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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA-948; DEA-407VA]

RIN 1117-AB78; 1117-AB40; 1117-AB88

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients

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

ACTION: Final rule.

SUMMARY: In the January 17, 2025, issue of the *Federal Register*, the Drug Enforcement Administration and the Department of Health and Human Services published two final rules related to the practice of telemedicine, titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients." These final rules were originally scheduled to become final on February 18, 2025. In accordance with the Presidential Memorandum of January 20, 2025, titled "Regulatory Freeze Pending Review," the Drug Enforcement Administration and the Department of Health and Human Services delayed the effective dates of these two final rules to March 21, 2025, by issuing a final rule; delay of effective dates and request for comments in the February 19, 2025, issue of the *Federal Register*. The Drug Enforcement Administration received 32 comments in response to the request for public comments regarding the delayed effective date. Considering these comments, the Department of Justice wishes to further postpone the effective dates for the purpose of further reviewing any questions of fact, law, and policy that the rules may raise.

Therefore, the Drug Enforcement Administration and the Department of Health and Human Services will delay the effective date of the two final rules titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients" to December 31, 2025.

DATES: As of March 20, 2025, the effective dates of the final rules amending 21 CFR part 1306 and 42 CFR part 12 published in the *Federal Register* on January 17, 2025, at 90 FR 6504 and 90 FR 6523, respectively, are effective December 31, 2025.

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

SUPPLEMENTARY INFORMATION:

Discussion

On January 17, 2025, the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) published two final rules titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" (90 FR 6504) and "Continuity of Care via Telemedicine for Veterans Affairs Patients" (90 FR 6523). These rules, respectively, amended their regulations to expand the circumstances under which: 1) practitioners registered by DEA are authorized to prescribe schedule III-V controlled substances approved by the Food and Drug Administration for the treatment of opioid use disorder via a telemedicine encounter, including an audio-only telemedicine encounter[1] and 2) Department of Veterans Affairs practitioners acting within the scope of their Veterans Affairs employment are authorized to prescribe schedule II-V controlled substances via telemedicine to a Veterans Affairs patient with whom they have not conducted an in-person medical evaluation, if another Veterans Affairs

[1] 90 FR 6504 (Jan. 17, 2025).

practitioner has, at any time, previously conducted an in-person medical evaluation of the Veterans Affairs patient, subject to certain conditions.[2]

On January 20, 2025, the President of the United States issued a memorandum to all executive departments and agencies titled "Regulatory Freeze Pending Review" (the Freeze Memo).[3] Paragraph 3 of the Freeze Memo ordered agencies to "consider postponing for 60 days from the date of this memorandum the effective date for any rules that have been published in the *Federal Register,* or any rules that have been issued in any manner but have not taken effect, for the purpose of reviewing any questions of fact, law, and policy that the rules may raise." The purpose of this delay was "to allow interested parties to provide comments about issues of fact, law, and policy raised by the rules postponed under this memorandum, and consider reevaluating pending petitions involving such rules." In accordance with the Freeze Memo, DEA and HHS published a final rule; delay of effective dates and request for comment in the February 19, 2025, issue of the *Federal Register*.[4]

In the preamble to that rule, DEA explained that the "new effective dates will not delay or limit the ability of the practitioners covered by these two rules to prescribe via telemedicine, because the 'Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications,' which has been in effect since May 10, 2023, permits practitioners to prescribe via telemedicine through December 31, 2025."[5] In addition, this delay allowed Department of Justice (DOJ) and HHS officials further opportunity to review any potential questions of fact, law, and policy raised by those two final rules.

DEA solicited public comment regarding the delayed effective dates of these two final rules. DEA also solicited public comment on whether there may be a need for their effective dates to be extended beyond the new effective date of March 21, 2025, and to address issues of

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[2] 90 FR 6523 (Jan. 17, 2025).
[3] 90 FR 8249 (Jan. 28, 2025).
[4] 90 FR 9841 (Feb. 19, 2025).
[5] 90 FR 9841, 98842 (citing 88 FR 30037 (May 10, 2023), as extended by 88 FR 30037 (May 10, 2023) and 89 FR 91253 (Nov. 19, 2024)).

fact, law, and policy raised by these rules, for consideration by officials of the two agencies. DEA received a total of 32 comments. Of the 32 comments received, three commenters specifically requested a further delay in the effective date of the two final rules and 13 commenters requested that the final rules become effective as soon as possible. Since a new effective date will not delay or limit the ability of the practitioners covered by these two rules to prescribe via telemedicine, because the 'Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications permits practitioners to prescribe via telemedicine through December 31, 2025, and to allow DOJ additional time to further review any questions of fact, law, and policy that the rules may raise, DEA and HHS will further delay the effective date of the two final rules published in the January 17, 2025, issue of the *Federal Register*, titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter"[6] and "Continuity of Care via Telemedicine for Veterans Affairs Patients"[7] to December 31, 2025. This document finalizes the delayed effective date of these final rules to December 31, 2025.

Comments Received

DEA received 32 comments in response to the request for comments regarding the effective date of the two final rules in the January 17, 2025, issue of the *Federal Register*, titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter"[8] and "Continuity of Care via Telemedicine for Veterans Affairs Patients"[9]. Of these comments, 13 commenters requested to finalize the effective date of the two final rules as soon as possible, which was scheduled to be March 21, 2025.

Three commenters explicitly requested that the effective date be delayed beyond March 21, 2025; however, these comments did not provide an alternative effective date for these two final rules. Four commenters generally agreed with the final rules without specifying a

[6] 90 FR 6504 (Jan. 17, 2025).
[7] 90 FR 6523 (Jan. 17, 2025).
[8] 90 FR 6504 (Jan. 17, 2025).
[9] 90 FR 6523 (Jan. 17, 2025).

preference with respect to their effective dates. Eleven commenters expressed concerns unrelated to the effective date. One commenter provided general comments but did not respond with respect to the delayed effective date.

Based on the foregoing reasons, DEA and HHS are further delaying the effective date of the two final rules published in the January 17, 2025, issue of the *Federal Register* titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter"[10] and "Continuity of Care via Telemedicine for Veterans Affairs Patients"[11] to December 31, 2025.

Regulatory Analyses

Change to the effective date of these final rules does not affect the economic impact calculated in the final rules. Per Office of Management and Budget (OMB) Circular A-4, analysis is conducted on a time frame which includes all important benefits and costs, and such time frame generally begins at the point when the final rule is expected to begin to have effects.[12] No portion of the analysis conducted in these final rules was dependent on the original effective date, and therefore the change in the time frame does not change any part of the analysis.

Executive Orders 12866 and 13563 (Regulatory Review)

The change to the effective date has no change on the analysis conducted in this section in these two rules. This document merely effectuates a limited delay in the effective dates of two rules, previously scheduled to take effect March 21, 2025. There is no change to the substance of these two final rules.

Regulatory Flexibility Act

The change to the effective date has no change on the analysis conducted in this section in the final rules.

Paperwork Reduction Act of 1995

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[10] 90 FR 6504 (Jan. 17, 2025).
[11] 90 FR 6523 (Jan. 17, 2025).
[12] OMB Circular A-4, section 3(b): "The time frame for your analysis should include a period before and after the date of compliance that is long enough to encompass all the important benefits and costs likely to result from the regulation. A logical beginning point for your stream of estimates would be the point in which the regulation will begin to have effects…"

The change to the effective date has no change on the analysis conducted in this section in the final rules.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

DEA and HHS are committed to the principles of collaboration and consultation with Tribal governments, as demonstrated through its plans to conduct the appropriate Executive Order 13175 Tribal consultations and recognizes the significance of these consultations and their role in shaping regulations that impact Tribal communities. Relevant issues regarding Tribal Consultation were discussed in the two final rules published on January 17, 2025.

Unfunded Mandates Reform Act of 1995

The estimated annual impact of this notice is minimal. Thus, DEA and HHS have 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.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 19, 2025, by Acting Administrator Derek Maltz. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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

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