

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. This good cause final action simply extends the date for the EPA to take action on a petition. Thus, Executive Order 13175 does not apply to this rule.

*G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This good cause final action simply extends the date for the EPA to take action on a petition and does not have any impact on human health or the environment.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section II.B of this

document, including the basis for that finding.

**IV. Statutory Authority**

The statutory authority for this action is provided by sections 110, 126 and 307 of the CAA as amended (42 U.S.C. 7410, 7426 and 7607).

**V. Judicial Review**

Under section 307(b)(1) of the CAA, judicial review of this final rule is available only by the filing of a petition for review in the U.S. Court of Appeals for the appropriate circuit by November 28, 2016. Under section 307(b)(2) of the CAA, the requirements that are the subject of this final rule may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Administrative practices and procedures, Air pollution control, Electric utilities, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone.

Dated: September 19, 2016.

**Gina McCarthy,**

*Administrator.*

[FR Doc. 2016–23155 Filed 9–26–16; 8:45 am]

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**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:** Final rule.

**SUMMARY:** This final rule outlines annual reporting requirements for practitioners who are authorized to treat up to 275 patients with covered medications in an office-based setting. This final rule will require practitioners to provide information on their annual caseload of patients by month, the number of patients provided behavioral health services and referred to behavioral health services, and the features of the practitioner’s diversion control plan. These reporting requirements will help the Department of Health and Human Services (HHS) ensure compliance with the requirements of the final rule,

“Medication Assisted Treatment for Opioid Use Disorders,” published in the **Federal Register** on July 8, 2016.

**DATES:** *Effective Date:* This final rule is effective on October 27, 2016.

**FOR FURTHER INFORMATION CONTACT:** Jinhee Lee, Pharm.D., Public Health Advisor, Center for Substance Abuse Treatment, 240–276–2700

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at <http://www.gpo.gov/fdsys>.

**I. Background**

On July 8, 2016, HHS issued a final rule entitled “Medication Assisted Treatment for Opioid Use Disorders” in the **Federal Register** (81 FR 44712). That final rule increases access to medication-assisted treatment (MAT) with covered medications,<sup>1</sup> in an office-based setting, by allowing eligible physicians to request approval to treat up to 275 patients if certain conditions are met. 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. HHS issued a supplemental Notice of Proposed Rulemaking (SNPRM) along with the final rule, which included reporting requirements for practitioners who increase their patient limit to 275.

*A. Regulatory History*

On March 30, 2016, HHS issued a Notice of Proposed Rulemaking, “Medication Assisted Treatment for Opioid Use Disorders.” On July 8, 2016, HHS issued a final rule which finalized the regulation with the exception of sections relating to the requirement to provide reports to SAMHSA (§ 8.630(b)) and the reporting requirements (§ 8.635). Also on July 8, 2016, HHS published a Supplemental Notice of Proposed Rulemaking (SNPRM) in the **Federal Register** which proposed reporting requirements for practitioners whose Request for Patient Limit Increase is approved under Section 8.625. The purpose of the reporting requirements is to help HHS assess practitioner compliance with the additional responsibilities of

<sup>1</sup> Covered medications means the drugs or combination of drugs that are covered under 21 U.S.C. 823(g)(2)(C).

practitioners who are authorized to treat up to the highest patient limit, as outlined in the final rule, “Medication Assisted Treatment for Opioid Use Disorders.” 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.

The comment period for the SNPRM ended on August 8, 2016. HHS received 37 comments electronically and nine additional comments from a public listening session which was held on August 2, 2016. Additionally, HHS received 27 comments about the reporting requirements during the comment period for the Medication Assisted Treatment Notice for Proposed Rulemaking (NPRM) issued in March 2016. Comments primarily came from individuals who currently prescribe covered medications and national organizations representing practitioners and public health agencies. HHS also received several comments during conversations with the Department of Defense and the Department of Veterans Affairs and incorporated this feedback into this final rule.

### B. Overview of Final Rule

This final rule adopts the same basic structure and framework as the supplemental proposed rule. Subpart F, Section 8.635 describes what the reporting requirements are for practitioners whose Request for Patient Limit Increase application is approved.

HHS has made some changes to the proposed reporting requirements based on the comments we received with respect to the SNPRM. HHS has also updated Section 8.630 by adding the requirement proposed in the NPRM that practitioners need to provide reports to SAMHSA as specified in Section 8.635 to maintain their approval to treat up to 275 patients.

HHS has responded to the comments received in response to the March 2016 NPRM and this SNPRM, and provided an explanation of each of the changes made to the proposed rule in the preamble.

## II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

### A. General Comments

HHS received numerous comments providing support for the proposed reporting requirements. Commenters stated that the requirements would be particularly valuable in minimizing

diversion and improving access to and quality of care. However, other commenters expressed concerns that the reporting requirements were too burdensome and would limit the number of practitioners who apply for the increased patient limit, particularly for individual practitioners or small group practices. Others expressed that the reporting requirements should be consistent for all practitioners prescribing buprenorphine for MAT. Some commenters also stated that there was no evidence that the reporting requirements would improve the quality of patient care or minimize misuse or diversion. Other commenters noted that other areas of medicine do not have reporting requirements.

HHS has modified the reporting requirements in response to the comments. Given the importance of ensuring practitioners comply with the Medication Assisted Treatment for Opioid Disorders requirements while minimizing their reporting burden, we believe that the updated reporting requirements as outlined in § 8.635 and further specified in report form instructions to be issued after finalization of this rule, strike the appropriate balance. Additional detail regarding these reporting requirements will be provided in the practitioner reporting form which will be available for public comment shortly after finalization of this rule.

HHS also received a variety of comments related to the issue of MAT that did not specifically relate to the SNPRM but generally fell into five main categories. The categories and comments are described below.

#### Need for Clarification

*Comment:* HHS received a comment requesting clarification on how the information collected will be used.

*Response:* The information collected through these reporting requirements will enable HHS to assess compliance with the requirements of 42 CFR part 8, subpart F.

*Comment:* HHS received a comment requesting clarification on how to calculate the numbers for each reporting requirement.

*Response:* Guidance on how to calculate the numbers for each reporting requirement will be issued by HHS.

*Comment:* HHS received a comment requesting clarification on whether the requirements apply to all practitioners approved for the higher limit, or only those who qualify with the qualified practice setting criteria.

*Response:* The reporting requirements apply to all practitioners who are

approved for the higher patient limit of 275.

*Comment:* HHS received a comment requesting clarification about what, if any, supporting data and documentation will be required along with the annual report.

*Response:* Practitioners may be required to submit supporting data and documentation along with the annual report. Future guidance will be provided for more information.

*Comment:* HHS received a comment asking whether there are specific benchmarks practitioners are required to meet when they report percentages.

*Response:* HHS is not requiring practitioners to meet specific benchmarks.

*Comment:* HHS received a comment inquiring about the implications of 42 CFR part 2, and how information obtained through the reporting requirements will be used if patients do not provide consent to use their information.

*Response:* 42 CFR part 2 protects the identity of individuals as substance use disorder patients and prohibits the disclosure of any information that would identify an individual as a substance use disorder patient. The reporting requirements do not seek patient identifying information; therefore, the requirements are not in conflict with the restrictions of 42 CFR part 2.

#### Final Rule To Increase Patient Limit

HHS received several comments regarding the final rule, “Medication Assisted Treatment for Opioid Use Disorders,” published in the **Federal Register** on July 8, 2016. One commenter stated that the highest patient limit should be higher than 275. Another commenter recommended that there be no additional requirements associated with increasing the patient limit from 100 to 275. Other commenters expressed concerns that the final rule does not require practitioners to ensure patients receive the full array of services, prevent diversion, or follow nationally recognized evidence-based guidelines. An additional commenter recommended that SAMHSA audit practitioners to ensure that they are in compliance with the rule. A final commenter requested clarification regarding whether hospitalists who work in an acute inpatient hospital facility are eligible for the higher patient limit because they do not track patients after they are discharged.

*Response:* Comments related to the final rule, Medication Assisted Treatment for Opioid Use Disorders, that do not directly relate to the

proposed reporting requirements which were the subject of the SNPRM, are outside the scope of this final rule and will not be addressed in this preamble.

#### Access to Buprenorphine

HHS received several comments pertaining to access to buprenorphine. One comment expressed concerns about the impact of workforce shortages on access, and another commenter stated that clinical pharmacists should be allowed to prescribe buprenorphine, which would increase access. An additional commenter recommended that HHS work with stakeholders to explore mechanisms to address systemic barriers.

*Response:* These comments do not relate to the reporting requirements under 42 CFR part 8, subpart F, and therefore, will not be addressed in this preamble.

#### Comprehensive Addiction and Recovery Act of 2016

*Comments:* HHS received a small number of comments about the Comprehensive Addiction and Recovery Act of 2016 (CARA). One commenter asked whether physician assistants and nurse practitioners are required to report quality and patient outcomes data. Another commenter requested additional information on training requirements.

*Response:* Comments related to CARA do not relate to the reporting requirements, and therefore, will not be addressed in this preamble.

#### Other Comments

*Comments:* HHS received a number of comments that did not relate to reporting requirements, including a comment about the impact of the Drug Enforcement Administration's (DEAs) narcotic prescribing guidelines on the rights of people living with chronic pain, a comment about the impact of negative perceptions on individuals who receive MAT, a comment about the importance of ensuring that Drug Addiction Treatment Act of 2000 (DATA 2000) patients receive behavioral support services, a comment that the proposed reporting requirements would also be beneficial for those practitioners who are not seeking the higher patient limit increase but treat individuals with opioid use disorders, a comment to combine the existing opioid treatment program reporting requirements with those stated in this final rule, and a comment about the importance of coordination across HHS.

*Response:* These comments do not relate to the reporting requirements, and

therefore, will not be addressed in this preamble.

#### B. Subpart F

*The average monthly caseload of patients receiving buprenorphine-based MAT, per year.*

*Comments:* HHS received a comment recommending that the first proposed reporting requirement, "The average monthly caseload of patients receiving buprenorphine-based MAT, per year" be replaced with the following two questions: "(1) For the final 3 months of the reporting year, what was the average monthly caseload of patients receiving buprenorphine-based MAT? and (2) Are you currently accepting new opioid use disorder patients requiring MAT?"

An additional commenter recommended that HHS collect the following baseline data points: Total number of patients admitted that year, total number of patients carried over from the previous year, and total number of patients discharged.

*Response:* HHS recognized that asking practitioners to calculate and report averages could be burdensome and has, therefore, changed this reporting requirement. The revised text now asks practitioners to report annual caseloads of patients by month. By seeking information on the annual caseload of patients by month, HHS believes this updated reporting requirement, as further elaborated upon in the proposed report form instructions, will strike the appropriate balance between collecting valuable information needed to assess compliance with the rule and avoiding undue burden to practitioners.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, HHS replaced this reporting requirement with one that asks the practitioner to report annual caseload of patients by month.

*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 and (2) Change in clinical status.*

*Comments:* HHS received numerous comments about the second proposed reporting requirement, "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 and (2) Change in clinical status." One commenter requested clarification on

how psychosocial and case management services are defined and another commenter requested clarification on how clinical status is defined. Another commenter stated that psychosocial or case management services are not required or normative according to the evidence base. Another commenter expressed concerns that this reporting requirement will require patients to receive behavioral health services, but many will be unable to do so and will, therefore, refuse treatment. An additional commenter stated that this proposed requirement is irrelevant because so many patients receive services from a 12-step program.

Commenters provided several suggestions for alternative reporting requirements about psychosocial and case management services. One commenter suggested that practitioners be required to report the percentage of patients who had one hour of counseling in the past month. Another commenter recommended that the reporting requirement be divided into two separate measures: "(1) The number referred to psychosocial or case management services, and (2) the number who actually received psychosocial or case management services." An additional commenter recommended that the proposed reporting requirement be replaced with the following two questions: "(1) The percentage of patients receiving psychosocial counseling and/or other appropriate support services; and (2) The percentage of patients receiving case management services." Another commenter recommended that the proposed reporting requirement be replaced with: "(1) The number of patients who were provided psychosocial or case management services at the same location as the practitioner, and how frequently those patients utilized the services; and (2) the number of patients the practitioner referred for psychosocial or case management services at a different location." An additional commenter recommended that practitioners be required to report on the number of patients who were provided counseling services at the same location as the practitioner and how frequently those patients utilized the counseling services. One commenter also recommended that practitioners be required to provide information on the frequency, location, and type of psychosocial services provided. Another commenter recommended that practitioners be required to report whether the referral was to a more intensive or less intensive level of care.

Finally, one commenter recommended HHS collect data on referrals and behavioral health service provision using a six-point Likert scale.

*Response:* This reporting requirement has been revised and now asks the practitioner to report on the number of patients provided behavioral health services and referred to behavioral health services. By seeking information on the number of patients that were provided services and referred for behavioral health services, HHS believes this updated reporting requirement, as further elaborated upon in the report form instructions, will strike the appropriate balance between collecting valuable information needed to assess compliance with the rule and avoiding undue burden to practitioners.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, HHS replaced the second reporting requirement with one that requires the practitioner to report on the number of patients provided behavioral health services and referred to behavioral health services.

*Percentage of patients who had a prescription drug monitoring program query in the past month.*

*Comments:* HHS received several comments about the proposed reporting requirement, “Percentage of patients who had a PDMP query in the past month.” One commenter stated that this data would not be informative because his practice conducts these queries for all patients. This commenter also stated that the state PDMP should provide this information instead. Another commenter suggested that the PDMP query should take place quarterly. An additional commenter stated that HHS should identify a way to collect similar data in Missouri, which does not have a PDMP. One commenter recommended that practitioners also be asked about the number of patients who had a PDMP query before the prescriptions were filled.

Another commenter stated that practitioners receive alerts from local pharmacies and the State if a patient receiving buprenorphine attempts to fill another opioid prescription by any practitioner, and asked whether this information could be used as a response for this reporting requirement. The commenter noted that they do not routinely run PDMP data on patients receiving buprenorphine, but do query PDMP data for every controlled substance refilled by phone.

HHS also received several comments focused more broadly on diversion control. One commenter recommended

that SAMHSA provide guidelines for practitioners to develop diversion control plans. Another commenter suggested that HHS require practitioners with a waiver under DATA 2000 to participate in PDMPs. Several commenters also recommended that HHS ask about the number of patients who received urine drug screens, the results of drug screens, and the number of patients who received call-backs for pill counts. Several commenters noted that not every practitioner has access to a PDMP and encouraged HHS to use language that would apply in those situations. Finally, one commenter recommended that HHS ask about PDMP use and drug-use monitoring screening tests using a six-point Likert scale.

*Response:* The intention of including PDMP queries was to assess a practitioner’s compliance with the rule’s requirements related to a diversion control plan. In light of the comments received, which focused more broadly on various aspects of diversion control, HHS determined that the best way to satisfy the intent of the proposal and assess compliance is to seek information about the features of the practitioner’s diversion control plan, as required in § 8.620, more generally.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, HHS modified the third reporting requirement to require the practitioner to report on the features of his or her diversion control plan.

*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 practitioner due to referral by the practitioner to a more or less intensive level of care; (3) No longer desire to continue use of buprenorphine; and (4) Are no longer receiving buprenorphine for reasons other than 1–3.*

*Comments:* HHS received numerous comments about the proposed reporting requirement, “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 practitioner due to referral by the practitioner to a more or less intensive level of care; (3) No longer desire to continue use of buprenorphine; and (4) Are no longer receiving buprenorphine for reasons other than 1–3.” A large number of commenters expressed concern with the first item, noting that

it suggests that buprenorphine treatment is temporary and/or that individuals who receive it are not in recovery. One commenter expressed concern with the third and fourth item, noting that it is difficult to differentiate between these two subsets of patients. Some commenters expressed that it is difficult to determine what number of patients “sustain recovery” and that SAMHSA should provide guidance on what constitutes an appropriate course of treatment. Another commenter stated that a practitioner is unable to control whether a patient follows through on a referral.

Other commenters recommended alternative questions to ask for this proposed reporting requirement, including: The percentage of patients who are prescribed an average dose of 16 mg or less; the percentage of patients who left treatment because the practitioner terminated treatment due to non-compliance; patient mortality rates; the number of patients who left treatment because of the financial cost of treatment; and the number of patients who left treatment to receive treatment in an either higher or lower intensity setting or were deemed successful.

Another commenter stated that the data collected in this reporting requirement should not include those lost to follow-up or relapse. Finally, an additional commenter stated that some patients at the commenter’s facility graduate from treatment and only use counselors as needed. The commenter stressed that these patients should not be counted as patients not receiving treatment.

*Response:* HHS determined that the proposed requirement will be too burdensome for practitioners. Therefore, HHS is not including this reporting requirement in Subpart F.

#### Additional Reporting Requirements

*Comments:* HHS received several comments recommending additional reporting requirements for practitioners. One commenter recommended that the reporting requirements focus on quality measures rather than process measures. Another commenter recommended that HHS create a core set of requirements that practitioners attest to on an annual basis, which could include both quality and process measures.

Other commenters recommended HHS collect data on: The amount of buprenorphine that patients receive; the number of times they receive buprenorphine; the number of active patients for whom third party reimbursement was provided; patient mortality rates; frequency of patient visits; and the percentage of

prescriptions written for less than 30 days, 30–59 days, 60–89 days, and 90 days or more.

*Response:* Because HHS aims to strike the appropriate balance between collecting valuable information to assess compliance with Subpart F and minimizing the burden on practitioners, these proposed reporting requirements will not be added. HHS believes that the requirements included in this final rule are sufficient to ensure compliance with the assurances to which the practitioner attests to in the Request for Patient Limit Increase.

**Alternative Ways To Meet and Provide Reporting Requirements**

*Comments:* HHS received a number of comments proposing alternative ways to collect data from practitioners. One commenter suggested that HHS obtain information by adding questions about psychosocial treatment to DEA’s questions as an alternative to the proposed reporting requirements. Another commenter stated that the DEA audit program should be sufficient to ensure compliance. Other commenters suggested that data could be obtained from the state PDMP, from electronic medical record systems, or from insurance claims data. Finally one commenter recommended HHS incorporate these reporting requirements into the set of measures associated with financial incentives under the Centers for Medicare & Medicaid Services’ new Medicare Incentive Payment System’s program.

*Response:* The proposed alternative ways to collect data from practitioners will not generate all of the information HHS is seeking through the proposed reporting requirements. Therefore, HHS will not collect the data using any of these approaches.

*Comments:* HHS received several comments recommending that there be an electronic form through which

practitioners can submit the required data.

*Response:* HHS will explore developing a form that can be submitted electronically through which practitioners can submit the required data.

*Comments:* HHS received several comments recommending HHS convene an expert panel to review and re-evaluate the reporting requirements either prior to adoption or after the first reporting period.

*Response:* HHS received numerous public comments regarding the reporting requirements during the comment period for the Medication Assisted Treatment for Opioid Use Disorders NPRM (published in March 2016), and during the comment period for the reporting requirements proposed in the SNPRM (published in July 2016). These comments were received from a variety of stakeholders, including experts in the field. Therefore, HHS does not believe that convening an expert panel is necessary to ensure that the reporting requirements are appropriate.

*Comment:* HHS received a comment recommending that reporting requirements be voluntary.

*Response:* HHS believes that making these requirements voluntary would dramatically compromise the quality and amount of data received. Therefore, HHS will make these requirements mandatory in order to ensure that HHS is able to assess compliance with the requirements of 42 CFR part 8, subpart F.

*Comment:* HHS received a comment recommending using the reporting requirement information to determine whether practitioners with the 100-patient waiver should be able to increase their patient limit to 275.

*Response:* Practitioners who are subject to the 100-patient limit are not required to report data.

*Comments:* HHS received comments recommending collecting reporting data from practitioners more than once per year.

*Response:* HHS believes that requiring practitioners to submit data more than once per year would be unduly burdensome.

**III. Collection of Information Requirements**

The SNPRM called for new collections of information under the Paperwork Reduction Act of 1995. The final rule calls for much of the same collections of information as the SNPRM. As defined in implementing regulations, “collection of information” comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. In this section, HHS first identifies and describes the types of information waived practitioners must collect and report and then HHS provides an estimate of the total annual burden. The estimate covers the employees’ time for reviewing and posting the collections required.

*Title:* Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements.

*Reporting, 42 CFR 8.635:* Reporting will be required annually to assess compliance with the requirements of 42 CFR part 8, subpart F. Reporting requirements will include a request for information regarding: (1) Annual caseload of patients by month; (2) number of patients provided behavioral health services and referred to behavioral health services; and (3) features of the practitioner’s diversion control plan. These requirements will be further specified in the report form instructions to be issued after finalization of this rule.

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

*Comment:* HHS received a comment stating that the estimated burden of three hours per year is inaccurate.

*Response:* While the commenter stated that the estimated burden of three hours per year is inaccurate, the commenter did not provide evidence to support their claim. As a result, HHS retains the original estimate of three hours per year. More information on

this estimate can be found below in the Regulatory Impact Analysis.

**IV. Regulatory Impact Analysis**

HHS has examined the impact of this final 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. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995), and Executive Order 13132 on Federalism (August 4, 1999). HHS has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866, and will not have a significant economic impact on a substantial number of small entities. Although the reporting requirements

have changed since the proposed rule, they have not done so in a way that would alter their estimated impact. As described below, the estimated costs associated with this final rule are below one million dollars each year, and the estimated per-practitioner burden is three hours annually, supporting the conclusion that this rule will not have a significant economic impact on a substantial number of small entities.

Under this final rule practitioners approved to treat up to 275 patients will have to submit information about their practice annually to SAMHSA for purposes of monitoring regulatory compliance. The goal of the reporting requirement is to ensure that practitioners are providing buprenorphine treatment in compliance with the final rule Medication Assisted Treatment for Opioid Use Disorders (81 FR 44711). It is anticipated that the data

for the reporting requirement can be pulled directly from an electronic or paper health record, and that practitioners will not have to update their record-keeping practices after receiving approval to treat up to 275 patients. We estimate that compiling and submitting the report would require approximately 1 hour of physician time and 2 hours of administrative time. According to the U.S. Bureau of Labor Statistics, the average medical and health services manager's hourly pay in 2014 was \$49.84, and the average hourly wage for a physician was \$93.74. After adjusting upward by 100 percent to account for overhead and benefits, these wages correspond to a cost of \$99.68 and \$187.48 per hour, respectively. The cost of this reporting requirement per practitioner approved for the 275-patient limit is estimated to be the cost

of 1 hour of a practitioner's time plus 2 hours of an administrator's time.

As noted above, using the mid-point estimate, we estimate that 1,150 practitioners will request approval for the 275-patient limit in year 1 and 200 practitioners will request a 275-patient waiver in subsequent years. We assume that all of these requests will be approved. The costs associated with this reporting requirement are reported below. In addition, it is estimated that SAMHSA will incur a cost of \$100 per practitioner approved for the 275-patient limit to process the practitioner data reporting requirement. These costs are reported below as well.

We assume DEA will not incur additional costs in association with this final rule as DEA will incorporate site visits for practitioners with the 275-patient limit into their regular site visit schedule.

	Number of physician reports	Physician costs	SAMHSA costs
Year 1 .....	1,150	\$445,000	\$115,000
Year 2 .....	1,350	522,000	135,000
Year 3 .....	1,550	600,000	155,000
Year 4 .....	1,750	677,000	175,000
Year 5 .....	1,950	754,000	195,000

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

Health professions, Methadone, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HHS amends 42 CFR part 8 as follows:

**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. Amend § 8.630 by adding paragraph (b) to read as follows:

**§ 8.630 What must practitioners do in order to maintain their approval to treat up to 275 patients?**

\* \* \* \* \*

(b) All practitioners whose Request for Patient Limit Increase has been approved under § 8.625 must provide reports to SAMHSA as specified in § 8.635.

■ 3. 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) *General.* All practitioners whose Request for Patient Limit Increase is approved under § 8.625 must submit to SAMHSA annually a report along with documentation and data, as requested by SAMHSA, to demonstrate compliance with applicable provisions in §§ 8.610, 8.620, and 8.630.

(b) *Schedule.* The report must be submitted within 30 days following the anniversary date of a practitioner's Request for Patient Limit Increase approval under § 8.625, and during this period on an annual basis thereafter or on another annual schedule as determined by SAMHSA.

(c) *Content of the Annual Report.* The report shall include information concerning the following, as further detailed in report form instructions issued by the Secretary:

- (1) The annual caseload of patients by month.
- (2) Numbers of patients provided behavioral health services and referred to behavioral health services.
- (3) Features of the practitioner's diversion control plan.

(d) *Discrepancies.* SAMHSA may check reports from practitioners prescribing under the higher patient limit against other data sources to the extent allowable under applicable law. If discrepancies between reported information and other data are identified, SAMHSA may require additional documentation from the practitioner.

(e) *Noncompliance.* 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: September 21, 2016.

**Kana Enomoto,**  
Principal Deputy Administrator, Substance Abuse and Mental Health Services Administration.

Approved: September 22, 2016.

**Sylvia M. Burwell,**  
Secretary, Department of Health and Human Services.

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