



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; Correction

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

ACTION: Correcting amendment.

SUMMARY: This document corrects two outdated references that should have been deleted and one outdated reference in the final rule that appeared in the February 2, 2024 **Federal Register** titled “Medications for the Treatment of Opioid Use Disorder,” specifying final modified and updated certain provisions related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of Opioid Use Disorder with Medications for Opioid Use Disorders in OTPs. The effective date of the final rule was April 2, 2024, and the compliance date was October 2, 2024.

DATES: Effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2024-01693 of February 2, 2024, the Medications for the Treatment of Opioid Use Disorder final rule (89 FR 7528), there were two outdated references that should have been deleted and one outdated reference that is in this correcting document.

II. Summary of Errors

Section 8.3(b) of the regulation erroneously references Accreditation Body application form SMA-167. HHS is correcting the text to reference form SMA-163.

Section 8.11 of the regulation currently links to section 303(g)(1) of the Controlled Substances Act instead of section 303(h), which is the correct reference, and to 42 CFR 8.4(b)(1)(iii), a section which does not exist in the final rule, instead of 42 CFR 8.4(b). HHS is revising the section to replace the outdated text with the correct references.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA generally exempts rules from the requirements of notice and comment rulemaking when an agency “for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest” (5 U.S.C. 553(b)(B)).

HHS has determined that notice and public comment are unnecessary because this amendment to the regulation provides only technical or non-substantive changes to specify the location of cross-referenced regulations currently in effect. Such technical, non-substantive changes are “routine determination[s], insignificant in nature and impact, and inconsequential to the industry and to the public.” (*Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 94 (D.C. Cir. 2012)) (quotation marks and citation omitted). Accordingly, HHS for good cause finds that notice and public procedure thereon are unnecessary for changing this regulation.

In addition, HHS finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date of less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to “adjust to the new regulation” before the rule takes effect. (*Am. Federation of Government Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981)). Therefore, HHS finds good cause for these amendments to become effective on the date of publication of this action.

III. Waiver of Proposed Rulemaking

Section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 1871(e)(1)(B)(i) of the Act mandates a 30-day delay in effective date after issuance or publication of a rule. Section 1871(b)(2)(C) of the Act provides an exception from the notice and 60-day comment period and delay in effective date requirements of the Act, under the good cause standard set forth in 5 U.S.C. 553(b)(B).

Section 1871(e)(1)(B)(ii) of the Act provides an exception from the delay in effective date requirements of the Act as well. Section 553(b)(B) authorizes an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 1871(e)(1)(B)(ii) of the Act allows the agency to avoid the 30-day delay in effective date where the waiver is necessary to comply with statutory requirements, or such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects typographical errors in the Medications for the Treatment of Opioid Use Disorder final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the Medications for the Treatment of Opioid Use Disorder final rule. As a result, the corrections made through this document are intended to resolve inadvertent errors so that the Medications for the Treatment of Opioid Use Disorder final rule accurately reflects the policies adopted therein.

In addition, even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the Medications for the Treatment of Opioid Use Disorder final rule or delaying the effective date of the corrections are unnecessary because we are not making any substantive revisions to the Medications for the Treatment of Opioid Use Disorder final rule, but rather, we are simply correcting the Code of Federal Regulations to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the Medications for the Treatment of Opioid Use Disorder final rule. Further comment is not needed to inform our decision to rectify the ministerial errors noted in this final rule and correction. For these reasons, we believe there is good cause to waive notice and comment and delay in effective date, even if they were required.

List of Subjects in 42 CFR Part 8

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

Accordingly, 42 CFR part 8 is corrected by making the following correcting amendments:

PART 8—MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

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.

2. Amend § 8.3 by revising paragraph (b) to read as follows:

§ 8.3 Application for approval as an Accreditation Body.

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(b) *Application for initial approval.* Electronic copies of an Accreditation Body application form [SMA-163] shall be submitted to: <https://dpt2.samhsa.gov/sma163/>.

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3. Amend § 8.11 by revising paragraphs (a)(1) and (5) and (c)(3) to read as follows:

§ 8.11 Opioid Treatment Program certification.

(a) ***

(1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(h) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(h) of the Controlled Substances Act and must be determined to be qualified by the Attorney General under section 303(h), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

* * * * *

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for 1 year by an Accreditation Body as provided under § 8.4(b), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

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(c) ***

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification in this section; the Secretary will notify the Drug Enforcement Administration that the OTP has been determined to be qualified to provide OUD treatment under section 303(h) of the Controlled Substances Act.

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Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.