

Medication-Assisted Treatment: Changes in Federal Law and Regulation

October 2016

Expanded Prescribing Rights: The [Comprehensive Addiction and Recovery Act of 2016](#), signed into law in July of 2016, authorized qualifying Nurse Practitioners (NP) and Physician Assistants (PA) to prescribe buprenorphine for the treatment of opioid addiction (often referred to as ‘medication-assisted treatment’, or MAT).¹ More specifically, the law states that for a NP or PA to qualify to prescribe buprenorphine, the NP or PA must:

1. Be licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.
2. Have completed at least 24 hours of training through classroom situations, seminars at professional society meetings, electronic communications, or otherwise.²
3. If required by State law, the NP or PA must be supervised by, or work in collaboration with, a physician who is qualified to prescribe buprenorphine.

However, prescribing for these professions cannot begin immediately. The Substance Abuse and Mental Health Services Administration (SAMHSA) coordinates the waiver process required to prescribe buprenorphine for the treatment of opioid addiction. Before prescribing can begin, a Notice of Intent form for NPs and PAs to prescribe will need to be posted for public comment, and then time will be needed to allow for comments to be received and processed. In addition, SAMHSA has not yet updated their resources to include information for NPs and PAs, which will be posted on SAMHSA’s [website](#) once they are available, along with other new information as it is released, to include free trainings where available.³

Ultimately, the process for obtaining a waiver may be similar to the current process for physicians, which includes:

1. Completing the required training, including [buprenorphine training](#).⁴ Physicians are currently required to complete 8 hours of training, while NPs and PAs will be required to complete 24 hours of training.
2. Applying for a [waiver](#) from the registration requirements of other federal laws.⁵
3. Submitting the waiver to SAMHSA for approval.

Increased Patient Limits: The Department of Health and Human Services (HHS) recently issued [new federal regulation](#), effective August 8, 2016, which increases the patient limit to 275 for the prescribing of buprenorphine in treating opioid addiction.⁶ Prior to the new regulation, an approved waiver authorized a physician to have 30 patients in the first year and 100 patients thereafter. In order to qualify for a 275 patient limit a practitioner must:

1. Possess a current waiver to treat up to 100 patients and have maintained the waiver without interruption for at least one year;
2. Hold additional credentialing, meaning board certification in addiction medicine or addiction psychiatry, or provide MAT in a ‘qualified practice setting’ (which includes federally qualified health centers);⁷
3. Have not had his/her Medicare enrollment and billing privileges revoked; and
4. Have not been found in violation of the Controlled Substances Act.

The form to request a patient limit of 275 is not currently available to the public; however, one may be requested from SAMHSA by contacting info@buprenorphine.samhsa.gov or 866-287-2728.

The new regulation outlined additional rules related to increasing the MAT patient limit to 275, to include:

- **Three-Year Renewal.** Practitioners granted a waiver for a 275 patient limit must reaffirm their eligibility every three years by submitting a renewal form at least 90 days before the end of their waiver period.
- **Emergency Situation Waiver.** Practitioners who currently have a waiver to treat up to 100 patients but do not meet the required qualifications may request an ‘emergency situation’ waiver to treat up to 275 patients temporarily (not longer than 6 months).⁸
- **Patient Definition.** Any individual that receives a prescription for buprenorphine under MAT from the practitioner is considered a patient for at least the length of prescription. If a practitioner provides consult services but does not prescribe buprenorphine to the individual, the patient is not counted toward the MAT patient limit.⁹
- **Reporting Requirements.** Current [record keeping requirements](#) require practitioners to keep records and inventories of all controlled substances dispensed, including approved buprenorphine products.¹⁰ Additional record keeping requirements were proposed under the new regulation for prescribers authorized at a 275 patient cap; however, based on public feedback, those additional requirements are currently under review and no final rule has been set at this time.

Additional Resources:

- [Medication and Counseling Treatment](#) – Learn more about MAT to treat substance use disorders.¹¹
- [Buprenorphine](#) – Learn more about Buprenorphine and how it helps in treating opioid addiction.¹²
- [Buprenorphine Waiver Management](#) – Information from SAMHSA on the waiver application and management process to prescribe buprenorphine.¹³
- [Training Materials and Resources](#) – MAT webinars, workshops and other materials – currently geared towards physicians, however will likely have a section for NPs and PAs in the future.¹⁴
- [Medication-Assisted Treatment: Buprenorphine and the HCH Community](#) – Policy Brief explores the challenges and opportunities to treating persons experiencing homelessness with buprenorphine.¹⁵
- [Providers’ Clinical Support System](#) -- This resource offers education, training, and clinical tools, as well as a mentorship program that could assist health center staff receive more support.¹⁶
- [SAMHSA-HRSA Center for Integrated Health Solutions MAT Overview](#) – Resources related to implementation, financing, training, and materials for consumers/families and practitioners. There is also a section on SBIRT, an evidence based approach to Screening, Brief Intervention, and Referral to Treatment effective for opioid use disorders.¹⁷
- [Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction](#) – a quick guide for practitioners on pharmacology, patient assessment, treatment protocols, special populations, and policies and procedures.¹⁸
- [Medication-Assisted Treatment for Opioid Addiction: Facts for Family & Friends](#) – an easy-to-read guide to essential elements of addiction and treatment that can also be used with patients.¹⁹
- [National Institute on Drug Abuse Info Facts: Treatment Approaches to Drug Addiction](#) – frequently asked questions about drug addiction and treatment options²⁰

- [Medication Assisted Therapy Toolkit](#) – Includes wide range of information related to securing buy-in from staff, Board and community, financing, licensing and credentialing, screening and assessing patients, combining medication and therapy, and sustaining a MAT program.²¹
- [Opioids: The Prescription Drug & Heroin Overdose Epidemic](#) – Comprehensive HHS website focused on opioids that includes resources for health professionals and a section on MAT.²²

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¹ Comprehensive Addiction and Recovery Act of 2016. Available at: <https://www.gpo.gov/fdsys/pkg/BILLS-114s524enr/pdf/BILLS-114s524enr.pdf>.

² The Training has to be provided by a qualified organization, including: The American Society of Addiction Medicine; The American Academy of Addiction Psychiatry; The American Medical Association; The American Osteopathic Association; The American Nurses Credentialing Center; The American Psychiatric Association; The American Association of Nurse Practitioners; The American Academy of Physician Assistants; Or any other organization that the Secretary of the Department of Health and Human Services (HHS) determines is appropriate. The training should include: Opioid maintenance and detoxification; Appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder; Initial and periodic patient assessments (including substance use monitoring); Individualized treatment planning, overdose reversal, and relapse prevention; Counseling and recovery support services; Staffing roles and considerations; Diversion control; and Other best practices, as identified by the Secretary of HHS.

³ SAMHSA, Medication-Assisted Treatment. Available at: <http://www.samhsa.gov/medication-assisted-treatment>.

⁴ SAMHSA, Buprenorphine Training for Physicians. Available at: <http://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>.

⁵ SAMHSA, Qualify for a Physician Waiver. Available at: <http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver>.

⁶ Final regulations are available at: <https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16120.pdf>.

⁷ 1. A Qualified Practice Setting provides professional coverage for patient medical emergencies during hours when the practitioner’s practice is closed; 2. 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; 3. Uses health information technology (health IT) systems such as electronic health records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information; 4. Is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law. 5. Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

⁸ An emergency situation is defined as a situation where local services are overwhelmed and unable to meet the demand for MAT as a direct consequence of a precipitating event. The precipitating event must have an abrupt onset, such as physician incapacity, natural or human-caused disaster, and/or an outbreak in drug use that results in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

⁹ Note this patient definition is for the purposes of defining a patient in the context of the MAT patient limit and does not intend to apply to a definition of “patient” with respect to the Health Center Program.

¹⁰ For more information, see http://www.ecfr.gov/cgi-bin/text-idx?SID=9dcf178be57df5a3bf5db2d8d40be95f&node=se21.9.1304_103&rgn=div8.

¹¹ SAMHSA, Medication and Counseling Treatment. Available at: <http://www.samhsa.gov/medication-assisted-treatment/treatment>.

¹² SAMHSA, Buprenorphine. Available at: <http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>.

¹³ SAMHSA, Buprenorphine Waiver Management. Available at: <http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management>.

¹⁴ SAMHSA, Buprenorphine Training for Physicians. Available at: <http://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>.

¹⁵ National Health Care for the Homeless Council (May 2016). Available at: <https://www.nhchc.org/wp-content/uploads/2016/05/policy-brief-buprenorphine-in-the-hch-community-final.pdf>.

¹⁶ Providers Clinical Support System for Medication-Assisted Treatment. Available at: <http://pcssmat.org/>.

¹⁷ SAMHSA-HRSA Center for Integrated Health Solutions MAT Overview. Available at: <http://www.integration.samhsa.gov/clinical-practice/mat/mat-overview>.

¹⁸ Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Available at: <http://store.samhsa.gov/product/Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction/SMA05-4003>.

¹⁹ Medication-Assisted Treatment for Opioid Addiction: Facts for Family & Friends. Available at: <http://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf>.

²⁰ NIDA Info Facts: Treatment Approaches to Drug Addiction. Available at: https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/df_treatment_approaches_final_7_2016.pdf.

²¹ Getting Started with Medication-assisted Treatment. Available at: <http://www.niatx.net/PDF/NIATx-MAT-Toolkit.pdf>.

²² Opioids: The Prescription Drug & Heroin Overdose Epidemic. Available at: <http://www.hhs.gov/opioids/>.