9.3 USPS Marketing Mail

9.3.1 Basic Standards

Bundles of flats in an automation price mailing must be cosacked with bundles of flats in a Presorted price mailing under the following conditions:

* * * * *

[Revise the first sentence of item h to read as follows:]

h. A complete postage statement(s), using the correct USPS form, must accompany each mailing job prepared under these procedures. * * *

* * * * *

9.4 Bound Printed Matter

9.4.1 Basic Standards

Bundles of flat-size pieces in a Presorted price mailing qualifying for and claiming the barcode discount under 263.3.0, 263.2.0, and 263.5.0 must be cosacked with bundles of flat-size pieces from a Presorted price mailing (not claiming the barcode discount) under the following conditions:

* * * * *

[Revise the first sentence of item h to read as follows:]

h. A complete postage statement(s), using the correct USPS form, must accompany each mailing job prepared under these procedures. * * *

* * * * *

10.0 Merging Bundles of Flats Using the City State Product

10.1 Periodicals

10.1.1 Basic Standards

* * * Carrier route bundles in a carrier route mailing may be placed in the same sack or on the same pallet as 5-digit bundles from machinable (barcoded or nonbarcoded) price mailings (including pieces cobundled under 11.0) under the following conditions:

* * * * *

[Revise the first sentence of item i to read as follows:]

i. A complete postage statement(s), using the correct USPS form, must accompany each mailing job prepared under these procedures. * * *

* * * * *

10.2 USPS Marketing Mail

10.2.1 Basic Standards

Carrier route bundles from a carrier route price mailing may be placed in the same sack or on the same pallet as 5-digit bundles from an automation price mailing and 5-digit bundles from a Presorted price mailing (including pieces cobundled under 11.0) under the following conditions:

* * * * *

[Revise the text of item k to read as follows:]

k. A complete postage statement, using the correct USPS form, must accompany each mailing job prepared under these procedures.

* * * * *

12.0 Merging Bundles of Flats on Pallets Using a 5% Threshold

12.1 Periodicals

12.1.1 Basic Standards

* * * Five-digit bundles from a barcoded price mailing and 5-digit bundles from a nonbarcoded price mailing (including pieces cobundled under 11.0) may be placed on the same pallet as carrier route bundles under the following conditions:

* * * * *

[Revise the first sentence in the introductory text of item f to read as follows:]

f. A complete postage statement, using the correct USPS form, must accompany each mailing job. * * *

* * * * *

12.2 USPS Marketing Mail

12.2.1 Basic Standards

* * * Five-digit bundles from an automation price mailing and 5-digit bundles from a Presorted price mailing (including pieces cobundled under 11.0) may be placed on the same pallet as carrier route bundles under the following conditions:

* * * * *

[Revise the text of item j to read as follows:]

j. A complete postage statement, using the correct USPS form, must be submitted for each mailing job prepared under these procedures.

* * * * *

13.0 Merging Bundles of Flats on Pallets Using the City State Product and a 5% Threshold

13.1 Periodicals

13.1.1 Basic Standards

* * * Five-digit bundles from a barcoded price mailing and 5-digit bundles from a nonbarcoded price mailing (including pieces cobundled under 11.0) may be placed on the same pallet as carrier route bundles under the following conditions:

* * * * *

[Revise the first sentence in the introductory text of item g to read as follows:]

g. A complete postage statement, using the correct USPS form, must be submitted for each mailing job. * * *

* * * * *

13.2 USPS Marketing Mail

13.2.1 Basic Standards

* * * Five-digit bundles from an automation price mailing and 5-digit bundles from a Presorted price mailing (including pieces cobundled under 11.0) may be placed on the same pallet as carrier route bundles under the following conditions:

* * * * *

[Revise the text of item k to read as follows:]

k. A complete postage statement, using the correct USPS form, must be submitted for each mailing job prepared under these procedures.

* * * * *

17.0 Plant-Verified Drop Shipment

* * * * *

17.2 Program Participation

* * * * *

17.2.3 Verification at Origin BMEU

PVDS verification can be performed at the origin business mail entry unit (BMEU) under these conditions:

* * * * *

[Revise the text of item d to read as follows:]

d. Form 8125 accompanies each PVDS (or segment, if the PVDS is contained in more than one vehicle).

* * * * *

Tram T. Pham,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2023–02824 Filed 2–10–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 8

RIN 0930–AA39

Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') is issuing this supplemental notice of proposed rulemaking (SNPRM) to solicit public comment on its proposal to remove provisions authorized under the

Controlled Substances Act (CSA), as amended by the Drug Addiction Treatment Act of 2000 (DATA–2000). These changes are as a result of amendments made in the Consolidated Appropriations Act, 2023, which was enacted on December 29, 2022. Among other things, section 1262(a)(1) of this Act amended the CSA by eliminating the requirement that practitioners obtain a waiver to prescribe certain schedule III–V medications for the treatment of opioid use disorder (OUD).

DATES: Comments due on or before March 14, 2023.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at *https://www.regulations.gov.* Follow the instructions at *https://www.regulations.gov* for submitting electronic comments. Attachments should be in Microsoft Word or Portable Document Format (PDF), and please refer to RIN 0930–AA39 in all comments.
- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 5600 Fishers Lane, Room 13–E–30, Rockville, MD 20857.

Note: Due to the COVID–19 pandemic, SAMHSA notes receipt of mail may be delayed and encourages submission of comments electronically to the docket.

Inspection of Public Comments: All comments received by the accepted methods and due date specified above may be posted without change to content to *https://www.regulations.gov,* which may include personal information provided about the commenter, and such posting may occur after the closing of the comment period. However, the Department may redact certain content from comments before posting, including threatening language, hate speech, profanity, graphic images, or individually identifiable information about a third-party individual other than the commenter. Because of the large number of public comments normally received on **Federal Register** documents, SAMHSA is not able to provide individual acknowledgments of receipt. Please allow sufficient time for mailed comments to be received timely in the event of delivery or security delays. Comments submitted by fax or email, and those submitted after the comment period will not be accepted.

FOR FURTHER INFORMATION CONTACT: Robert Baillieu, MD, MPH, Physician and Senior Advisor, SAMHSA/CSAT, 5600 Fishers Lane, Room 13–E–30, Rockville, MD 20857, Phone: 202–923–0996, Email: *Robert.Baillieu@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Purpose

The purpose of this supplemental notice of proposed rulemaking (SNPRM) is to implement amendments made by the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), which immediately eliminated the requirement to obtain a waiver in order to prescribe certain schedule III–V medications for the treatment of OUD, commonly known as the ''X waiver.'' Accordingly, the Department is proposing to formally remove DATA 2000 related provisions (formerly under 21 U.S.C. 823(h)(2)) from 42 CFR part 8, which no longer have practical or legal effect on medical provider practices under existing law.[1]

Before the Consolidated Appropriations Act, 2023 was enacted, ''qualifying practitioners'' were required to obtain waivers (formerly under 21 U.S.C. 823(h)(2)) from a separate registration requirement, formerly under 21 U.S.C. 823(h)(1), that was needed in order to enable dispensing of certain schedule III–V narcotic medications used in maintenance or detoxification treatment. Practitioners with a waiver of this kind were limited in the number of patients they could treat with this type of medication at any one time.

In July 2016, the Department published a final rule (81 FR 44711) that added subpart F to 42 CFR part 8 under the authority of former 21 U.S.C. 823(h)(2)(B)(iii)(III). Among other things, subpart F authorized eligible practitioners with a waiver under 21 U.S.C. 823(h)(2) to request approval to treat up to 275 patients under certain conditions. On December 16, 2022, the Department published an NPRM proposing three changes to subpart F: (1) altering section headings to remove the current question-and-answer style and replacing it with a standard format; (2) updating § 8.610 to remove stigmatizing language and to also clarify that the 275-patient waiver is limited to three years in duration and; (3) removing § 8.635 to eliminate annual reporting requirements for practitioners approved to treat up to 275 patients. See NPRM entitled ''Medications for the Treatment of Opioid Use Disorder'' (87 FR 77330).

[1] It should be noted that Section 103(a)(1) of Public Law 117–215 redesignated 21 U.S.C. 823(g) as 21 U.S.C. 823(h).

II. Summary of Major Provisions

Pursuant to section 1262 of the Consolidated Appropriations Act, 2023, the Department proposes to remove in its entirety subpart F of 42 CFR part 8 in addition to language throughout 42 CFR part 8 that specifically references or implicates the DATA–2000 waiver process. The terms DATA–2000 waiver and DATA-waiver used throughout this document refer to the waiver provisions under 21 U.S.C. 823(h)(2) in effect prior to amendment by the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). Although not used in this document, the DATA-waiver has also colloquially been referred to as the ''X-waiver''.

III. Summary of Impacts

As the specific changes proposed in this SNPRM are in conformity with amendments made by section 1262(a)(1) of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), these changes will have no practical or legal effect on medical provider practices under existing law.

Public Participation

Request for Comments

In addition to seeking public comments on the full NPRM published December 16, 2022, the Department requests public comment on this Supplemental proposed amendment to the regulations under 42 CFR part 8, *Medications for the Treatment of Opioid Use Disorder.* The Department welcomes public comment on any benefits or drawbacks of the proposed amendments set forth above in this proposed rule.

The Department seeks comment on all issues raised by the proposed changes consistent with the law, including any potential unintended adverse consequences, and benefits to people with opioid use disorders. Because of the large number of public comments normally received on **Federal Register** documents, the Department is not able to acknowledge or respond to them individually. In developing the final rule, the Department will consider all comments that are received by the date and time specified in the **DATES** section of the Preamble.

Because mailed comments may be subject to delays due to security procedures, please allow sufficient time for mailed comments to be received by the deadline in the event of delivery delays. Any attachments submitted with electronic comments on

www.regulations.gov should be in Microsoft Word or Portable Document Format (PDF). Please note that comments submitted by fax or email and those submitted after the comment period deadline will not be accepted.

V. Background

On December 16, 2022, HHS issued a notice of proposed rulemaking entitled ''Medications for the Treatment of Opioid Use Disorder'' (87 FR 77330). In that NPRM, the Department proposed to modify certain provisions of part 8 to update Opioid Treatment Program (OTP) accreditation and certification standards, treatment standards for the provision of medications for opioid use disorder as dispensed by OTPs, and requirements for individual practitioners eligible to dispense (including by prescribing) certain types of Medication for Opioid Use Disorder (MOUD) with a waiver under 21 U.S.C. 823(h)(2). Subparts A through D of 42 CFR part 8 pertain to OTP accreditation, certification and treatment standards. Within these sections, there are no specific rules that pertain to the DATA-Waiver. Subpart F of this rulemaking provides criteria to expand access to buprenorphine by allowing eligible practitioners to request approval to treat up to 275 patients.

On December 29, 2022, the President signed the ''Consolidated Appropriations Act, 2023'' (Pub. L. 117–328). Section 1262 of the Act amends the Controlled Substances Act (21 U.S.C. 823(h)) and provisions in the Public Health Service Act [2] to remove the requirement that practitioners obtain a special waiver to prescribe certain medications, including buprenorphine, for the treatment of OUD.

The proposed changes in this SNPRM remove all language pertaining to the DATA-Waiver from 42 CFR part 8, pursuant to the ''Consolidated Appropriations Act, 2023'' and the changes proposed in this SNPRM that pertain to 42 CFR part 8, subpart F replace and supersede any subpart F changes proposed in the Department's December 16, 2022, NPRM (87 FR 77330). Any other proposed changes in this SNPRM are a supplement to the NPRM published on December 16, 2022 (87 FR 77330).

VI. Summary of the SNPRM

In compliance with section 1262 of the Consolidated Appropriations Act, 2023, this supplemental NPRM proposes changes to 42 CFR part 8, and revises some of the Department's proposals published on December 16, 2022 (87 FR 77330). These changes include removing 42 CFR part 8, subpart F, eliminating references to the DATA-waiver from 42 CFR part 8, subpart A, § 8.1, and modifying definitions in subpart A accordingly.

Impact Analysis

The Department has examined the impact of these proposed changes as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (October 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (August 10, 1999); Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (November 9, 2000); Executive Order 13985 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009 (January 25, 2021); the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 847 (March 29, 1996); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (March 22, 1995); the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (September 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (August 16, 2002); the Assessment of Federal Regulations and Policies on Families, Public Law 105–277, sec. 654, 112 Stat. 2681 (October 21, 1998); and the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995), and included it in the NPRM published on December 16, 2022. Please refer to the NPRM for this analysis (87 FR 77330). The Department requests comment on how the previously-conducted analysis should be revised to encompass the effects of the CFR changes set forth in this SNPRM.

List of Subjects in 42 CFR Part 8

Administrative practice and procedure, Health professions, Methadone, Reporting and recordkeeping requirements, Substance misuse.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to supplement its December 16, 2022 NPRM (87 FR 77330) by further amending 42 CFR part 8 as follows:

■ 1. The authority citation for part 8 continues to read as follows:

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

Subpart A—General Provisions

■ 2. Revise § 8.1 to read as follows:

§ 8.1 Scope.

This subpart and subparts B through D of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under this subpart and subparts B through D, an applicant seeking to become an OTP must first obtain from the Secretary or, by delegation, from the Assistant Secretary for Mental Health and Substance Use, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the applicant obtaining accreditation from an accreditation body that has been approved by the Secretary. This subpart and subparts B through D also establish the procedures whereby an entity can apply to become an approved accreditation body, and the requirements and general standards for accreditation bodies to ensure that OTPs are consistently evaluated for compliance with the Secretary's standards for treatment of OUD with MOUD.

■ 2. Amend § 8.2 by:

■ a. Removing the definitions for *Additional credentialing, Approval term, Covered medications,* and *Emergency situation.*

■ b. Revising the definition for *Patient.*

■ c. Removing the definition for *Patient limit.*

■ d. Revising the definition for *Practitioner.*

■ e. Removing the definition for *Practitioner incapacity.*

The revisions read as follows:

§ 8.2 Definitions.

* * * * *

Patient, for purposes of this part, means any individual who receives continuous treatment or withdrawal management in an OTP.

* * * * *

[2] Specifically, section 1262 of the Act amends provisions in the Public Health Service Act (42 U.S.C. 290bb–36d(c); and 42 U.S.C. 290dd–3) that reference practitioners dispensing MOUD pursuant to 21 U.S.C. 823(h).

Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a state to prescribe and/or dispense medications for opioid use disorders and is authorized to practice within an OTP.

* * * * *

Subpart F—[Removed]

■ 4. Remove subpart F, consisting of §§ 8.610 through 8.655.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–03012 Filed 2–10–23; 8:45 am]

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