

# Rules and Regulations

Federal Register

Vol. 90, No. 32

Wednesday, February 19, 2025

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

## 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; delay of effective dates and request for comments.

**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 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 are delaying the effective dates of these two final rules to March 21, 2025, and are soliciting public comments specifically regarding this delayed effective date.

**DATES:**

*Effective date delay:* As of February 14, 2025, the effective date of the two

final rules amending 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 delayed to March 21, 2025.

*Comment date:* Electronic comments must be submitted, and written comments must be postmarked, on or before February 28, 2025.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-948” or “Docket No. DEA-407VA” on all correspondence, including any attachments.

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type comments directly into the comment field on the web page or to attach a file containing comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment generated by <https://www.regulations.gov>. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper comments:* Paper comments that duplicate the electronic submission are discouraged. Should you wish to mail a paper comment *in lieu of* submitting a comment electronically, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. Hand-delivered comments will not be accepted.

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

**SUPPLEMENTARY INFORMATION:**

### Posting of Public Comments

Please note that all comments received, including attachments and other supporting materials, in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) generally will make all comments available for public inspection online at <https://www.regulations.gov>. The Freedom of Information Act applies to all comments received. Confidential information or personal identifying information (PII), such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

Comments with confidential information, which should not be made publicly available, should be submitted as written/paper submissions. Two written/paper copies should be submitted. One copy will include the confidential information with a heading or cover sheet that states “CONTAINS CONFIDENTIAL INFORMATION.” DEA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy should have the claimed confidential information redacted/blacked out. DEA will make this copy available for public inspection online at <https://www.regulations.gov>. Other information, such as name and contact information, that should not be made available, may be included on the cover sheet but not in the body of the comment, and must be clearly identified as “confidential.” Any information clearly identified as “confidential” will not be disclosed except as required by law.

### Discussion

On January 17, 2025, 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<sup>1</sup> 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 VA practitioner has, at any time, previously conducted an in-person medical evaluation of the VA patient, subject to certain conditions.<sup>2</sup>

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).<sup>3</sup> 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 is “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 addition, this delay will allow Department of Justice and Department of Health and Human Services officials further opportunity to review any potential questions of fact, law, and policy raised by those two final rules.

This document extends the effective date of the final rules in the January 17, 2025, issue of the **Federal Register**, titled “Expansion of Buprenorphine Treatment via Telemedicine Encounter”<sup>4</sup> and “Continuity of Care via Telemedicine for Veterans Affairs Patients,”<sup>5</sup> from February 18, 2025, to March 21, 2025, consistent with paragraph 3 of the January 20, 2025, Freeze Memo. These 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.<sup>6</sup>

DEA is soliciting comments on the extension of the effective date of these two final rules to March 21, 2025. DEA also is soliciting comments on whether there may be a need for their effective dates to be extended beyond that date, and address issues of fact, law, and policy raised by these rules, for consideration by officials of the two agencies.

### 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.<sup>7</sup> 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 is not expected to change any part of the analysis.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). In addition, the agencies find good cause that the usual notice and comment procedures are impracticable because the very limited time available for action to delay the February 18th effective dates forecloses the opportunity for a full notice and comment process. 5 U.S.C. 553(b)(B). Furthermore, because this rule is procedural rather than substantive, the usual requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable. DEA also finds good cause to provide an immediate effective date for this rule, because the temporary delay in the effective date until March 21, 2025, is necessary to give Agency officials the opportunity for further review and consideration of the new regulation, consistent with the memorandum described previously. DEA and HHS believe that affected entities need to be informed as soon as possible of the extension and its length

to plan and adjust their implementation process accordingly.

Nonetheless, DEA and HHS are soliciting comments on the delay of the effective date to March 21, 2025.

### *Executive Orders 12866 and 13563 (Regulatory Review)*

The change to the effective date is expected to have 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 February 18, 2025. There is no change to the substance of these two final rules.

### *Regulatory Flexibility Act*

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

### *Paperwork Reduction Act of 1995*

The change to the effective date is expected to have 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.

<sup>6</sup> 88 FR 30037 (May 10, 2023), as extended by 88 FR 30037 (May 10, 2023) and 89 FR 91253 (Nov. 19, 2024).

<sup>7</sup> 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 . . .”

<sup>1</sup> 90 FR 6504 (Jan. 17, 2025).

<sup>2</sup> 90 FR 6523 (Jan. 17, 2025).

<sup>3</sup> 90 FR 8249 (Jan. 28, 2025).

<sup>4</sup> 90 FR 6504 (Jan. 17, 2025).

<sup>5</sup> 90 FR 6523 (Jan. 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 February 12, 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.*

**Dorothy A. Fink,**

*Acting Secretary, Department of Health and Human Services.*

[FR Doc. 2025-02793 Filed 2-14-25; 8:45 am]

**BILLING CODE 4410-09-P**

**POSTAL SERVICE****39 CFR Parts 111 and 211****Cremated Remains Packaging Requirements**

**AGENCY:** Postal Service™.

**ACTION:** Final rule.

**SUMMARY:** The Postal Service is amending Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52) by requiring mailers to solely use the Cremated Remains shipping supplies provided by the Postal Service when mailing human or animal cremated remains, also referred to as cremains or ashes, domestically or internationally.

**DATES:** Effective March 1, 2025.

**FOR FURTHER INFORMATION CONTACT:** Dale Kennedy, (202) 268-6592, or Jennifer Cox, (202) 268-2108.

**SUPPLEMENTARY INFORMATION:** The Postal Service hereby amends Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52 or Publication 52), with the provisions set forth herein. While not codified in title 39 of the Code of Federal Regulations (CFR), Publication 52 is a regulation of the Postal Service, and changes to it may be published in the **Federal Register**. 39 CFR 211.2(a)(2). Moreover, Publication 52 is incorporated by reference into *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM) section 601.8.1, which is incorporated by reference, in turn, into the Code of Federal Regulations. Publication 52 is publicly available, in a read-only format, via the Postal Explorer® website at <https://pe.usps.com>. In addition, links to Postal Explorer are provided on the landing page of *USPS.com*, the Postal Service's primary customer-facing website, and on *Postal Pro*, an online informational source available to postal customers.

**Summary of New Measures**

The Postal Service will require mailers shipping human or animal cremated remains in any state (*e.g.*, ashes, keepsakes and jewelry) to be shipped in the Cremated Remains packaging supplied by the Postal Service. Previously, mailers were permitted to use any box if it was marked with Label 139—*Cremated Remains*.

The Postal Service understands the mailing of cremated remains is a sensitive matter and believes this will improve visibility and enhance handling methods throughout processing and transportation.

**Response to Comments**

In response to the proposed rule (89 FR 93238, November 26, 2024), the Postal Service received one favorable formal response to the changes to Pub 52.

**Kevin Rayburn,**

*Attorney, Ethics & Legal Compliance.*

The Postal Service adopts the following changes to Publication 52, *Hazardous, Restricted, and Perishable Mail*, incorporated by reference into *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM), section 601.8.1, which is further incorporated by reference in the Code of Federal Regulations. 39 CFR 111.1, 111.3. Publication 52 is also a regulation of the Postal Service, changes to which may be published in the **Federal Register**. 39 CFR 211.2(a). Accordingly, for the reasons stated in the preamble,

the Postal Service amends Publication 52 as follows:

**Publication 52, Hazardous, Restricted and Perishable Mail**

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**4 Restricted Matter**

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**45 Other Restricted Materials**

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**451.22 Cremated Remains**

*[Revise section as follows:]*

Human or animal cremated remains in any state (*e.g.*, ashes, keepsakes and jewelry) are permitted for mailing as follows:

a. Domestic:

1. Must be sent via Priority Mail Express Service.

2. Must be packaged according to 451.3b and Packaging Instruction 10C.

3. Mailers must use one of the special Priority Mail Express cremated remains branded boxes (BOX-CRE) available on *usps.com*.

4. Extra Services permitted with mailpieces containing cremated remains are additional insurance and return receipt only.

5. Shipping labels may be printed and affixed through Click-N-Ship or other USPS-approved methods or at a Post Office location. Mailer generated labels must bear an Intelligent Mail package barcode (IMpb) with the proper cremated remains Service Type Code (STC) and include the proper Extra Services Code (ESC) in the Shipping Services File (see Publication 199 on *PostalPro* at *postalpro.usps.com*).

b. International:

1. When permitted by the destination country, cremated remains must be sent via Priority Mail Express International service. Mailers must verify that the destination country accepts Priority Mail Express International and cremated remains before mailing.

2. Mailers must use one of the special Priority Mail Express cremated remains branded boxes (BOX-CRE) available on *usps.com*.

3. Must be packaged as required in 451.3b and Packaging Instruction 10C.

4. The contents "cremated remains" must be indicated on the applicable customs declaration form.

\* \* \* \* \*

**451.3 Packaging and Marking**

*[Revise item b. and create new item c. as follows:]*

b. *Powders.* Dry materials that could cause soiling, damage, discomfort or destruction, upon escape (leakage) must be packaged in sift proof or other sealed