

denied, the claimant shall be advised of the reason for such denial.

§ 230.41 Reconsideration of claims.

A written request for reconsideration of denied claims must be based on evidence recently developed or not previously presented. It must be submitted within 10 days of the postmarked date of the letter denying the claim. The ruling official shall advise the Asset Forfeiture Coordinator if a timely reconsideration of the denial is made. The Office of Inspector General, Office of General Counsel shall rule on the reconsideration request.

§ 230.42 Disposition of property declared abandoned where title vests in the government.

Property declared abandoned, including cash and proceeds from the sale of property subject to this part, may be shared with federal, state, or local agencies. Abandoned property may also be destroyed, sold, or placed into official use. However, before abandoned property can be shared with another agency, sold, or placed into official use, the Executive Special Agent in Charge must confer with the Office of Inspector General, Office of General Counsel. Unless the Executive Special Agent in Charge determines the cash or proceeds of the sale of the abandoned property are to be shared with other law enforcement agencies, such cash or proceeds shall be converted to money orders and transmitted to: United States Postal Service, Disbursing Officer, 2825 Lone Oak Parkway, Eagan, MN 55121-9640.

Stanley F. Mires,

Attorney, Federal Compliance.

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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: Proposed rule.

SUMMARY: The Secretary of the Department of Health and Human Services (the Secretary) (HHS) proposes a rule to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances

Act (CSA) from 100 to 200. The purpose of the proposed rule is to increase access to treatment for opioid use disorder while reducing the opportunity for diversion of the medication to unlawful use.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 31, 2016.

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

- *Electronically: Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the instructions for submitting comments.

- *Regular Mail or Hand Delivery or Courier:* Written comments mailed by regular mail must be sent to the following address only: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *Express or Overnight Mail:* Written comments sent by hand delivery, or regular, express or overnight mail must be sent to the following address only: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857.

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

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

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Pharm.D., Public Health Advisor, Center for Substance Abuse Treatment, 240-276-0545, Email address: WaiverRegulations@samhsa.hhs.gov.

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Acronyms

ASAM	American Society of Addiction Medicine
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FR	Federal Register
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
MAT	Medication-Assisted Treatment
NOI	Notification of Intent
NPRM	Notice of Proposed Rulemaking
OTP	Opioid Treatment Program

QA Quality Assurance
 QI Quality Improvement
 RFA Regulatory Flexibility Act
 SAMHSA Substance Abuse and Mental
 Health Services Administration
 U.S.C. United States Code

I. Executive Summary

A. Purpose

The purpose of this proposed rule is to expand access to medication-assisted treatment (MAT) by allowing eligible practitioners to request approval to treat up to 200 patients under section 303(g)(2) of the Controlled Substances Act (CSA). The rulemaking 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. We hope that this proposed rule will stimulate broader availability of high-quality MAT both in specialized addiction treatment settings and throughout more mainstream health care delivery systems.

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). Currently, the only FDA-approved medications that meet this standard are buprenorphine and the combination buprenorphine/naloxone (hereinafter referred to as buprenorphine). Buprenorphine is a schedule III controlled substance under the CSA. 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. Pursuant to 21 U.S.C. 823(g)(2)(B)(iii), the Secretary is authorized to change this patient limit by regulation at any one time.

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. 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. As specified in the statute, the training requirement may be satisfied in several ways: One may hold subspecialty 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 the Secretary considers to demonstrate the ability of the physician to treat and manage persons with opioid use disorder.

Access to MAT has been subject to patient limits via the provisions contained in the CSA and enforced by DEA. Since 21 U.S.C. 823(g)(2) was originally modified by legislation in 2000 to allow the provision of MAT without registering as an OTP, additional modifications have been made to address the application of the patient limit in group medical practices and to create a higher patient limit for practitioners with 1 year of experience. These changes, while important, have not proven sufficient to support the development of adequate treatment capacity to keep pace with the growth of the national crisis of opioid misuse and overdose. To the extent that the current patient limit contributes to this access challenge, this proposed rule seeks to make a useful change in an effort to improve access.

B. Summary of Major Provisions

The proposed rule would revise the highest patient limit from 100 patients per practitioner with an existing waiver (waivered practitioner) to 200 patients for practitioners who meet certain criteria. Practitioners who have a waiver to treat 100 patients for at least 1 year would be eligible to apply for a waiver to treat up to 200 patients if they possess a subspecialty board certification in addiction medicine or addiction psychiatry or practice in a qualified practice setting as defined in this proposed rule. In either case, practitioners with the higher limit of 200 would also be required to accept greater responsibility for ensuring behavioral health services and care coordination are received and for ensuring quality assurance and improvement practices, diversion control, and continuity of care in

emergencies. The higher limit would also carry with it the duty to regularly reaffirm the practitioner's ongoing eligibility and to participate in data reporting and monitoring as required by SAMHSA. In addition, practitioners in good standing with a current waiver to prescribe to up to 100 patients (*i.e.*, the practitioner has filed an NOI and satisfied all required criteria) could request the higher limit in emergency situations for a limited time period. SAMHSA would review all emergency situation requests in consultation, to the extent practicable, with appropriate governmental authorities before such requests would be granted.

C. Summary of Impacts

The proposed rule is intended to increase access to MAT for some patients with an opioid use disorder, providing them with a path to recovery; reduce costs across different sectors (*e.g.* health care, criminal justice, and social service); and, ultimately, reduce the number of opioid-related overdose deaths. From 2016–2020, present value benefits of \$11,019 million and annualized benefits of \$2,336 million are estimated using a 3 percent discount rate; present value benefits of \$10,148 million and annualized benefits of \$2,313 million are estimated using a 7 percent discount rate. Present value costs of \$955 million and annualized costs of \$202 million are estimated using a 3 percent discount rate; present value costs of \$880 million and annualized costs of \$201 million are estimated using a 7 percent discount rate.

II. Public Participation

Comments Invited

HHS invites interested parties to submit comments on all aspects of the proposed rule. When submitting comments, please reference a specific portion of the proposed rule, provide an explanation for any recommended change, and include supporting data. Specific agency questions for comment are listed in section VII. Comments responding to these questions should reference them by number.

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

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

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

III. Background

A. Opioid Use Disorder

Substance use disorder is a treatable chronic disease caused by changes to the structure and function of the brain due to exposure to intoxicating substances.¹ Most of these substances alter the brain by increasing the release of the neurotransmitter dopamine, which plays an important role in the brain's reward system.² Chronic exposure to drugs disrupts the way the brain controls both life-sustaining behaviors and those related to drug use.³ Opioid use disorder is a type of substance use disorder that has the added complexity of disrupting the naturally occurring function of endorphins throughout the body.⁴ This is what underlies the rapid formation of dependence and tolerance, and the withdrawal syndrome typically observed when opioid use is discontinued.⁵ The cycle of tolerance and withdrawal leads persons dependent on opioids to take larger doses, seek more potent opioids, or adopt methods of administration, such as injection, to intensify the opioid's effects.^{6,7} The possibility of

experiencing euphoria, while an element of drug initiation, becomes more and more remote as the euphoric feelings experienced become less pleasurable and use of the drug becomes necessary for the user to feel "normal".⁸ As a result, most opioid dependent persons must continue to use opioids in order to maintain function and to forestall the painful symptoms of withdrawal.⁹

Opioid use disorder is essentially the same phenomenon. The potential for addiction and the symptoms of tolerance and withdrawal are very similar, whether the opioid is heroin or a prescription pain reliever, such as oxycodone or hydrocodone, because the brain responds to all opioids similarly. Untreated opioid dependence is associated with adoption of high-risk opioid use behaviors.^{10 11 12} A person who is no longer able to avoid withdrawal with the amount of opioid he or she is accustomed to or can afford to buy may transition to using opioids by injection, for example, because this route of administration can more quickly and efficiently deliver the drug to the brain via injection into the bloodstream rather than through the digestive tract.^{13 14} However, use of opioids by injection carries additional risks of infection with hepatitis C virus and human immunodeficiency virus (HIV), local and systemic infections, cardiovascular and respiratory problems, and higher overdose risk.^{15 16 17}

⁷ Peavy, K.M., Banta-Green, C.J., Kingston, S., Hanrahan, M., Merrill, J.O., & Coffin, P.O. (2012). "Hooked on" prescription-type opiates prior to using heroin: Results from a survey of syringe exchange clients. *Journal of Psychoactive Drugs*, 44(3), 259-265.

⁸ National Institute on Drug Abuse, *supra* note 2.

⁹ *Id.*

¹⁰ Peavy, *supra* note 7.

¹¹ Jones, C.M. (2013). Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers, United States, 2002-2004 and 2008-2010. *Drug and Alcohol Dependence*, 132(1-2):95-100.

¹² Lankenau, S.E., Teti, M., Silva, K., Bloom, J.J., Harocopos, A., & Treese, M. (2012). Initiation into prescription opioid misuse amongst young injection drug users. *International Journal of Drug Policy*, 23(1), 37-44.

¹³ Peavy, *supra* note 7.

¹⁴ Drug Delivery Methods (2015). Retrieved from <http://learn.genetics.utah.edu/content/addiction/delivery/>.

¹⁵ National Institute on Drug Abuse (2014). *Heroin* (Number 15-0165). Retrieved from https://d14rmgtrwz5a.cloudfront.net/sites/default/files/heroinrrs_11_14.pdf.

¹⁶ Bruneau, J., Roy, E., Arrunda, N., Zang, G., & Juras-Aswad, D. (2012). The rising prevalence of prescription opioid injection and its association with hepatitis C incidence among street-drug users. *Addiction*, 107(7):1318-27.

¹⁷ Conrad, C., Bradley, H.M., Broz, D., Buddha, S., Chapman, E.L., Galang, R.R., Duwve, J.M. (2015).

The majority of these individuals do not recognize that repeated use of opioids, albeit legitimate, may increase the risk of developing an opioid use disorder, which may lead some individuals to switch from prescription drugs to cheaper and more risky substitutes like heroin. Based on combined 2014 National Survey on Drug Use and Health data, there are 1.9 million people aged 12 or older with a past-year pain reliever use disorder and 539,000 people with a past-year heroin use disorder.

As many as 86 percent of persons who met diagnostic criteria for opioid use disorder in 2014 could be classified as dependent on opioids.¹⁸ In addition to changing the structure and function of the brain, when a person has dependence, the whole body has adapted to the presence of the opioid and does not function properly when the substance is absent, thus making it extremely difficult to discontinue use without formal treatment.¹⁹ Many people with opioid dependence who undergo detoxification in order to stop using opioids subsequently relapse to opioid use.²⁰ As many as 95 percent of patients who undergo detoxification only, relapse to opioid use within weeks.^{21 22}

Community outbreak of HIV infection linked to injection drug use of oxycodone—Indiana, 2015. *Morbidity and Mortality Weekly Report*, 64(16): 443-44.

¹⁸ Substance Abuse and Mental Health Services Administration (2015). *Prescription drug misuse and abuse*. Retrieved from: <http://www.samhsa.gov/prescription-drug-misuse-abuse>.

¹⁹ Definition of dependence. (2007). Retrieved from: <http://www.drugabuse.gov/publications/teaching-packets/neurobiology-drug-addiction/section-iii-action-heroin-morphine/8-definition-dependence>.

²⁰ Kleber, H. D. (2007). Pharmacologic treatments for opioid dependence: detoxification and maintenance options. *Dialogues in Clinical Neuroscience*, 9(4), 455-470. National Institute on Drug Abuse. Patients Addicted to Opioid Painkillers Achieve Good Results With Outpatient Detoxification. Retrieved from: <http://www.drugabuse.gov/news-events/nida-notes/2015/02/patients-addicted-to-opioid-painkillers-achieve-good-results-outpatient-detoxification> on December 12, 2015.

²¹ Ling, W., Amass, L., Shoptaw, S., Annon, J.J., Hillhouse, M., Babcock, D., Brigham, G., Harrer, J., Reid, M., Muir, J., Buchan, B., Orr, D., Woody, G., Krejci, J., Ziedonis, D., Group, the B.S.P. (2005). A multi-center randomized trial of buprenorphine-naloxone versus clonidine for opioid detoxification: findings from the National Institute on Drug Abuse Clinical Trials Network. *Addiction (Abingdon, England)*, 100(8), 1090-1100.

²² Weiss, R.D., Potter, J.S., Fiellin, D.A., Byrne, M., Connery, H.S., Dickinson, W., Gardin, J., Griffin, L.M., Gourevitch, N.M., Haller, D., Hasson, A., Huang, Z., Jacobs, P., Kosinski, S.A., Lindblad, R., McCance-Katz, F.E., Provost, E.S., Selzer, J., Somoza, C.E., Sonne, C.S., Ling, W. (2011). Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for

¹ The Science of Drug Abuse and Addiction: The Basics. (2014, September 1). Retrieved from: <http://www.drugabuse.gov/publications/media-guide/science-drug-abuse-addiction-basics>.

² National Institute on Drug Abuse (2014). *Drugs, brains, and behavior: The science of addiction*. (NIH Pub No. 14-5605). Retrieved from: https://d14rmgtrwz5a.cloudfront.net/sites/default/files/soa_2014.pdf.

³ *Id.*

⁴ National Institute on Drug Abuse. Impacts of Drugs on Neurotransmission. Retrieved from: <http://www.drugabuse.gov/news-events/nida-notes/2007/10/impacts-drugs-neurotransmission>.

⁵ *Id.*

⁶ Kosten, T.R., & George, T.P. (2002). The Neurobiology of Opioid Dependence: Implications for Treatment. *Science & Practice Perspectives*, 1(1), 13-20.

Adverse consequences associated with prescription drug misuse have also increased. Prescription drugs, especially opioid analgesics, have increasingly been implicated in drug overdose deaths over the last decade.²³ The National Vital Statistics System indicated there were 18,893 opioid analgesics overdose related deaths in 2014, which is nearly 5 times greater than the number of related deaths in 1999.²⁴ Deaths related to heroin have also sharply increased, more than tripling between 2010 and 2014.²⁵ Rates of prescription drug misuse related to emergency department visits and treatment admissions have risen significantly in recent years.²⁶ The Centers for Disease Control and Prevention reports that almost 7,000 people are treated in emergency departments each day for using opioids in a manner other than as directed.²⁷ Opioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths. In 2014, opioids were involved in 28,647 deaths, or 61 percent of all drug overdose deaths; the rate of opioid overdoses has tripled since 2000.²⁸

The economic costs of illegal drug use, including the use of medications that are prescribed for others, are considerable. According to the Office of National Drug Control Policy, the economic cost of drug addiction in the United States was estimated at \$193 billion in 2007, the last available

estimate.²⁹ Indeed, opioid use disorders contribute to over \$72 billion in medical costs alone each year.³⁰ These costs—costs related to treatment and prevention services; other health care costs, such as those for individuals with co-occurring illnesses that result from or are exacerbated by use and misuse of drugs obtained illicitly; and costs associated with lost productivity, social welfare, and crime—impose burdens on the workplace, healthcare system, and communities.

B. Medication-Assisted Treatment (MAT)

Opioid use disorder is a treatable medical condition from which it is possible to recover.³¹ Medication, along with other behavioral therapy, has the potential to play an important role in the successful treatment of opioid use disorder and provide a foundation for recovery.³² Research indicates that medication combined with behavioral health services produces the best outcomes.³³ ³⁴ Effective treatment is comprehensive and tailored to each patient's drug use patterns; medical and psychiatric co-morbidities, and social corollaries of substance use disorder; and includes consideration of the person's vocational and legal needs.³⁵

MAT is the use of medication in combination with behavioral health services to provide a whole-patient, individualized approach to the treatment of substance use disorder, including opioid use disorder.³⁶ MAT is a safe and effective strategy for decreasing the frequency and quantity of opioid use and reducing the risk of overdose and death.³⁷ Although MAT

has significant evidence to support it as an effective treatment, it remains highly underutilized, with only an estimated 1 million out of an estimated 2.5 million who needed treatment actually receiving it in 2012.³⁸ This gap is a function of many factors, including treatment capacity and negative attitudes, prejudice, and discrimination that prevent individuals from seeking services. A full discussion of the barriers to MAT utilization can be found in the regulatory impact analysis of this document.

Methadone, buprenorphine, and naltrexone are the three main types of active ingredients³⁹ contained in FDA approved products currently used to treat opioid use disorder in the U.S.⁴⁰ Treatment of opioid use disorder using methadone can only be provided in OTPs regulated by SAMHSA under 42 CFR part 8 and requires patient assessments, on-site counseling, daily monitoring and observation of the medication use, and careful control of any take-home methadone.⁴¹ ⁴² Also, methadone for opioid use disorder can only be dispensed in an OTP clinic setting.³⁴ Unlike methadone, medicines containing buprenorphine are permitted to be dispensed in either an office-based setting or in an OTP, significantly increasing treatment access.⁴³ Under 21 U.S.C. 823(g)(2), qualified practitioners can prescribe, administer, or dispense medicines containing buprenorphine for treatment of opioid use disorder in various settings, including in an office, community hospital, health department, or correctional facility. As with all medications used in MAT, buprenorphine is prescribed as part of a comprehensive treatment plan that includes counseling and participation in social support programs.⁴⁴

C. Statutory and Rulemaking History

There is a long history of laws and rules to protect people from unnecessary or inappropriate exposure to opioids. Two important laws are the CSA and the Controlled Substances Import and Export Act, which became law in 1970. Together, these statutes and their implementing regulations

Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial. *Archives of General Psychiatry*, 68(12), 1238–1246.

²³ Macrae, J. (2015, July 27). HHS Launches Multi-pronged Effort to Combat Opioid Abuse. Retrieved from: <http://www.hhs.gov/blog/2015/07/27/hhs-launches-multi-pronged-effort-combat-opioid-abuse.html>. Centers for Disease Control and Prevention. Wide-ranging Online Data for Epidemiologic Research (WONDER), Multiple-Cause-of-Death file, 2000–2014. 2015.

²⁴ CDC/NCHS, National Vital Statistics System, Mortality File. Retrieved from: http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

²⁵ HHS takes strong steps to address opioid-drug related overdose, death and dependence. (2015, March 26) Retrieved from: <http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html>.

²⁶ Substance Abuse and Mental Health Services Administration, *supra* note 18.

²⁷ Centers for Disease Control and Prevention. Wide-ranging Online Data for Epidemiologic Research (WONDER), Multiple-Cause-of-Death file, (2015, October 28). *Understanding the epidemic: When the prescription becomes the problem*. Retrieved from: <http://www.cdc.gov/drugoverdose/epidemic/>.

²⁸ Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014. *MMWR Morb Mortal Wkly Rep*. 2016;64(50):1378–82. Retrieved from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

²⁹ Study Shows Illicit Drug Use Costs U.S. Economy More Than \$193 Billion. (2011, June 1). Retrieved from: https://www.whitehouse.gov/sites/default/files/ondcp/newsletters/ondcp_update_june_2011.pdf.

³⁰ Coalition Against Insurance Fraud. (2007). Prescription for peril: how insurance fraud finances theft and abuse of addictive prescription drugs. Retrieved from: <http://www.insurancefraud.org/downloads/drugDiversion.pdf>.

³¹ Bart, G. (2012). Maintenance Medication for Opiate Addiction: The Foundation of Recovery. *Journal of Addictive Diseases*, 31(3), 207–225. <http://doi.org/10.1080/10550887.2012.694598>.

³² Medication and Counseling Treatment. (2015, September 28). Retrieved from: <http://www.samhsa.gov/medication-assisted-treatment/treatment>.

³³ National Institute on Drug Abuse, *supra* note 2.

³⁴ Buprenorphine. (2015, September 25). Retrieved from: <http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>.

³⁵ National Institute on Drug Abuse, *supra* note 2.

³⁶ Medication and Counseling Treatment, *supra* note 32.

³⁷ Kresina, T.F., & Lubran, R.L. (2011). Improving public health through access to and utilization of medication assisted treatment. *International Journal of Environmental Research and Public Health*, 8(10):4102–17.

³⁸ Volkow, N.D., Frieden, T.R., Hyde, P.S., & Cha, S.S. (2014). Medication-assisted therapies—tackling the opioid-overdose epidemic. *New England Journal of Medicine*, 370(22):2063–6.

³⁹ Naloxone is an active ingredient in some forms of buprenorphine when used by other than the recommended sublingual (under the tongue) route.

⁴⁰ Volkow, *supra* note 38.

⁴¹ *Id.*

⁴² Methadone. (2015, September 28). Retrieved from: <http://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>.

⁴³ Kresina, *supra* note 37.

⁴⁴ *Id.*

govern the manufacturing and distribution of controlled substances. Controlled substances are those medications or chemical substances that are scheduled I through V under the CSA, with Schedule I having the most relative abuse potential and likelihood of causing dependence when abused, and Schedule V having the least potential for abuse and dependence.⁴⁵

In 2000, Congress amended the CSA (21 U.S.C. 801 *et seq.*) to establish “waiver authority for physicians who dispense or prescribe certain narcotic drugs for maintenance treatment or detoxification treatment” (Drug Addiction Treatment Act of 2000, Pub. L. 106–310, Title XXXV, 114 Stat. 1222, codified at 21 U.S.C. 823(g)(2)). This waiver authority established the existing 30 and 100 patient limits. Pursuant to such waiver authority, the statutory and regulatory requirement (21 U.S.C. 823(g)(1) and 21 CFR 1301.13(e)) that a practitioner obtain a separate DEA registration to prescribe buprenorphine for maintenance or detoxification treatment is waived. Prior to this amendment, practitioners who wanted to provide maintenance or detoxification treatment using opioid drugs were required to be registered as Narcotic Treatment Programs, today commonly referred to as OTPs.

Under the provisions of the CSA implementing regulations (21 CFR 1301.28(b)(1)(iii) and (iv)), the 30-patient limitation applied equally to individual practices and to group practices (*i.e.*, 30 patients per group practice), severely limiting the number of patients who could be treated by physicians in group practices. In 2005, the CSA was amended to lift the patient limitation on prescribing opioid addiction treatment medications by practitioners in group practices (Pub. L. 109–56) so that practitioners could prescribe up to 30 patients individually regardless of whether they are in a group or solo practice.⁴⁶ In 2006, the CSA was further amended by the Office of National Drug Control Policy Reauthorization Act of 2006 (Pub. L. 109–469) to permit the treatment of up to 100 patients by each qualifying practitioner. As a result, DEA made conforming changes their regulations.⁴⁷

⁴⁵ Controlled Substance Schedules. (2015). Retrieved from: <http://www.deadiversion.usdoj.gov/schedules/>.

⁴⁶ “A bill to amend the Controlled Substances Act to lift the patient limitation on prescribing drug addiction treatments by medical practitioners in group practices, and for other purposes” (Pub. L. 109–56).

⁴⁷ See 21 CFR 1301.28(b)(1)(iii) and (iv).

D. Current Process for Obtaining a Practitioner Waiver Under 21 U.S.C. 823(g)(2)

To be able to prescribe buprenorphine for the maintenance or detoxification of opioid use disorder, qualified practitioners must file a Request for Patient Limit Increase with SAMHSA. In accordance with 21 U.S.C. 823(g)(2)(D)(iii), SAMHSA processes the Request for Patient Limit Increase by verifying the practitioner’s medical license and qualification to prescribe buprenorphine, and informs the DEA of whether the practitioner meets all of the statutory requirements for a waiver. If the statutory requirements for a waiver are met, the DEA verifies the practitioner’s current registration and assigns an identification number to the practitioner. This information is conveyed to the practitioner by a letter issued from SAMHSA. At this point, the practitioner is considered to be a waived practitioner.

Waived practitioners must comply with all sections of the CSA regarding validity of prescriptions, recordkeeping, inventory, and medication administration or dispensing. DEA is authorized to conduct periodic on-site inspections of all registrants. As of 2013, DEA had systematically visited nearly all waived practitioners. Most inspections were uneventful, and the majority of practitioners were found to be in compliance. Problems encountered typically involved administrative issues and required practitioners to make changes to recordkeeping practices. Should DEA find violations of law, it can revoke a practitioner’s right to prescribe buprenorphine and take further legal action, if necessary.

E. Evaluations of the Current System

Evaluations of the process for granting waivers under the 21 U.S.C. 823(g)(2) waiver system are limited. In 2006, SAMHSA published the results of an evaluation that examined the availability and effectiveness of treatment as well as adverse consequences.⁴⁸

A number of barriers to MAT adoption using buprenorphine in an office-based setting were identified in this evaluation, with three in particular that were consistently identified amongst waived practitioners as problematic: (1) The 30-patient limit, (2) limited third-party reimbursement, and

(3) high medication/treatment costs. Additional barriers identified include a hesitation to initiate buprenorphine prescribing because of (1) a lack of a sufficient number of patients needing MAT for opioid use disorders, (2) difficult initial treatment setup and logistics, and (3) patients’ reluctance around counseling as a component of treatment. A number of non-waived practitioners cited common challenges to obtaining a waiver, including lack of appropriate training or experience, concerns about recordkeeping and potential audits by DEA, and a scarcity of appropriate concomitant counseling resources in their areas.

More recently, in September 2014, SAMHSA, in partnership with the National Institute on Drug Abuse, convened a meeting of expert professionals for a Buprenorphine Summit to gather the perspectives of leaders from the field regarding the state of practice and their assessment of possible strategies for moving forward. This Summit presented an opportunity for active and collaborative discussion about caring for patients; designing, operating, and sustaining programs; supporting recovery; and training practitioners. The participants explored what is known about the adoption of MAT with buprenorphine-containing products to treat opioid use disorder; reasons why it has not been as widely prescribed as might have been expected; and ways that Federal agencies, health professionals, and concerned individuals might enable buprenorphine treatment to become more accessible.

Participants from the Summit provided some reasons waived practitioners were not prescribing buprenorphine, including but not limited to the following: Practitioners do not have practice partners with waivers or practice partners who can provide cross-coverage because of the interpretation of the patient limit; they lack institutional support; their community lacks psychosocial resources for patients; they feel that with current patient limits, they cannot treat a sufficient volume of patients to meet all of the costs of providing buprenorphine given current third-party reimbursement; the regulations and scrutiny particular to prescribing buprenorphine can make them feel as if they are doing something questionable by prescribing it; and current confidentiality rules make it difficult to integrate substance use disorder care with primary care.

Some of the ideas that came out of the Summit included strategies to expand availability of buprenorphine treatment for opioid use disorders, such as

⁴⁸ 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.

examining the elimination of restrictions on prescribing buprenorphine. Specific ideas included enabling non-physician practitioners to prescribe buprenorphine (which would require a legislative change); raising the cap on how many patients a practitioner can have in treatment at a time; and allowing practitioners to cross-cover one another on a short-term basis, which is a practice standard across medicine, without being in violation of the patient limit. The latter two are addressed in this Notice of Proposed Rulemaking (NPRM).

F. Need for Rulemaking

In the intervening 15 years since enactment of 21 U.S.C. 823(g)(2), there have been a number of changes, including the amendment that (1) allowed for practitioners in group practices to prescribe up to 30 patients individually regardless of whether they are in a group or sole practice, and (2) allowed for practitioners who had a waiver for at least 1 year to submit a second NOI to treat up to 100 patients at a time. Other changes include expansion in insurance coverage and parity protections due to passage of the Mental Health Parity and Addiction Equity Act, as well as the Affordable Care Act. Educational and training activities have also expanded, including the FDA Risk Evaluation and Mitigation Strategy (REMS) for buprenorphine and SAMHSA's Provider Clinical Support System for MAT. In addition, a new subspecialty board certification has been developed for allopathic physicians in addiction medicine, creating a pathway for more physicians to obtain broader knowledge of substance use disorders in general.

Despite this progress, the nation finds itself in the midst of a public health crisis of opioid addiction, misuse, and related morbidity and mortality.⁴⁹ Each day in the United States, 44 people die from overdose of prescription pain relievers.⁵⁰ As previously stated, in 2014, opioids were involved in 28,647 deaths, or 61 percent of all drug overdose deaths; the rate of opioid overdoses has tripled since 2000.⁵¹

There are approximately 1,400 OTPs and 31,857 practitioners waived to prescribe buprenorphine. The use of

extended-release injectable naltrexone has also made an important contribution to increasing access to MAT in the private physician office-based setting, but the number of patients receiving treatment with naltrexone in such settings is not known. Providers wishing to serve more people have the option of both office-based MAT with buprenorphine products as well as specialty addiction treatment programs that include an OTP. However, recent research has also shown that an estimated 1 million people out of 2.3 million individuals in the U.S. with opioid abuse or dependence were untreated.⁵² This assumes that practitioners were treating patients at maximum capacity. Data from DATA-waived providers in 2008⁵³ indicate that practitioners are likely only reaching 57 percent of their total patient capacity for buprenorphine treatment. At the State level, an estimated 3 patients per 1,000 people in the U.S. had an unmet need for treatment, assuming that practitioners were treating patients at maximum potential capacity.⁵⁴

While the Federal Guidelines for OTPs, published early in 2015, promote the use of both buprenorphine and naltrexone, in addition to methadone, in the approximately 1,400 OTPs, increasing access to MAT through OTPs is limited by several factors. These factors include the fact that the patient capacity of individual OTPs is typically determined by State licensing requirements, building permits, or other State or local regulations. Geography and the daily nature of methadone treatment are other factors that affect the ability to expand access to MAT via OTPs in general, but they do not directly relate to the capacity of an individual OTP to treat patients. Rather they are limitations on the expansion of access to more individuals utilizing methadone specifically.

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 unique authority to increase the patient limit on treatment under 21 U.S.C. 823(g)(2) by rulemaking, the proposed rule is an essential element of

a comprehensive approach to increasing access to MAT.

Increasing the limits on the number of patients per waived practitioner has been requested by many individuals, organizations, and entities. In a letter to the Secretary, ASAM notes that the prescribing limit is a major barrier to patient access to care and the current limits place arbitrary limits on the number of patients a practitioner can treat. It also notes that no other medications are limited in such a manner.⁵⁵ The American Psychiatric Association, American Academy of Addiction Psychiatry, and the American Osteopathic Academy of Addiction Medicine also wrote to the Secretary and stated that as "the number of people addicted to these opioids increases, there continues to be a shortage of physicians who are appropriately trained to treat them. The shortage severely complicates and impairs our ability to effectively address the epidemic, particularly in many rural and underserved areas of the nation."⁵⁶

In sum, given the public health crisis of opioid misuse and abuse and the treatment gap between those individuals with an opioid use disorder and those currently receiving treatment, this proposed rule is needed to raise the patient cap in an effort to increase access to MAT with buprenorphine and associated counseling and supports. In keeping with the spirit of mental health parity, we emphasize that competency in addiction care should exist throughout the healthcare continuum. To balance optimal access and safety, we strive to ensure that the credentials needed to prescribe MAT are within reach for interested physicians, programs are practical to implement, and reporting requirements are not perceived as a barrier to participation. We seek comment on whether the proposed rule appropriately strikes this balance.

IV. Summary of Proposed Rule

A. General

To date, SAMHSA has implemented the provisions of 21 U.S.C. 823(g)(2) without rulemaking due to the clear and specific provisions included in the statute. As authorized by the statute at 21 U.S.C. 823(g)(2)(B)(iii), SAMHSA is initiating rulemaking at this time to increase access to MAT with

⁴⁹ FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use. (2015, October 21). Retrieved from: <https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector>.

⁵⁰ Centers for Disease Control and Prevention, *supra* note 27.

⁵¹ Rudd, *supra* note 28.

⁵² 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–e63.

⁵³ Arken 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.

⁵⁴ Jones, *supra* note 53.

⁵⁵ Letter to Secretary Burwell from the American Society for Addiction Medicine, July 31, 2014.

⁵⁶ Letter to Secretary Burwell from the American Psychiatric Association, American Academy of Addiction Psychiatry, and the American Osteopathic Academy of Addiction Medicine, July 25, 2014.

buprenorphine in the office-based setting as authorized under 21 U.S.C. 823(g)(2). The proposed rule would increase the highest available patient limit for qualified practitioners to receive a waiver from 100 to 200. This new higher patient limit would significantly increase patient capacity for practitioners qualified to prescribe at this level while also ensuring that waived practitioners would be able to provide the full treatment continuum associated with MAT.

Practitioners authorized to treat up to 200 patients under 21 U.S.C. 823(g)(2) would be required to meet infrastructure, capacity, and reporting requirements that exceed those required for the lower limits. The incremental increase from 100 to 200 patients and the concomitant reporting requirements would allow the Department to monitor the quality of care being delivered, identify any changes in the rate of diversion, and improvements in health outcomes for opioid-dependent patients. It would attach additional criteria and responsibilities to practitioners who would be able to treat up to 200 patients with the specific aims of ensuring quality of care and minimizing diversion. Importantly, the additional criteria and responsibilities are not intended to be unduly burdensome to the practitioner who wishes to expand his or her MAT treatment practice and we seek comment on the associated burden. Rather, they are intended to reflect the current standard of care for the treatment of opioid use disorder while also recognizing the growing demand for opioid use disorder treatment integrated into the non-specialist practice in more mainstream settings. This proposed rule does not add these additional requirements to practitioners who have a waiver to treat 100 or fewer patients under 21 U.S.C. 823(g)(2). The proposed rule also would create an option for an increased patient limit for practitioners responding to emergency situations that require immediate, increased access to MAT pharmacotherapies. Also included in the proposed rule are key definitions.

This proposal would add subpart F to 42 CFR part 8. To accomplish this, additional changes would be made to part 8. Proposed changes to part 8 to accommodate the proposed rule include retitling the part to encompass all MAT over which the Secretary has regulatory authority. Consequently, under the proposed rule, subpart A would be entitled General Provisions. 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.

B. Scope (§ 8.1)

Under the proposed rule, the scope of part 8 would encompass rules that are applicable to OTPs, and to waived practitioners who seek to provide MAT to more than 100 patients. New subparts B through D under the proposed rule would contain the rules relevant to OTPs. Subpart E would be reserved and Subpart F would contain the proposed new rule. Section 8.1 would also explain 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 200.

C. Definitions (§ 8.2)

The definitions section would apply to the entirety of part 8. Definitions that would apply only to OTPs would be revised to reflect this in the specific definition. Two definitions would be eliminated: “Registered opioid treatment program” would be deleted because the term is not used anywhere in the text of the regulations; and the definition for “opiate addiction” would be renamed “opioid use disorder.”

This proposed rule also includes a 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 subject to 21 U.S.C. 823(g)(2). As a result, there has been confusion among providers, insurers, pharmacists, and diversion investigators. This stems in part from the difference between formal admission and discharge practices that are customarily used in OTPs and other substance use disorder treatment programs and the more open-ended relationship between patient and practitioner in general medical and psychiatric practice. This confusion has also complicated the data collection necessary to assess access to treatment on community, state, and national levels. It has also hindered cross-coverage due to a concern that covering a patient for a short period of time keeps a practitioner accountable for that patient for an extended period of time.

The proposed rule would revise the 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. By proposing that patient “means any individual who receives MAT from a practitioner or program subject to this part,” the definition would apply to the entire

period during which the eligible medication is expected to be used by the patient while under that practitioner’s care. For example, if a practitioner 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 has expired. However, if a cross-covering practitioner is merely available for consult but does not provide a prescription for buprenorphine while the prescribing practitioner is away, the patients being covered do not count towards the cross-covering practitioner’s patient limit at all. Therefore, this definition would be expected to help ensure consistency and clarity in how waived practitioners count patients towards the limit. We seek comments on this definition and other examples of coverage arrangements where clarity would be helpful.

The proposed rule would include the following definition of patient limit: “the maximum number of individual patients a practitioner may treat at any time using covered medications.”

Taken together, these two definitions would provide clear and fair guidance for regulatory enforcement and would be expected to reduce undercounting of patients by practitioners and, furthermore, would exclude those patients with whom a practitioner interacts as a professional courtesy or in a transitory fashion on behalf of another waived physician from being counted against the covering practitioner’s patient limit for an extended period of time. In this way it is expected that waived practitioners will be able to provide reciprocal cross-coverage of patients for brief periods, such as weekends or vacations, without implications, long-term or possibly at all, for their respective individual limits.

Other new definitions would include “behavioral health services,” “nationally recognized evidence-based guidelines” and “emergency situation.” These definitions would be in-line with definitions offered elsewhere and applied in the field. They would be minimally modified from other existing definitions to clarify the application of these terms to the unique circumstances of the practitioner providing MAT under 21 U.S.C. 823(g)(2).

In addition, this proposed rule would 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 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; and the Federation of State Medical Boards' Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office. SAMHSA would expect that guidelines falling into this definition may change over time but would not plan to keep a list for practitioners to consult.

D. Opioid Treatment Programs (§§ 8.3 Through 8.34)

Proposed retitled subparts B, C, and D would contain §§ 8.3 through 8.34. Proposed changes to these sections would be 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.

E. Which Practitioners Are Eligible for a Patient Limit of 200? (§ 8.610)

This is the first proposed section of the new subpart F. Proposed § 8.610 would describe which practitioners are eligible for a patient limit of 200. Under routine conditions, a practitioner would qualify for the higher limit in one of two ways: By possessing subspecialty board certification in addiction medicine or addiction psychiatry or by practicing 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 a higher limit. The purpose of offering the 200 patient limit to practitioners in these two categories is to recognize the benefit offered to patients through: (1) The advanced training and maintenance of knowledge and skill associated with the acquisition of subspecialty board certification; and (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 to 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, SAMHSA believes that the care team and practice systems will function to help ensure this same level of care. We seek comments on this proposed approach, including comments on whether there are other ways for SAMHSA to ensure quality and safety while encouraging practitioners to take on additional patients.

F. What Constitutes a Qualified Practice Setting? (§ 8.615)

Proposed § 8.615 would 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 having: (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; (3) health information technology (HIT) 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 (6) 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 would be 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 seeks comment on additional, alternate pathways by which a practitioner may become eligible to apply for a patient waiver of 200.

G. What is the process to request a patient limit of 200? (§ 8.620)

Proposed § 8.620 would 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 Request for Patient Limit Increase. A proposed draft of the Request for Patient Limit Increase is in the docket. Public comment is requested. 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 approval to treat up to 200 patients is not renewed or is denied. The new Request for Patient Limit Increase process would require providers to affirm that they would meet these requirements. The proposed definitions of "behavioral health services," "diversion control plan," "emergency situation," "nationally recognized evidence-based guidelines" and "practitioner incapacity" would be provided 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 would not be expected to be burdensome to practitioners. Resources exist to help in the development in patient placement in the event transfer to other addiction treatment would be required, for example, if a provider chose to no longer practice at the 200 patient limit. Examples of these resources would include but are not limited to: Single

State Authorities and State Opioid Treatment Authorities. Practitioners approved to treat up to 200 patients would also be required to reaffirm their ongoing eligibility to fulfill these requirements every 3 years as described in § 8.640.

H. How will a request for patient limit increase be processed? (§ 8.625)

Proposed § 8.625 would describe how SAMHSA will process a Request for Patient Limit increase. The process for requesting a patient limit up to 200 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 of 200 would have a term not to exceed 3 years. 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 200 patients.

I. What must practitioners do in order to maintain their approval to treat up to 200 patients under § 8.625? (§ 8.630)

Proposed § 8.630 would 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. This includes compliance with reporting requirements specified in § 8.635.

J. What are the reporting requirements for practitioners whose request for patient limit increase is approved under § 8.625? (§ 8.635)

Proposed § 8.635 would describe the reporting requirements for practitioners whose Request for Patient Limit Increase is approved under § 8.625. Reporting would be required annually to ensure that eligibility requirements are being maintained and that waiver conditions are being fulfilled. We seek 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. Reporting requirements may include a request for information regarding:

- 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.

We seek comment on this list.

K. What is the process for renewing a practitioner's request for patient limit increase approval? (§ 8.640)

Proposed § 8.640 would 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.

L. What are the responsibilities of practitioners who do not submit a renewal request for patient limit increase or whose request is denied? (§ 8.645)

Proposed § 8.645 would describe the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase or whose 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.

M. Can SAMHSA suspend or revoke a practitioner's patient limit increase approval? (§ 8.650)

Proposed § 8.650 would 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 has 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.

N. Can a practitioner request to temporarily treat up to 200 patients in emergency situations? (§ 8.655)

Proposed § 8.655 would 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 would be 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.

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 200 patients expires. Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authority 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 authority, 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.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Currently, the information collection associated with the 30-patient and 100-patient limits is approved under OMB Control No. 0930-0234. In order to fairly evaluate whether changes to an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered in rulemaking. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. This proposed rule includes changes to information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the PRA (5 CFR part 1320). Some of the provisions would involve changes from

the information collections set out in the previous regulations.

Information collection requirements would be:

A. Approval, 42 CFR 8.620(a) through (c): In order for a practitioner to receive approval for a patient limit of 200, 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 is available for review in the public docket;
- 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 of this chapter, 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 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. Reporting, 42 CFR 8.635: Reporting will be required annually to ensure that eligibility requirements are being

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

D. 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.

E. Patient Notice, 42 CFR 8.645: Describes the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase. Practitioners who do not renew their Request for Patient Limit Increase 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.

F. 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 200 patients, to request a temporary increase to treat up to 200 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 200 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 (hour)	Total burden (hour)	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
8.635	Annual Report	1,350	1	3	4,050	64.47	261,104
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	311,502

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.

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

VI. Regulatory Impact Analysis

A. Introduction

HHS has examined the impact of this proposed rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act of 1980 (Pub. L. 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 proposed 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 proposed 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 \$144 million, using the most current (2014) implicit price deflator for the gross domestic product. HHS expects this proposed 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 proposed rule, if finalized, would 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 proposed changes in the rule represent the Federal Government regulating its own program. Accordingly, HHS concludes that the proposed 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 Proposed 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 practitioner, 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 subspecialty 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 proposed 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 proposed rule would revise the highest patient limit from 100 patients per practitioner with an existing waiver (waivered practitioner) to 200 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 200 patients if they meet the requirements defined in this proposed rule and after submitting a Request for Patient Limit Increase to SAMHSA.

Practitioners approved to treat up to 200 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 will also carry with it the duty to regularly reaffirm the practitioner's ongoing eligibility and to participate 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 200 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 proposed 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 proposed 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. Although this is a positive aspect of the proposed rule and will help to ensure continuity of care in select situations, 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 this change will contribute significantly to the impact of this proposed rule, and we do not estimate the associated costs and benefits.

C. Need for the Proposed Rule

The United States is facing an unprecedented increase in prescription opioid abuse, heroin use and opioid-related overdose deaths. In 2014, 18,893 overdose deaths involved prescription opioids and 10,574 involved heroin.⁵⁷

⁵⁷ 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_

Underlying many of these deaths is an untreated opioid use disorder.^{58 59 60} In 2014, more than 2.2 million people met diagnostic criteria for an opioid use disorder.⁶¹

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.⁶² 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.⁶³ 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.⁶⁴

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.^{65 66} 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.

⁵⁸ 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.

⁵⁹ Hall AJ, Logan JE, Toblin RL, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA*. 2008;300(22):2613–2620.

⁶⁰ Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011;305(13):1315–1321.

⁶¹ Jones CM. Unpublished analysis of the 2014 National Survey on Drug Use and Health Public Use File. 2015.

⁶² *Id.*

⁶³ 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.

⁶⁴ 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.

⁶⁵ 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.

⁶⁶ 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.⁶⁷ The infectious disease consequences associated with opioid injection have been found to account for a substantial proportion of the economic burden and disability associated with opioid use disorders.⁶⁸

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.^{69 70 71 72 73 74} Reductions in opioid-related mortality also have been shown for buprenorphine.^{75 76 77}

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.⁷⁸ 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 shortage of practitioners eligible to prescribe buprenorphine or in counties that have no practitioners with a waiver to prescribe buprenorphine.⁷⁹ These are primarily rural counties and areas located in the middle of the country.⁸⁰ Only about 5 percent of practitioners with the 100 patient limit are located in rural counties.⁸¹

Evidence suggests that utilization of buprenorphine is limited directly by the existence of treatment caps. 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.^{82 83 84} 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 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).⁸⁵ 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, which furthers the argument that these proposed changes will increase 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.⁸⁶ 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).⁸⁷ 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 proposed rule by submitting a Request for Patient Limit Increase to treat up to 200 patients.

D. Analysis of Benefits and Costs

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

This proposed 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 200 patients with buprenorphine. We believe that this may translate to a

⁶⁷ Conrad, *supra* note 17.

⁶⁸ 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.

⁶⁹ 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.

⁷⁰ 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.

⁷¹ 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.

⁷² 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.

⁷³ 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.

⁷⁴ 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.

⁷⁵ Clark RE, Samnaliev M, Baxter JD, Leung GY. The evidence doesn't justify steps by state Medicaid programs to restrict opioid addiction treatment with buprenorphine. *Health Aff (Millwood)*. 2011;30(8):1425–1433.

⁷⁶ 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.

⁷⁷ 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.

⁷⁸ Jones, *supra* note 53.

⁷⁹ 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.

⁸⁰ 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.

⁸¹ 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.

⁸² 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.

⁸³ 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.

⁸⁴ Substance Abuse and Mental Health Services Administration, *supra* note 49.

⁸⁵ 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>.

⁸⁶ Stein *supra* note 82.

⁸⁷ Jones, *supra* note 53.

financial opportunity for these physicians, depending on the costs associated with treating these additional patients.

Relatedly, this proposed rule may increase the value of the waiver to treat opioid use disorder under 21 U.S.C. 823(g)(2). The proposed rule would require practitioners to have a waiver to treat 100 patients for 1 year and to have a subspecialty board certification in addiction medicine, a subspecialty board certification in addiction psychiatry, or to practice in a qualified practice setting as defined in the rule in order to request approval to treat 200 patients. If getting to the 200-patient limit provides sufficient benefits to practitioners, this proposed rule may also increase incentives for other practitioners to apply for the lower patient limit waivers, insofar as they are milestones towards the 200-patient cap. In addition, this rule may also make it more valuable for practitioners to have subspecialty board certifications in addiction medicine and addiction psychiatry, or to practice in a qualified practice setting. The proposed rule, then, may increase the number of practitioners in these categories and thus the number of practitioners eligible for the 200 patient limit in the future.

b. Increased Treatment for Patients

Permitting practitioners to treat up to 200 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 finalization of this proposed rule. In addition, we expect that other factors could amplify the impact of the changes proposed 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 2015.⁸⁸ Further, the Affordable Care Act expanded coverage includes populations at high-risk for opioid use disorders that previously did not have sufficient access to health insurance coverage.⁸⁹ 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 are often cited as important reasons that individuals seeking treatment have not used buprenorphine.^{90 91 92 93} A NPRM to extend parity protections to Medicaid managed care was released in the spring of 2015. 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 ancillary services, are additional barriers to providing MAT with buprenorphine in the office-based setting.^{94 95} 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.^{96 97 98} 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 200 patients at a time would be a step towards supporting practitioners that seek to hire nurses and other clinical staff to reduce practitioners' time requirements and to provide the ancillary 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.^{99 100}

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 a final rule that builds upon this proposal and public comments, SAMHSA will work to educate providers about the requirements and opportunities for requesting and obtaining approval to treat up to 200 patients under 21 U.S.C. 823(g)(2). SAMHSA will prepare materials summarizing the changes as a result of the final rule, and provide these materials to practitioners potentially affected by the rulemaking upon publication of the final rule. 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

⁹⁰ Volkow, *supra* note 38.

⁹¹ 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.

⁹² 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.

⁹³ 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>.

⁹⁴ 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.

⁹⁵ 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.

⁹⁶ 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.

⁹⁷ Labelle, C. Nurse Care Manager Model. <http://buprenorphine.samhsa.gov/presentations/LaBelle.pdf>.

⁹⁸ 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.

⁸⁸ 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/insur201511.pdf>.

⁸⁹ Jones, *supra* note 53.

⁹⁹ 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.

¹⁰⁰ 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>.

the Federal Opioid Treatment Program Standards.

e. Practitioners Costs To Evaluate the Policy Change

We expect that, if this proposed rule is finalized, practitioners potentially affected by this proposed 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 200 patients, and decide whether or not it is advantageous to pursue approval to treat up to 200 patients and make any necessary changes to their practice, such as obtaining subspecialty board certifications in either addiction medicine or addiction psychiatry, 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,¹⁰¹ 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 200 patients at a given time are required to submit a Request for Patient Limit Increase form to SAMHSA. The proposed 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 seek comment on our assumptions regarding the time required to complete the form.

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 proposed 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^{102 103}, the results of the 2015 ASAM survey described earlier, and discussions with stakeholders, we estimate that between 500 and 1,800 practitioners will request approval to treat 200 patients within the first year of the proposed rule. We estimate that between 100 and 300 additional practitioners will request approval to treat 200 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. We seek comment on information which will allow us to refine our estimate of the number of practitioners who will submit a Request for Patient Limit Increase in response to this proposed rule.

	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 resubmit a Request for Patient Limit Increase every 3 years to maintain his or her waiver to treat up to 200 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 submit a renewal 3 years later. Our estimates are summarized in the table below.

	Number of renewals	Cost (\$)
Year 1-3	0	0
Year 4	1,150	\$108,000
Year 5	200	19,000
Total	1,350	127,000

¹⁰¹ 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.

¹⁰² Arfken, *supra* note 54.

¹⁰³ Jones, *supra* note 53.

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

Practitioners may also be interested in the ability to eventually treat up to 200 patients, and may make changes toward achieving that goal. As discussed previously, these proposed 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 proposed changes could increase the number of practitioners who seek subspecialty board certifications in either addiction medicine or addiction psychiatry or meet the requirements for practicing in a qualified practice setting as outlined in the proposed 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 do not have information to estimate the number of practitioners who will change behavior along these dimensions in response to this proposed rule. We seek comment on information which will allow us to estimate the number of practitioners who would apply to treat additional patients, the number who will seek additional subspecialty board certifications, and the number who will move toward meeting the requirements for treating in a qualified practice setting in response to the proposed changes.

i. Federal Costs Associated With Processing New 200 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 proposed 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 200 patients within the first year of the rule, and between 100 and 300 additional practitioners will request approval to treat 200 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 provider as eligible to prescribe buprenorphine for the treatment of opioid use disorder as a result of this proposed 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 of New Treatment

Once requests to treat up to 200 patients generated by the proposed 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 proposed 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 proposed 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 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.

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 200-patient limit due to the extra oversight and quality of care requirements in the proposed rule. Specifically, we assumed that 80 percent of patients would receive outpatient psychosocial services. This would raise the cost of providing MAT with buprenorphine to \$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 proposed rule to be \$4,349 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 proposed rule. For purposes of analysis, we assume that each practitioner who requests approval to treat 200 patients will treat between 20 and 40 additional patients each year. This is based on our experience with the increase from the 30 patient limit to the 100 patient limit.^{104 105} We note that in that case, there were no new costs imposed on practitioners beyond those associated with additional treatment, whereas in this proposed 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 72,000 additional patients treated in the first year; and an additional 2,000 to 12,000 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 30 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 30 patients receiving the full spectrum of care). We use these ranges to estimate costs and benefits of the rule as proposed. Based on this information, we estimate the treatment costs associated with new patients receiving treatment with buprenorphine as a result of this proposed rule will be between \$43.5 million and \$313 million in the first year with a central estimate of \$150 million, and an additional \$8.7 million to \$52.2 million in each subsequent year with a central estimate of \$26.1 million. We seek comment on information which

¹⁰⁴ Arfken, *supra* note 54.

¹⁰⁵ Jones, *supra* note 53.

will allow us to refine our efforts to quantify the number of people who may receive additional treatment with buprenorphine as a result of this proposed rule.

	Additional people receiving treatment	Treatment costs (Millions)
Year 1	34,500	\$150
Year 2	40,500	176
Year 3	46,500	202
Year 4	52,500	228
Year 5	58,500	254

Evidence suggests that the benefits associated with additional buprenorphine utilization are likely to exceed their cost. One study estimated 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.^{106 107} Following a food safety rule recently published by FDA,¹⁰⁸ 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. In the absence of data on the percentage of patients newly receiving buprenorphine treatment who would achieve this status, we illustrate the calculation of rule-induced benefits using 100 percent as an input. We acknowledge that this approach would, all else equal, lead to overestimation of health benefits and request comment that would allow for refinement of the estimates. As a result, we estimate monetized health benefits of \$1,747 million in the first year, with estimated monetized health benefits rising by \$304 million in each subsequent year as more individuals receive treatment as a result of the rule. These monetized health benefits are

¹⁰⁶ 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.

¹⁰⁷ 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.

¹⁰⁸ This RIA can be found here: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf>

summarized below. We acknowledge that this approach may underestimate or overestimate health benefits and request comment that would allow for refinement of the estimates. We also explore the sensitivity of these results to our assumptions regarding the health benefits related to treatment in our section on sensitivity analysis.

	Additional people receiving treatment	Monetized health benefits (millions)
Year 1	34,500	\$1,747
Year 2	40,500	2,050
Year 3	46,500	2,354
Year 4	52,500	2,658
Year 5	58,500	2,961

k. Potential for Diversion

While we expect many benefits associated with this proposed 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 pediatric exposures, and found that as buprenorphine use increased between 2002 and 2011, the number of unintentional pediatric exposures in the State increased.¹⁰⁹ Thus, it is possible that the increased utilization of buprenorphine as a result of this proposed 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 2014.¹¹⁰

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.^{111 112}

¹⁰⁹ Centers for Disease Control and Prevention. Buprenorphine prescribing practices and exposures reported to a poison center—Utah, 2002–2011. *MMWR* 2012;61:997–1001.

¹¹⁰ Drug Enforcement Administration. National Forensic Laboratory Information System. 2014 Annual Report. Available at: <https://www.nflis.deadiversion.usdoj.gov/Reports.aspx>.

¹¹¹ 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.

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 200 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 proposed rule. We do not have sufficient information to estimate the extent to which these unintended consequences could occur.

l. Practitioner Reporting Requirements

Under this proposed rule, as outlined earlier, practitioners approved to treat up to 200 patients would have to submit information about their practice annually to SAMHSA for purposes of monitoring regulatory compliance. The goal of the reporting requirement is to ensure that practitioners are providing high-quality, evidence-based buprenorphine treatment. It is anticipated that the data for the reporting requirement can be pulled directly from an electronic or paper health record, and that practitioners would not have to update their record-keeping practices after receiving approval to treat 200 patients. We estimate that compiling and submitting the report would require approximately 1 hour of physician time and 2 hours of administrative time. According to the U.S. Bureau of Labor Statistics⁸⁹, the average medical and health services manager's hourly pay in 2014 was \$49.84, which corresponds to a cost of \$99.68 per hour after adjusting upward by 100 percent to account for overhead and benefits. Therefore, the cost of this reporting requirement per practitioner approved for the 200 patient limit is estimated to be the cost of 1 hour of a practitioner's time plus an hour of an administrator's time.

As noted above, using the mid-point estimate, we estimate that 1,150 practitioners will request a 200-patient waiver in year 1 and 200 practitioners will request a 200-patient waiver in subsequent years. We assume that all of these requests will be approved. The costs associated with this reporting

¹¹² 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.

requirement are reported below. In addition, it is estimated that SAMHSA will incur a cost of \$100 per practitioner approved for the 200 patient limit to process the practitioner data reporting

requirement. These costs are reported below as well.

DEA may also incur costs in association with this proposed rule if, for example, DEA increases the number of site visits they conduct because

providers are treating more than 100 patients. We tentatively assume that DEA will incur no costs as a result of these reporting requirements, and we seek comment on this assumption.

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

m. Costs Associated With Waiver Requests in Emergencies

Under the proposed rule, practitioners in good standing with a current waiver to treat up to 100 patients may request temporary approval to treat up to 200 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. We seek comment on the assumptions in this section.

n. Summary of Impacts

The proposed rule's impacts will take place over a long period of time. As discussed previously, we expect the existence of the waiver to treat 200 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 proposed 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 proposed 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 proposed rule.

ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED 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	11,019	10,148	2,336	2,313
COSTS	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Costs	955	880	203	201

E. Sensitivity Analysis

The total estimated benefits of the changes proposed here are sensitive to assumptions regarding the number of practitioners who will seek a waiver to treat 200 patients as a result of the proposed rule, the number of individuals who will receive MAT as a result of the proposed 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 200 patients in the first year, and 100 to 300 practitioners will apply for a waiver to treat up to 200

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 \$1,054 million to \$3,618 million and annualized costs ranging from \$92 million to \$313 million.

We estimate that practitioners who receive a waiver to treat 200 patients will treat between 20 and 40 additional patients each year, with a central estimate of an average of 30 additional patients. For alternative estimates of 20 to 40 additional patients per year, all else equal, we estimate annualized

benefits using a 3 percent discount rate ranging from \$1,557 million to \$3,115 million over the 5 years following implementation.

We estimate that individuals who receive MAT as a result of the proposed rule will experience average health improvements equivalent to 0.11 QALYs. For alternative estimates of these health improvements between 0.06 and 0.16 QALYs, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$1,274 million to \$3,398 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 \$1,523 million to \$3,046 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 \$250 million to \$9,148 million and annualized cost estimates ranging from \$62 million to \$417 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% Discount Rate (Millions of 2014 Dollars)		
	Low	Primary	High
Quantified Benefits	250	2,336	9,148
Quantified Costs	62	203	417

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 the proposed 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 specialty board certification or qualified practice setting requirements as defined in the proposed rule. One important objective of this proposed 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 conservative 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

addiction 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 200-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 proposed 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 proposed 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 proposed 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 proposed rule. As a result, we estimate that approximately 32,123 small entities will be affected by this proposed 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 proposed 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 200 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 proposed rule does not require practitioners to undertake these burdens, as this rulemaking does not require practitioners to seek a waiver to treat 200 patients. As a result, we anticipate that this proposed rule will not have a significant impact on a substantial number of small entities. We seek comment on the assumptions used in this section, and on the proposed rule's burden on small entities.

VII. Agency Questions for Comment

If any of the comments fall under any of the following questions, please indicate the question and number with your response.

(1) *Evidence Supporting an Optimal Patient Prescribing Limit*—This proposed rule is intended to improve patient access to buprenorphine for the treatment of opioid use disorder while also minimizing the risk of diversion and patient safety concerns. Based on the available information, including clinical guideline recommendations and expert stakeholder input, HHS is proposing a new 200-patient prescribing limit. HHS seeks comment that provides evidence that an alternate prescribing limit would be more appropriate than the one proposed in this rulemaking.

(2) *Potential New Formulations*—The Secretary shall establish a process by which patients who are treated with medications covered under 21 U.S.C. 823(g)(2)(C), and that have features that enhance safety or reduce diversion, as determined by the Secretary, may be counted differently toward the prescribing limit established in this proposed rule. The criteria for determining which if any of these medications or reformulations of existing medications may be considered, and how these patients will be counted toward the patient limit, will be based on the following principles:

a. Relative risk of diversion associated with medications that become covered under 21 U.S.C. 823(g)(2)(C) after the effective date of this proposed rule; and

b. Time required to monitor patient safety, assure medication compliance and effectiveness, and deliver or coordinate behavioral health services. HHS seeks comment on the principles by which the Secretary would determine which new medications would qualify.

(3) *Practitioner Training for 200 Patient Limit*—HHS is seeking specific comment related to the level of training necessary to request a patient limit increase to 200 patients outside of a qualified practice setting. Specifically, under the current rule for the patient limit of 30 and 100, the training requirement may be satisfied at the time of initial NOI through a number of pathways, but the most common ways are via a subspecialty board certification in addiction psychiatry or addiction medicine, an addiction certification from ASAM, or completion of an 8-hour training provided by an approved organization. In this NPRM, SAMHSA would require board certification in addiction psychiatry or addiction medicine, but would not require

additional training to progress to the 200-patient limit. However, this means that only practitioners with subspecialty board certifications will be eligible to apply for a patient waiver of 200 and practitioners satisfying training requirements via the other pathways for the 30 and 100 patients will not be eligible. SAMHSA is seeking comment on whether the range of provider qualifications is too broad or too narrow to expand access to high quality medication-assisted treatment for opioid use disorder. If commenters assert that opportunity to qualify should be broadened, we also welcome recommendations regarding alternate pathways that would affirm competence without necessitating specialty board certification.

(4) *Alternate pathways to qualify for 200-patient prescribing limit*—Under this proposal, only practitioners with current 100-patient waivers who are either board-certified in addiction medicine or addiction psychiatry or who practice in “qualified practice settings” or who request a temporary increase to treat up to 200 patients in order to address emergency situations may apply for the higher limit. HHS seeks comment on additional, alternate pathways by which a practitioner may become eligible to apply for a patient waiver of 200.

(5) *Process to request a patient limit of 200*—HHS is seeking specific comment related to the requirements as defined in § 8.620(a) through (c). Specifically, how much cost will be associated with each requirement and what fraction of practitioners practicing in qualified practice settings will be able to fulfill such requirements.

(6) *Patient Volume Necessary*—We are not aware of data that indicate what patient volume per practitioner is necessary in order to make the provision of buprenorphine to patients not cost prohibitive. We seek data on how many patients a physician would need to treat in order to make the training requirements, administrative requirements, and other requirements not cost prohibitive to the practitioner by type of clinical environment type (e.g., large group practice, small physician-owned practice, hospitals, Medicaid-accepting addiction treatment centers, etc.).

(7) *Frequency of Renewal Request for Patient Limit Increase to 200 Patients*—Currently, to be able to prescribe/dispense buprenorphine for the maintenance or detoxification of opioid use disorder, qualified practitioners must file a NOI with SAMHSA. Under this proposal, qualified practitioners in good standing with a current waiver to

dispense to up to 100 patients may file a Request for Patient Limit Increase to treat up to 200 patients for a term of 3 years. SAMHSA is seeking comment on whether requiring the renewal for qualified practitioners seeking to treat up to 200 patients every 3 years is sufficient or whether practitioners should renew the waiver every year or every 2 years, instead of every 3 years.

(8) *Synchronization of Renewal Request with DEA Practitioner Registration Renewal*—We seek comment on whether SAMHSA should synchronize the 3-year Request for Patient Limit Increase renewal with the renewal of the DEA practitioner registration to reduce practitioner burden.

(9) *Estimation of the Time Required to Seek Approval to Treat up to 200 Patients*—As stated in the Regulatory Impact Analysis, SAMHSA is seeking comment on the assumptions regarding the time required to complete the request for the higher patient limit.

(10) *Estimation of the Change in Practitioner Behavior*—As stated in the Regulatory Impact Analysis, SAMHSA does not have information to estimate the number of practitioners who would change behavior in response to this proposed rule. SAMHSA is seeking comment on the estimation of the number of practitioners who are not currently eligible to submit a Request for Patient Limit Increase to treat up to 200 patients but as a result of the proposed rule would take steps, such as obtain subspecialty board certification, or change practice settings, in order to qualify to treat up to 200 patients.

(11) *Estimation of the Number of Practitioners who are Eligible to Submit a Request for Patient Limit Increase to Treat up to 200 Patients*—As stated in the Regulatory Impact Analysis, SAMHSA seeks comment on an estimation of the number of practitioners who, based on the proposed rule, would be eligible to submit a Request for Patient Limit Increase to treat up to 200 patients, and, as a result of the proposed rule, would do so.

(12) *Estimation of the Number of People who will Receive MAT with Buprenorphine*—As stated in the Regulatory Impact Analysis, SAMHSA seeks comment in order to refine the estimation of the number of people who will receive MAT with buprenorphine as a result of the proposed rule.

(13) *Reporting Periods*—SAMHSA seeks comment on whether the reporting periods and deadline could be combined with other, existing reporting requirements in a way that would make

reporting less burdensome for practitioners.

(14) *Balance of Access and Safety*—SAMHSA seeks comment on whether the proposed rule appropriately strikes the balance between ensuring that the credentials needed to prescribe MAT are within reach for interested practitioners, programs are practical to implement, and reporting requirements are not perceived as a barrier to participation.

List of Subjects in 42 CFR Part 8

Health professions, Methadone, Reporting and recordkeeping requirements.

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

PART 8—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 their places the phrases “opioid use disorder” and “Opioid use disorder”, respectively, wherever they appear.

■ 4. Redesignate subpart C, consisting of §§ 8.21 through 8.34, as subpart D and revise the heading 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

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

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

■ 6. Add subpart B, redesignate §§ 8.3, 8.4, 8.5, and 8.6 to the new subpart B, and revise the heading to read as follows:

Subpart B—Accreditation of Opioid Treatment Programs

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

Subpart A—General Provisions

■ 8. 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 200 patients with medications covered under section 303(g)(2)(C) of the CSA.

■ 9. Amend § 8.2 as follows:

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

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

■ c. Revise the definition of “Certification”;

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

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

■ f. Add, in alphabetical order, the definition of “Nationally recognized evidence-based guidelines”;

■ g. Add, in alphabetical order, the definition of “Opioid dependence”;

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

■ i. Revise the definitions of “Opioid treatment program” and “Opioid use disorder”;

■ j. Add, in alphabetical order, the definition of “Opioid use disorder treatment”;

■ k. Revise the definition of “Patient”;

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

■ m. Remove the definition of “Registered opioid treatment program”; and

■ n. Add, in alphabetical order, the definition of “Waivered practitioner”.

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.

* * * * *

Approval term means the 3 year period in which a practitioner is approved to treat up to 200 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, remotely via telemedicine shown in clinical trials to facilitate MAT outcomes or non-professional interventions.

Board certification in addiction medicine or psychiatry means the receipt of board certification in a particular addiction medicine or psychiatry specialty and/or subspecialty of medical practice (e.g., subspecialty board certification in addiction medicine or psychiatry) from the American Board of Medical Specialties, a subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) or American Board of Addiction Medicine (ABAM), or an addiction certification from the American Society of Addiction Medicine (ASAM).

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.

* * * * *

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.

* * * * *

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 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 means any individual who receives MAT from a practitioner or program subject to this part.

Patient limit means the maximum number of individual patients a practitioner may treat at any one time using covered medications.

Practitioner incapacity means the inability of a waived 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.

* * * * *

Waivered 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).

■ 10. 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 E [Reserved]

■ 11. Reserve subpart E.

■ 12. Add subpart F, consisting of §§ 8.610 through 8.655, to read as follows:

Subpart F—Authorization to Increase Patient Limit to 200 Patients

Sec.

8.610 Which practitioners are eligible for a patient limit of 200?

8.615 What constitutes a qualified practice setting?

8.620 What is the process to request a patient limit of 200?

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 200 patients?

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

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 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 200 patients in emergency situations?

Subpart F—Authorization to Increase Patient Limit to 200 Patients

§ 8.610 Which practitioners are eligible for a patient limit of 200?

A practitioner is eligible for a patient limit of 200 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 a subspecialty board certification in addiction psychiatry or addiction medicine; or

(2) Provides 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 which:

(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 (HIT) systems such as electronic health records, if otherwise required to use it in the practice setting. HIT means the electronic systems that healthcare 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 200?

In order for a practitioner to receive approval for a patient limit of 200, 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 and part 2 of this chapter, 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 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.

§ 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 200 patients using covered medications. A practitioner's approval to treat up to 200 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 will be denied.

§ 8.630 What must practitioners do in order to maintain their approval to treat up to 200 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) All practitioners whose Request for Patient Limit Increase has been approved under § 8.625 must provide reports to SAMHSA as specified in § 8.635.

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

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

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

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

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

(i) Treatment initiation.

(ii) Change in clinical status.

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

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

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

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

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

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

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

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

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

§ 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 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.

(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 request is denied?

Practitioners who are approved to treat up to 200 patients in accordance with § 8.625, but who do not renew

their Request for Patient Limit Increase, or whose 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) *Suspension.* SAMHSA may suspend its approval of a practitioner's Request for Patient Limit Increase under § 8.625 if it has reason to believe that immediate action is necessary to protect public health or safety.

(b) *Revocation.* SAMHSA may revoke its approval of a practitioner's Request for Patient Limit Increase under § 8.625 at any time during the 3 year approval term if SAMHSA determines that the practitioner made any misrepresentations in the practitioner's Request for Patient Limit Increase, or if SAMHSA determines that the practitioner no longer satisfies the requirements of this subpart, or has been found to have violated the CSA pursuant to 21 U.S.C. 824(a).

§ 8.655 Can a practitioner request to temporarily treat up to 200 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 200 patients under § 8.610 may request a temporary increase to treat up to 200 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 200 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 authority 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 authority 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: March 23, 2016.

Kana Enomoto,

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

Approved: March 24, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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