state that the authorization granted in paragraph (b) expires at the end of December 31, 2026, instead of December 31, 2025.

Paragraph (b) is amended to state that the authorization granted in paragraph (b) expires at the end of December 31, 2026, instead of December 31, 2025.

V. INTERACTION BETWEEN THIS RULEMAKING AND THE TWO FINAL RULES

PUBLISHED ON JANUARY 17, 2025

On January 17, 2025, DEA and HHS published two final rules titled “Expansion of Buprenorphine Treatment via Telemedicine Encounter” (90 FR 6504, adding 21 CFR 1306.51) and “Continuity of Care via Telemedicine for Veterans Affairs Patients” (90 FR 6523, adding 21 CFR 1306.52), collectively the “Two Final Rules.” On February 19, 2025, DEA and HHS delayed the effective date of these rules until March 21, 2025 (90 FR 9841). On March 24, 2025, DEA and HHS, responding to comments, further delayed the effective date of the Two Final Rules until December 31, 2025 (90 FR 13410). The Two Final Rules will go into effect on December 31, 2025 (90 FR 13410).

Together, the Two Final Rules and this temporary rule describe three separate and distinct sets of authorities for telemedicine prescribing, and each imposes a unique set of requirements with respect to prescribing done pursuant to it. A prescribing practitioner may issue a prescription via telemedicine under the temporary rule even if he/she could also issue that prescription under one or both of the Two Final Rules, provided all the requirements in 21 CFR 1307.41(c)/42 CFR 12.1(c) of this temporary rule are met. Only if a prescription is issued pursuant to one of the Two Final Rules do the requirements of the applicable rule need to be met. Thus, even registrants covered by one or both of the Two Final Rules may continue to utilize the telemedicine flexibilities under the fourth temporary rule, which imposes fewer requirements than the Two Final Rules.

VI. REGULATORY ANALYSES

Administrative Procedure Act

DEA and HHS are issuing this temporary rule without prior notice and an opportunity to comment, within less than 30 days prior to its effective date of January 1, 2026, pursuant to the “good cause” exceptions in the *Administrative Procedure Act* (APA).¹⁷ Agencies may forgo the notice-and-comment and 30-day delayed effective date requirements under the APA 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.”¹⁸

As discussed earlier, DEA, jointly with HHS, is publishing this fourth 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 the impending *telemedicine cliff*: the abrupt reduction of access to care – pending promulgation of a final rule – for patients that do not have an existing provider-patient relationship with their provider that is predicated on a prior in-person medical evaluation. It would be impracticable and contrary to the public interest for DEA and HHS to publish a notice of proposed rulemaking; await, review, and respond to new comments; and issue a final rule in the time remaining before the third extension expires on December 31, 2025. As discussed more fully above, patients would experience a reduction in access to care if the existing telemedicine flexibilities ended on December 31, 2025, which could lead to potential harm – due to an inability to access timely care and potentially lifesaving medication – for some patients. The abrupt 41-day cessation of Medicare’s telemedicine flexibilities on September 30, 2025, previewed the negative impact a *telemedicine cliff* has on patients’ access to care when no permanent laws or regulations are in place when such flexibilities expire.

For the reasons established above, DEA, jointly with HHS, finds that notice and public comment on this rule are impracticable and contrary to the public interest and that there is good cause to make it effective less than 30 days after its publication.

¹⁷ 5 U.S.C. 553(b)(B); 5 U.S.C. 553(d)(3). The 30-day delayed effective date requirement is also excepted pursuant to 5 U.S.C. 553(d)(1) as this rulemaking grants an exemption from the requirements of the *Ryan Haight Act*.

¹⁸ 5 U.S.C. 553(b)(B).

Executive Orders 12866, 13563, and 14192 (Regulatory Review)

DEA has determined that this rulemaking is a “significant regulatory action” under section 3(f) of Executive Order (E.O.) 12866, *Regulatory Planning and Review*, but it is not a section 3(f)(1) significant action. Accordingly, this temporary rule has been submitted to the Office of Management and Budget (OMB) for review and has been drafted and reviewed in accordance with E.O. 12866, *Regulatory Planning and Review*, E.O. 13563, *Improving Regulation and Regulatory Review*, and E.O. 14192, *Unleashing Prosperity Through Deregulation*. This temporary rule is a “deregulatory action” under an E.O. 14192, because it is final and has a total cost less than zero. The net present value of the estimated cost savings is \$17.2 million.¹⁹

DEA, jointly with HHS, is publishing this Fourth Temporary Rule to further extend certain exceptions DEA granted to its existing regulations in March 2020 as a result of the COVID-19 PHE to avoid a lapse of care for patients. The additional extension of the COVID-19 flexibilities until December 31, 2026 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 Special Registration for Telemedicine NPRM.

Without this Fourth Temporary Rule, the COVID-19 PHE telemedicine flexibilities are scheduled to expire on December 31, 2025. This rule extends the expiration of those flexibilities through December 31, 2026. Because this rule does not create or remove any regulatory requirements, DEA and HHS estimate that there is no cost associated with this Fourth Temporary Rule. However, DEA and HHS believe this extension creates a benefit in the form of cost savings to patients.

¹⁹ On January 17, 2025, DEA published the “Special Registrations for Telemedicine and Limited State Telemedicine Registrations” NPRM [90 FR 6541], which proposed a framework for a Special Registration for Telemedicine, pursuant to 21 U.S.C. 802(54)(E), authorizing practitioners and mid-level practitioners with the Special Registration to prescribe controlled substances via audio-video telemedicine (and in limited instances, audio-only telemedicine) without having ever conducted an in-person medical evaluation of the patient, provided they adhere to the proposed prescription, recordkeeping, and reporting requirements. DEA believes the patient cost savings quantified in the NPRM also applies to this temporary extension. From the NPRM, the estimated patient cost savings in the first year is \$18.4 million, with net present value of \$17.2 million at a seven percent discount rate.

Executive Order 12988, Civil Justice Reform

The Fourth 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 Fourth 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 Fourth 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 Special Registration for Telemedicine NPRM may have Tribal implications, consistent with the definition in E.O. 13175. As such, DEA intends to hold further virtual consultations with Tribal governments and organizations and address any concerns raised into the final set of Special Registration for Telemedicine regulations.

Regulatory Flexibility Act

The Administrator, in accordance with the *Regulatory Flexibility Act* (5 U.S.C. 601–612) (RFA), has reviewed this Fourth Temporary Rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This Fourth 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 Fourth Temporary Rule, the COVID-19 PHE telemedicine flexibilities would expire on December 31, 2025. While this Fourth Temporary Rule does not create or remove any regulatory requirements, this Fourth Temporary Rule extends the expiration of those flexibilities through December 31, 2026. 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.

Executive Order 14267, Reducing Anti-Competitive Regulatory Barriers

The temporary rule does not reduce competition, entrepreneurship, and innovation.

Executive Order 14294, Overcriminalization of Federal Regulations

Executive Order 14294 specifies that all NPRMs and final rules published in the Federal Register, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the *mens rea* requirement for each element of the offense. This temporary final rule does not involve a criminal regulatory offense and thus E.O. 14294 does not apply.

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).²⁰ 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.

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:

²⁰ 5 U.S.C. 804(2).

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, 2026. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2026.

(b) During the period May 12, 2023, through December 31, 2026, 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

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

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

4. 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, 2026. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2026.
- (b) During the period May 12, 2023, through December 31, 2026, 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 was signed on December 15, 2025, by Administrator Terrance C. Cole. 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.

Gregory Aul,
Federal Register Liaison Officer,
Drug Enforcement Administration.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services

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