



## FAQs About the Final Rule Raising the Buprenorphine Patient Limit

On August 8, 2016, a [final rule](#) from the Substance Abuse and Mental Health Services Administration (SAMHSA) went into effect to increase access to medication-assisted treatment (MAT) with buprenorphine products in the office setting by allowing eligible practitioners to request approval to treat up to 275 patients. These FAQs are meant to help members and the public understand the nuances of the final rule's requirements and provide examples of best practices required by the final rule.

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## Who is Eligible to Apply?

1. Practitioners who have held a 100-patient buprenorphine waiver for at least one year without interruption MAY be eligible to apply for a 275-patient waiver.
  - a. There are no exceptions to the requirement for holding a 100-patient waiver for one uninterrupted year before applying.
  - b. Practitioners who do not hold a 100-patient waiver may apply for one after holding a 30-patient waiver for at least one year. The final rule does not change the application process for a 30- or 100-patient waiver. ASAM's webpage on the [DATA 2000 Patient Limit](#) has information on the entire waiver application process.
2. Practitioners who have held a 100-patient waiver for at least one year without interruption can apply for a 275-patient waiver IF they have "additional credentialing" OR they work in a "qualified practice setting." Practitioners DO NOT need to meet both requirements.
  - a. "Additional credentialing" means board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties\* or certification by the American Osteopathic Association, the American Board of Addiction Medicine, or the American Society of Addiction Medicine. Certified practitioners do not have to meet the requirements of the qualified practice setting.

\*Addiction Medicine was recognized as a multispecialty subspecialty by the American Board of Medical Specialties in March 2016. The American Board of Preventive Medicine is now handling the board certification in addiction medicine for physicians that hold an ABMS specialty. For information on the requirements to sit for the exam and the next exam date, contact ABPM at (312) 939-2276 or [sign up for their email list](#). All other questions can be directed to [ABAM's FAQ](#) on the recognition of Addiction Medicine.
  - b. "Qualified practice setting" means a practice that meets ALL of the following requirements. SAMHSA leaves it up to each individual practitioner to put in place their own processes and systems to fulfill the listed requirements. ASAM provides examples of how one might fulfill some of these requirements on its website. To be a "qualified practice setting," the practice must:
    - i. Provide professional coverage for patient medical emergencies during hours when the practitioner's practice is closed.

1. It is not required that coverage be provided by another waived practitioner.
  2. Examples of being able to provide 24 hours of coverage include:
    - a. Collaborating with a nearby 24-hour urgent care center or emergency room to establish a plan to connect patients on buprenorphine treatment with assistance when the practice is closed.
    - b. Being on call, having another staff member from your practice on call, or providing the practitioner's contact information to the staff of a nearby emergency room so they can contact a clinician in an emergency.
    - c. Having an after-hours nursing phone line in operation.
- ii. Ensure 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.
1. Counseling or case-management services must be either offered on-site or through a referring relationship that allows for a warm hand-off of the patient and ongoing care coordination between the counselors/case-managers and practitioners. The practice cannot only provide a phone number.
  2. It is not necessary to provide access to all of the listed examples of case-management services, but the practice must offer to help patients access some form of on-site or nearby case-management services and document the use of case-management services for purposes of ongoing care coordination.
- iii. Use health information technology (health IT) systems such as electronic health records and electronic medical records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information.
1. This requirement only applies to practices that are already required to use health IT systems. If the practice is not already required by law or regulation to have in place and use health IT systems, then this requirement does not apply to that practice. This requirement is not a new mandate to purchase a health IT system.
  2. For those practices already required by law or regulation to have and use a health IT system, this requirement does not add any criteria as to what kinds of health IT software or products they must have and use.

- iv. Register for their State's Prescription Drug Monitoring Program (PDMP) where operational and in accordance with Federal and State law.
    - 1. Currently, 49 states, the District of Columbia and Guam have operational PDMPs. For information on states' PDMP contacts, please click [here](#).
  - v. Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.
    - 1. The practice must have the ability to accept at least one form of third-party payment. There are no criteria as to what third-party payment the practice must accept and it does not have to be a government program.
3. Additionally, the final rule allows for practitioners with a 100-patient waiver who are NOT otherwise eligible for a 275-patient waiver to request a temporary increase to treat up to 275 patients for up to 6 months in an emergency situation.
- a. The final rule defines an emergency situation to mean that an existing State, tribal or local system for substance use disorder services is overwhelmed or unable to meet the existing need for MAT as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as practitioner incapacity, be a natural or human-caused disaster, or an outbreak associated with drug use. It must also result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property or loss of community infrastructure.
    - i. Practitioner incapacity means the inability of a practitioner, as a result of an involuntary event, to physically or mentally perform the tasks and duties required to provide MAT in accordance with nationally recognized evidence-based guidelines. This can include a physician that unexpectedly passes away or leaves their profession.
  - b. To request a temporary increase, the practitioner must provide information and documentation that:
    - i. 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 the rule and provides a justification for an immediate increase in that practitioner's patient limit;
    - ii. 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

- iii. Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires.
- c. SAMHSA will consult with the appropriate governmental authorities at the state, local and federal level in order to determine whether the emergency situation that a practitioner describes justifies an immediate increase. If SAMHSA determines that a practitioner's request should be granted, SAMHSA will notify the practitioner that his or her request has been approved within 45 days. The period of such approval shall not exceed 6 months.
- d. If a practitioner wishes to receive an extension of the approval period granted, 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 necessitating an increased patient limit continues.
- e. SAMHSA still has the ability to revoke or suspend a temporary increase for the same reasons they outline in the application process for a 275-patient waiver.
- f. Even if a community has a coordinated response to increase access to MAT with buprenorphine in an emergency situation, each practitioner must apply for the temporary increase individually.

## How do I Apply?

1. Eligible practitioners must complete the online [Waiver Notification Form](#) from SAMHSA to apply for a 275-patient waiver. The form can only be completed online; paper forms are no longer being used by SAMHSA. Each practitioner will need their Drug Enforcement Administration number, State Medical License Number and Training Certificate Information readily available when applying. When applying, the practitioner will need to provide assurance that they are eligible through ONE of the two pathways and attest that they will follow these eight requirements:
  - a. Adhere to nationally recognized evidence-based guidelines for treating patients with opioid use disorder. The final rule defines nationally recognized evidence-based guidelines as documents 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. ASAM has links to all the nationally recognized evidence-based guidelines listed in the final rule available on our [DATA 2000 Patient Limit](#) webpage.

- b. Provide patients with necessary behavioral health services either directly or through a formal agreement with another entity. The final rule defines behavioral health services as any nonpharmacological interventions carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered interventions (e.g., cognitive behavioral therapy or insight-oriented psychotherapy) delivered in person, interventions delivered remotely by telemedicine shown in clinical trials to facilitate MAT outcomes, or nonprofessional interventions such as 12-step program participation.
  - i. Mutual-help programs may include 12-step programs such as Alcoholics Anonymous (AA), Narcotics Anonymous (NA) and Methadone Anonymous (MA). Other mutual-help groups include Self-Management and Recovery Therapy (SMART) and Moderation Management. Many providers recommend mutual-help programs, but there is anecdotal information to suggest that some of these programs may be less welcoming to patients receiving medications for opioid use disorder. Practitioners should know what mutual-help programs in their area are accepting of patients on MAT.
- c. Provide appropriate releases of information in accordance with Federal and State laws and regulations to permit coordination of care with behavioral health, medical and other practitioners. ASAM has created a [sample form](#) to help practitioners fulfill this requirement.
- d. Use patient data to inform improvement of outcomes.
  - i. As practitioners treat more patients after they are approved, SAMHSA requires that they continuously use the evidence and data they acquire through the processes they establish according to the final rule's requirements to improve the buprenorphine treatment services they provide.
- e. Adhere to a diversion control plan to reduce the possibility of diversion of buprenorphine. SAMHSA's guidance document "[Understanding the Final Rule for a Patient Limit of 275](#)" states that a diversion control plan should contain specific measures to reduce the possibility of diversion of buprenorphine from legitimate treatment use and should assign specific responsibilities of the medical and administrative staff of the practice for carrying out these measures. The plan should address how the environment at the practice can prevent onsite diversion; how to prevent diversion with regard to dosing and take-home medication; and how to prevent patients from receiving a prescription from more than one practitioner and later diverting some of the prescribed medication. ASAM has created a [draft diversion policy](#) and [sample treatment agreement](#) to help practitioners fulfill this requirement.

- f. Have considered how to ensure continuous access in the event of an emergency situation. The final rule's definition of an emergency situation is contained in number 3 under the "Who is Eligible to Apply?" section. SAMHSA has a [Buprenorphine Treatment Physician Locator](#), a directory of [Single State Agencies for Substance Abuse Services](#) and [State Opioid Treatment Authorities](#) who may be able to assist practitioners with a plan to ensure continuous access to care in an emergency situation.
        - g. Notify all patients above the 100-patient limit that they will no longer be able to provide MAT services using buprenorphine in the event that the practitioner's request for the higher patient limit is not renewed or the renewal request is denied, and make every effort to transfer patients to other treatment providers.
          - i. An example of a transfer of care plan is connecting with other waived buprenorphine prescribers in the area and establishing communication with them regarding the transfer of care of buprenorphine patients in the event of an emergency or if a physician can no longer treat more than 100 patients. This can include physicians who have a 100-patient waiver who are not at their limit or physicians who have a 275-patient waiver that are not at their limit. In addition, SAMHSA has an [Opioid Treatment Program Directory](#) and a directory of [State Opioid Treatment Authorities](#) who may be able to assist practitioners with a plan to transfer patients to other providers.
        - h. Practitioners must also provide any additional documentation to demonstrate compliance as requested by SAMHSA.
2. SAMHSA will approve or deny a request for a 275-patient waiver within 45 days of receiving an initial or renewal [Waiver Notification Form](#). If SAMHSA determines that the practitioner holds "additional credentialing" or practices in a "qualified practice setting," and is able to meet the eight attestations listed above, the request will be approved. After it is approved, SAMHSA will notify the DEA of this approval. The request will be denied if the request is deficient in any respect or if the practitioner has knowingly submitted false statements or made misrepresentations of fact. If the request is denied, SAMHSA will notify the practitioner of the reason (or reasons) for denial. However, if the deficiencies are resolved in a manner and time approved by SAMHSA, the request will be approved.
3. SAMHSA may suspend or revoke the approval of the patient limit increase if it is determined that any of the following events is in effect or has taken place:
  - a. Immediate action is necessary to protect public health or safety.
  - b. The practitioner made misrepresentations in his or her request for the patient limit increase.

- c. The practitioner no longer satisfies the requirements of the patient limit increase.
- d. The practitioner has been found to have violated the Controlled Substances Act.

## What Do I Need To Do To Stay Compliant?

1. Practitioners who are approved for the 275-patient waiver must maintain all eligibility requirements, including either holding “additional credentialing” or practicing in a “qualified practice setting,” and meeting the eight attestations that must be made on the [Waiver Notification Form](#) during the 3-year approval term. If practitioners fail to maintain these requirements, SAMHSA may revoke its approval. ASAM’s webpage on the [DATA 2000 Patient Limit](#) provides several resources that may help practitioners stay compliant with the final rule.
2. The final rule requires practitioners approved for the 275-patient waiver to renew their waiver every 3 years. To renew the patient limit increase after the 3-year approval term, practitioners must submit a renewal request, which includes the same information that is required for an initial patient limit increase request. The renewal request must be submitted at least 90 days before the expiration of the previous approval term. If SAMHSA does not reach a final decision on the renewal request before the expiration of the previous approval term, the approval term will be extended until SAMHSA reaches a final decision. In the case of a waiver renewal denial, there will be no grace period for the transfer of patients once SAMHSA has alerted the practitioner of their decision; the practitioner must stop prescribing immediately. SAMHSA is in the process of looking into an automated process that would alert practitioners of when they are approaching 90 days before the expiration of their waiver in order to remind them to submit a renewal request.
3. At this point, there has not been any guidance information from the DEA to assert that they will require different documentation standards nor regularly audit or increase audits of practitioners approved for the 275-patient waiver. However, practitioners who are approved for the 275-patient waiver must be able to support their eligibility through “additional credentialing” or working in a “qualified practice setting,” along with the eight attestations that must be made on the [Waiver Notification Form](#). ASAM recommends that approved practitioners have documentation to show adherence to all requirements under the final rule and our webpage on the [DATA 2000 Patient Limit](#) provides several resources that can help practitioners do so.
4. Adherence to the eight requirements on the [Waiver Notification Form](#) will be monitored and enforced through the application process when eligible practitioners check off an attestation that they will follow each requirement under the final rule. In addition, adherence will be monitored and enforced through the reporting requirements. HHS opened a supplementary comment period on the proposed reporting requirements for physicians with a 275-patient waiver, which closed on August 8. As soon as the reporting requirements are finalized and released, ASAM will update this FAQ and our website with



in-depth information on the reporting requirements. On behalf of our membership, ASAM submitted these [written comments on the reporting requirements](#).

5. Practitioners with a 275-patient waiver can prescribe to their 275 patients at multiple different locations and/or in multiple different states. The metric that waived physicians are required to abide by is that they cannot prescribe buprenorphine for opioid addiction treatment to more than their patient limit at any one time, so location is not taken into account. However, practitioners who are approved for a 275-patient waiver through the “qualified practice setting” pathway must treat their additional 175 patients at the location that fulfills the requirements of a “qualified practice setting.”
6. All patients receiving buprenorphine, including those receiving new formulations of the drug, such as implantable and injectable buprenorphine, will be counted toward the 275-patient limit.

## CARA Just Became Law. What Does that Mean?

1. The [Comprehensive Addiction and Recovery Act \(CARA\)](#) was signed into law by President Obama on July 22, 2016. Section 303 of CARA makes several changes to the law regarding office-based opioid addiction treatment with buprenorphine. Specifically, it:
  - a. Expands prescribing privileges to nurse practitioners (NPs) and physician assistants (PAs) for five years (until October 1, 2021). See below for additional information about this change.
  - b. Gives the HHS Secretary the authority to exclude from the patient limit those patients to whom medications are directly administered.
  - c. Directs the HHS Secretary to review the provision of opioid addiction treatment services in the U.S. and submit a report to Congress, including an assessment of whether there is need to change the patient limit, every 3 years.
  - d. Allows states to lower the patient limit and allows states to require practitioners to comply with additional practice setting, education or reporting requirements. States may not lower the patient limit below 30.
    - i. For practitioners in states that are looking to adopt additional requirements for prescribing buprenorphine, please get in contact with the state medical society and [ASAM state chapter](#) to respond to any changes.
2. NPs and PAs will go through the same application process as physicians who apply for a waiver to prescribe buprenorphine. This means they must apply for a 30-patient waiver and then a 100-patient waiver after the first year prescribing. NPs and PAs are not currently eligible to apply prescribe up to 275 patients since none have held a 100-patient

waiver for one year. HHS has 18 months to issue regulations to include NPs and PAs to ensure quality of care and prevent diversion.

3. For NPs and PAs to be eligible to apply for a buprenorphine waiver, they must complete 24 hours of training that covers opioid maintenance and detoxification, clinical use of all FDA-approved drugs for MAT, patient assessment, treatment planning, psychosocial services, staff roles and diversion control. ASAM expects SAMHSA to issue additional guidance as to which courses qualify to fulfill this requirement in the near future. NPs and PAs can receive the 24 hours of training from one of the following organizations:
  - a. [ASAM](#)
  - b. [American Academy of Addiction Psychiatry](#) (AAAP)
  - c. [American Medical Association](#) (AMA)
  - d. [American Osteopathic Association](#) (AOA)
  - e. [American Psychiatric Association](#) (APA)
  - f. [American Nurses Credentialing Center](#) (ANCC)
  - g. [American Association of Nurse Practitioners](#) (AANP)
  - h. [American Academy of Physician Assistants](#) (AAPA)
  
4. NPs and PAs who are approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician IF required by state law.
  - a. Nurse practice laws and regulations are specific to each state. AANP has created an [interactive map](#) to provide licensure and regulatory requirements, as well as practice environment details, for all 50 states, the District of Columbia and the U.S. territories. AANP also has a [list](#) of state practice laws and regulations categorized by type.
  - b. Physician assistant practice laws and regulations are also specific to each state. AAPA has created a [table](#) that lists the requirements in regards to collaboration or supervision, ratios and prescribing for physician assistants for all 50 states and the District of Columbia.

## For More Information

1. Additional questions or requests for more information about the final rule and/or related regulations, laws and processes can be directed to Brad Bachman, ASAM's Advocacy, Policy & Payer Relations Specialist. Brad can be reached directly at 301-547-4107 or [bbachman@asam.org](mailto:bbachman@asam.org).
2. Practitioners that are having trouble completing the online [Waiver Notification Form](#) or have specific questions on any requirement or aspect of applying for a buprenorphine waiver can contact the SAMHSA Center for Substance Abuse Treatment (CSAT) Buprenorphine Information Center at 866-BUP-CSAT (866-287-2728) or send an email to [info@buprenorphine.samhsa.gov](mailto:info@buprenorphine.samhsa.gov). Please also visit SAMHSA's [Buprenorphine Waiver Management](#) webpage.