



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 8

[Docket No. 2016-0001]

RIN-0930-AA22

### Medication Assisted Treatment for Opioid Use Disorders; Correction

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS

**ACTION:** Correcting amendment.

**SUMMARY:** The Health and Human Services Department (HHS) is correcting a final rule that appeared in the Federal Register on July 8, 2016. The final rule increased the maximum number of patients to whom an individual practitioner may dispense or prescribe certain medications, including buprenorphine, from 100 to 275. Practitioners are eligible for the increased patient limit if they have prescribed covered medications to up to 100 patients for at least one year pursuant to secretarial approval, provided that they meet certain criteria and adhere to several additional requirements aimed at ensuring that patients receive the full array of services that comprise evidence-based medication-assisted treatment (MAT) and minimize the risks that medications provided for treatment are misused or diverted. One pathway through which

practitioners may become eligible to increase their patient limit is by obtaining additional credentialing from one of several credentialing bodies. In the final rule, the name of one of the credentialing bodies listed was incorrect. This action provides the correct name.

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

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

On July 8, 2016 (81 FR 44711), HHS published a final rule in the Federal Register, which increased the maximum number of patients to whom an individual practitioner may dispense or prescribe certain medications, including buprenorphine, from 100 to 275. One of the pathways through which practitioners can become eligible to increase their patient limit is by receiving additional credentialing.

In the final rule, the American Osteopathic Academy of Addiction Medicine (AOAAM), which provides training but not certification, was mistakenly included in the definition for “additional credentialing.” HHS intended to include the American Osteopathic Association (AOA) in this definition, not AOAAM. This intention was evident in HHS’s Notice of Proposed Rulemaking

(NPRM), published on March 30, 2016, which proposed defining “board certification” so as to include “subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) . . . .” AOAAM, on the other hand, was not referenced within the NPRM. Accordingly, HHS gave the public notice and an opportunity to comment on its proposal to include AOA board certification as one of the credentials that would make practitioners eligible to practice at the higher patient cap. No public comments were received that related to AOA’s role in the proposed rule.

HHS’s intention to reference AOA (not AOAAM) was also reflected in the preamble of the final rule; AOA board certification was referenced in Section B of the Regulatory Impact Analysis, which stated that “[t]he training requirement may be satisfied in several ways: one may hold board certification in . . . addiction medicine from the American Osteopathic Association . . . .” HHS also explained in the preamble of the final rule that, “HHS removed the term ‘board certification’ and added ‘additional credentialing’ to clarify that all practitioners who currently qualify to treat up to 100 patients are eligible for the higher patient limit if they are included as specialists as described in 21 U.S.C. 823 (g)(2)(G)(ii)(I)-(III).” Notably, AOA board certification is specifically listed in 21 U.S.C. 823(g)(2)(G)(ii)(III), as amended by the Comprehensive Addiction and Recovery Act of 2016 (CARA), Public Law 114-198. As a result, the listing of AOAAM instead of AOA was the result of a technical error that needs to be corrected immediately.

If this error is not immediately corrected, practitioners who have received training from AOAAM, and who do not satisfy any of the other “additional credentialing” requirements under

the final rule, may argue that they are eligible to increase their patient limit even though they do not possess the qualifications that HHS has deemed necessary to dispense or prescribe relevant medications safely and effectively at the higher patient cap. In addition, the error has resulted in SAMHSA receiving numerous questions seeking clarification regarding the credentials that osteopathic providers need to have in order to be eligible for the higher patient limit. Failure to correct this error could, therefore, significantly compromise the quality of care delivered to patients in need of MAT and could pose a substantial threat to public safety.

The technical error at issue will therefore be fixed by removing the reference to the “American Osteopathic Academy of Addiction Medicine” in the final rule’s definition of “additional credentialing,” and inserting a reference to the “American Osteopathic Association.” It should be noted that although reference was made to “subspecialty board certification” by AOA in the NPRM, the term “subspecialty” will not be included in the final rule’s definition of “additional credentialing” because CARA amended the Controlled Substances Act by removing the term “subspecialty” from the description of AOA board certification under 21 U.S.C.

823(g)(2)(G)(ii)(III). CARA was enacted on July 22, 2016, after the final rule was published on July 8, 2016. As explained in the preamble of the final rule, HHS’s reason for changing the definition of “board certification” in the NPRM to “additional credentialing” in the final rule was to ensure that the training credentials described in 21 U.S.C. 823(g)(2)(G)(ii)(I)-(III) (which include AOA board certification) were included as eligible pathways for practicing at the higher patient cap. Therefore, the technical fix made to the definition of “additional credentialing” in the final rule reflects HHS’s continuing intention to include the type of training described in 21 U.S.C. 823(g)(2)(G)(ii)(I)-(III), as amended by CARA.

## List of Subjects in 42 CFR Part 8

Health professions, Methadone, Reporting and recordkeeping requirements.

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

### **PART 8—MEDICATION ASSISTED TREATMENT FOR OPIOID USE DISORDERS**

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

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

2. In §8.2, revise the definition of Additional Credentialing to read as follows:

#### **§8.2 Definitions.**

\* \* \* \* \*

Additional Credentialing means board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine.

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Dated: September 2, 2016\_\_\_\_\_

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**Wilma Robinson**

Deputy Executive Secretary, U.S. Department of Health and Human Services

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