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42 CFR Part 8

Medication Assisted Treatment for Opioid Use Disorders; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 8**

**RIN 0930-AA22**

**Medication Assisted Treatment for Opioid Use Disorders**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule increases access to medication-assisted treatment (MAT) with buprenorphine and the combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) in the office-based setting as authorized under the United States Code. Section 303(g)(2) of the Controlled Substances Act (CSA) 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. This final rule will expand 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 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.

**DATES:** *Effective Date:* This final rule is effective on August 8, 2016.

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

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

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**I. Background**

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) for use in maintenance and detoxification treatment without registering as an opioid treatment program (OTP). Buprenorphine is a schedule III controlled substance under the CSA. To qualify to treat any patients with buprenorphine, the practitioner must be a physician, possess a valid license to practice medicine, be a registrant of the Drug Enforcement Administration (DEA), have the capacity to refer patients for appropriate counseling and other necessary ancillary services, and have completed required training.

The CSA also imposes a limit on the number of patients a practitioner may treat with certain types of FDA-approved narcotic drugs, such as buprenorphine, at any one time. Specifically, 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.

Pursuant to 21 U.S.C. 823(g)(2)(B)(iii), the Secretary is authorized to change the patient limit by regulation.

*A. Regulatory History*

On March 30, 2016, the Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM), entitled, "Medication Assisted Treatment for Opioid Use Disorders", in the **Federal Register**, and invited comment on the proposed rule.<sup>1</sup> The comment period ended on May 31, 2016. In total, HHS received 498 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Individuals that currently prescribe buprenorphine and other health care professionals, such as nurse practitioners and pharmacists; health care policymakers; national organizations representing providers and public health agencies; and individuals who self-identified as current buprenorphine patients. A significant number of comments came from individuals who were part of a mass mail campaign organized by a national organization representing substance use disorder treatment specialists.

*B. Overview of Final Rule*

The final rule adopts the same basic structure and framework as the proposed rule: Subpart A sets forth the

general provisions of the rule; current subparts A, B, and C would change to subparts B, C, and D, respectively; the titles of these subparts would be revised to make it clear that they apply only to OTPs; subpart E is reserved and subpart F contains the final rule. Subpart A, § 8.1 details the scope of the rule and explains that the proposed rules in the new subpart F pertain only to those practitioners using a waiver under 21 U.S.C. 823(g)(2) with a patient limit of 101 to 275. Subpart A, § 8.2 provides the definitions that apply to the entirety of part 8 and § 8.3 discusses opioid treatment programs. Subpart F discusses the authorization to increase the patient limit to 275 patients. Subpart F, § 8.610 describes which practitioners are qualified for a patient limit of 275; subpart F, § 8.615 describes a qualified practice setting; subpart F, § 8.620 discusses the process to request a patient limit of 275; subpart F, § 8.625 details how a request will be processed; subpart F, § 8.630 describes what a practitioner must do to maintain the 275 patient limit; subpart F, § 8.635 is reserved; subpart F, § 8.640 details the renewal process for practitioners who desire to keep their 275 patient limit; subpart F, § 8.645 discusses the responsibilities of practitioners whose renewal request for the 275 patient limit was denied or who did not request for a renewal of the 275 patient limit; subpart F, § 8.650 details the conditions under which SAMHSA can suspend or revoke a patient limit increase approval; and subpart F, § 8.655 provides the rules applicable to patient limit increases in emergency situations.

HHS has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

HHS has changed the highest patient limit from 200 to 275.

HHS also changed § 8.610 by revising the language in this section. This change will allow additional addiction specialists to treat up to 275 patients by including all practitioners with additional credentialing as defined in § 8.2.

HHS has decided to delay the finalization of the proposed reporting requirements in § 8.635 and is publishing elsewhere in this issue of the **Federal Register** a Supplemental Notice of Proposed Rulemaking to solicit additional comments on the proposed reporting requirements prior to finalizing them. We expect to finalize the reporting requirements expeditiously.

HHS has responded to the comments received on the proposed rule, and provided an explanation of each of the

<sup>1</sup> 81 FR 17639 (Mar. 30, 2016).

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 a number of comments that expressed general support and advocacy for the proposed rule. Many of these comments pointed to the lives that will be saved and the long waitlists for MAT that will be shortened.

Commenters also noted that the rule provides parity with other conditions/medications and that the rule will help provide a research-based understanding of addiction.

There were also some comments that expressed disagreement with the proposed rule. These commenters said that MAT was not as effective as traditional models and that buprenorphine is a drug of diversion and misuse, and could result in poor outcomes. Some commenters cited a need for more providers rather than higher prescribing limits. Several commenters suggested that the application and renewal procedure and the recordkeeping and reporting requirements will dissuade physicians from applying for the higher patient limit.

A comment also suggested that very few additional patients will receive addiction treatment with buprenorphine as a result of the proposed rule, due to the small number of subspecialists eligible to treat an additional 100 patients each, unclear criteria for what constitutes a qualified practice setting, and continued poor reimbursement.

Given the evidence supporting buprenorphine-based MAT as an effective treatment for opioid use disorder and the magnitude of the opioid crisis, this rule is intended to increase access to buprenorphine-based MAT, prevent diversion, and ensure quality services are provided. With respect to the comment specifically related to the issues of subspecialty board certification and unclear criteria for a qualified practice setting, the final rule addresses these issues by replacing the "board certification" definition with an "additional credentialing" definition and also provides further clarity regarding the criteria for a qualified practice setting. HHS appreciates that increasing the patient limit for certain MAT providers is a complex issue and is not the only avenue for addressing the opioid public health crisis. HHS is promoting access to all forms of MAT for opioid use disorder through multiple activities included in the Secretary's

Opioid Initiative. Given the Secretary's authority to increase the patient limit on treatment under 21 U.S.C. 823(g)(2) by rulemaking, the rule is an essential element of a comprehensive approach to increasing access to MAT.

HHS also received a wide variety of comments related to the issue of MAT that did not specifically relate to a section of the proposed rule, but generally fell into five main categories. The categories and comments are as follows.

#### Other Practitioners

Many commenters wrote about the eligibility and role of nurse practitioners and/or physician assistants in prescribing buprenorphine. The vast majority of these commenters suggested that nurse practitioners and physician assistants should be allowed to prescribe buprenorphine under the new regulation. Two major associations wrote in support of registered nurses with addiction specialty training to be able to prescribe. Numerous comments stated that HHS needed to include other practitioners especially in order to reach rural and medically underserved regions.

HHS also received several comments opposed to allowing nurse practitioners and physician assistants to prescribe buprenorphine.

Questions related to expanding eligible prescribers are outside the scope of this rulemaking; the statute limits who is eligible to prescribe buprenorphine for MAT. 21 U.S.C. 823(g)(2) limits the practitioners eligible for waiver in this context to physicians, and, therefore, HHS is not authorized to include other types of providers in this rule. However, HHS recognizes the issues raised by commenters and the President's FY 2017 Budget proposes a buprenorphine demonstration program to allow advance practice providers to prescribe buprenorphine. This would allow HHS to begin testing other ways to improve access to buprenorphine throughout the country.

#### New Formulations

In the NPRM, HHS proposed that the Secretary would establish a process by which patients who are treated with medications covered under 21 U.S.C. 823(g)(2)(C), that have features that enhance safety or reduce diversion, as determined by the Secretary, may be counted differently toward the prescribing limit established in the proposed rule. Such medications are referred to here as "new formulations." HHS also proposed that the criteria for determining which if any of these new formulations may be considered, and

how these patients will be counted toward the patient limit, will be based on the following principles: (a) The relative risk of diversion associated with medications that become covered under 21 U.S.C. 823(g)(2)(C) after the effective date of the proposed rule; and (b) the time required to monitor patient safety, assure medication compliance and effectiveness, and deliver or coordinate behavioral health services.

HHS did not receive any comments that provided specific criteria to be used to count new formulations differently under the patient limit. One commenter suggested that abuse-deterrent labeling should not be a requirement. HHS did receive a small number of comments about new formulations which recommended that patients being treated with these new formulations not be counted against a patient limit. One commenter stated that HHS should establish a process for counting the patients differently if there is a risk to public health. Another commenter recommended the establishment of a process for evaluating new formulations that would be triggered by a petition from a product manufacturer, trade association, practitioner, State or local agency, or representatives of opioid use disorder patients or their families.

HHS received a number of comments recommending a cautious approach, including one suggestion to not count patients as fractions and another to consider the potential impact of a formulation-based counting methodology on practitioners and patient-driven recovery. One commenter expressed concern that new formulations that require less oversight from a practitioner may result in the reduction of psychosocial and other support services. HHS also received a comment that it is too soon to determine how patients treated with the new formulations should be counted.

HHS will review new formulations as they are approved by FDA for use in the treatment of opioid use disorder and is strongly supportive of innovative formulations that increase access to MAT.

With respect to the comments suggesting that no limit apply to patients treated with new formulations, HHS does not believe that raising the limit beyond that specified in this rule is warranted at this time.

After reviewing the comments, HHS has determined under the final rule, all patients treated with medications covered under 21 U.S.C. 823(g)(2)(C), including new formulations, will be counted against the patient limit established by this rule in the same

manner. HHS may choose to revisit this issue in the future.

#### Patient Cost and Coverage

HHS received several comments describing insurance-related issues that commenters believe affect access to treatment with buprenorphine. These comments, which are outside the scope of this rulemaking, focused on topics such as varying formats for requesting approval for treatment services and prescription coverage, reimbursement rates, coverage criteria, pharmacy practices, implementation of substance use disorder parity laws, and use of quality metrics. HHS received comments stating that the proposed rule does not address the many reasons why providers are not prescribing MAT to the fullest extent of their current waivers, including concerns about public and private insurer reimbursement for the additional reporting, documentation, and counseling as well as concerns about on-site DEA inspections.

HHS appreciates these comments and is aware of the issues associated with access to buprenorphine. However, these issues are beyond the scope of this rulemaking given HHS' regulatory authority under 21 U.S.C. 823(g)(2)(B)(iii).

#### Prescribing Practices

HHS received many comments that related to prescribing practices. One comment recommended that a prescriber of buprenorphine not be permitted to make a diagnosis of opioid use disorder or dependency in order to prevent the development of "pill mills." Another comment stated that Vivitrol® should be offered along with buprenorphine and another stated that it should be prescribed in place of buprenorphine.

Several commenters focused on limiting prescriptions of opioids. Others proposed limiting the allowable dosing of buprenorphine. One commenter recommended that the number of patients allowed for treatment by a waived practitioner should be tied to the recommended dose in order to incentivize physicians to prescribe appropriate doses of buprenorphine in an effort to decrease diversion. The commenter also stated that a physician treating 200 patients should not be allowed to prescribe more than an average of 2,800 mg of buprenorphine per day. HHS also received a comment that practitioners prescribing buprenorphine up to a higher patient limit should be required to see patients at least once a month.

HHS received a comment recommending that physicians obtain a written agreement from each patient stating that the patient: Will receive an initial assessment and treatment plan; will be subject to medication adherence and substance use monitoring; and understands all available treatment options, including all FDA-approved drugs for treatment of opioid use disorder and their potential risks and benefits. One commenter suggested that HHS issue firm recommendations on safe medication renewal quantities and weaning and reduction timeframes. Another commenter suggested taking into consideration the individual's age, gender, ethnicity, and culture during treatment.

HHS recognizes that there are multiple approaches to addressing opioid use disorder. However, many of these issues are beyond the scope of this rule.

#### Other Approaches to Opioid Use Disorders

Many comments provided suggestions on how to broadly address the problem of opioid use disorder. HHS received several comments noting that, despite being able to prescribe buprenorphine to only a limited number of patients, practitioners are not subject to any limits when prescribing opioids for pain. Some commenters recommended that either the limit to prescribe buprenorphine be removed or that an opioid prescribing limit be established. One commenter asked that if HHS believes that there should be a limit on the number of patients treated with buprenorphine, why HHS is not also seeking a limit on the number of patients prescribed schedule II opioids for chronic pain. And another commenter suggested that physicians who prescribe opioids should be required to offer treatment for opioid use disorders.

HHS also received a few comments that concerned treatment using antidepressants, anxiolytics, and antipsychotics where patient limits do not apply. The commenters felt the same concept should be applied to buprenorphine.

A buprenorphine patient limit was introduced in statute. HHS' rulemaking is intended to implement the statutory provisions. With respect to opioid prescribing, the Centers for Disease Control and Prevention (CDC) recently released the Guideline for Prescribing Opioids for Chronic Pain and SAMHSA supports the Providers' Clinical Support System-Opioid program, which is a national training and mentoring project that makes available at no cost

continuing medical education (CME) programs on the safe and effective use of opioids for treatment of chronic pain and safe and effective treatment of opioid use disorder. HHS received comments focused on the system of treatment for opioid use disorders, including the integration of behavioral health into primary care; screening for substance use disorders and connecting to treatment via Screening, Brief Intervention, and Referral to Treatment (SBIRT); reimbursement issues; and use of opioid antagonists such as naloxone in preventing opioid overdose.

A comment stated that the organization wanted to make sure patients receive long-term evidence-based care to treat opioid use disorder. HHS also received several comments stating that it needed to ensure that a full continuum of care is available for patients. While ongoing work is occurring throughout HHS on improving access to treatment, these specific issues are outside the scope of this rulemaking.

HHS also received a comment recommending that we consider additional strategies to incentivize primary care providers to apply for waivers to prescribe buprenorphine, including educational campaigns to address any misperceptions related to buprenorphine prescribing and DEA audits, greater dissemination of research and data regarding evidence-based MAT, and continual engagement with stakeholders to ensure the legal and regulatory framework is appropriate and effective. Another commenter also expressed the need for a national educational campaign about misuse of prescription opioid analgesics. One commenter recommended that HHS work with other local, State and Federal entities, including the Centers for Medicare & Medicaid Services (CMS), FDA, CDC, and DEA to develop education for the public that is both comprehensive and targeted to address the knowledge gaps of relevant stakeholders. HHS received comments expressing the importance of increasing the number of resources, training, and qualified personnel to prescribe buprenorphine and administer and monitor patients. Another commenter also felt that we should consider additional measures to educate physicians about best practices to minimize the risk of diversion, including the distribution of best practice guidance documents. An additional comment expressed concerns that clinics owned and operated by non-physicians, or employing part-time newly waived physicians, with no full-time addiction physician oversight

and supervision will greatly increase the potential for diversion. HHS intends to continue to work to educate eligible practitioners about the waiver process and ensure that the process is as efficient as possible.

HHS also received a comment expressing concerns that raising the limit will not sufficiently address improving access to individuals located in geographic regions where buprenorphine or other MAT medications are currently unavailable, because only a third of buprenorphine-waivered physicians are qualified to treat 100 patients at a time.

HHS shares the commenters' concern that some populations are geographically disadvantaged in terms of access to MAT. HHS believes this final rule will help address this concern by expanding the ability for physicians in all areas, including rural areas, to treat patients with opioid use disorder while minimizing the risk of diversion. In addition, the shift in policy from allowing a practitioner with a waiver to treat up to 200 patients in the NPRM to allowing a practitioner with a waiver to treat up to 275 patients is likely to have a significant impact in rural areas which are currently served by smaller numbers of practitioners with waivers.

HHS appreciates the many comments aiming to more broadly address the issue of opioid use. While this rule is more limited in scope, HHS is working to address some of the ideas expressed in the comments through other actions taken to implement the Secretary's Opioid Initiative.

#### Other Comments

HHS received several comments estimating the number of practitioners who would seek a waiver for the higher patient limit. For example, one comment stated that between 8 and 15 Vermont physicians would seek the additional waiver to treat 200 patients, noting that it would have the potential to increase access to office-based outpatient treatment services by between 25 and 50 percent from its current utilization rate. HHS considered these estimates as it calculated the Regulatory Impact Analysis (RIA) for the rule.

HHS received a comment asking why there were different rules for methadone and another one that asked why the rules were different than the rules in Canada.

Methadone is not included as part of this rule because methadone is a Schedule II drug, while the only medications covered under this rule are in Schedule III, IV, or V, pursuant to 21 U.S.C. 823(g)(2)(C). In addition, the

United States and Canada regulate opioid use disorder treatment under different laws.

HHS received a comment stating that impaired decision-making, especially for safety sensitive professions (*e.g.*, airline pilots, transit workers, health care professionals), posed public/patient safety concerns due to possible cognitive and motor impairment related to buprenorphine and stated that naltrexone may be considered as an alternative.

While this issue is beyond the scope of this rule, HHS encourages all practitioners to fully inform their patients about MAT, whether it is appropriate for an individual patient and, if so, which FDA-approved medications may be most appropriate for that patient.

Another commenter requested guidance on what constitutes an appropriate course of treatment and how "recovery" should be determined, which will enable them to meet the reporting requirements more successfully. An additional commenter requested that guidance specify whether or not an in-office induction is required.

HHS appreciates these comments and will bear them in mind as it develops guidance documents after the final rule goes into effect.

#### Subpart A—General Provisions

In the proposed rule, HHS proposed increasing the highest available patient limit for qualified practitioners to receive a waiver from 100 to 200. This proposed higher patient limit was intended to significantly increase patient capacity for practitioners qualified to prescribe at this level while also ensuring that waived practitioners would be able to provide comprehensive treatment associated with MAT.

Under the final rule, practitioners authorized to treat up to 275 patients will be required to meet infrastructure requirements that exceed those required for practitioners who have a waiver to treat 100 or fewer patients. HHS proposed additional criteria and responsibilities for practitioners to be able to treat up to the higher patient limit with the specific aims of ensuring quality of care and minimizing diversion. Importantly, the additional criteria and responsibilities were not intended to be unduly burdensome to practitioners who wish to expand their MAT treatment practice. Also, the rule does not add these additional requirements to practitioners who have a waiver to treat up to 100 patients under 21 U.S.C. 823(g)(2). The rule also creates an option for an increased

patient limit for practitioners responding to emergency situations that require immediate, increased access to medications covered under 21 U.S.C. 823(g)(2)(C). In addition, HHS included key definitions that will help practitioners understand and implement the requirements of this rule.

As proposed in the NPRM, this rule will be added to 42 CFR part 8 as subpart F. Accordingly, changes to part 8 were necessary to integrate the contents of the new regulations established by this rule into part 8. For example, part 8, subparts A, B, and C, had to be reordered as subparts B, C, and D, respectively. The titles of these subparts were revised to make it clear that they apply only to OTPs.

The comments and HHS' responses are set forth below.

*Comment:* HHS received several comments stating that raising the patient limit to 200 was not likely to make a significant impact on addressing the treatment gap. Some commenters suggested the limit should be raised to 500 patients or that there should be no patient limit at all. Other commenters supported the proposed limit of 200 patients. One commenter suggested that the patient limit be removed for physicians operating in a nationally accredited or State licensed substance use disorder treatment center.

*Response:* In the NPRM, HHS proposed raising the patient limit for certain qualified physicians to 200. This was based on a conservative estimate of the number of patients who could be treated by a single physician in a high-quality, evidence-based manner that minimizes the risk of diversion. However, prior to the NPRM, the proposed patient limit of 200 did not have the benefit of public comment. Although many commenters expressed that a 200 patient limit was appropriate, a number of commenters stated that the 200 patient limit was not sufficient to substantially address the treatment gap, with some commenters suggesting the limit be raised to 500 and others stating there should be no patient limit. HHS reviewed all pertinent comments and completed a reassessment of the available data. In particular, an analysis of the number of patients treated in OTPs—a set of structured clinics that deliver comprehensive care for opioid use disorder—helped to guide HHS' deliberation. Using data from the 2013 National Survey of Substance Abuse Treatment Services, the average number of patients who could be managed at any given time in an OTP ranged from 262 to 334, demonstrating that high-quality, evidence-based MAT could be provided to a larger number of patients

in this structured and regulated environment. Given that HHS expects that buprenorphine provision in the outpatient setting will involve a less structured and regulated environment, we believe setting the limit within the lower range of the average number of patients who could be treated in an OTP is prudent. Thus, based on our reassessment of the data and review of public comments, HHS has determined that increasing the patient limit to 275 balances the pressing need to expand access to MAT with the desire to ensure the provision of high-quality, evidence-based MAT while limiting the risk of diversion. We note that this rule is intended to expand access directly by increasing patient capacity for practitioners who get a waiver to treat more than 100 patients, and indirectly by increasing the incentive to enter into the field of addiction medicine or addiction psychiatry by expanding opportunities within the field.

*Comment:* HHS received a comment requesting that the rule provide some waiver increase for all certified office-based opioid treatment with buprenorphine physicians. The commenter also recommended that all physicians currently holding a waiver to prescribe up to 100 patients and who have been in good standing for the past year be allowed increases as follows: (1) If they are not board certified and not working in a qualified practice setting, they should be allowed to treat an additional 50 patients; (2) If they are not board certified but are working in a qualified practice setting, they should be allowed to treat an additional 100 patients; (3) If they are board certified but not working in a qualified practice setting, they should be allowed to treat an additional 150 patients; and (4) If they are board certified and are working in a qualified practice setting, they should be allowed to treat an additional 200 patients.

*Response:* The rule seeks to balance the increased accountability associated with the higher limit of 275 with the opportunity for practitioners to attain efficiencies of scale and provide two distinct and non-duplicative pathways by which practitioners can access the higher limit. This reflects HHS' desire to provide pathways to the higher limit to a range of motivated practitioners, with a modest and tolerable burden to the practitioner.

*Comment:* HHS received a comment recommending that ABAM-certified physicians not be limited in the number of patients to whom they can prescribe buprenorphine. HHS also received a comment encouraging HHS to lift the patient limit for any practitioner

providing MAT using buprenorphine in all programs licensed or certified by a State oversight agency for substance use.

*Response:* HHS appreciates the comment and the role of ABAM-certified practitioners and has modified the proposed rule to include these professionals among those eligible for the highest limit of 275. With respect to the comments suggesting that no limit apply to patients treated by practitioners in programs licensed or certified by a State oversight agency, HHS believes, for the reasons stated, that the 275 patient limit is the appropriate limit.

*Comment:* HHS received a comment recommending that the patient limit be based on the percentage of the practice that provides addiction treatment.

*Response:* Relevant patient limits in this context apply to a specific waived practitioner, not to a practice of multiple providers. Accordingly, HHS believes that the approach taken in the final rule provides the best available method to clearly establish a higher patient limit that can be monitored and enforced.

*Comment:* HHS received a comment requesting greater clarity about whether a patient treated with buprenorphine at an OTP is counted toward the practitioner's patient limit. The commenter recommended that patients treated in opioid treatment programs not be counted toward the patient limit.

*Response:* Patients receiving buprenorphine administered or dispensed by an OTP, from medication ordered under the program's DEA registration, are patients of the OTP and do not count toward any practitioner's patient limit.

#### Summary of Regulatory Changes

For the reasons set forth above and considering the comments and additional information received, we have changed the proposed patient limit of 200 to 275 patients per practitioner for practitioners who meet the requirements laid out in the final rule.

#### Subpart A—Scope (§ 8.1)

HHS proposed that the scope of part 8 would cover rules that are applicable to OTPs, and to waived practitioners who seek to treat more than 100 patients with applicable medications. New subparts B through D under the final rule contain the rules relevant to OTPs. Subpart E is reserved and Subpart F contains the new final rule. Section 8.1 also explains that the rules in the new subpart F pertain only to those practitioners using a waiver under 21 U.S.C. 823(g)(2) with a patient limit of 101 to 275.

#### Summary of Regulatory Changes

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 8.1 without modification.

#### Subpart A—Definitions (§ 8.2)

HHS proposed definitions that would apply to the entirety of part 8. HHS also proposed revising definitions that would apply only to OTPs. Two definitions were proposed for elimination: "Registered opioid treatment program" and "opiate addiction."

HHS proposed a revised definition of "patient." At present, the definition of "patient" in § 8.2 is limited to those individuals receiving treatment at an OTP, which excludes those individuals receiving office-based opioid treatment with buprenorphine, *i.e.*, those practitioners subject to 21 U.S.C. 823(g)(2).

HHS proposed a revised definition of patient to make it inclusive of all persons receiving MAT with an opioid medication, consistent with the expanded scope of proposed revisions to 42 CFR part 8. HHS proposed that patient "means any individual who receives MAT from a practitioner or program subject to this part." Upon further review, we determined that modifications to the proposed definition of "patient" were needed to clarify the scope of patients covered under this rule (for purposes of the patient limit), and to distinguish such patients from opioid treatment program patients for which no patient limit applies. We are now defining patient as, for purposes of subparts B–E, meaning any individual who receives maintenance or detoxification treatment in an opioid treatment program. For purposes of subpart F patient means any individual who is dispensed or prescribed covered medications by a practitioner. The patient definition modifications reflected in the final rule are consistent with the intention of the NPRM. As we explained in the NPRM, if a practitioner, for example, provides cross-coverage for another practitioner and in the course of that coverage the covering practitioner provides a prescription for buprenorphine, the patient counts towards the cross-covering practitioner's patient limit until the prescription or medication has expired. However, if a cross-covering practitioner is merely available for consult but does not dispense or prescribe buprenorphine while the prescribing practitioner is away, the patients being covered do not count

towards the cross-covering practitioner's patient limit. Therefore, this definition is expected to help ensure consistency and clarity in how waived practitioners count patients towards the patient limit.

HHS proposed that the rule include the following definition of patient limit: "the maximum number of individual patients a practitioner may treat at any time using covered medications." Given the changes to the definition of "patient," the definition for "patient limit" was modified to mean the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time. This modification ensures alignment between the definition of "patient" and "patient limit."

Taken together, the definitions of "patient" and "patient limit" provide clear and fair guidance for regulatory enforcement and are expected to reduce undercounting of patients by practitioners. These definitions are also intended to clarify that patients who are not dispensed or prescribed medication covered by this rule should not be counted against a practitioner's patient limit. Accordingly, waived practitioners will be able to provide reciprocal cross-coverage to patients of other practitioners (assuming the dispensing or prescribing of covered medication is not involved) for brief periods, such as weekends or vacations, without requiring such patients to be added to the patient count of the practitioner who is providing cross-coverage.

Other new definitions proposed include "behavioral health services," "emergency situation," "nationally recognized evidence-based guidelines," "practitioner incapacity" and "waived practitioner."

HHS proposed to define "nationally recognized evidence-based guidelines" to mean a document produced by a national or international medical professional association, public health entity, or governmental body with the aim of ensuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions. Some examples include the American Society of Addiction Medicine (ASAM) National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use; SAMHSA's Treatment Improvement Protocol 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; the World Health Organization Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid

Dependence; the Department of Veterans Affairs/Department of Defense/Clinical Practice Guideline on Management of Substance Use Disorder; and the Federation of State Medical Boards' Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office. HHS expects that guidelines meeting this definition may change over time but does not plan to keep a list for practitioners to consult.

The definitions of "practitioner" and "practitioner incapacity" were modified to remove the term "waived" since that term does not appear in the regulatory text. In addition, the definition of "certification" was renamed "opioid treatment program certification" to clarify that the definition in § 8.2 specifically applies to certification of OTPs.

In addition, the final rule includes a definition of Medication-Assisted Treatment (MAT) that was provided in the preamble of the NPRM, but that was not inserted into the rule text of the NPRM. Accordingly, "Medication-Assisted Treatment" is now defined in the text of the final rule.

The final rule also replaced "board certification" with "additional credentialing" due to the removal of the term "subspecialty" with respect to practitioners that can request a higher limit outside of a qualified practice setting.

The comments and our responses are set forth below.

*Comment:* HHS received a small number of comments regarding the definition of patient as it relates to counting a patient towards the cross-covering practitioner's patient limit. One commenter requested that we develop a way for practitioners to provide coverage for other physicians without having to count these patients as part of their patient limit. Another commenter recommended that the patients served during cross-coverage count either toward the practitioner's patient limit for 30 days or the number of days' supply provided by the prescription, whichever is greater. Another commenter recommended that prescriptions for less than 30 days during cross-coverage should not count against the practitioner's patient limit.

*Response:* HHS is aware that providing coverage in a time-limited manner has posed a challenge to practitioners and patients. By defining "patient" for purposes of subpart F as, "any individual who is dispensed or prescribed covered medications by a practitioner," the definition links the patient to the practitioner who provides the patient with his or her covered medications. Such patients will remain

a patient of the prescribing practitioner for the duration of the prescription or for as long as the dispensed medication lasts. As noted above, in cases where a cross-covering practitioner does not provide a patient with covered medication, the patient will not count toward that practitioner's patient limit. In the event that the cross-covering practitioner dispenses or prescribes covered medication to a patient, the patient will only count towards the cross-covering practitioner for as long as the medication lasts or until the prescription expires.

*Comment:* HHS received one comment requesting additional examples of the types of guidelines that would satisfy the requirement to use nationally recognized evidence-based guidelines.

*Response:* HHS has added another example to the list provided in the preamble of the NPRM with regard to the definition of "nationally recognized evidence-based guidelines."

*Comment:* HHS received a comment that suggested the establishment of standards of care that DATA 2000 providers must follow.

*Response:* HHS requires in the rule the use of nationally recognized evidence-based guidelines, but declines to establish a specific standard of care in regulating the practice of medicine as it exceeds the scope of the Secretary's authority.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and after considering the comments received, HHS is modifying several of the proposed definitions in § 8.2 to enhance clarity and consistency with the scope of 21 U.S.C. 823(g)(2). Specifically, HHS has modified the definitions for "patient" and "patient limit," and modified the terms "practitioner" and "practitioner incapacity." Finally, 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).

#### Subparts B, C, and D—Opioid Treatment Programs (§§ 8.3 Through 8.34)

HHS proposed retitling subparts B, C, and D §§ 8.3 through 8.34 so as to implement the addition of subpart F. We proposed changes to these sections limited to changing the mailing address for program certification and accreditation body approval and updating terms, such as "opiate" and

“opiate addiction” to “opioid” and “opioid use disorder,” respectively.

The comments and our responses are set forth below.

*Comment:* HHS received one comment that recommended that it develop result-oriented performance standards for methadone maintenance treatment programs (also referred to as opioid treatment programs); provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of programs’ performance; and assure increased program oversight oriented toward performance standards.

*Response:* HHS is not addressing the performance standards for opioid treatment programs in this rule.

*Comment:* HHS received a comment stating that the Federal government should be putting pressure on States to open access to care through OTPs in States that are more likely to prohibit opioid treatment programs from operating.

*Response:* HHS is committed to increasing access to MAT through various strategies, but cannot address this specific issue through the final rule.

#### Summary of Regulatory Changes

HHS did not receive any comments related to §§ 8.3 through 8.34 that were capable of being addressed in the final rule. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions §§ 8.3 through 8.34 without modification.

#### Subpart F—Which Practitioners Are Eligible for a Patient Limit of 275 (§ 8.610)

Proposed § 8.610 described how practitioners can qualify for the 200 patient limit. Such practitioners would be required to possess subspecialty board certification in addiction medicine or addiction psychiatry or practice in a qualified practice setting as defined in the rule. In either case, practitioners with the higher limit would have to possess a waiver to treat 100 patients for at least 1 year in order to gain experience treating at the higher limit. The purpose of offering the 200 patient limit to practitioners in these two categories was to recognize the benefit offered to patients by either: (1) The advanced training, knowledge, and skill of practitioners with a subspecialty board certification; or (2) the higher level of direct service provision and care coordination envisioned in the qualified practice setting. This approach would restrict access to the 200 patient limit to a subset of the practitioners waived to provide care up to 100 patients. In addition to ensuring higher quality of

care, the criteria for the higher limit would be intended to minimize the risk of diversion of controlled substances to illicit use and accidental exposure that could result from increased prescribing of buprenorphine. A practitioner with board certification in an addiction subspecialty would have to have the training and experience necessary to recognize and address behaviors associated with increased risk of diversion. In the qualified practice settings, HHS believes that the care team and practice systems will function to help ensure this same level of care. HHS requested comments on this proposed approach, including comments on whether there are other ways for HHS to ensure quality and safety while encouraging practitioners to take on additional patients.

The comments and HHS responses are set forth below.

*Comment:* HHS received numerous comments expressing concerns about the restrictive nature of the requirement to obtain subspecialty board certification in order to reach the higher patient limit.

*Response:* HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. HHS believes that this new requirement balances the need to maintain a qualified workforce while having realistic expectations that do not prohibit capable practitioners from increasing their patient limits.

*Comment:* One comment expressed concerns that the rule will create a two-tiered system resulting in patients with the same diagnosis receiving markedly different quality and intensity of services, and recommended that we create a continuum of care whereby all patients with the same diagnosis receive equally high quality, evidence-based care.

*Response:* HHS disagrees that the rule creates a two-tiered system. Rather, it extends and enhances the system that currently exists in an effort to improve access to treatment for those with opioid use disorders.

*Comment:* HHS received a comment recommending that we implement an accreditation initiative for qualified practitioners seeking to increase the number of patients for whom they prescribe buprenorphine.

*Response:* HHS does not believe this approach is warranted at this time.

*Comment:* HHS received a comment stating that all physicians who currently have credentials provided by one of the following professional organizations be eligible to request the increased patient

limit: (1) ABAM; (2) ASAM; (3) American Board of Psychiatry and Neurology (ABPN); and (4) American Osteopathic Association. Another commenter recommended that HHS allow osteopathic physicians who are also boarded in other areas to be board-certified in addiction medicine.

*Response:* HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. However, given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should additional credentialing as defined in § 8.2 to safely and appropriately provide treatment up to 275 patients outside of a qualified practice setting. Therefore, HHS declines to incorporate some of the proposed approaches into the rule.

*Comment:* HHS received a small number of comments requesting a grandfathering clause for physicians who are currently working full time in the addiction field and who have missed the option to become board certified without doing a fellowship by the change in the availability of the ABAM exam.

*Response:* Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should have additional credentialing as defined in § 8.2.

*Comment:* HHS received a comment recommending that physicians who have been recognized by SAMHSA for their Science and Service to their office-based treatment patients should be given priority when applying for the increased patient limit.

*Response:* Given the significant responsibility associated with prescribing the applicable medications covered under the final rule, HHS believes that practitioners should have additional credentialing as defined in § 8.2 or practice in a qualified practice setting to safely and appropriately provide treatment to up to 275 patients. We believe most, if not all, of these practitioners will meet these requirements. Therefore, HHS declines to incorporate this approach into the rule.

*Comment:* HHS received a comment recommending that OTP licensure be the only pathway to creating addiction treatment programs that treat more than 100 patients.

*Response:* HHS believes that the pathways outlined in the final rule provide appropriate pathways through which practitioners can become eligible to prescribe buprenorphine to up to 275



patients, while taking into account quality care and risk of diversion. Given OTP capacities and other regulatory requirements, limiting access to treating up to 275 patients to OTPs would reduce the ability to increase access to care in as meaningful a way as can be accomplished through the pathways included in the final rule.

*Comment:* HHS received several comments recommending an alternate pathway for non-specialists in addiction medicine, which would require them to complete an additional 36 hours of addiction-related CME every three years. HHS received another comment proposing an alternate pathway that includes 24 hours of training, with Naloxone education as a part of that training.

*Response:* HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. However, given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should have additional credentialing as defined in § 8.2 to safely and appropriately provide treatment to up to 275 patients outside of a qualified practice setting. Therefore, HHS has declined to incorporate this approach into the rule.

*Comment:* HHS received a comment suggesting that an alternate pathway be considered on a case by case basis in highly rural areas where practitioners may not be board certified or part of a qualified practice setting. The commenter recommended that providers who request the higher patient limit in these settings be required to have a mentor with extensive expertise and with whom they have regular consultation.

*Response:* Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should be board certified or practicing in a qualified practice setting to safely and appropriately provide this treatment to up to 275 patients. Therefore, HHS has declined to incorporate this approach into the rule.

*Comment:* HHS received a comment that it should not raise the patient limit for any practitioner who has not completed an accredited fellowship or residency in addiction medicine.

*Response:* HHS believes that the pathways outlined in the final rule provide appropriate pathways through which practitioners can become eligible to prescribe buprenorphine to up to 275 patients, while taking into account quality care and risk of diversion.

Limiting access to treating up to 275 patients to practitioners who have completed accredited fellowships or residencies in addiction medicine would reduce the ability to increase access to care in as meaningful a way as can be accomplished through the pathways included in the final rule. Therefore, HHS has declined to incorporate this approach into the rule.

*Comment:* HHS received a comment recommending that, in addition to providing current pathways to become eligible for the higher patient limit, HHS reserve the authority to identify any additional criteria that could make a practitioner qualified to apply for the higher limit.

*Response:* HHS retains this authority.

*Comment:* HHS received a few comments about the length of time it takes for practitioners to qualify to treat the higher patient limit. These comments noted that it will take two years for new practitioners to become eligible to prescribe buprenorphine to the higher patient limit and some suggested creating a faster pathway.

*Response:* In more than doubling the patient limit as a result of the final rule for certain practitioners with a 100 patient limit, HHS believes it is critical to ensure that practitioners who obtain the higher patient limit have at least one year of experience prescribing at the current highest patient limit. Practitioners who have had a waiver to treat up to 100 patients for at least a year will be eligible to apply for the higher limit immediately.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, HHS replaced “board certification” with “additional credentialing” in § 8.2 which will allow additional practitioners to become eligible for the 275-patient limit. At the beginning of § 8.610, we replaced the text that states that “A practitioner is eligible for a patient limit of 200,” with language that states the total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C. 823(g)(2)(B)(iii) is 275. Other than increasing the applicable patient limit to 275 (the basis for which has been discussed elsewhere in this preamble) the modified language does not reflect an intention to substantively change any other aspect of the patient limit from that which was proposed in the NPRM. Rather, the language modification is intended to align the final rule’s text with the terminology used in 21 U.S.C. 823(g)(2)(B)(iii).

#### Subpart F—Qualified Practice Setting (§ 8.615)

HHS proposed § 8.615 to describe the necessary elements of a qualified practice setting, which can include practices with as few as one waived provider as long as these criteria are met, and can include both private practices and community-based clinics. Necessary elements of a qualified practice setting would include: (1) The ability to offer patients professional coverage for medical emergencies during hours when the practitioner’s practice is closed; this does not need to involve another waived practitioner, only that coverage be available for patients experiencing an emergency even when the office is closed; (2) the ability to ensure access to patient case-management services including behavioral health services; (3) health information technology (health IT) systems such as electronic health records, when practitioners are required to use it in the practice setting in which he or she practices; (4) participation in a prescription drug monitoring program (PDMP), where operational, and in accordance with State law. PDMP means a statewide electronic database that collects designated data on substances dispensed in the State. For practitioners providing care in their capacity as employees or contractors of a Federal government agency, participation in a PDMP would be required only when such participation is not restricted based on State law or regulation based on their State of licensure and is in accordance with Federal statutes and regulations; and (5) employment, or a contractual obligation to treat patients in a setting that has the ability to accept third-party payment for costs in providing health services, including written billing, credit and collection policies and procedures, or Federal health benefits.

The elements were identified as common to many high-quality practice settings, which includes both private practices as well as federally qualified health centers and community mental health centers, and therefore worthy of replication. The elements would be expected to be common to OTPs, and OTPs currently in operation but not providing MAT under 21 U.S.C. 823(g)(2). Taken together, this would facilitate additional opportunities to expand access to MAT. Another consideration in the selection of these elements was the need to limit the expansion of group practices formed for the sole purpose of pooling the individual practitioner limits to maximize revenue but which fail to

offer a full continuum of services. HHS sought comment on additional, alternate pathways by which a practitioner could become eligible to apply for a higher patient limit.

The comments and HHS responses are set forth below.

*Comment:* HHS received a small number of comments expressing concerns that a qualified practice setting does not include a mandate to have trained substance use disorder counseling staff on site or available by an affiliation agreement. One commenter also recommended requiring a set ratio of addiction counselors in qualified practice settings. HHS also received a small number of comments recommending that HHS implement a requirement that provides for waived practitioners to hire behavioral health providers as part of their practice or have a formalized agreement with outside providers to offer these services.

*Response:* HHS has carefully considered the required elements of a qualified practice setting and has balanced the benefits of ensuring quality services and preventing diversion with the costs of being too restrictive. A requirement to have substance use disorder counseling or other behavioral health providers on staff on site or available by an affiliation agreement could limit the number of entities that would meet the requirements of a qualified practice setting and therefore not sufficiently increase access to treatment. A specific set ratio of addiction counselors in a qualified practice setting may also restrict the number of entities which would meet the definition of qualified practice setting and limit the impact of the rule.

*Comment:* HHS received a small number of comments noting that the narrow definition of a qualified practice setting makes it difficult for rural physicians or physicians in underserved settings to meet these qualifications.

*Response:* HHS believes that entities such as federally qualified health centers, community mental health centers, OTPs, and certain private practices which exist in rural and other underserved areas can meet the definition of a qualified practice setting.

*Comment:* One comment recommended that HHS require third-party accreditation for qualified practice settings via the Commission on Accreditation of Rehabilitation Facilities (CARF) or the Joint Commission on Accreditation of Health Care Organizations (JCAHO).

*Response:* Requiring accreditation of qualified practice settings could create a barrier for individual practitioners who have a waiver to prescribe

buprenorphine and have an interest in applying for the higher patient limit. HHS believes the burden imposed on these practitioners would be unreasonable and is not justified. Accordingly, HHS has not made any changes to the rule based on this comment.

*Comment:* One commenter also encouraged pharmacists to enter into collaborative practice agreements with physicians and other prescribers as part of a qualified practice setting.

*Response:* HHS encourages collaborative relationships between physicians and pharmacists, but declines to require it as a specific requirement as part of the definition of qualified practice setting.

*Comment:* HHS received a comment suggesting that skilled nursing homes and long-term residency facilities be added to the list of settings in which buprenorphine induction and maintenance can occur.

*Response:* Any facility that meets the requirements of a qualified practice setting will be considered a qualified practice setting.

*Comment:* One commenter suggested any medical facility offering MAT should offer both buprenorphine and Vivitrol®.

*Response:* HHS supports the full array of services, including medications, that comprise evidence-based MAT, but this requirement is beyond its scope.

*Comment:* HHS received a comment expressing concerns that the rule will consolidate the use of medication in large treatment centers, which will lead to increased prices for patients.

*Response:* HHS expects that the practitioners who obtain a waiver to prescribe to up to 275 patients as well as additional practitioners who decide to obtain a waiver for 30 or 100 patients either in an effort to eventually obtain a 275 patient limit or because they feel more confident that treatment capacity in the community is sufficient to keep them from being overwhelmed by demand, will increase access to MAT at both individual practices as well as among practitioners affiliated with treatment centers. HHS does not have information to assess how this will impact patient prices for care.

#### After-Hours Coverage

*Comment:* HHS received a comment recommending that all practitioners who prescribe MAT should have after-hours coverage, regardless of the size of the practice.

*Response:* Adopting the approach urged by the commenter, which would apply to all practitioners prescribing MAT regardless of their authorized

patient limit, is beyond the scope of the rule.

#### Health Information Technology (Health IT)

*Comment:* HHS received a small number of comments requesting clarification about what exactly constitutes a qualifying use of health IT. Specifically, the commenter asked whether the definition of “meaningful use” under the Medicare regulations would apply, and whether a program specifically designed for medical use would be required or if a practitioner could simply maintain a spreadsheet of all enrolled patients.

*Response:* The rule requires that practitioners use health IT like electronic health records or health information exchanges only if such records are otherwise required to be used in the practitioner’s practice setting. The rule does not create a new requirement to use electronic health records.

*Comment:* HHS received a comment stating that electronic health records are not as efficient as paper reporting.

*Response:* HHS disagrees. Some of the specific benefits associated with electronic health records include the ability to access patient charts remotely, the receipt of notifications about potential medical errors, the receipt of important reminders about providing preventive care and meeting clinical guidelines, and the ability to communicate directly with patients. All of these benefits enable practitioners to make well-informed, safe, and timely treatment decisions and ultimately provide higher-quality care.

#### Prescription Drug Monitoring Programs (PDMPs)

*Comment:* HHS received a small number of comments expressing concerns about the requirement to check PDMPs. These comments noted that not all States have operational PDMPs and questioned the extent to which PDMPs benefit patients.

*Response:* HHS supports PDMPs as a tool to address opioid use disorders and notes that at the time of the proposed rule, there were 49 States with operational PDMPs. The rule requires the use of a PDMP where a program is operational and its use is permitted/required in accordance with State law.

*Comment:* Several comments stated that providers should be incentivized to use PDMPs. One commenter recommended that the final rule require regular review of the PDMP for patients receiving buprenorphine and documentation of the reviews in the patient’s chart. Another commenter

suggested a mandatory review of State PDMPs on each visit to make certain that buprenorphine/naloxone is filled appropriately and no other narcotics are being prescribed.

*Response:* HHS understands this comment to refer to all patients who may be prescribed buprenorphine. HHS appreciates these comments; but the suggestions fall beyond the scope of this rule.

*Comment:* One comment requested that HHS provide assistance to States in developing and improving prescription drug monitoring programs.

*Response:* Providing assistance to States in developing and improving PDMPs is outside the scope of the rule, but HHS does have several programs that have provided this assistance to States in the past and has a program at CDC that currently does so. More information can be found here—<http://www.cdc.gov/drugoverdose/pdmp/states.html>.

*Comment:* One commenter stated that registration with a State prescription database should be a requirement for all waived physicians, not just the ones with the higher limit.

*Response:* Imposing requirements on practitioners treating patients for all waived practitioners is beyond the scope of this rule.

#### Provision of Behavioral Health Services

*Comment:* HHS received a comment requesting clarification about how a qualified practice is required to provide access to case management services and whether providing the phone number for other providers would satisfy this requirement.

*Response:* The intent of the requirement is that a practitioner have services available on site or have a referring relationship to case management or counseling services that allows for warm hand-offs of the patient and ongoing care coordination, not just the ability to provide a phone number.

*Comment:* HHS received numerous comments about the need for comprehensive psychosocial or case management treatment and team-based care along with buprenorphine.

*Response:* HHS agrees that comprehensive behavioral support services are a critical component of the effective delivery of MAT, including buprenorphine-based MAT. The standard of care<sup>2</sup> includes the provision

of behavioral health support services and HHS encourages all practitioners who are authorized to prescribe buprenorphine to ensure that their patients receive these services.

*Comment:* HHS received a small number of comments in favor of raising the patient limit without requiring formal counseling. One commenter stated that many patients feel that attending less formal counseling that is not delivered by licensed or certified health care professionals such as Narcotics Anonymous meetings are counterproductive.

*Response:* HHS believes that in order to ensure quality care, providing behavioral health support services is a key component to delivering effective MAT and encourages all practitioners prescribing covered medications to ensure that their patients receive it. The selection of behavioral health support services is a clinical decision to be made between the practitioner and the patient.

*Comment:* HHS received a small number of comments requesting that it provide a clearer definition of the format of referral to behavioral health providers. One commenter requested that HHS issue guidance that clearly defines the format of referral agreements. One comment requested that HHS define the format of referral to behavioral health services to require active referring rather than just the capacity to refer. Similarly, another commenter recommended that providers with a waiver to prescribe buprenorphine be required to include a Letter of Agreement with an organization for counseling services.

*Response:* HHS believes that limiting the referral to a specific format may be unduly restrictive and have unintended consequences. As noted earlier, HHS declines to require a specific written agreement as part of the behavioral health services component of the qualified practice setting definition, but may provide further guidance with respect to example referral agreements at a later date.

*Comment:* HHS received a comment asking whether a peer recovery support specialist would be considered capable of meeting the requirements for providing behavioral health services.

*Response:* Peer recovery support services are one possible behavioral health service. The selection of specific psycho-social interventions is a clinical decision to be made between the practitioner and the patient.

*Comment:* HHS received a comment noting that current guidelines for concurrent psychosocial treatment with buprenorphine are not enforced and, as

a result, raising the patient limit may not effectively increase access to care.

*Response:* The enforcement of concurrent psychosocial treatment with buprenorphine exceeds the scope of this rule.

#### Third-Party Payment

*Comment:* HHS received numerous comments expressing concerns with the requirement that practitioners prescribe in a setting that accepts third-party payment.

*Response:* This requirement was created to minimize the public health and safety risks, such as diversion, that are associated with dispensing or prescribing medications that are not supported by an appropriate medical diagnosis and assessment of medical need. Such risks are often associated with “cash only: entities that do not accept any third-party payment for services. Using third-party payment provides a record that buprenorphine has been provided to an individual and thus allows for more accountability, lowering the risk of diversion. However, not everyone who needs treatment has a third-party payer (e.g., insurance or Medicaid coverage). Thus, to avoid creating more barriers to treatment for these individuals, this regulation would not require third-party payment for all patients by practitioners operating at the higher patient limit and instead would only require that the provider be authorized and capable of billing third-party payers as an indication of their level of accountability. Moreover, with increasing coverage of substance use disorder treatment through private insurance and Medicaid programs in many States, substance use disorder treatment providers should have additional incentives to qualify and engage in third-party billing.

*Comment:* HHS received a comment requesting clarification on whether a practice would need to accept all third-party payment sources, including Medicare and Medicaid. The commenter also asked whether a practitioner can require payment in cash but provide billing information for the patient to submit to their insurance for reimbursement.

*Response:* Practitioners who qualify for the higher patient limit by practicing in a qualified practice setting must be able to accept third-party payments. However, the intention of the requirement is not that the practitioner must accept only third-party payments or must accept all third-party payment sources. Rather, the practitioner in a qualified practice setting must accept at least some third-party payment systems. The practitioner in a qualified practice

<sup>22</sup> Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004

setting cannot have a “cash only” business.

*Comment:* HHS received a comment recommending that physicians be incentivized to care for Medicaid patients by not counting a certain number of Medicaid patients towards their higher limit.

*Response:* This issue is beyond the scope of this rule.

*Comment:* HHS received several comments stating that the requirement to accept third-party payments should be expanded to include all individuals with the higher patient limit, not just those using the “qualified practice setting” exception.

*Response:* The elements of a qualified practice setting are intended to provide practitioners who have not qualified for the higher patient limit as a result of possessing additional credentialing as defined in § 8.2 with the necessary specialty training to prevent diversion and provide quality services. HHS declines to incorporate this approach into the rule.

#### Diversion Control Plan

*Comment:* HHS received numerous comments about the need for formal diversion mitigation strategies, such as wrapper counts, drug testing, enforcement of the parity law for treatment, and the use of more efficient and lower dose, dual therapy preparations.

*Response:* HHS agrees that a diversion plan is important. The final rule requires that providers who receive the higher patient limit attest to having such a plan. The specifics of the diversion plan will be left to the individual practitioner.

*Comment:* HHS received a comment recommending that physicians obtain a written agreement from each patient stating that the patient: Will receive an initial assessment and treatment plan; will be subject to medication adherence and substance use monitoring; and understands all available treatment options, including all FDA-approved drugs for treatment of opioid use disorder and their potential risks and benefits.

*Response:* HHS supports the intent of the comment but these issues are related to provider-patient relationships and therefore beyond the scope of this rule.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.615 without modification.

#### Subpart F—Process To Request a Higher Patient Limit of 275 (§ 8.620)

HHS proposed § 8.620 to describe the process to request a patient limit of 200. Similar to the waiver process for the 30 and 100 patient limits, the process would begin with filing a form, in this case, a Request for Patient Limit Increase. A proposed draft of the Request for Patient Limit Increase was posted along with the NPRM and has been submitted to the Office of Management and Budget for final review. The higher patient limit would carry with it greater responsibility for behavioral health services, care coordination, diversion control, and continuity of care in emergencies and for transfer of care in the event that the practitioner does not request renewal of the higher patient limit or the practitioner’s renewal request is denied. The new Request for Patient Limit Increase process would require providers to affirm that they would meet these requirements. HHS proposed definitions of “behavioral health services,” “diversion control plan,” “emergency situation,” “nationally recognized evidence-based guidelines,” and “practitioner incapacity” in § 8.2 to assist practitioners in understanding what is expected of them in making these attestations. These responsibilities would be aligned with the standards of ethical medical and business practice and are not expected to be burdensome to practitioners. Single State Authorities, State Opioid Treatment Authorities and other resources/entities exist to help in the development of patient placement in the event that transfer to other addiction treatment would be required, for example, if a practitioner chose to no longer practice at the higher patient limit. HHS proposed that practitioners approved at the higher limit would also be required to reaffirm their ongoing eligibility to fulfill these requirements every 3 years as described in § 8.640.

The comments and our responses are set forth below.

*Comment:* HHS received a comment expressing the following concerns about the Request for Patient Limit Increase form: Question 7A9 assumes that physicians have an “original” 100 patients, and additional patients above the 100 patient level who would need to be transferred elsewhere in the event that a physician’s renewal request for the higher patient limit is denied. However, the commenter noted that it is unrealistic to assume that a physician would be treating the exact same original 100 patients three years, or even

one year, after being approved to treat more than 100 patients.

*Response:* The patient level refers to those patients the practitioner is treating at the time the request is denied. It is the practitioner’s responsibility to review his or her case load and identify which patients over the 100 patient limit he or she will notify.

*Comment:* A commenter noted that Question 8 requires physicians to certify that they will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination. The commenter requests information about the purpose of this certification, as it appears to be a significant restriction on a physician’s ability to practice medicine and prescribe other medications as needed.

*Response:* The certification check box on the Request for Patient Limit Increase is to ensure that waived practitioners certify that they are using only medications covered under 21 U.S.C. 823(g)(2)(C). Patients for whom a practitioner does not dispense or prescribe covered medications should not be counted against the patient limit. This does not mean that practitioners are prohibited from prescribing medications to treat conditions other than a substance use disorder among their office-based opioid treatment with buprenorphine patients.

*Comment:* HHS received a comment recommending that it consider the impact of the 42 CFR part 2 substance use disorder treatment confidentiality provisions on patients who do not share their substance use records with their other providers.

*Response:* The appropriate sharing of patient information is important. As such, HHS included an attestation that practitioners receiving a waiver to treat up to 275 patients provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act and implementing regulations and 42 CFR part 2.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.620 without modification.

#### Subpart F—How Will a Patient Request for a Higher Limit Be Processed (§ 8.625)

HHS proposed § 8.625 to describe how SAMHSA will process a Request for Patient Limit Increase. The process

for requesting a higher patient limit would be processed similarly to how the current 30 or 100 patient waiver is processed, with one difference. Whereas the lower patient limit waivers are not time limited, the waiver for the higher limit would have a term not to exceed 3 years with the option for renewal. Thus, a practitioner would be required to submit a new Request for Patient Limit Increase every 3 years if he or she desired to continue treating up to the higher patient limit. In addition, we proposed, among other things, that if SAMHSA denied a practitioner's Request for Patient Limit Increase on the basis of deficiencies that could be resolved, SAMHSA would allow a designated time period for resolving such deficiencies. We also proposed that, if such deficiencies are not resolved during the designated time period, SAMHSA would deny the practitioner's Request for Patient Limit Increase. It should be noted that DEA has independent enforcement authority and this rule in no way affects that authority or changes the way in which DEA and SAMHSA interact with respect to waivers.

After considering this process, the Department has made a minor modification to § 8.625(c) by replacing the word "will" with the word "may" in the last sentence of this paragraph. This modification gives SAMHSA the flexibility to approve a practitioner's Request for Patient Limit Increase, if, for example, relevant deficiencies are resolved to the satisfaction of SAMHSA shortly after the expiration of the designated time period.

The comments and HHS responses are set forth below.

*Comment:* HHS received a comment recommending that the length of the term to prescribe buprenorphine should gradually increase to a term of 3 years. The commenter stated that initially it should be a 1-year term, then a 2-year term, and then a 3-year term thereafter.

*Response:* HHS has sought to strike the right balance between encouraging practitioners to apply for the higher patient limit and ensuring that they are providing high quality care. HHS believes that asking practitioners to submit a Request for Patient Limit Increase more frequently than every 3 years would create an unnecessary burden and act as a deterrent to requesting the higher limit.

*Comment:* HHS received one comment suggesting that, rather than using a 3-year term, the highest patient limit should be based on a periodic review of the practice and its outcome statistics.

*Response:* HHS does not have the administrative capacity to conduct a periodic review of all waived practitioners' outcome statistics and other aspects of their practices beyond its anticipated oversight activities to ensure compliance with the rule.

*Comment:* HHS received a comment suggesting that the turn-around time for approving waiver requests be shortened from 45 to 30 days.

*Response:* HHS appreciates the commenters desire to shorten the time frame within which SAMHSA would process a Patient Request for a Higher Limit; however, due to staff and resource limitations, HHS believes the 45 day time period is a balanced approach for ensuring requests are turned around in an appropriate time frame to meet both the practitioner and SAMHSA's needs. HHS notes that it views this timeframe as a maximum, not a minimum, and will endeavor to process these requests quickly.

#### Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comment HHS received, HHS is finalizing the provisions as proposed in § 8.625 with the exception of the word change noted in § 8.625(c).

Subpart F—What must practitioners do in order to maintain their approval to treat up to 275 patients under § 8.625 (§ 8.630)

HHS proposed § 8.630 to describe the conditions for maintaining a waiver for each 3-year period for which waivers are valid, including maintenance of all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b). Compliance with the requirements specified in § 8.620 would have to be continuous.

HHS did not receive any comments specific to § 8.630.

#### Summary of Regulatory Changes

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions as proposed in § 8.630 without modification.

#### Subpart F—RESERVED (§ 8.635)

HHS proposed § 8.635 to describe the reporting requirements for practitioners whose Request for Patient Limit Increase is approved under § 8.625. HHS requested comments on whether the proposed reporting periods and deadline could be combined with other, existing reporting requirements in a way that would make reporting less burdensome for practitioners. HHS

proposed the following 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.

The comments and HHS responses are set forth below.

HHS received a number of comments on these requirements. Many commenters expressed concern that the reporting requirements were burdensome and could decrease practitioners' interest in reaching the higher patient limit. Some commenters said that the reporting requirements would not ensure the appropriate level of behavioral health care. There were other concerns that the requirements were not consistent between practitioners who had waivers to treat up to 100 patients and practitioners with the higher patient limit. In addition, there was confusion about the periodicity of the reporting requirements. Overall, many commenters requested clarity.

HHS proposed to include reporting requirements as part of its approach to increasing access to MAT while ensuring that patients receive the full array of services that comprise evidence-based MAT and minimizing the risk that the medications provided for treatment are misused or diverted. HHS appreciates the comments received and, in light of them, has decided to delay finalizing this section of the proposed rule and to publish elsewhere in this issue of **Federal Register** a Supplemental Notice of Proposed Rulemaking on the reporting requirements proposed in § 8.635 of the

NPRM. As explained in the Supplemental Notice of Proposed Rulemaking published elsewhere in this issue of the **Federal Register**, HHS will consider the public comments on this Supplemental Notice as well as comments already received on the March 30, 2016 NPRM in finalizing the reporting requirements. We expect to finalize the reporting requirements expeditiously following the receipt of additional public comment.

#### *Summary of Regulatory Changes*

HHS is reserving § 8.635

#### Subpart F—Process for Renewing Patient Limit Increase Approval (§ 8.640)

We proposed § 8.640 to describe the process for a practitioner renewing his or her approval for the higher patient limit. In order for a practitioner to renew an approval, he or she would have to submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of the approval term.

The comments and HHS responses are set forth below.

*Comment:* HHS received several comments recommending that the renewal request be synchronized with the renewal of the DEA registration in an effort to reduce administrative burdens.

*Response:* HHS agrees that coordination among Federal agencies is beneficial and will work with DEA to synchronize these forms to the extent possible.

*Comment:* HHS received a comment stating that the current certification and recertification process should be retained and that additional recertification requirements are unnecessary. The commenter also stated that the DEA registration renewal process, as well as the regular oversight of waived physicians conducted by SAMHSA, is sufficient to ensure safety and proper prescribing practices and that a duplicative recertification process will only discourage participation by providers.

*Response:* HHS believes that due to the fact that practitioners with the higher patient limit will now be able to treat up to almost 3 times as many patients as prior to the rule, additional requirements related to renewing the practitioner's Request for Patient Limit Increase is prudent to ensure high quality care and minimize diversion.

*Comment:* HHS received a comment stating that the 90 day timeline for receiving approval is too long. The commenter also stated that language

should be added regarding when a response to a request should be provided and what one does when the response does not come by the stated time.

*Response:* HHS believes the commenter was confused with respect to the 90 day time period. The NPRM indicated that "Practitioners who intend to continue to treat up to 200 patients beyond their current 3 year approval term must submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of their approval term." It does not state that SAMHSA has 90 days to process the renewal request. In addition, the proposed rule states that "If SAMHSA does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until SAMHSA reaches a final decision." Thus, the preamble of the proposed rule discusses what happens if the response from SAMHSA is not obtained by a certain date.

#### *Summary of Regulatory Changes*

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.640 without modification.

#### Subpart F—Responsibilities of Practitioners Who Do Not Submit a Renewal Request for Patient Limit Increase or Whose Renewal Request Is Denied (§ 8.645)

HHS proposed § 8.645 to describe the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase or whose renewal request is denied. Under § 8.620(b)(7), practitioners would notify all patients affected above the 100 patient limit that the practitioner would no longer be able to provide MAT services using covered medications and would make every effort to transfer patients to other addiction treatment.

#### *Summary of Regulatory Changes*

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions as proposed in § 8.645 without modification.

#### Subpart F—Suspension or Revocation of a Practitioner's Patient Limit Increase Approval (§ 8.650)

HHS proposed § 8.650 to describe under what circumstances SAMHSA

would suspend or revoke a practitioner's patient limit increase of 200. If SAMHSA had reason to believe that immediate action would be necessary to protect public health or safety, SAMHSA would suspend the practitioner's patient limit increase of 200. If SAMHSA determined that the practitioner had made misrepresentations in his or her Request for Patient Limit Increase, or if the practitioner no longer satisfied the requirements of this subpart, or he or she had been found to have violated the CSA pursuant to 21 U.S.C. 824(a), SAMHSA would revoke the practitioner's patient limit increase of 200. It should be noted that DEA has independent enforcement authority and this rule in no way affects that authority or changes the way in which DEA and SAMHSA interact with respect to waivers.

The comments and HHS responses are set forth below.

*Comment:* HHS received a comment that practitioners who perform poorly on outcome and quality measures should be limited to 100 patients or less, or even have their waiver revoked if outcomes and quality are extremely poor.

*Response:* HHS believes allowing for suspension or revocation when SAMHSA determines that a practitioner no longer satisfies the requirements of the rule is appropriate and commensurate with ensuring that patients receive quality care. Additionally, such requirements relating to practitioners who have waivers to treat up to 30 and 100 patients are beyond the scope of this rule.

*Comment:* HHS received a comment requesting that we add an appeals mechanism for physicians to dispute erroneous determinations of not being in compliance with requirements for the patient limit increase.

*Response:* HHS declines to set forth a specific appeal mechanism in the rule, but notes that practitioners are able to re-apply if their Request for Patient Limit Increase is denied.

#### *Summary of Regulatory Changes*

The proposed language under § 8.650 provided only one circumstance under which SAMHSA could suspend a practitioner's Patient Limit Increase approval, and three instances under which SAMHSA could revoke this approval. After further consideration, HHS has modified the language in § 8.650 in an effort to allow the Secretary to suspend or revoke a practitioner's Request for Patient Limit Increase approval on the basis of any of

the criteria identified in this section to provide additional flexibility. For the reasons set forth in the proposed rule and considering the comments received, HHS is finalizing the remaining provisions of this section as proposed in the NPRM.

#### Subpart F—Practitioner Patient Limit Increase During Emergency Situations (§ 8.655)

HHS proposed § 8.655 to describe the process, including the information and documentation necessary, for a practitioner with an approved 100 patient limit to request approval to temporarily treat up to 200 patients in an emergency situation. The intention of this provision is to help assure continuity of care for patients whose care might otherwise be abruptly terminated due to the death or disability of their practitioner. This provision would also help communities respond rapidly to a sudden increase in demand for medication-assisted treatment. Sudden increases in demand for treatment may be experienced when there is a local disease outbreak associated with drug use, or when a natural or human-caused disaster either displaces persons in treatment from their practitioner or program or destroys program infrastructure. The emergency provision generally would not be intended to correct poor resource deployment due to lack of planning. The emergency provision of the proposed rule would only be considered if other options for addressing the increased demand for medication-assisted treatment could not address the situation.

HHS proposed that the practitioner must provide information and documentation that: (1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the emergency qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit; (2) identifies a period of time in which the higher patient limit should apply, and provides a rationale for the period of time requested; and (3) describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to the higher patient limit expires. Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an

immediate increase in the higher patient limit. If, after consultation with the governmental authorities, SAMHSA determines that a practitioner's request under this section should be granted, SAMHSA will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months. A practitioner wishing to receive an extension of the approval period granted must submit a request to SAMHSA at least 30 days before the expiration of the six month period and certify that the emergency situation continues. Except as provided in this section and § 8.650, requirements in other sections under subpart F do not apply to practitioners receiving waivers in this section.

The comments and HHS responses are set forth below.

*Comment:* HHS received a comment that the governmental authority, not the physician, should make a request to temporarily treat the higher patient limit in emergency situations.

*Response:* The waiver authorized under 21 U.S.C. 823(g)(2) may be granted to practitioners who dispense or prescribe covered medications to patients. Therefore, only practitioners may request a temporary patient limit increase under emergency situations. However, along with working with practitioners, SAMHSA will consult, to the extent possible, with governmental authorities to address emergency situations.

*Comment:* HHS received a comment recommending that it focus resources on creating sustainable, expanded treatment capacity to relieve those physicians impacted by the emergency request who may not be qualified or have the infrastructure to treat over 100 patients per the proposed rule.

*Response:* HHS agrees with the commenter that sustainable, expanded treatment capacity is the goal for all practitioners who experience emergency situations. By granting an extension of the six-month emergency provision, this will allow practitioners with a waiver to treat up to 100 patients, with up to a year of experience with prescribing covered medications, and will better position them to apply for a Request for Patient Limit Increase.

*Comment:* HHS received a small number of comments asking how quickly providers will be notified about whether they are approved to increase their patient limit during an emergency, with one commenter requesting that this information be included in the final rule. Another commenter recommended that providers receive a response within 48 to 72 hours.

*Response:* Every effort will be made to assure prompt decision-making and communication regarding requests to increase a practitioner's patient limit in response to an emergency. Given the wide variety of situations, number of stakeholders and decision-makers involved, and range of acuity of possible emergency situations, a specific deadline will not be established in the final rule.

*Comment:* HHS received a comment that the application process for an emergency should be simplified.

*Response:* HHS believes the application process outlined in the rule is necessary to ensure public safety and welfare. Furthermore, HHS believes that there is a compelling reason to require an application process given that the practitioner could be taking on almost 3 times as many patients without the necessary training or qualified practice setting supports.

*Comment:* HHS received a comment recommending that the State Opioid Treatment Authority or Single State Agency determine whether physicians can assure continuous access to care in the event of practitioner incapacity or emergency and whether physicians will be able to notify all patients that they are no longer able to provide buprenorphine, in the event that the request for the higher patient limit is not renewed or the renewal request is denied.

*Response:* HHS cannot address this issue within the scope of this rule.

*Comment:* HHS received a comment stating that emergency provisions should be explicitly expanded to include exemption from the patient limit for categories of patients in immediate need of treatment where no other practitioner is available. The comment specifically mentioned pregnant women with an opioid use disorder, and persons with a recent non-fatal opioid overdose.

*Response:* The patient limit applies to practitioners and not patients; therefore, the circumstances related to the availability of practitioners with waivers must dictate the emergency, not the circumstances of individual patients.

*Comment:* HHS received a comment recommending that practitioners be able to treat an unlimited number of patients during an emergency.

*Response:* HHS does not believe that this approach is warranted at this time.

*Comment:* HHS received several comments describing a need for a clearer definition of emergency situations.

*Response:* HHS' intent is to reserve this option for true emergency situations. Recognizing that no two

emergencies look the same, HHS envisions that this option for a temporary higher patient limit could be triggered when a waived practitioner dies or becomes physically or mentally incapacitated or whose waiver is suspended or revoked. Other possible scenarios include: Unforeseen displacement of a large population of individuals in need of medication-assisted treatment due to disaster; outbreak of acute infections that are blood borne or otherwise associated with injection drug use such as HIV. In all cases the emergency increase of a practitioner's patient limit is meant to be temporary. The affected community and practitioner(s) should plan to definitively meet the need for treatment and resolve the emergency by expanding all forms of MAT and meeting criteria for the higher patient limit via non-emergency criteria at the earliest possible date.

#### *Summary of Regulatory Changes*

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.655 without modification.

### **III. Information Collection Requirements**

The NPRM called for new collections of information under the Paperwork Reduction Act of 1995. The final rule calls for the most of the same collections of information as the NPRM. As defined in implementing regulations, "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. In this section, we first identify and describe the types of information applicants and waived practitioners must collect and report, and then we provide 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.

*OMB Control Number:* 0930-03XX.

*Summary of the Collection of Information:* The final rule estimates up to six categories of information collection, each of which is described in the following analysis:

*A. Approval, 42 CFR 8.620(a) through (c):* In order for a practitioner to receive approval for a patient limit of 275, a practitioner must meet all of the

requirements specified in § 8.610 and submit a Request for Patient Limit Increase to SAMHSA that includes all of the following:

- Completed 3-page Request for Patient Limit Increase Form, a draft of which was posted in the public docket along with the NPRM;
- Statement certifying that the practitioner:
  - Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders;
  - Will provide patients with necessary behavioral health services as defined in § 8.2 or will provide such services through an established formal agreement with another entity to provide behavioral health services;
  - Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule and part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;
  - Will use patient data to inform the improvement of outcomes;
  - Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;
  - Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in § 8.2; and
  - Will notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment.

*B. Diversion Control Plan, 42 CFR 8.12(c)(2):* Creating and maintaining a diversion control plan is one of the requirements that practitioners must attest to before they are approved to treat at the higher limit. This plan is not required to be submitted to SAMHSA.

*C. Renewal, 42 CFR 8.640:* Describes the process for a practitioner renewing his or her approval for the higher patient limit. In order for a practitioner to renew an approval, he or she must

submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of the approval term.

*D. Patient Notice, 42 CFR 8.645:* Describes the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase or whose renewal request is denied. Practitioners who do not renew their Request for Patient Limit Increase or whose renewal request is denied must notify all patients above the 100 patient limit that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment. The Patient Notice is a model notice to guide practitioners in this situation when they notify their patients.

*E. Emergency Provisions, 42 CFR 8.655:* Describes the process for practitioners with a current waiver to prescribe up to 100 patients, and who are not otherwise eligible to treat up to 275 patients, to request a temporary increase to treat up to 275 patients in order to address emergency situations as defined in § 8.2. To initiate this process, the practitioner shall provide information and documentation that: (1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit; (2) Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and (3) Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires. If a practitioner wishes to receive an extension of the approval period granted under this section, he or she must submit a request to SAMHSA at least 30 days before the expiration of the 6-month period, and certify that the emergency situation as defined in § 8.2 necessitating an increased patient limit continues.

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 (\$)
8.620(a) through (c) ....	Request for Patient Limit Increase.	517	1	.5	259	93.74	24,232
8.12(c)(2) .....	Diversion Control Plan	517	1	.5	259	93.74	24,232
8.640 .....	Renewal Request for a Patient Limit Increase.	0	1	.5	0	93.74	0
8.645 .....	Patient Notice .....	0	1	3	0	93.74	0
8.655(d) .....	Request for a Temporary Patient Increase for an Emergency.	10	1	3	30	64.47	1,934
Total .....	.....	2,394	.....	.....	4,598	.....	50,398

Note that these estimates differ from those found in the RIA because the estimates here are wage cost estimates while the estimates in the RIA are resource cost estimates which incorporate costs associated with overhead and benefits.

HHS received several comments regarding the Collection of Information.

One commenter wanted to include in the Request for Patient Limit Increase information that required the implementation of random tablet/film counts and urine screens. Another commenter wanted mandatory Point-of-Care Urine Drug Screens on each visit to document the presence of buprenorphine/naloxone and the absence of other opioids. HHS also received a comment recommending that drug testing be included as part of treatment with buprenorphine and thus noted in the information that would be collected in the Request for Patient Limit Increase.

HHS believes that drug screens are likely part of a practitioner's diversion control plan and part of the data that will inform the practitioner's ability to help the patient achieve better outcomes. Thus, HHS is not revising the information to be collected as part of the Request for Patient Limit Increase.

HHS received a comment recommending that pharmacists be included in the pool of practitioners to which a release of information should be considered.

HHS believes it may be appropriate to release certain information to pharmacists if the patient provides consent. HHS declines to require that pharmacists be included in the pool of practitioners to which information may be released.

#### IV. Regulatory Impact Analysis

##### A. Introduction

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).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. HHS expects that this final rule will have an annual effect on the economy of \$100 million or more in at least 1 year and therefore is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. HHS anticipates that the final rule will not have a significant economic impact on a substantial

number of small entities. We provide supporting analysis in section F.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$146 million, using the most current (2015) implicit price deflator for the gross domestic product. HHS expects this final rule to result in expenditures that would exceed this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. HHS has determined that the final rule does not contain policies that would have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The changes in the rule represent the Federal Government regulating its own program. Accordingly, HHS concludes that the final rule does not contain policies that have federalism implications as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

##### B. Summary of the Final Rule

Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)) allows individual practitioners to dispense and prescribe Schedule III, IV, or V controlled substances that have been approved by the FDA specifically for use in

maintenance and detoxification treatment without obtaining the separate registration required by 21 CFR 1301.13(e) and imposes a limit on the number of patients a practitioner may treat at any one time.

Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial NOI to treat a maximum of 30 patients at a time. After one year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. To qualify, the practitioner must be a physician, possess a valid license to practice medicine, be a registrant of the DEA, have the capacity to refer patients for appropriate counseling and other appropriate ancillary services, and have completed required training. The training requirement may be satisfied in several ways: one may hold board certification in addiction psychiatry from the American Board of Medical Specialties or addiction medicine from the American Osteopathic Association; hold an addiction certification from the American Society of Addiction Medicine (ASAM); complete an 8-hour training provided by an approved organization; have participated as an investigator in one or more clinical trials leading to the approval of a medication that qualifies to be prescribed under 21 U.S.C. 823(g)(2); or complete other training or have such other experience as the State medical licensing board or Secretary of HHS considers to demonstrate the ability of the practitioner to treat and manage persons with opioid use disorder.

Pursuant to 21 U.S.C. 823(g)(2)(B)(iii), the Secretary is authorized to promulgate regulations that change the total number of patients that a practitioner may treat at any one time.

The laws pertaining to the utilization of buprenorphine were last revised approximately ten years ago at a time when the extent of the opioid public health crisis was less well-documented. The purpose of the final rule is to expand access to MAT with buprenorphine while encouraging practitioners administering buprenorphine to ensure their patients can receive the full array of services that comprise evidence-based MAT and to minimize the risk of drug diversion. The final rule revises the highest patient limit from 100 patients per practitioner with an existing waiver (waivered practitioner) to 275 patients for practitioners who meet certain criteria in addition to those established in statute. Practitioners who have had a waiver to treat 100 patients for at least one year could obtain approval to treat up to 275 patients if they meet the

requirements defined in this final rule and after submitting a Request for Patient Limit Increase to SAMHSA. Practitioners approved to treat up to 275 patients will also be required to accept greater responsibility for providing behavioral health services and care coordination, and ensuring quality assurance and improvement practices, diversion control, and continuity of care in emergencies. The higher limit also requires regularly reaffirming the practitioner's ongoing eligibility and participating in data reporting and monitoring as required by SAMHSA. In addition, practitioners in good standing with a current waiver to treat up to 100 patients (*i.e.*, the practitioner has filed a NOI and satisfied all required criteria) may request approval to treat up to 275 patients in specific emergency situations for a limited time period specified in the rule. We anticipate that qualifying emergency situations will occur very infrequently. As a result, we do not anticipate that this provision will contribute significantly to the impact of this final rule. SAMHSA will review all emergency situation requests, to the extent practicable, in consultation with appropriate governmental authorities before such requests are granted. Finally, the final rule defines patient limit in such a way that firmly ties the individual patient to the prescribing practitioner of record rather than to the covering practitioner at a given moment. This will enable waived practitioners to provide reciprocal cross-coverage of patients for brief periods, such as weekends or vacations, without being considered to be in excess of their respective individual limits. This will help to ensure continuity of care in select situations, and we expect that this will primarily affect the timing of treatment rather than the quantity of treatment. As a result, we do not anticipate that the changes related to cross-coverage will contribute significantly to the impact of this final rule, and we do not estimate associated costs and benefits.

### C. Need for the Rule

The United States is facing an unprecedented increase in prescription opioid misuse, heroin use, and opioid-related overdose deaths. In 2014, 18,893 overdose deaths involved prescription opioids and 10,574 involved heroin.<sup>3</sup>

<sup>3</sup> Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014. Atlanta, GA: Center for Disease Control and Prevention. Available at [http://www.cdc.gov/nchs/data/health\\_policy/AADR\\_](http://www.cdc.gov/nchs/data/health_policy/AADR_)

Underlying many of these deaths is an untreated opioid use disorder.<sup>4 5 6</sup> In 2014, more than 2.2 million people met diagnostic criteria for an opioid use disorder.<sup>7</sup>

Beyond the increase in overdose deaths, the health and economic consequences of opioid use disorders are substantial. In 2011, the most recent year data are available, an estimated 660,000 emergency department visits were due to the misuse or abuse of prescription opioids, heroin, or both.<sup>8</sup> A recent analysis estimated the costs associated with emergency department and hospital inpatient care for opioid abuse-related events in the United States was more than \$9 billion per year.<sup>9</sup> The societal costs of prescription opioid abuse, dependence, and misuse in the United States in 2011 were estimated at \$55.7 billion annually, not including societal costs related to heroin use.<sup>10</sup>

Beginning around 2006, the United States started to experience a significant increase in the rate of hepatitis C virus infections. The available epidemiology indicates this increase is largely due to the increased injection of prescription opioids and heroin.<sup>11 12</sup> In addition, in 2015, a large outbreak of HIV in a small rural community in Indiana was linked to injection of prescription opioids, primarily injection of the prescription opioid oxycodone. Over 80 percent

*drug\_poisoning\_involving\_OA\_Heroin\_US\_2000-2014.pdf.*

<sup>4</sup> Johnson EM, Lanier WA, Merrill RM, et al. Unintentional Prescription opioid-related overdose deaths: description of decedents by next of kin or best contact. *Utah, 2008–2009.* *J Gen Intern Med.* 2013;28(4):522–529.

<sup>5</sup> Hall AJ, Logan JE, Toblin RL, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA.* 2008;300(22):2613–2620.

<sup>6</sup> Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011;305(13):1315–1321.

<sup>7</sup> Jones CM. Unpublished analysis of the 2014 National Survey on Drug Use and Health Public Use File. 2015.

<sup>8</sup> *Id.*

<sup>9</sup> Chandwani HS, Strassels SA, Rascati KL, Lawson KA, Wilson JP. Estimates of charges associated with emergency department and hospital inpatient care for opioid abuse-related events. *J Pain Palliat Care Pharmacother.* 2013;27(3):206–13.

<sup>10</sup> Birnbaum HG, White AG, Schiller M, Waldman T, et al. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Med.* 2011;12(4):657–67.

<sup>11</sup> Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006–2012. *Clin Infect Dis* 2014;59:1411–9.

<sup>12</sup> Zibbell JE, Iqbal K, Patel RC, Suryaprasad A, et al. Increases in hepatitis C virus infection related to injection drug use related to injection drug use among persons aged ≤30 years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012. *MMWR Morb Mortal Wkly Rep.* 2015;64(17):453–8.

of the 135 cases, as of April 2015, identified in the outbreak were co-infected with hepatitis C virus.<sup>13</sup> The infectious disease consequences associated with opioid injection have been found to account for a significant proportion of the economic burden and disability associated with opioid use disorders.<sup>14</sup>

There is robust literature documenting the effectiveness and cost-effectiveness of the use of buprenorphine in the treatment of opioid use disorder. Buprenorphine has been shown to increase treatment retention and to reduce opioid use, relapse risk, and risk behaviors that transmit HIV and hepatitis.<sup>15 16 17 18 19 20</sup> Reductions in opioid-related mortality have been shown for buprenorphine.<sup>21 22 23</sup>

<sup>13</sup> Conrad C, Bradley HM, Broz D, et al. Community outbreak of HIV infection linked to injection drug use of oxycodone—Indiana, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(16): 443–4.

<sup>14</sup> Degenhardt L, Whiteford HA, Ferrari AJ, Charlson FJ, et al. Global burden of disease attributable to illicit drug use and dependence: findings from the Global Burden of Disease Study 2010. *Lancet* 2013;382(9904):1564–74.

<sup>15</sup> Clark RE, Baxter JD, Aweh G, O'Connell E, et al. Risk factors for relapse and higher costs among Medicaid members with opioid dependence or abuse: opioid agonists, comorbidities, and treatment history. *J Subst Abuse Treat.* 2015;57:75–80.

<sup>16</sup> Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev.* 2014 Feb 6;2:CD002207. doi: 10.1002/14651858.CD002207.pub4.

<sup>17</sup> Kraus ML, Alford DP, Kotz MM, et al. Statement of the American Society of Addiction Medicine consensus panel on the use of buprenorphine in office-based treatment of opioid addiction. *J Addict Med.* 2011;5(4):254–263.

<sup>18</sup> Bonhomme J, Shim RS, Gooden R, Tyus D, Rust G. Opioid addiction and abuse in primary care practice: a comparison of methadone and buprenorphine as treatment options. *J Natl Med Assoc.* 2012;104(7–8):342–350.

<sup>19</sup> Tsui JJ, Evans JL, Lum PJ, Hahn JA, Page K. Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA Intern Med.* 2014;174(12):1974–1981.

<sup>20</sup> Woody GE, Bruce D, Korhuit PT, Chhatre S, et al. HIV risk reduction with buprenorphine-naloxone or methadone: findings from a randomized trial. *J Acquir Immune Defic Syndr.* 2015;68(5):554–61.

<sup>21</sup> Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.* Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

<sup>22</sup> Schwartz RP, Gryczynski J, O'Grady KE, et al. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995–2009. *Am J Public Health.* 2013;103(5):917–922.

<sup>23</sup> Carrieri MP, Amass L, Lucas GM, Vlahov D, Wodak A, Woody GE. Buprenorphine use: the international experience. *Clin Infect Dis.* 2006;43(suppl 4):S197–S215.

Despite these well-documented benefits, buprenorphine treatment for opioid use disorder is significantly underutilized and often does not incorporate the full scope of recommended clinical practices that make up evidence-based MAT. Generally, there is significant unmet need for MAT treatment among individuals with opioid use disorders.<sup>24</sup> There is also substantial geographic variation in the capacity to prescribe buprenorphine. Research suggests that 10 percent of the population live in areas where there is a limited number of practitioners eligible to prescribe buprenorphine or in counties that have no practitioners with a waiver to prescribe buprenorphine.<sup>25</sup> These are primarily rural counties and areas located in the middle of the country.<sup>26</sup> Only about 5 percent of practitioners currently authorized to treat up to the 100 patient limit are located in rural counties.<sup>27</sup>

Evidence suggests that utilization of buprenorphine is limited directly by the existence of treatment limits. Practitioners currently providing MAT with buprenorphine under 21 U.S.C. 823(g)(2) report that being limited to treating not more than 100 patients at a time is a barrier to expanding treatment.<sup>28 29 30</sup> A recent survey by ASAM found that among the 1,309 respondents (approximately 35 percent of ASAM's membership), comprising a range of addiction stakeholders, including those working in OTPs and outpatient or office-based practice

<sup>24</sup> Jones CM, Campopiano M, Baldwin G, McCance-Katz E. National and state treatment need and capacity for opioid agonist medication-assisted treatment. *Am J Public Health* 2015;105(8):e55–63.

<sup>25</sup> Rosenblatt RA, Andrilla CH, Catlin M, Larson EH. Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *Ann Fam Med.* 2015 Jan–Feb;13(1):23–6. doi: 10.1370/afm.1735.

<sup>26</sup> Dick AW, Pacula RL, Gordon AJ, Sorbero M, et al. Growth in buprenorphine waivers for physicians increased potential access to opioid agonist treatment, 2002–11. *Health Affairs* 2015;34(6):1028–1034.

<sup>27</sup> Stein BD, Pacula RL, Gordon AJ, Burns RM, et al. Where is buprenorphine dispensed to treat opioid use disorders? The role of private offices, opioid treatment programs, and substance abuse treatment facilities in urban and rural counties. *Milbank Quarterly* 2015;93(3):56561–583.

<sup>28</sup> Molfenter T, Sherbeck C, Zehner M, Starr S. Buprenorphine Prescribing Availability in a Sample of Ohio Specialty Treatment Organizations. *J Addict Behav Ther Rehabil.* 2015;4(2). pii: 1000140.

<sup>29</sup> Molfenter T, Sherbeck C, Zehner M, Quanbeck A, et al. Implementing buprenorphine in addiction treatment: payer and provider perspectives in Ohio. *Subst Abuse Treat Prev Policy.* 2015;10:13. doi: 10.1186/s13011-015-0009-2.

<sup>30</sup> Substance Abuse and Mental Health Services Administration. (2006). *The SAMHSA Evaluation of the Impact of the DATA Waiver Program.* Retrieved from [http://www.buprenorphine.samhsa.gov/FOR\\_FINAL\\_summaryreport\\_colorized.pdf](http://www.buprenorphine.samhsa.gov/FOR_FINAL_summaryreport_colorized.pdf).

settings, 544, or 41.6 percent, were currently treating more than 80 patients, and 796, or 60.8 percent, reported there was demand for treatment in excess of the current 100 patient limit under the Drug Addiction Treatment Act of 2000 (Pub. L. 106–310).<sup>31</sup> Increasing the number of patients that a single practitioner can treat with buprenorphine, then, could have a direct impact on buprenorphine capacity and utilization.

In addition to direct barriers to treating additional patients imposed by the patient limit, there are indirect barriers to expanding treatment capacity. In particular, increases in a practitioner's ability to expand his or her patient base will allow the practitioner to take advantage of economies of scale to increase the practice's efficiency. For example, a practitioner with a larger practice is more likely to be able to afford to hire specialized support staff, which allows the practitioner to reduce time spent on tasks best suited for another individual. This may help to enable the provision of the full complement of ancillary services that make up evidence-based MAT. Increasing a practitioner's maximum capacity for treatment has the potential to make treating patients with buprenorphine more economically feasible, with the likelihood of increasing capacity to prescribe buprenorphine.

The statutory change implemented in 2007 that increased the limit on the number of buprenorphine patients a practitioner could treat from 30 to 100, after having a 30 patient limit for 1 year, was associated with a significant increase in the use of buprenorphine.<sup>32</sup> In 2007, when practitioners were first able to treat up to 100 patients, nearly 25 percent of eligible practitioners submitted a NOI to treat 100 patients (1,937 practitioners out of 7,887 practitioners).<sup>33</sup> The findings from the ASAM survey discussed above and additional information indicate there is sufficient demand from both providers and patients to raise the patient limit. In addition, based on the experience in 2007, it is expected that some proportion of eligible practitioners will respond to the final rule by submitting a Request for Patient Limit Increase to treat up to 275 patients.

<sup>31</sup> American Society of Addiction Medicine. 2015. Available at: <http://www.asam.org/magazine/read/article/2015/12/08/addiction-specialists-weigh-in-on-the-data-2000-patient-limits>.

<sup>32</sup> Stein *supra* note 27.

<sup>33</sup> Jones, *supra* note 24.

### D. Analysis of Benefits and Costs

#### a. Increased Ability for Waivered Practitioners To Treat Patients With Buprenorphine-Based MAT

This final rule directly expands opportunities for physicians who currently treat or who may treat patients with buprenorphine, as they will now have the potential to treat up to 275 patients with buprenorphine. We believe that this may translate to a financial opportunity for these physicians, depending on the costs associated with treating these additional patients.

Relatedly, this final rule may increase the value of the waiver to treat opioid use disorder under 21 U.S.C. 823(g)(2). The final rule requires practitioners to have a waiver to treat 100 patients for 1 year and to have additional credentialing as defined in § 8.2 or to practice in a qualified practice setting as defined in the rule in order to request approval to treat up to 275 patients. If getting to the 275-patient limit provides sufficient benefits to practitioners, this final rule may also increase incentives for other practitioners to apply for the lower patient limit waivers, insofar as they are milestones towards the 275-patient limit. In addition, this rule may also make it more valuable for practitioners to have additional credentialing as defined in § 8.2, or to practice in a qualified practice setting. The final rule, then, may increase the number of practitioners in these categories and thus the number of practitioners eligible for the 275-patient limit in the future.

#### b. Increased Treatment for Patients

Permitting practitioners to treat up to 275 patients will only be successful if it results in practitioners serving additional patients. As discussed previously, there are many reasons to expect this to happen as a result of the publication of this final rule. In addition, we expect that other factors could amplify the impact of the changes in the rule. First, following the implementation of the Affordable Care Act, health insurance coverage has expanded dramatically in the United States. The uninsured rate among adults age 18–64 declined from 22.3 percent in 2010 to 12.7 percent during the first 6 months of 2015.<sup>34</sup> Further, the Affordable Care Act expanded coverage includes populations who may be at

high-risk for opioid use disorders that previously did not have sufficient access to health insurance coverage.<sup>35</sup> Second, parity protections from the Mental Health Parity and Addiction Equity Act and the Affordable Care Act will include coverage for mental health and substance use disorder treatment that is comparable to medical and surgical coverage in many types of insurance policies. Insurance coverage and cost of treatment have previously been cited as important reasons that individuals seeking treatment have not used buprenorphine.<sup>36 37 38 39</sup> A final rule to extend parity protections to Medicaid managed care plans was released earlier this year. These changes in health insurance coverage should improve access to substance use disorder treatment, including buprenorphine.

#### c. Increased Time To Treat Patients

Lack of practitioner time to treat patients with opioid use disorder, which includes a patient exam, medication consultation, counseling, and other appropriate treatment services, and lack of behavioral health staff to provide these treatment services, are additional barriers to providing MAT with buprenorphine in the office-based setting.<sup>40 41</sup> These barriers could be addressed by leveraging the time and skills of clinical support staff, such as nurses and clinical social workers. For example, in Massachusetts and Vermont, nurses provide screening, intake, education, and other ancillary services for patients treated with buprenorphine. This enables practitioners to treat additional patients and to provide the requisite

psychosocial services.<sup>42 43 44</sup> However, in order to afford a nurse or other clinician dedicated to providing evidence-based treatment for an opioid use disorder, practitioners need a minimum volume of patients. Allowing practitioners to treat up to 275 patients at a time could be a step towards supporting practitioners that seek to hire nurses and other clinical staff to reduce practitioners' time requirements and to provide the comprehensive services of high-quality MAT with buprenorphine. This impact of leveraging non-physicians to facilitate expanded access to buprenorphine has been demonstrated in both Vermont and Massachusetts.<sup>45 46</sup>

Discussions with stakeholders about approaches to expanding access to MAT, including the use of buprenorphine-based MAT, suggest that expanding the patient limit in general will result in increased efficiencies in treating opioid use disorder patients. It will allow treating practitioners to provide the physician-appropriate services consistent with their waiver. It will provide more efficient supportive care, not related to prescribing or administering buprenorphine-containing products, by allowing the treating practitioner to supervise this care, which can be provided by physician assistants, nurse practitioners, nurse case managers, and other behavioral health specialists.

#### d. Federal Costs Associated With Disseminating Information About the Rule

Following publication of this final rule, SAMHSA will work to educate providers about the requirements and opportunities for requesting and obtaining approval to treat up to 275 patients under 21 U.S.C. 823(g)(2). SAMHSA will prepare materials summarizing the changes as a result of

<sup>35</sup> Jones, *supra* note 7.

<sup>36</sup> Volkow ND, Frieden TR, Hyde PS, et al. Medication-assisted therapies—tackling the opioid-overdose epidemic. *New Eng J Med* 2014; 370(22):2063–6.

<sup>37</sup> Sohler NL, Weiss L, Egan JE, et al. Consumer attitudes about opioid addiction treatment: a focus group study in New York City. *J Opioid Manag.* 2013;9(2):111–119.

<sup>38</sup> Greenfield BL, Owens MD, Ley D. Opioid use in Albuquerque, New Mexico: a needs assessment of recent changes and treatment availability. *Addict Sci Clin Pract.* 2014;9:10. doi: 10.1186/1940-0640-9-10.

<sup>39</sup> American Society of Addiction Medicine. State Medicaid coverage and authorization requirements for opioid dependence medications. 2013. Available at: <http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>.

<sup>40</sup> Hutchinson E, Catlin M, Andrilla CH, Baldwin LM, Rosenblatt RA. Barriers to primary care physicians prescribing buprenorphine. *Ann Fam Med.* 2014 Mar–Apr;12(2):128–33.

<sup>41</sup> DeFlavio JR, Rolin SA, Nordstrom BR, Kazal LA Jr. Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians. *Rural Remote Health.* 2015;15:3019. Epub 2015 Feb 4.

<sup>42</sup> Alford D, LaBelle C, Richardson J, O'Connell J, et al. Treating homeless opioid dependent patients with buprenorphine in an office-based setting. *Society of General Internal Medicine.* 2007; 22: 171–176.

<sup>43</sup> LaBelle, C. Nurse Care Manager Model. <http://buprenorphine.samhsa.gov/presentations/LaBelle.pdf>.

<sup>44</sup> State of Vermont: Concept for Medicaid Health Home Program [http://hcr.vermont.gov/sites/hcr/files/VT\\_SPA\\_Concept\\_Paper\\_final\\_CMS\\_10\\_02\\_12.pdf](http://hcr.vermont.gov/sites/hcr/files/VT_SPA_Concept_Paper_final_CMS_10_02_12.pdf).

<sup>45</sup> LaBelle CT, Han SC, Bergeron A, Samet JH. Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Statewide Implementation of the Massachusetts Collaborative Care Model in Community Health Centers. *J Subst Abuse Treat.* 2016;60:6–13.

<sup>46</sup> Vermont Department of Health. The effectiveness of Vermont's System of Opioid Addiction Treatment. 2015. Available at: <http://legislature.vermont.gov/assets/Legislative-Reports/Opioid-system-effectiveness-1.14.15.pdf>.

<sup>34</sup> Centers for Disease Control and Prevention. Health insurance coverage: early release of estimates from the National Health Interview Survey, January–June 2015. Available at: [http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur\\_201511.pdf](http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur_201511.pdf).

this final rule, and provide these materials to practitioners potentially affected by the rulemaking upon its publication. SAMHSA has already established channels for disseminating information about rule changes to stakeholders; it is estimated that preparing and disseminating these materials will cost approximately \$40,000, based upon experience soliciting public comment on past rules and publications such as the Federal Opioid Treatment Program Standards.

e. Practitioners Costs To Evaluate the Policy Change

We expect that practitioners potentially affected by this policy change will process the information and decide how to respond. In particular, they will likely evaluate the requirements and opportunities associated with the ability to treat up to 275 patients, and decide whether or not it is advantageous to pursue approval to treat up to 275 patients and make any necessary changes to their practice, such as obtaining additional credentialing as defined in § 8.2, or the ability to treat patients in a qualified practice setting.

We estimate that practitioners may spend an average of thirty minutes processing the information and deciding what action to take. According to the U.S. Bureau of Labor Statistics,<sup>47</sup> the average hourly wage for a physician is \$93.74. After adjusting upward by 100 percent to account for overhead and benefits, we estimate that the per-hour cost of a physician's time is \$187.48. Thus, the cost per practitioner to process this information and decide upon a course of action is estimated to be \$93.74. SAMHSA will disseminate

information to an estimated 50,000 practitioners, which includes practitioners with a waiver to prescribe buprenorphine (*i.e.*, approximately 30,000 practitioners as of December 2015) and those who are reached through SAMHSA's dissemination network (*i.e.*, 20,000 practitioners). For purposes of analysis we assume that 75 percent of these practitioners will review this information, and, as a result, we estimate that dissemination will result in a total cost of \$3.5 million.

f. Practitioner Costs To Submit a Request for Patient Limit Increase

Practitioners who want to treat up to 275 patients at a given time are required to submit a Request for Patient Limit Increase form to SAMHSA. The form is three pages in length. We estimate that the form takes a practitioner an average of 1 hour to complete the first time it is completed, implying a cost of \$187.48 per submission after adjusting upward by 100 percent to account for overhead and benefits. A draft Request for Patient Limit Increase form is available in the docket. We did not receive public comment on these assumptions when proposed, and as a result they remain unchanged from those appearing in the proposed rule. We do not have ideal information with which to estimate the number of practitioners who will submit a Request for Patient Limit Increase form in response to this final rule, and we therefore acknowledge uncertainty regarding the estimate of the total associated cost. However, based on the experience with the patient limit increase from 30 to 100 implemented in 2007,<sup>48 49</sup> the results of the 2015 ASAM survey described earlier, public

comment, and discussions with stakeholders, and changes in qualifications necessary to request a waiver to treat up to 275 patients, we estimate that between 500 and 1,800 practitioners will request approval to treat up to 275 patients within the first year following publication of the final rule. This translates to between approximately 5 percent and 18 percent of eligible providers with the 100 patient limit requesting the higher patient limit in the first year. This is consistent with a public comment that indicated that 8 to 15 physicians (or 11 percent–21 percent) in Vermont would request the higher patient limit, as well as a recent study in Ohio which found among specialty treatment providers that 17 percent had turned away patients due to prescribing capacity limits.<sup>50</sup> In addition, our lower bound estimate of 5 percent is in line with an internal analysis by HHS that found approximately 5 percent of physicians with the 100 patient limit in 3 geographic diverse States were prescribing at or near their 100 patient limit. We estimate that between 100 and 300 additional practitioners will request approval to treat up to 275 patients in each of the subsequent 4 years. This would result in 600 to 2,100 practitioners in the second year, 700 to 2,400 practitioners in the third year, 800 to 2,700 in the fourth year, and 900 to 3,000 practitioners in the fifth year. We use the midpoint of each of these ranges to estimate costs and benefits in the first 5 years following publication of the final rule. This would result in a range of \$93,740 to \$337,464 in costs related to Request for Patient Limit Increase submissions in the first year.

	Number of requests for patient limit increase	Cost (\$)
Year 1 .....	1,150	215,600
Year 2–5 .....	200	37,500
Total .....	1,950	365,600

g. Practitioner Costs To Resubmit a Request for Patient Limit Increase

After approval, a practitioner would need to be resubmit a Request for Patient Limit Increase every 3 years to maintain his or her waiver to treat up to 275 patients. A practitioner would use

the same 3-page Request for Patient Limit Increase used for an initial waiver request. We estimate that this will take 30 minutes because practitioners will be more familiar with the Request for Patient Limit Increase. Consistent with the physician wage estimate above, we

estimate that resubmissions will require a practitioner an average of 30 minutes to complete, implying a cost of \$93.74 per resubmission. To calculate costs associated with resubmission, we assume that all physicians who submit a Request for Patient Limit Increase will

<sup>47</sup> U.S. Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Retrieved from: [http://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](http://www.bls.gov/oes/current/oes_nat.htm#29-0000).

<sup>48</sup> Arfken CL, Johanson CE, Menza SD, Schuster CR. Expanding treatment capacity for opioid

dependence with office-based treatment with buprenorphine: national surveys of physicians. *J Subst Abuse Treat.* 2010;39(2):96–104.

<sup>49</sup> Jones, *supra* note 24.

<sup>50</sup> Molfenter T, Sherbeck C, Zehner M, Starr S. Buprenorphine prescribing availability in a sample of Ohio specialty treatment organizations. *J Addict Behav Ther Rehabil.* 2015;4(2): doi:10.4172/2324–9005.1000140.

submit a renewal 3 years later. Our estimates are summarized in the table below.

	Number of renewals	Cost (\$)
Year 1–3 (renewals not necessary) .....	0	0
Year 4 .....	1,150	108,000
Year 5 .....	200	19,000
Total .....	1,350	127,000

**h. Private-Sector Costs Associated With Newly Applying for Any Waiver**

Practitioners may also be interested in the ability to eventually treat up to 275 patients, and may make changes toward achieving that goal. As discussed previously, these changes may increase the number of practitioners who apply for a waiver to treat 30 or 100 patients. This would require practitioners to complete the required training, possess a valid license to practice medicine, be a registrant of DEA, and have the capacity to refer patients for appropriate counseling and other appropriate ancillary services. In addition, these changes could increase the number of practitioners who seek additional credentialing as defined in § 8.2 or meet the requirements for practicing in a qualified practice setting as outlined in the final rule. This would likely include practice experience requirements, fees and time associated with preparing for and taking an exam, time and fees for continuing medical education requirements, and payment of certification fees. We lack information to estimate the number of practitioners who will change behavior along these dimensions, and did not receive this information through the public comment process. Thus, we do not provide estimates of costs and benefits.

**i. Federal Costs Associated With Processing New 275-Patient Limit Waivers**

In addition to the costs associated with practitioners seeking approval for the higher patient limit, costs will be incurred by SAMHSA and DEA in order to process the additional Requests for Patient Limit Increase generated by the final rule. For purposes of analysis, and based on contractor estimates, SAMHSA estimates that it will pay a contractor \$100 to process each waiver. As discussed previously, we estimate that between 500 and 1,800 practitioners will request approval to treat up to 275 patients within the first year of the rule, and between 100 and 300 additional practitioners will request approval to treat up to 275 patients in each of the subsequent 4 years. In addition, we

estimate that physicians will resubmit 500 to 1,800 renewals in year 4, and 100 to 300 renewals in year 5. As a result, we estimate costs to SAMHSA to process these waivers of \$50,000–\$180,000 in year 1, \$10,000–\$30,000 in year 2, \$10,000–\$30,000 in year 3, \$60,000–\$210,000 in year 4, and \$20,000–\$60,000 in year 5 following publication of the final rule. We estimate that DEA will allocate the equivalent of 1 FTE at the GS–11 level to process the additional requests coming to DEA for issuance of a new DEA number designating the physician as eligible to prescribe buprenorphine for the treatment of opioid use disorder as a result of this final rule. We estimate the associated cost is \$144,238, which we arrive at by multiplying the salary of a GS–11 employee at step 5, which is \$72,219 in 2015, by two to account for overhead and benefits.

**j. Costs and Benefits of New Treatment**

Once requests to treat up to 275 patients generated by the final rule are processed, approved practitioners would be able to increase the number of patients they treat with buprenorphine. These patients, then, could utilize additional medical services that are consistent with the expectations for high-quality, evidence-based MAT in the rule. We estimate the cost for buprenorphine and these additional medical services, including behavioral health and psychosocial services, as a result of the final rule to total \$4,349 per patient per year, as described below.

This estimate was derived using claims data from the 2009–2014 Truven Health MarketScan® database. According to the MarketScan® data, the annual cost of buprenorphine prescriptions and ancillary psychosocial services received totaled \$3,500 for individuals with private insurance and \$3,410 for individuals with Medicaid. Specifically, the average annual cost of buprenorphine prescriptions was \$2,100 for commercial insurance based on receipt of an average of seven buprenorphine prescriptions annually and \$2,600 for Medicaid based on receipt of an average of 10

buprenorphine prescriptions annually. We use estimates from commercial insurance and Medicaid in order to capture the range of costs per patient across different insurance programs. However, we note that the rule will impact patients with and incur costs to not only commercial insurance and Medicaid but also other public and private insurers.

According to the MarketScan® data, approximately 69 percent of Medicaid patients and 45 percent of privately insured patients received an outpatient psychosocial service related to substance use disorder in addition to their buprenorphine prescription. The average number of visits among those who received any psychosocial service was eight for privately insured patients at an average cost of \$3,000 per year and 10 for Medicaid patients at an average cost of \$1,100 per year. We assumed that the quality of care would increase among patients treated by practitioners with the 275-patient limit due to the extra oversight and quality of care requirements in the final rule. Specifically, we assumed that 80 percent of patients would receive outpatient psychosocial services.

The cost of providing MAT with buprenorphine, including prescriptions, ancillary, and psychosocial services, is estimated at \$4,590 for commercial insurance and \$3,525 for Medicaid beneficiaries. Based on data from IMS Health, it is estimated that approximately 18 percent of individuals receiving MAT with buprenorphine are Medicaid enrollees. Thus, we arrived at the estimated average cost for individuals new to the treatment system as a result of the final rule to be \$4,350 per patient per year.

The total resource costs associated with additional treatment is the product of additional treatment costs per person and the number of people who will receive additional treatment as a result of the final rule. For purposes of analysis, we assume that each practitioner who requests approval to treat up to 275 patients will treat between 20 and 50 additional patients each year. This is based on the

experience with the increase from the 30 patient limit to the 100 patient limit and taking into account the increase in demand for buprenorphine treatment since that statutory change.<sup>51 52</sup> In addition, we have adjusted the upper bound of this range in line with the shift to the availability of a waiver to treat up to 275 rather than 200 patients. We note that in that case, there were no new costs imposed on practitioners beyond those associated with additional treatment, whereas in this final rule there are new costs beyond those

associated with additional treatment. However, applying this assumption would result in an estimated range of 10,000 to 90,000 additional patients treated in the first year; and an additional 2,000 to 15,000 patients in each subsequent year. To estimate costs associated with this increase in the number of patients, we assume that, on average, each physician will treat the equivalent of 35 full-time patients (*i.e.*, some patients might receive fewer services and others might receive more, but for cost estimates we assume it

averages out to the equivalent of 35 patients receiving the full spectrum of care). We use these ranges to estimate costs and benefits of the rule. Based on this information, we estimate the treatment costs associated with new patients receiving treatment with buprenorphine as a result of this final rule will be between \$43.5 million and \$391 million in the first year with a central estimate of \$175 million, and an additional \$8.7 million to \$65.2 million in each subsequent year with a central estimate of \$30.4 million.<sup>53</sup>

	Additional people receiving treatment, relative to baseline	Treatment costs (millions)
Year 1 .....	40,250	\$175
Year 2 .....	47,250	205
Year 3 .....	54,250	236
Year 4 .....	61,250	266
Year 5 .....	68,250	297

Evidence suggests that the benefits associated with additional buprenorphine utilization are likely to exceed their cost. One study estimates the costs and Quality Adjusted Life Year (QALY) gains associated with long-term office-based treatment with buprenorphine-naloxone for clinically stable opioid-dependent patients compared to no treatment. The authors estimate total treatment costs over 2 years of \$7,700 and an associated 0.22 QALY gain compared to no treatment in their base case.<sup>54 55</sup> Following a food safety rule recently published by FDA,<sup>56</sup> we use a value of \$1,260 per quality-adjusted life day. This implies a value of \$460,215 (\$1,260 \* 365.25) per QALY, which we use to monetize the health benefits here. As a result, we estimate average annual benefits ranges of \$51,000 per person who achieves 6

months of clinical stability. Evidence suggests a 43.3 percent completion rate for a six month treatment course.<sup>57</sup> For other individuals, we estimate they experience half of the annual health benefits, equivalent to 0.055 QALYs. In addition, based on an internal analysis of data from the National Survey on Drug Use and Health, we estimate that 20 percent of new patients impacted by this rule will have received some form of non-medication-assisted treatment for opioid use disorder in the past year and 80 percent of patients will be new to treatment.<sup>58</sup> For the 20 percent of patients switching to buprenorphine from other non-MAT interventions, we adjust their estimated health benefit downward by 15 percent to account for benefits derived from non-MAT interventions prior to initiating buprenorphine treatment. As a result,

we estimate monetized health benefits of \$1,416 million in the first year, with estimated monetized health benefits rising by \$246 million in each subsequent year as more individuals receive treatment as a result of the rule. These monetized health benefits are summarized below. We also explore the sensitivity of these results to our assumptions regarding the health benefits related to treatment in our section on sensitivity analysis. HHS believes that the public will also experience benefits that go beyond the health benefits quantified and monetized here. These benefits include reductions in costs associated with criminal justice system interactions. While these are important benefits of this rule, HHS does not quantify the rule's effects along these dimensions.

	Additional people receiving treatment, relative to baseline	Monetized health benefits (millions)
Year 1 .....	40,250	\$1,416
Year 2 .....	47,250	1,662
Year 3 .....	54,250	1,909

<sup>51</sup> Arfken, *supra* note 48.

<sup>52</sup> Jones, *supra* note 24.

<sup>53</sup> As noted subsequently, some individuals newly receiving MAT would have accessed non-MAT interventions in the absence of this rule. Accounting for this would reduce the estimates of rule-induced costs.

<sup>54</sup> Schackman BR, Leff JA, Polsky D, Moore BA, Fiellin DA. Cost-Effectiveness of Long-Term Outpatient Buprenorphine-Naloxone Treatment for Opioid Dependence in Primary Care. *Journal of General Internal Medicine*. 2012;27(6):669–676. doi:10.1007/s11606-011-1962-8.

<sup>55</sup> These results omit lost utility associated with the illegal consumption of heroin or other opioids. Such omission is consistent with Zerbe, R.O. Is Cost-Benefit Analysis Legal? Three Rules. *Journal of Policy Analysis and Management* 17(3): 419–456, 1998.

<sup>56</sup> This RIA can be found here: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf>.

<sup>57</sup> Fiellin DA, Pantalon MV, Chawarski MC, Moore BA, Sullivan LE, O'Connor PG, Schottenfeld RS. Counseling plus Buprenorphine—Naloxone

Maintenance Therapy for Opioid Dependence. *New England Journal of Medicine*. 2006; 355:365–374. doi: 10.1056/NEJMoa055255

<sup>58</sup> Given that data from the National Survey on Drug Use and Health indicate only a minority of patients with substance use disorder treatment need actually recognize that need and seek treatment, we note that 20 percent likely represents the lower bound of the portion of new MAT recipients who would have received some form of non-MAT treatment in the absence of the rule, thus leading to some tendency in the benefits to be overestimated.

	Additional people receiving treatment, relative to baseline	Monetized health benefits (millions)
Year 4 .....	61,250	2,155
Year 5 .....	68,250	2,431

k. Potential for Diversion

While we expect many benefits associated with this final rule, it is possible that there would be unintended negative consequences. First, prior research looked at Utah statewide increases in buprenorphine use and the number of reported unintentional pediatric exposures, and found that as buprenorphine use increased between 2002 and 2011, the number of unintentional pediatric exposures in the State increased.<sup>59</sup> Thus, it is possible that the increased utilization of buprenorphine as a result of this final rule without appropriate patient counseling and action to ensure the safe use, storage, and disposal of buprenorphine, may lead to an increase in unintentional pediatric exposures. In addition, there has been an increase in diversion of buprenorphine as use of the product has increased. According to the National Forensic Laboratory Information System (NFLIS)—a system used to track diversion—buprenorphine is the third most common narcotic analgesic reported in NFLIS, with 15,209 cases reported in 2014. This represents 12.4 percent of all narcotic analgesic cases in NFLIS in 2014.<sup>60</sup>

It is important to note that studies have found that the motivation to divert buprenorphine is often associated with lack of access to treatment or using the medication to manage withdrawal—as opposed to diversion for the medication’s psychoactive effect.<sup>61 62</sup> Thus, the overall effect of this rulemaking on diversion is not clear given that the increased utilization of buprenorphine could affect the opportunity for diversion, but also

could, in some cases, reduce diversion because of improved access to high-quality, evidence-based buprenorphine treatment.

Moreover, to reduce the risk of diversion, one of the additional requirements placed on providers who seek the 275-patient limit is implementation of a diversion control plan. However, it is possible that State and local law enforcement could incur additional costs if diversion increases as a result of this final rule. We do not have sufficient information to estimate the extent to which these unintended consequences could occur, and did not receive any through public comment.

l. Practitioner Reporting Requirements

As discussed elsewhere in the preamble, HHS has decided to issue concurrently a Supplemental Notice of Proposed Rulemaking to seek additional comments on the proposed reporting requirements and is therefore delaying the finalization of the reporting requirements proposed in § 8.635 of the NPRM. At this time, we lack the information necessary to estimate the costs associated with future reporting requirements, and as a result do not estimate them here.

m. Costs Associated With Waiver Requests in Emergencies

Under the final rule, practitioners in good standing with a current waiver to treat up to 100 patients may request temporary approval to treat up to 275 patients in specific emergency situations. As discussed previously, we anticipate that qualifying emergency situations will occur very infrequently.

We estimate that practitioners will request ten of these waivers in each year. We estimate that requesting this waiver would require approximately 1 hour of physician time and 2 hours of administrative time, and responding to the request would require resources approximately equivalent to responding the three Requests for Patient Limit Increase submissions, which is \$300. As a result, we estimate that this requirement is associated with costs of approximately \$7,000 in each year following publication of the final rule.

n. Summary of Impacts

The final rule’s impacts will take place over a long period of time. As discussed previously, we expect the existence of the waiver to treat up to 275 patients will increase the desirability of waivers to treat 30 and 100 patients. This implies that more practitioners will work toward fulfilling the requirements associated with receiving these waivers. Further, this may make practitioners early in their career more likely to choose addiction medicine or addiction psychiatry as their specialty. All of this implies that the final rule will have a growing impact on capacity to prescribe buprenorphine as time passes. Since the lack of capacity to treat patients using buprenorphine is a barrier to its utilization, this suggests that the final rule will lead to growing increases in the utilization of buprenorphine, and growing increases in the associated positive health and economic effects.

The following table presents these costs and benefits over the first 5 years of the final rule.

ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES

BENEFITS	Present value over 5 years by discount rate (millions of 2014 dollars)		Annualized value over 5 years by discount rate (millions of 2014 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Benefits .....	8,935	8,228	1,894	1,875

<sup>59</sup> Centers for Disease Control and Prevention. Buprenorphine prescribing practices and exposures reported to a poison center—Utah, 2002–2011. MMWR 2012;61:997–1001.

<sup>60</sup> Drug Enforcement Administration. National Forensic Laboratory Information System. 2014

Annual Report. Available at: <https://www.nflis.deadiversion.usdoj.gov/Reports.aspx>.

<sup>61</sup> Lofwall MR, Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug Alcohol Depend. 2012;126(3):379–83.

<sup>62</sup> Genberg BL, Gillespie M, Schuster CR, Johanson CE, et al. Prevalence and correlates of street-obtained buprenorphine use among current and former injectors in Baltimore, Maryland. Addict Behav. 2013;38(12):2868–73.



ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES—Continued

COSTS	3 Percent	7 Percent	3 Percent	7 Percent
	Quantified Costs .....	1,109	1,022	235

E. Sensitivity Analysis

The total estimated benefits of the changes here are sensitive to assumptions regarding the number of practitioners who will seek a waiver to treat up to 275 patients as a result of the final rule, the number of individuals who will receive MAT as a result of the final rule, the average per-person health benefits associated with this additional treatment, and the dollar value of these health improvements. We estimate that 500 to 1,800 practitioners will apply for a waiver to treat up to 275 patients in the first year, and 100 to 300 practitioners will apply for a waiver to treat up to 275 patients in subsequent years following publication of the final rule, with central estimates at the midpoint of each range. For alternative estimates in these ranges using a 3 percent discount rate, all else equal, we estimate annualized benefits ranging from \$855 million to \$2,934 million and annualized costs ranging from \$107 million to \$364 million.

We estimate that practitioners who receive a waiver to treat up to 275 patients will treat between 20 and 50 additional patients each year, with a central estimate of an average of 35 additional patients. For alternative estimates of 20 to 50 additional patients per year, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$1,082 million to \$2,706 million and annualized costs ranging from \$135 million to \$336 million over the 5 years following implementation.

We estimate that individuals who receive MAT as a result of the final rule will experience average health improvements equivalent to approximately 0.08 QALYs. For alternative estimates of these health improvements between 0.04 and 0.12 QALYs, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$991 million to \$2,973 million over the 5 years following implementation. To estimate

the dollar value of health benefits, we use a value of approximately \$460,000 per QALY. For alternative values per QALY between \$300,000 and \$600,000, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$1,235 million to \$2,469 million over the 5 years following implementation.

Alternative assumptions along these four dimensions, when varied together, using a 3 percent discount rate, imply annualized benefit estimates ranging from \$167 million to \$8,576 million and annualized cost estimates ranging from \$61 million to \$519 million. We note that, in all scenarios discussed in this section, annualized benefits substantially exceed annualized costs. There are, however, uncertainties not reflected in this sensitivity analysis, which might lead to net benefits results that are smaller or larger than the range of estimates summarized in the following table.

LOW, HIGH, AND PRIMARY BENEFIT AND COST ESTIMATES

BENEFITS	Annualized value over 5 years 3 percent discount rate (millions of 2014 dollars)		
	Low	Primary	High
Quantified Benefits .....	167	1,894	8,576
COSTS	Low	Primary	High
	Quantified Costs .....	61	235

F. Analysis of Regulatory Alternatives

We carefully considered the option of not pursuing regulatory action. However, existing evidence indicates that opioid use disorder and its related health consequences is a substantial and increasing public health problem in the United States, and it can be addressed by increasing access to effective treatment. As discussed previously, the lack of sufficient access to treatment is directly affected by the existing limit on the number of patients each practitioner with a waiver can currently treat using buprenorphine, and removing this barrier to access is very likely to increase the provision of this treatment. Finally, the provision of MAT with buprenorphine provides tremendous benefits to the individual who

experiences health gains associated with treatment, as well as to society which bears smaller costs associated with the negative effects of opioid use disorders. These benefits are expected to greatly exceed the costs associated with increases in treatment. As a result, we expect the benefits of this regulatory action to exceed its costs.

We also considered allowing practitioners waived to treat up to 100 patients to apply for the higher prescribing limit without having to meet the additional credentialing as defined in § 8.2 or qualified practice setting requirements as defined in the final rule. One important objective of this final rule is to expand access while mitigating the risks associated with expanded access. In addition, the effects

of this rule are difficult to project, leading us to adopt a measured approach to increasing access. Given the complexity of the condition, the increased potential for diversion associated with a higher prescribing limit, and the need to ensure high quality care, it was determined that addition specialist physicians and those with the infrastructure and capacity to deliver the full complement of services recommended by clinical practice guidelines would be best suited to balance these concerns.

Finally, we considered the alternative of having no reporting requirement for physicians with the 275-patient limit. Although this alternative would reduce the 1 hour of physician time and 2 hours of administrative time estimated

for data reporting in our analysis, we did not pursue this alternative. The reporting requirements are intended to reinforce recommendations included in clinical practice guidelines on the delivery of high quality, effective, and safe patient care. Specifically, nationally-recognized clinical guidelines on office-based opioid treatment with buprenorphine suggest that optimal care include administration of the medication and the use of psychotherapeutic support services. They also recommend that physicians and practices prescribing buprenorphine for the treatment of opioid use disorder in the outpatient setting take steps to reduce the likelihood of buprenorphine diversion. Each of these tenets is reflected in the reporting requirements.

### G. Regulatory Flexibility Analysis

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. The categories of entities affected most by this final rule will be offices of practitioners and hospitals. We expect that the vast majority of these entities will be considered small based on the Small Business Administration size standards or non-profit status, and assume here that all affected entities are small. According to SAMHSA data, as of March 2016, there were 32,123 practitioners with a waiver to prescribe buprenorphine for the treatment of opioid use disorder. This group of practitioners is most likely to be impacted by the final rule, but we lack information on the total number of associated entities. We acknowledge that some practitioners with a waiver may provide services at multiple entities, many entities may employ multiple practitioners with a waiver, and some entities currently unaffiliated with these practitioners will be impacted by this final rule. As a result, we estimate that approximately 32,123 small entities will be affected by this final rule.

HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. As discussed above, the final rule imposes a small burden on entities. This burden is primarily associated with processing information disseminated by SAMHSA, opting to completing the waiver process to treat additional patients, and submitting information after receiving a waiver to treat 275 patients, which are estimated

to take a maximum of 4 hours per practitioner in any given year. This represents less than 1 percent of hours worked for an individual working full-time. Further, this final rule does not require practitioners to undertake these burdens, as this rulemaking does not require practitioners to seek a waiver to treat 275 patients. As a result, we anticipate that this final rule will not have a significant impact on a substantial number of small entities.

### 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. Revise the heading of part 8 as set forth above.

■ 3. Amend part 8 as follows:

■ a. Remove the word “opiate” and add the word “opioid” in its place wherever it appears; and

■ b. Remove the phrases “opioid addiction” and “Opioid addiction” and add in their places the phrases “opioid use disorder” and “Opioid use disorder”, respectively, wherever they appear.

■ 4. Revise the heading to subpart A to read as follows:

#### Subpart A—General Provisions

■ 5. Revise § 8.1 to read as follows:

#### § 8.1 Scope.

(a) Subparts A through C of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid use disorders. The regulations also establish the Secretary’s standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid use disorder must first obtain from the Secretary or, by delegation, from the

Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary’s standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary’s standards for treatment of opioid use disorder with an opioid agonist treatment medication.

(b) The regulations in subpart F of this part establish the procedures and requirements that practitioners who are authorized to treat up to 100 patients pursuant to a waiver obtained under section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)), must satisfy in order to treat up to 275 patients with medications covered under section 303(g)(2)(C) of the CSA.

■ 6. Amend § 8.2 as follows:

■ a. Revise the definitions of “Accreditation body” and “Accreditation body application”;

■ b. Add, in alphabetical order, the definitions of “Additional Credentialing,” “Approval term,” and “Behavioral health services”;

■ c. Add, in alphabetical order, the definitions of “Covered medications,” “Dispense,” “Diversion control plan,” and “Emergency situation”;

■ d. Revise the definition of “Interim maintenance treatment”;

■ e. Add, in alphabetical order, the definitions of “Medication-Assisted Treatment (MAT),” “Nationally recognized evidence-based guidelines,” and “Opioid dependence”;

■ f. Remove the definition of “Opioid treatment”;

■ g. Revise the definitions of “Opioid treatment program”;

■ h. Add, in alphabetical order, the definitions of “Opioid program treatment certification,” “Opioid use disorder,” and “Opioid use disorder treatment”;

■ i. Revise the definition of “Patient”;

■ j. Add, in alphabetical order, the definitions of “Patient limit,” “Practitioner,” and “Practitioner incapacity”; and

■ k. Remove the definition of “Registered opioid treatment program”.

The revisions and additions read as follows:

**§ 8.2 Definitions.**

\* \* \* \* \*

*Accreditation body* means a body that has been approved by SAMHSA in this part to accredit opioid treatment programs using opioid agonist treatment medications.

*Accreditation body application* means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body.

\* \* \* \* \*

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

*Approval term* means the 3 year period in which a practitioner is approved to treat up to 275 patients that commences when a practitioner's Request for Patient Limit Increase is approved in accordance with § 8.625.

*Behavioral health services* means any non-pharmacological intervention carried out in a therapeutic context at an individual, family, or group level.

Interventions may include structured, professionally administered interventions (e.g., cognitive behavior therapy or insight oriented psychotherapy) delivered in person, interventions delivered remotely via telemedicine shown in clinical trials to facilitate medication-assisted treatment (MAT) outcomes, or non-professional interventions.

\* \* \* \* \*

*Covered medications* means the drugs or combinations of drugs that are covered under 21 U.S.C. 823(g)(2)(C).

\* \* \* \* \*

*Dispense* means to deliver a controlled substance to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled substance.

*Diversion control plan* means a set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly.

*Emergency situation* means that an existing State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for medication-assisted treatment as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as practitioner incapacity; natural or human-caused disaster; an outbreak associated with drug use; and

result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

\* \* \* \* \*

*Interim maintenance treatment* means maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

\* \* \* \* \*

*Medication-Assisted Treatment (MAT)* means the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder.

*Nationally recognized evidence-based guidelines* means a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions.

\* \* \* \* \*

*Opioid dependence* means repeated self-administration that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

\* \* \* \* \*

*Opioid treatment program* or "OTP" means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1).

*Opioid treatment program certification* means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards described in § 8.12.

*Opioid use disorder* means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opioid-induced problems.

*Opioid use disorder treatment* means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to an opioid use disorder. This term includes a range of services including detoxification

treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

*Patient* for purposes of subparts B through E of this part, means any individual who receives maintenance or detoxification treatment in an opioid treatment program. For purposes of subpart F of this part, patient means any individual who is dispensed or prescribed covered medications by a practitioner.

*Patient limit* means the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time.

*Practitioner* means a physician who is appropriately licensed by the State to dispense covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).

*Practitioner incapacity* means the inability of a practitioner as a result of an involuntary event to physically or mentally perform the tasks and duties required to provide medication-assisted treatment in accordance with nationally recognized evidence-based guidelines.

\* \* \* \* \*

■ 7. Amend § 8.3 by revising the introductory text of paragraph (b) to read as follows:

**§ 8.3 Application for approval as an accreditation body.**

\* \* \* \* \*

(b) *Application for initial approval.* Electronic copies of an accreditation body application form [SMA-167] shall be submitted to: <http://buprenorphine.samhsa.gov/pls/bwns/waiver>.

Accreditation body applications shall include the following information and supporting documentation:

\* \* \* \* \*

Subpart C [Redesignated as Subpart D]

■ 8. Redesignate subpart C, consisting of §§ 8.21 through 8.34, as subpart D and revise the heading to read as follows:

**Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body**

Subpart B [Redesignated as Subpart C]

■ 9. Redesignate subpart B, consisting of §§ 8.11 through 8.15, as subpart C and revise the heading to read as follows:

### Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

- 10. Add a heading for new subpart B to read as follows:

#### Subpart B—Accreditation of Opioid Treatment Programs

##### §§ 8.3, 8.4, 8.5, and 8.6 [Transferred to Subpart B]

- 11. Transfer §§ 8.3, 8.4, 8.5, and 8.6 to new subpart B.

#### Subpart E [Reserved]

- 12. Add reserved subpart E.
- 13. Add subpart F, consisting of §§ 8.610 through 8.655, to read as follows:

#### Subpart F—Authorization To Increase Patient Limit to 275 Patients

Sec.

- 8.610 Which practitioners are eligible for a patient limit of 275?
- 8.615 What constitutes a qualified practice setting?
- 8.620 What is the process to request a patient limit of 275?
- 8.625 How will a Request for Patient Limit Increase be processed?
- 8.630 What must practitioners do in order to maintain their approval to treat up to 275 patients?
- 8.635 [Reserved]
- 8.640 What is the process for renewing a practitioner's Request for Patient Limit Increase approval?
- 8.645 What are the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase, or whose renewal request is denied?
- 8.650 Can SAMHSA's approval of a practitioner's Request for Patient Limit Increase be suspended or revoked?
- 8.655 Can a practitioner request to temporarily treat up to 275 patients in emergency situations?

#### Subpart F—Authorization To Increase Patient Limit to 275 Patients

##### § 8.610 Which practitioners are eligible for a patient limit of 275?

The total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C.

823(g)(2)(B)(iii) is 275 if:

- (a) The practitioner possesses a current waiver to treat up to 100 patients under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) and has maintained the waiver in accordance with applicable statutory requirements without interruption for at least one year since the practitioner's notification of intent

(NOI) under section 303(g)(2)(B) to treat up to 100 patients was approved;

(b) The practitioner:

- (1) Holds additional credentialing as defined in § 8.2; or
- (2) Provides medication-assisted treatment (MAT) utilizing covered medications in a qualified practice setting as defined in § 8.615;
- (c) The practitioner has not had his or her enrollment and billing privileges in the Medicare program revoked under § 424.535 of this title; and
- (d) The practitioner has not been found to have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a).

##### § 8.615 What constitutes a qualified practice setting?

A qualified practice setting is a practice setting that:

- (a) Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
- (b) Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
- (c) Uses health information technology (health IT) systems such as electronic health records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information;
- (d) Is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law. PDMP means a statewide electronic database that collects designated data on substances dispensed in the State. For practitioners providing care in their capacity as employees or contractors of a Federal government agency, participation in a PDMP is required only when such participation is not restricted based on their State of licensure and is in accordance with Federal statutes and regulations;
- (e) Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

##### § 8.620 What is the process to request a patient limit of 275?

In order for a practitioner to receive approval for a patient limit of 275, a practitioner must meet all of the requirements specified in § 8.610 and

submit a Request for Patient Limit Increase to SAMHSA that includes all of the following:

- (a) Completed Request for Patient Limit Increase form;
- (b) Statement certifying that the practitioner:
  - (1) Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders;
  - (2) Will provide patients with necessary behavioral health services as defined in § 8.2 or through an established formal agreement with another entity to provide behavioral health services;
  - (3) Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule (45 CFR part 160 and 45 CFR part 164, subparts A and E) and 42 CFR part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;
  - (4) Will use patient data to inform the improvement of outcomes;
  - (5) Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;
  - (6) Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in § 8.2; and
  - (7) Will notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment;

(c) Any additional documentation to demonstrate compliance with § 8.610 as requested by SAMHSA.

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##### § 8.625 How will a Request for Patient Limit Increase be processed?

(a) Not later than 45 days after the date on which SAMHSA receives a practitioner's Request for Patient Limit Increase as described in § 8.620, or renewal Request for Patient Limit Increase as described in § 8.640, SAMHSA shall approve or deny the request.

(1) A practitioner's Request for Patient Limit Increase will be approved if the practitioner satisfies all applicable requirements under §§ 8.610 and 8.620. SAMHSA will thereafter notify the

practitioner who requested the patient limit increase, and the Drug Enforcement Administration (DEA), that the practitioner has been approved to treat up to 275 patients using covered medications. A practitioner's approval to treat up to 275 patients under this section will extend for a term not to exceed 3 years.

(2) SAMHSA may deny a practitioner's Request for Patient Limit Increase if SAMHSA determines that:

(i) The Request for Patient Limit Increase is deficient in any respect; or

(ii) The practitioner has knowingly submitted false statements or made misrepresentations of fact in the practitioner's Request for Patient Limit Increase.

(b) If SAMHSA denies a practitioner's Request for Patient Limit Increase (or renewal), SAMHSA shall notify the practitioner of the reasons for the denial.

(c) If SAMHSA denies a practitioner's Request for Patient Limit Increase (or renewal) based solely on deficiencies that can be resolved, and the deficiencies are resolved to the satisfaction of SAMHSA in a manner and time period approved by SAMHSA, the practitioner's Request for Patient Limit Increase will be approved. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the designated time period, the Request for Patient Limit Increase may be denied.

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

(a) A practitioner whose Request for Patient Limit Increase is approved in accordance with § 8.625 shall maintain all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b), during the practitioner's 3-year approval term. Failure to do so may result in SAMHSA withdrawing its approval of a practitioner's Request for Patient Limit Increase.

(b) [Reserved]

**§ 8.635 [Reserved]**

**§ 8.640 What is the process for renewing a practitioner's Request for Patient Limit Increase approval?**

(a) Practitioners who intend to continue to treat up to 275 patients beyond their current 3 year approval term must submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under

§ 8.620 at least 90 days before the expiration of their approval term.

(b) If SAMHSA does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until SAMHSA reaches a final decision.

**§ 8.645 What are the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase, or whose renewal request is denied?**

Practitioners who are approved to treat up to 275 patients in accordance with § 8.625, but who do not renew their Request for Patient Limit Increase, or whose renewal request is denied, shall notify, under § 8.620(b)(7) in a time period specified by SAMHSA, all patients affected above the 100 patient limit, that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment.

**§ 8.650 Can SAMHSA's approval of a practitioner's Request for Patient Limit Increase be suspended or revoked?**

(a) SAMHSA, at any time during a practitioner's 3 year approval term, may suspend or revoke its approval of a practitioner's Request for Patient Limit Increase under § 8.625 if it is determined that:

(1) Immediate action is necessary to protect public health or safety;

(2) The practitioner made misrepresentations in the practitioner's Request for Patient Limit Increase;

(3) The practitioner no longer satisfies the requirements of this subpart; or

(4) The practitioner has been found to have violated the CSA pursuant to 21 U.S.C. 824(a).

(b) [Reserved]

**§ 8.655 Can a practitioner request to temporarily treat up to 275 patients in emergency situations?**

(a) Practitioners with a current waiver to prescribe up to 100 patients and who are not otherwise eligible to treat up to 275 patients under § 8.610 may request a temporary increase to treat up to 275 patients in order to address emergency situations as defined in § 8.2 if the practitioner provides information and documentation that:

(1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an

emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit;

(2) Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and

(3) Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires.

(b) Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an immediate increase in the higher patient limit.

(c) If SAMHSA determines that a practitioner's request under this section should be granted, SAMHSA will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months.

(d) If a practitioner wishes to receive an extension of the approval period granted under this section, he or she must submit a request to SAMHSA at least 30 days before the expiration of the six month period, and certify that the emergency situation as defined in § 8.2 necessitating an increased patient limit continues. Prior to taking action on a practitioner's extension request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an extension of an increase in the higher patient limit.

(e) Except as provided in this section and § 8.650, requirements in other sections under subpart F of this part do not apply to practitioners receiving waivers in this section.

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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