

February 14, 2023

Robert Baillieu, MD, MPH
Physician and Senior Advisor
Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

Submitted via regulations.gov

Re: RIN 0930-AA39; Notice of Proposed Rulemaking on Medications for the Treatment of Opioid Use Disorder; and Supplemental Notice of Proposed Rulemaking on Medications for the Treatment of Opioid Use Disorder and Removal of the DATA 2000 Waiver Requirements

Dear Dr. Baillieu,

The National Association of Chain Drug Stores (NACDS) thanks the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opportunity to comment on the Notice of Proposed Rulemaking for Medication for the Treatment of Opioid Use Disorder published for public comment on December 16, 2022. We commend the agency for recognizing the need to modernize the regulatory framework for treatment with medications for opioid use disorder (MOUD) to expand patient access to these therapies, especially considering how treatment practices have changed over the years to leverage different healthcare practitioners to provide this care. Most recently, legislation enacted by Congress on December 29, 2022 eliminated the DATA 2000 Waiver Program (“X-Waiver”), thereby allowing any DEA registered practitioner who is authorized under state law to prescribe schedule III medications to prescribe buprenorphine for opioid use disorder (OUD) without an X-Waiver, without any patient caps, and without any associated reporting processes. This landmark policy change will help to improve access to MOUD for the estimated 1.6 million Americans with OUD.¹

We note that just this week, SAMHSA published a Supplemental Notice of Proposed Rulemaking (SNPRM) on Medications for the Treatment of Opioid Use Disorder and Removal of the DATA 2000 Waiver Requirements that proposes to align the language of December 2022 NPRM with the recent statutory change that eliminated the DATA 2000 Waiver Program. ***NACDS strongly supports the SNPRM that would eliminate all outdated references to and requirements for X-Waiver prescribers and the underlying policy change that eliminated the DATA 2000 Waiver Program. By empowering more healthcare providers to prescribe medications like buprenorphine to treat OUD in settings outside of a traditional opioid treatment program, this will dramatically expand treatment capacity of the broader healthcare system and give patients more options for where they can receive needed care.***

We further urge SAMSHA to ensure that the regulatory framework for MOUD treatment continues to accommodate evolving practice models that deliver OUD treatment services in new and innovative ways and in different patient care settings – including in the pharmacy setting. Pharmacy providers can play an important role

¹ O’Donnell J, Gladden RM, Mattson CL, Hunter CT, Davis NL. Vital Signs: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants — 24 States and the District of Columbia, January–June 2019. *MMWR Morb Mortal Wkly Rep* 2020; 69:1189–1197. DOI: <http://dx.doi.org/10.15585/mmwr.mm6935a1>

in connecting patients with OUD – 86% of whom are not receiving treatment – to MOUD services.² Pharmacists are qualified and well-suited to partner with clinicians and other behavioral health professionals to provide an array of services in support of patients’ recovery and related wraparound services. Since pharmacists are the most accessible healthcare provider to most Americans, leveraging their access is an essential yet underutilized way of extending clinicians’ reach in providing destigmatizing care to patients with behavioral healthcare needs – especially in communities hardest hit by the mental health and substance abuse treatment provider shortages and for individuals from racial and ethnic minority groups that experience access barriers to healthcare services. A growing body of evidence shows the positive impact that pharmacists have on improving access to these services. Discussed in further detail below, the benefits involving pharmacy providers in behavioral health services are clear — increased treatment capacity and improved patient outcomes. As such, NACDS urges SAMSHA to consider how clinicians and other treatment professionals have and can continue to work with pharmacy partners to expand access to evidence-based treatment and recovery support services and help improve patient outcomes for patients with OUD.

A. Pharmacy providers can expand access to treatment services and fill gaps in care for patients with OUD – especially for patients in racial and ethnic minority groups who are disproportionately impacted by inequitable access to healthcare services.

In most communities, pharmacists are the most accessible healthcare provider with 90% of Americans living within 5 miles of a pharmacy. Leveraging this access is especially critical for delivering needed care to medically underserved communities and for individuals from racial and ethnic minority groups that experience greater access barriers to healthcare services. Notably, longstanding inequities and social determinants of health faced by Black, Indigenous, and People of Color (BIPOC) including uneven healthcare access, lack of insurance coverage, poverty, and crowded living conditions can exacerbate access to treatment services for these individuals.³ The experience of the COVID-19 pandemic has shown that pharmacies serve as a critical access point for the provision of healthcare services for this otherwise underserved population of patients, as more than 40% of individuals vaccinated at pharmacies were from racial and ethnic minority groups.⁴ Further, pharmacies provide more than 20,000 COVID-19 testing sites nationwide, and 70% of such sites are in areas with moderate to severe social vulnerability.⁵ Utilizing pharmacists to support the provision of treatment services can similarly help improve access to care for patients in racial and ethnic minority groups.

Working together, pharmacy providers and clinicians can help improve access to MOUD and patient support, as new access points to behavioral health support in communities are much needed, especially considering that a mere 14% of adults with OUD are receiving treatment.⁶ Promisingly, a recent study examined the distribution of community pharmacies across a state relative to the location of substance abuse treatment centers and opioid-related overdoses to explore the potential for community pharmacies to play a greater role in opioid abuse

² N. Krawczyk et al. Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019, International Journal of Drug Policy, Volume 110, December 2022. Available at:

<https://www.sciencedirect.com/science/article/pii/S0955395922002031?via%3Dihub>

³ <https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-questions-and-answers/>

⁴ GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, available at <https://www.gao.gov/assets/gao-22-105079.pdf>

⁵ White House, FACT SHEET: Biden Administration Announces Historic \$10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/>

⁶ N. Krawczyk et al. Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019, International Journal of Drug Policy, Volume 110, December 2022. Available at:

<https://www.sciencedirect.com/science/article/pii/S0955395922002031?via%3Dihub>

prevention and treatment.⁷ The study found that community pharmacies were more prevalent than substance abuse treatment centers — especially in rural counties — which could make them an important partner in enhancing access to MOUD and prevention efforts in underserved areas.⁸

B. A growing body of evidence supports leveraging pharmacy providers in the provision of MOUD.

Pharmacy providers have an important role to play working with physicians and other healthcare providers to identify and connect patients in need of treatment for OUDs to that care. Pharmacies are increasingly helping to bridge access gaps for behavioral health needs and have directly helped battle opioid abuse for years. In fact, evidence shows that pharmacist involvement in OUD and other substance use disorder (SUD) care helps improve access and outcomes, while reducing the risk of relapse.^{9, 10} Providing patients with access to these services at pharmacies can also help to destigmatize treatment and in doing so, improve patient compliance with prescribed therapies. Pharmacists' accessibility and clinical expertise makes them uniquely suited to provide care to patients with OUD. Access to treatment and support are critical to help individuals struggling to overcome this burden.

Especially at the point of dispensing, pharmacies and pharmacists are uniquely positioned to offer Screening, Brief Intervention, and Referral to Treatment (SBIRT) services to at-risk patients. A recent study¹¹ noted that by allowing community pharmacists to be more involved in direct patient care, community pharmacists can help eliminate gaps and barriers in treatment and increase access to naloxone and other MOUD, as well as play a critical role in implementing strategies to help reduce population OUD risk. For example, pharmacists can contribute to reducing OUD prevalence by using SBIRT to identify persons who are misusing alcohol, opioids, and other substances. Through a screening process, pharmacists identify those at risk and provide brief counseling and motivational interviewing, as well as linkage to care when needed.

Evidence indicates that risk for opioid medication misuse can be identified by pharmacy providers in rural and urban community pharmacies—and patients are generally open to screenings and discussions with pharmacists about potentially problematic usage.¹² Given the strong ties of community pharmacies in neighborhoods across the country, work is underway to implement collaborative, community-based SBIRT models where patients are first screened in the comfort and convenience of their local, familiar, community pharmacy and then receive intervention and linkage to care from the pharmacists they know and trust. Pharmacist-provided SBIRT services also increase provider capacity while eliminating gaps and barriers to SUD screening and treatment. This model can increase access to screening and education, as well as help to eliminate gaps in linking patients to treatment through local coordination. Pharmacist-provided SBIRT services have been developed in Pennsylvania, Virginia, and Ohio. Notably within Virginia, the state Medicaid program now expressly supports coverage for pharmacist provided SBIRT.

⁷ Look, K., Kile, M., Morgan, K. et al. (2018). Community Pharmacies as Access Points for Addiction Treatment. *Research in Social and Administrative Pharmacy*, S1551-7411(18)30217-1. <https://www.ncbi.nlm.nih.gov/pubmed/29909934>

⁸ Ibid.

⁹ DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, *Journal of the American Pharmacists Association*, 55(2), 187-192, available at: <https://www.ncbi.nlm.nih.gov/pubmed/25749264>

¹⁰ Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy*, 36(2), 312- 321.

¹¹ Pringle JL, Aruru M, Cochran J; "Role of pharmacists in the Opioid Use Disorder (OUD) Crisis"; *Research in Social & Administrative Pharmacy*; 2018; doi: <https://doi.org/10.1016/j.sapharm.2018.11.005>.

¹² Cochran, G., Rubinstein, H., Bacci, J. et al. (2016). Screening Community Pharmacy Patients for Risk of Prescription Opioid Misuse. *Journal of Addiction Medicine*, 9(5) 411-416. <https://www.ncbi.nlm.nih.gov/pubmed/26291546>

Once patients are identified as having an OUD or other SUD, pharmacists can offer a critical role in providing convenient options for receiving MOUD services. When pharmacists partner with physicians and other healthcare professionals to provide MOUD, they streamline and help improve care. Pharmacists' responsibilities for MOUD and other SUD treatment can also include administration of injectables, directly observed therapy, treatment plan development, patient communication, care coordination, adherence monitoring and improvement activities, among others. Moreover, pharmacies can also offer an array of wraparound services (where permitted in different states) that can be especially beneficial to at-risk patient groups such as the provision of services for take-home naloxone, prescribing of PEP & PrEP therapies, prescribing of hormonal contraceptives, immunization services (including for hepatitis B, HPV and others), tobacco cessation services, needle exchange and access to various other basic healthcare services. A patient may not be easily able to attend routine appointments with a traditional medical provider due to circumstances such as work or family commitments, or more recently, the capacity limitations brought on by the COVID-19 pandemic. However, the extended hours of many pharmacies provide additional opportunities for individuals to receive needed interventions and support - especially for patients who cannot take time off during typical work hours and who would greatly benefit from access to care in the evenings and weekends.

Study findings from a Rhode Island pilot conducted February 2021-April 2022 found that patients who received MOUD treatment services at a pharmacy were 72% more likely to continue treatment for a month as compared to patients who received the same care in a more typical outpatient program.¹³ The risk of an overdose or an emergency room visit for other reasons were roughly the same for patients in both settings. The pilot, originally funded by a \$1.6 million NIDA grant, involved 6 pharmacies working with 125 patients to manage their MOUD.¹⁴ In the pilot, patients receive their initial MOUD prescription from a physician. After the physician determined the patient was stable on their medication, a pharmacist working under a collaborative practice agreement then took over the patient's care. Visiting the pharmacy once or twice a week, patients met in a private room with their pharmacist. The pharmacist swabbed under the patient's tongue, sending that sample to a lab for analysis to inform whether that patient took the full dose of their prescribed medication or used any illicit substances. With this information, pharmacists then counseled patients about recovery goals, challenges, and successes. They also employed motivational interviewing, a counseling technique that helps patients overcome ambivalence and make behavioral changes. Most patients enrolled in the pilot took buprenorphine, but patients also had the option of a once-a-month injection of naltrexone.

Currently, notable state programs are actively leveraging community pharmacies and pharmacists to improve access to different SUD treatment medications. In certain states, such as Ohio, pharmacists can administer naltrexone as part of a treatment plan for patients. There are also pilot programs in Kentucky and Maryland. The Kentucky project allows pharmacists to manage patients on naltrexone¹⁵ and the Maryland program offers buprenorphine through a single pharmacy connected to the Health Department.¹⁶ Further, in Kentucky, the Board of Pharmacy has authorized pharmacists to execute clinical protocols and initiate the dispensing of medications for several conditions, including OUD pursuant to recommendations by the American Society of Addiction Medicine.¹⁷

¹³ Green TC, Serafinski R, Clark SA, Rich JD, Bratberg J. Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies. *N Engl J Med.* 2023 Jan 12;388(2):185-186. doi: 10.1056/NEJMc2208055. PMID: 36630629.

¹⁴ <https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-carepharmacy/m1mcceVILRXX1W9X3WdeOP/story.html>

¹⁵ [https://www.pharmacytoday.org/article/S1042-0991\(17\)31120-9/fulltext](https://www.pharmacytoday.org/article/S1042-0991(17)31120-9/fulltext)

¹⁶ <https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-carepharmacy/m1mcceVILRXX1W9X3WdeOP/story.html>

¹⁷ Kentucky Board of Pharmacy. Board Approved Protocols. <https://pharmacy.ky.gov/Pages/Board-Approved-Protocols.aspx>

Leveraging all qualified health professionals, especially pharmacists, to address this public health issue is imperative. Implementing more pharmacy-based OUD support programs, similar to what was stood up in the Rhode Island example, would allow more clinicians to expand access to essential treatment services for their patients in need. Many of these programs build on the existing relationships that pharmacists have with their patients. Community pharmacies are an untapped resource that can offer screenings, referrals, and educational counseling and help improve access to these needed SUD services. With pharmacists being recognized and utilized as pain management and SUD providers, more patients may receive timely and effective interventions and treatments.

C. Conclusion

NACDS members are committed to supporting policies and strategies that both prevent opioid abuse and improve access to treatment for individuals suffering OUDs and other SUDs. NACDS thanks SAMHSA for considering our comments on this important matter. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251.

Sincerely,



Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

###

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.