

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 8**

**RIN 0930-AA22**

**Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements**

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Supplemental Notice of Proposed Rulemaking.

**SUMMARY:** On March 30, 2016, the U.S. Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking (NPRM) to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA). On July 6, 2016, HHS published a final rule based on the NPRM but delayed finalizing the reporting requirements outlined in the NPRM. In this Supplemental Notice of Proposed Rulemaking (SNPRM), HHS seeks further comment on the same reporting requirements outlined in the NPRM. These reporting requirements would require annual reporting by practitioners who are approved to treat up to 275 patients under subpart F to help HHS ensure compliance with the requirements of the “Medication Assisted Treatment for Opioid Use Disorders” final rule published elsewhere in this issue of the Federal Register. HHS will consider the public comments on this SNPRM as well as any comments already received on the March 30, 2016 NPRM before issuing a final rule pertaining to the reporting requirements.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Regulatory Information Number (RIN) 0930-AA22, by any of the following methods:

- Electronically: Federal eRulemaking Portal: Go to <http://www.regulations.gov> and follow the instructions for submitting comments.
- Regular Mail or Hand Delivery or Courier: Written comments mailed by regular mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- Express or Overnight Mail: Written comments sent by hand delivery, or regular, express or overnight mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857.

*Instructions:* To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will become a matter of public record and will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process and viewing public comments, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Jinhee Lee, Pharm.D., Public Health Advisor, Center for Substance Abuse Treatment, 240-276-0545, E-mail address: [WaiverRegulations@samhsa.hhs.gov](mailto:WaiverRegulations@samhsa.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### **A. Purpose**

The purpose of this Supplemental Notice of Proposed Rulemaking (SNPRM) is to solicit additional comment on the proposed reporting requirements in the U.S.

Department of Health and Human Services (HHS) March 30, 2016 Notice of Proposed Rulemaking (NPRM) on Medication Assisted Treatment for Opioid Use Disorders under section 303(g)(2) of the Controlled Substances Act (CSA) (81 FR 17639). These requirements will assist HHS in ensuring practitioner compliance with the requirements of 42 CFR part 8, subpart F.

#### **B. Summary of Major Provisions**

These proposed regulatory provisions, which amend § 8.635 of 42 CFR part 8, subpart F, would establish annual reporting requirements for practitioners who are approved to treat up to 275 patients under 42 CFR part 8, subpart F.

#### **C. Summary of Impacts**

A summary of the anticipated impact of the reporting requirements, along with the other provisions of 42 CFR part 8, subpart F, was provided in the NPRM, dated

March 30, 2016. Please see the NPRM, I. Executive Summary, Paragraph C (Summary of Impacts) for a summary of impacts of the reporting requirements in the context of 42 CFR part 8, subpart F.

## **II. Public Participation**

### Comments Invited.

HHS invites interested parties to submit comments on all aspects of this proposal. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable and/or confidential information that is included in a comment. We post all comments received as soon as possible after they have been received on the following web site: <http://www.regulations.gov>. Follow the search instructions on that web site to view public comments.

Comments received before the close of the comment period will also be available for public inspection, generally beginning approximately 3 weeks after publication of the proposed rule, at the headquarters of the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call 240-276-1660.

We will consider all comments we receive by the date and time specified in the “Dates” section of this preamble, and will respond to the comments in the preamble of the final rule. Please allow sufficient time for mailed comments to be received before the close of the comment period.

## **III. Background**

On March 30, 2016 HHS issued a Notice of Proposed Rulemaking (NPRM) entitled “Medication Assisted Treatment for Opioid Use Disorders” in the Federal Register. Elsewhere in this issue of the Federal Register, HHS is publishing a final rule with the same title. That final rule increases access to medication-assisted treatment (MAT) with certain medications, including buprenorphine and combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) medications, in office-based setting as authorized under 21 U.S.C. 823(g)(2). Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)) allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled substances that have been approved by the Food and Drug Administration (FDA). Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time. After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. The final rule expands access to MAT by allowing eligible practitioners to request approval to treat up to 275 patients under section 303(g)(2) of the CSA. The final rule also includes requirements to help ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.

The proposed regulatory provisions in this SNPRM will help HHS assess practitioner compliance with the requirements of 42 CFR part 8, subpart F.

#### **IV. Summary of SNPRM**

In the NPRM, HHS proposed 42 CFR, part 8, subpart F, § 8.635 to describe the reporting requirements for practitioners whose Request for Patient Limit Increase is

approved under § 8.625. The purpose of the reporting requirements is to help HHS assess practitioner compliance with the additional responsibilities of practitioners who are authorized to treat up to the higher patient limit, as outlined in the MAT final rule published elsewhere in this issue of the Federal Register. Reporting is an integral component of HHS's approach to increase access to MAT while helping to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted. While HHS received many comments on the burden of these requirements, the comments did not provide specific suggestions on how HHS can ensure compliance in a manner that is not overly burdensome to practitioners. HHS seeks additional comment on the proposed reporting requirements:

- a. The average monthly caseload of patients receiving buprenorphine-based MAT, per year
- b. Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:
  1. Treatment initiation
  2. Change in clinical status
- c. Percentage of patients who had a prescription drug monitoring program query in the past month
- d. Number of patients at the end of the reporting year who:

1. Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery
2. Are not being seen by the provider due to referral by the provider to a more or less intensive level of care
3. No longer desire to continue use of buprenorphine
4. Are no longer receiving buprenorphine for reasons other than 1-3.

In addition, HHS seeks comment on the following questions:

Are there different or additional elements that should be reported in order to assist HHS in ensuring compliance with the final rule?

Are there ways in which some elements can be combined that will lessen the burden for reporting practitioners while maintaining the important function of collecting information that ensure compliance with the final rule?

Are there other ways that HHS can collect the necessary information to ensure compliance with the final rule?

Would it be less burdensome to report on the number of patients in treatment for each month of the reporting period that:

- (i) were provided counseling services at the same location as the practitioner, and how frequently those patients utilized the counseling services;
- (ii) the practitioner referred for counseling services at a different location?

Would it be less burdensome to report on the number of patients at the end of the reporting year who had terminated utilization of covered medications?

Are there other suggested changes that would be less burdensome while maintaining the important function of collecting information that ensure compliance with the final rule?

## **V. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether changes to an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered in rulemaking. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. This proposed rule

includes changes to information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the PRA (5 CFR part 1320).

Some of the provisions would involve changes from the information collections set out in the previous regulations.

Information collection requirements would be:

**Reporting, 42 CFR 8.635:** Reporting will be required annually to ensure that eligibility requirements are being maintained and that waiver conditions are being fulfilled. Reporting requirements may include a request for information regarding: (1) the average monthly caseload of patients receiving buprenorphine-based MAT, per year; (2) the percentage of active buprenorphine patients (patients in treatment as of reporting date) who received psychosocial or case management services (either by direct provision or by referral) in the past year due to treatment initiation or change in clinical status; (3) Percentage of patients who had a prescription drug monitoring program query in the past month; (4) Number of patients at the end of the reporting year who: (a) Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery, (b) Are not being seen by the provider due to referral by the provider to a more or less intensive level of care, (c) No longer desire to continue use of buprenorphine, (d) Are no longer receiving buprenorphine for reasons other than (a) through (c). To facilitate public comment, we have placed a draft version of the collection template in the public docket.

Annual burden estimates for these requirements are summarized in the following table:

42 CFR Citation	Purpose of Submission	Number of respondents	Responses/ Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)	Hourly Wage Cost (\$)	Total Wage Cost (\$)
8.635	Annual Report	1,350	1	3	4,050	\$64.47	\$261,104

For more detailed estimates, please refer to the public docket, which includes a copy of the draft supporting statement submitted as part of the NPRM and associated with this information collection.

## **VI. Regulatory Impact Analysis**

HHS has examined the impact of this proposed rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act of 1980 (Pub. L. No. 96-354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4, March 22, 1995), and Executive Order 13132 on Federalism (August 4, 1999) and included it in the NPRM published on March 30, 2016. Please refer to the NPRM for this analysis (81 FR 17639).

### **List of Subjects in 42 CFR Part 8**

Health professions, Methadone, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HHS proposes to amend 42 CFR part 8 as follows:

#### **PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS**

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. Add § 8.635 to read as follows:

**§ 8.635 What are the reporting requirements for practitioners whose Request for Patient Limit Increase is approved?**

(a) All practitioners whose Request for Patient Limit Increase is approved under § 8.625 must submit reports to SAMHSA, along with documentation and data, as requested by SAMHSA, to demonstrate compliance with § 8.620, applicable eligibility requirements specified in § 8.610, and all attestation requirements in § 8.620(b).

(b) Reporting requirements may include a request for information regarding:

(1) The average monthly caseload of patients receiving buprenorphine-based MAT, per year.

(2) Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:

(i) Treatment initiation.

(ii) Change in clinical status.

(3) Percentage of patients who had a prescription drug monitoring program query in the past month; and

(4) Number of patients at the end of the reporting year who:

(i) Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery.

(ii) Are not being seen by the provider due to referral by the provider to a more or less intensive level of care.

(iii) No longer desire to continue use of buprenorphine.

(iv) Are no longer receiving buprenorphine for reasons other than paragraphs (b)(4)(i) through (iii) of this section.

(c) The report must be submitted within twelve months after the date that a practitioner's Request for Patient Limit Increase is approved under § 8.625, and annually thereafter.

(d) SAMHSA may check reports from practitioners prescribing under the higher patient limit against other existing data sources, such as PDMPs. If discrepancies between reported information and other existing data are identified, SAMHSA may require additional documentation from practitioners whose reports are identified as including these discrepancies.

(e) Failure to submit reports under this section, or deficient reports, may be deemed a failure to satisfy the requirements for a patient limit increase, and may result in the withdrawal of SAMHSA's approval of the practitioner's Request for Patient Limit Increase.

Dated: June 30, 2016.

**Kana Enomoto,**

Principal Deputy Administrator,

Substance Abuse and Mental Health Services Administration.

Approved: June 30, 2016.

**Sylvia M. Burwell,**

Secretary,

Department of Health and Human Services.

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