



December 23, 2020

Timothy J. Shea, Acting Administrator
Drug Enforcement Agency, Department of Justice
Attn: DEA Federal Register Representative/DPW, Diversion Control Division
8701 Morrissette Drive, Springfield, VA 22152

Re: RIN 1117-AB55 Docket No. DEA-499; Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment

Dear Acting Administrator Shea:

On behalf of the American Academy of Family Physicians (AAFP), which represents 136,700 family physicians and medical students across the country, I write to share our comments on the [interim final rule](#) regarding Dispensing and Administering Controlled Substances for Medication-Assisted Treatment as published in the *Federal Register* on November 2, 2020.

Family physicians provide comprehensive health care to patients of all ages, are tuned in to the needs of their community, and are often the first line of defense for primary care, chronic care management, and acute illness. To this end, family physicians play a crucial role in safe pain management prescribing practices, screening patients for opioid use disorder (OUD), naloxone administration, and medication assisted treatment (MAT) for patients with OUD.

The prevalence of overdose deaths and opioid dependency has rapidly increased over recent years, including over 2.3 million people facing OUD in 2015.¹ Immediately prior to the COVID-19 pandemic, the opioid epidemic accounted for 71,000 deaths in one year.² As individuals grapple with unprecedented challenges from COVID-19, opioid overdoses continue to rise with more than 40 states reporting an increase in opioid-related deaths and experts estimating the total deaths have already surpassed last year's toll.³ The AAFP is firmly committed to combating the opioid epidemic, and we commend the DEA's swift implementation of temporary flexibilities to treat OUD during the public health emergency.

Physicians continue to face barriers to prescribing evidence-based treatment like buprenorphine and other MAT. Previous caps on patient volume for MAT administration have hindered the expansion and accessibility of MAT. Documentation, counseling, and inspection requirements are important to ensuring practices follow recommended guidelines but often make it difficult for small or rural practices to provide MAT given geographical and financial challenges.

Both pain management and therapy for substance use disorders require longitudinal, patient-centered, compassionate care, which are key tenants of primary care and family medicine. The AAFP is actively engaged in the national discussion on pain management and OUD and has developed a

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thorough [position paper](#) on this important topic. With these goals in mind, the AAFP offers the following recommendations for consideration.

Additional Flexibility Regarding the Patient Limit

This rule will update regulations to reflect the increased cap on the number of patients that a physician or other clinician can treat, including up to 275 patients if they meet the following requirements:

- The clinician possesses a current and valid waiver to treat up to 100 patients and has maintained the waiver without interruption for at least one year since the practitioner's notification of intent to treat up to 100 patients was approved;
- The clinician:
 - Is board certified or licensed in addiction medicine or addiction psychiatry; or
 - Provides MAT utilizing covered medications in a qualified practice setting, which, as defined in current regulation, includes most family practices;
- The clinician has not had his or her enrollment and billing privileges in the Medicare program revoked, or
- The clinician has not been found to have violated the Controlled Substances Act.

The AAFP fully supports raising the cap on the number of patients a qualified physician can treat without being separately registered as a narcotic treatment program. Previous caps at 30 and 100 arbitrarily limited OUD treatment expansion. This is a welcomed step forward to improving access to MAT and reducing regulatory burdens for physicians caring for patients with OUD.

The AAFP recommends the DEA solicit feedback and work with clinicians on other outstanding barriers, such as documentation and inspection burdens. Evidence indicates that the inability to refer patients to a mental or behavioral health clinician is a significant barrier to implementing MAT in primary care practices.^{4,5} Counseling requirements, which are sometimes implemented at the state level, have proven especially difficult for physicians by adding to administrative burden and mandating where and how people can obtain aftercare. Currently, there are 5,733 mental health care professional shortage areas across the U.S., making follow up care especially difficult for many Americans.⁶ While the AAFP supports a biopsychosocial approach to treating OUD, it must follow evidence-based practices with respect to the available workforce and geographic limitations.⁷

The AAFP recently [sent a letter](#) urging the DEA to promulgate final regulations to implement a telemedicine special registration process enabling clinicians to safely prescribe controlled substances remotely. The COVID-19 pandemic and the associated increases in opioid-related deaths have clearly demonstrated the need for increased access to telemedicine and the importance of improving access to MAT. We again recommend that the DEA expedite and complete efforts to specify the circumstances in which a special registration for telemedicine may be issued and the procedure for obtaining the registration.

Elimination of Time Limit for Certain Qualifying Practitioners and Expanding the Definition of Qualifying Other Practitioner

This section of the rule will permanently allow a non-physician practitioner (NPP), such as a nurse practitioner or physician assistant, to be considered a qualifying other practitioner who can dispense narcotic drugs for maintenance treatment or detoxification treatment. Additionally, this will expand the definition of qualifying practitioner until Oct. 1, 2023 to include a clinical nurse specialist, certified registered nurse anesthetist, or a certified nurse midwife who meets certain qualifications.

The AAFP strongly believes that care should be led by a physician. While the AAFP believes that health professionals should work collaboratively as clinically integrated teams in the best interest of patients, the AAFP **opposes** any regulation that undermines the physician-led team-based care models that have proven to be most effective in improving quality, efficiency, and most importantly, patient health. While we recognize and appreciate the role that NPPs play in reducing barriers to care, the NPPs' skill set is not interchangeable with that of a fully-trained physician. Both of these changes would undermine physician-led team-based care models and should be reconsidered before final implementation of this rule.

New Option to Allow a Physician to Become a Qualifying Physician

Previously, physicians could only become a qualified physician via DATA-waiver. This waiver required additional training which was often duplicative to training now offered in medical schools and residency programs. The SUPPORT Act of 2018 created an additional option for a physician to be considered a qualifying physician if they graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States within the five-year period immediately preceding the date that the physician submitted a written notification to the Secretary of HHS of their intent to dispense narcotic drugs for maintenance or detoxification treatment, and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency. In this IFR, the DEA finalizes this additional pathway to becoming a qualified physician.

The AAFP strongly supports implementation of this additional route to becoming a qualified physician. Studies show that regulatory requirements related to obtaining the DATA-waiver are a barrier to implementing office-based MAT.⁸ Many medical schools and residency programs meet the DEA's curriculum requirements, thereby making this a more efficient pathway without compromising patient safety.

Additionally, residents who have met the specified curriculum requirements should be allowed to prescribe under their own name and license as outlined in this regulation change. Residents are always supervised and therefore will have the appropriate guidance to prescribe management and detoxification treatment. In turn, this will remove barriers to patient access to MAT and increase the number of trained clinicians in the future.

Dispensing Controlled Substances for Maintenance or Detoxification Treatment

Prior to the implementation of this interim final rule, controlled substances (including medications used for MAT) could only be dispensed by a pharmacy to the ultimate user or research subject. This rule will allow a pharmacy to deliver a controlled substance to the prescribing practitioner's (or administering practitioner's) registered location for the purpose of maintenance or detoxification treatment, under the following conditions:

- The prescription must be issued by a qualifying practitioner and may not provide the practitioner with a stock of controlled substances for general dispensing.
- The practitioner must administer the controlled substance to the patient named on the prescription by implementation or injection within 14 days after the date of receipt of the controlled substance by the practitioner.
- The practitioner and pharmacy are authorized to conduct these activities in the State in which such activities take place.
- The prescribing and administering practitioners maintain complete and accurate records of all controlled substances delivered, received, administered, and disposed including the persons to whom controlled substances were delivered and such other information that the Attorney General may require by regulations.

The AAFP is appreciative of the flexibility allowing a pharmacy to deliver a controlled substance to practitioner's registered location as outlined in the interim final rule. We believe that the framework outlined by the DEA balances both the need to reduce regulatory burdens for office-based MAT and ensuring adequate safeguards are in place.

We appreciate the opportunity to provide these comments and we look forward to future engagement with the DEA on this important topic. If you have any further questions, please contact Meredith Yinger, Senior Regulatory Strategist, at myinger@aafp.org or 202-235-5126.

Sincerely,



Gary L. LeRoy, MD, FAAFP
Board Chair
American Academy of Family Physicians

¹ Haffajee, R. L., Bohnert, A., & Lagisetty, P. A. (2018). Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment. *American journal of preventive medicine*, 54(6 Suppl 3), S230–S242.

<https://doi.org/10.1016/j.amepre.2017.12.022>

² Stobbe, Mike; Sainz, Adrian. "US Overdose deaths Appear to Rise Amid Coronavirus Pandemic." Associated Press. October 20, 2020. <https://apnews.com/article/virus-outbreak-technology-pandemics-kentucky-22e4c7213a3f5a857cd50b8489325d9a>

³ Stobbe, Mike; Sainz, Adrian. "US Overdose deaths Appear to Rise Amid Coronavirus Pandemic." Associated Press. October 20, 2020. <https://apnews.com/article/virus-outbreak-technology-pandemics-kentucky-22e4c7213a3f5a857cd50b8489325d9a>

⁴ Hutchinson E, et al. Barriers to Primary Care Physicians Prescribing Buprenorphine. Annals of Family Medicine. 2014. Available at: <https://www.annfammed.org/content/12/2/128>

⁵ Haffajee RL, Bohnert ASB, Lagisettey PA. Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment. American Journal of Preventive Medicine. 2018. Available at: <https://www.sciencedirect.com/science/article/pii/S0749379718300746>

⁶ Kaiser Family Foundation. "Mental Health Care Health Professional Shortage Areas (HPSAs)." Last updated September 30, 2020. Accessed on December 11, 2020. <https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Practitioners%20Needed%20to%20Remove%20HPSA%20Designation%22,%22sort%22:%22desc%22%7D>

⁷ American Academy of Family Physicians. "Chronic Pain Management and Opioid Misuse: A Public Health Concern (Position Paper)." <https://www.aafp.org/about/policies/all/chronic-pain-management-opiod-misuse.html>

⁸ Haffajee RL, Bohnert ASB, Lagisettey PA. Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment. American Journal of Preventive Medicine. 2018. Available at: <https://www.sciencedirect.com/science/article/pii/S0749379718300746>