



February 10, 2023

Director Yngvild K. Olsen, M.D., M.P.H
The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

RE: RIN 0930–AA39 Medications for the Treatment of Opioid Use Disorder

Dear Director Olsen:

The American Academy of Nursing (Academy) is pleased to offer the following comments in response to the December 16, 2022, proposed rule regarding updates to 42 CFR Part 8 and improving access to and experience with opioid use disorder (OUD). The Academy serves the public and the nursing profession by advancing health policy and practices through the generation, synthesis, and dissemination of nursing knowledge. With more than 2,900 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia. The Academy has been recognized for its extraordinary contributions to the promotion of the public's health through practice, evidence, and innovation.

The Academy is committed to increasing accessibility to all forms of care, promoting high-impact advances in practice, innovation, and science, and building capacity to support nurses and other providers. To truly improve health, we believe policies must closely consider the social determinants of health and expand access to optimal care. The proposed rule signals a shift towards more flexible, systems-focused policies that will improve access to care for those seeking OUD treatment. The Academy commends the Substance Abuse and Mental Health Services Administration's (SAMHSA) efforts to promote practitioner autonomy in the treatment of opioid use disorder, remove stigmatizing or outdated language; create a patient-centered as well as culturally safe and supportive perspective for individuals; and reduce barriers to individuals seeking and receiving care.

As stated in the proposed rule, existing evidence indicates the need for promoting effective treatment in opioid treatment programs (OTPs).¹ In 2021, the U.S. Department of Health and Human Services (the Department) released an Overdose Prevention Strategy,² which announced new data showing expanded treatment capacity, lives saved from an overdose, and commitment to long-term recovery support.³ The Academy offers comments on the proposed rule in the following areas:

- Flexibility for Methadone Medication Take Homes in Opioid Treatment Programs;

¹ Substance Abuse and Mental Health Services Administration (SAMHSA), & Department of Health and Human Services (HHS). (2022, December 16). 77330 *Federal Register* /vol. 87, no. 241/Friday, December 16, 2022 ... Federal Register. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2022-12-16/pdf/2022-27193.pdf>

² Assistant Secretary for Public Affairs (ASPA). (2022, November 30). *Together we can save lives*. Overdose Prevention Strategy. Retrieved from <https://www.hhs.gov/overdose-prevention/>

³ Substance Abuse and Mental Health Services Administration (SAMHSA). (2022, December 13). *SAMHSA proposes update to Federal Rules to expand access to opioid use disorder treatment and help close gap in care*. HHS.gov. Retrieved from <https://www.hhs.gov/about/news/2022/12/13/samhsa-proposes-update-federal-rules-expand-access-opioid-use-disorder-treatment-help-close-gap-in-care.html#:~:text=According%20to%20Centers%20for%20Disease,than%2015%20percent%20from%202020.>

- Opioid Treatment Program Flexibility to Prescribe Medications for the Treatment of Opioid Use Disorder (MOUD) via Telehealth; and
- Expanding Access to Services.

Flexibility for Methadone Medication Take Homes in Opioid Treatment Programs

The Academy applauds SAMHSA and the Department for revisiting the limitations on prior and existing standards for medication administration and dispensing of methadone on unsupervised or “take home” use. As noted in the proposed rule, SAMHSA found evidence of no significant change in rates of diversion since this declaration and the Academy recommends the agency make this flexibility permanent if the data remains the same following one year after the end of the COVID public health emergency (PHE).⁴ Many patients do not have access to affordable and reliable transportation or may have other responsibilities (i.e., employment, serving as caretakers, etc.) and are not easily available to visit OTPs in person. Making this flexibility permanent ensures equitable access to care and we support SAMHSA’s proposed change in the rule. The Academy believes that through a transparent, evidence-based, and non-biased screening process for the identification and distribution of MOUDs, OTPs, Advanced Practice Registered Nurses (APRNs), and other practitioners will be in a better position to diagnose those individuals who qualify for take-home care. The proposed rule also plans to limit the use of stigmatization and this can only be achievable through accessible treatment, which is enhanced via the proposed change to “take home” regulations.

Opioid Treatment Program Flexibility to Prescribe Medications for the Treatment of Opioid Use Disorder (MOUD) via Telehealth

During the COVID-19 pandemic, we have seen the importance of telehealth. Virtual care and other forms of technology-enabled interactions provide fresh approaches and have the potential to be efficient, collaborative, cost-effective, as well as patient-centered.⁵ However, access to and the utilization of telehealth in low-income, rural, and other underserved areas that lack the technology infrastructure has only exacerbated access to OTPs.⁶ The Academy is on record recommending the expanded use of telehealth throughout the pandemic as well as infrastructure investments needed to create a system where all individuals, regardless of location, receive optimal care.⁷ The Academy applauds SAMHSA for increasing the need to make buprenorphine and methadone accessible to patients via telehealth. While these measures will increase access to treat OUDs, this could potentially further impact the digital divide⁸ and create health disparities at the same time. Individuals who reside in rural areas, or areas with poor/no/expensive broadband access, or lack a personal device (computer, internet, smartphone, tablet, etc.) are increasingly being left behind.⁹ Moreover, there are cultural issues related to the use of telehealth, particularly around trust. Therefore, there is a need for a holistic

⁴ American Academy of Nursing Joins the Nursing Community Coalition Urging Congress to Take Action to Make Waivers Permanent Beyond the Public Health Emergency (PHE) (2022)

https://higherlogicdownload.s3.amazonaws.com/AANNET/c8a8da9e-918c-4dae-b0c6-6d630c46007f/UploadedImages/NCC_Waiver_Request_Letter_Final_4_25_22.pdf

⁵ Solari-Twadell, P. A., Flinter, M., Rambur, B., Renda, S., Witwer, S., Vanhook, P., & Poghosyan, L. (2022). The impact of the COVID-19 pandemic on the future of telehealth in primary care. *Nursing Outlook*, 70(2), 315–322. <https://doi.org/10.1016/j.outlook.2021.09.004>

⁶ Patel, S. Y., Mehrotra, A., Huskamp, H. A., Uscher-Pines, L., Ganguli, I., & Barnett, M. L. (2021, February). *Variation in telemedicine use and outpatient care during the COVID-19 Pandemic in the United States*. Health Affairs. Retrieved from <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01786>

⁷ American Academy of Nursing Joins the Nursing Community Coalition Urging Congress to Take Action to Make Waivers Permanent Beyond the Public Health Emergency (PHE) (2022)

https://higherlogicdownload.s3.amazonaws.com/AANNET/c8a8da9e-918c-4dae-b0c6-6d630c46007f/UploadedImages/NCC_Waiver_Request_Letter_Final_4_25_22.pdf

⁸ Duff, N., E. Freiling, H. Burstin, K. J. Clark, and A. Salman, rapporteurs. 2022. NAM Action Collaborative on Countering the U.S. Opioid Epidemic Telehealth and Virtual Care Meeting Series: Introduction to Improving Telehealth and Virtual Care for Pain Management and Opioid/Substance Use Disorder. Discussion Proceedings, National Academy of Medicine, Washington, DC

⁹ American Academy of Nursing and Council for Advancement of Nursing Science offer comments regarding the ARPA-H initiative (2021) https://higherlogicdownload.s3.amazonaws.com/AANNET/c8a8da9e-918c-4dae-b0c6-6d630c46007f/UploadedImages/FINAL_ARPA-H_Letter.pdf

view that considers individual preferences and capabilities as well as a need for a better understanding of these preferences.¹⁰ SAMHSA should ensure OTPs collaborate with both patients and providers including APRNs to promote autonomy by developing safe and efficient hybrid models that meet their needs.¹¹

The Academy commends SAMHSA for reviewing the meaning of practitioner and recommends the agency includes full practice authority for the defined practitioners including APRNs. SAMHSA's unequal waiver requirements have contributed to the restrictions on APRNs' capacity to treat patients with OUDs.¹² The Academy recommends the proposed rule reflect section 1262 of the Consolidated Appropriations Act, 2023¹³, which removes the federal requirement for practitioners to submit a DATA 2000 waiver (X-Waiver) to prescribe medications, like buprenorphine for the treatment of OUDs.¹⁴ Practicing to the full extent of their education and training - the top of their licensure - allows APRNs to address the social determinants of health and help improve health equity by providing care management and team-based care.¹⁵ Due to underserved and disadvantaged patients experiencing a history of stigma in health care settings compared to their peers¹⁶, the Academy further recommends the proposed rule includes language under the Federal civil rights law prohibiting discrimination on the basis of race, color, national origin, sex, age or disability¹⁷ requiring APRNs and other practitioners and OTPs to undergo MOUD training and improve their education, policies, practices, and procedures to ensure that all patients have an equal opportunity to benefit from OTPs in clinical settings and via telehealth.

Expanding Access to Services

In Subpart A, Section 8.3 of the proposed rule, the Academy recommends modifying the recommendation of policies and procedures expected of accreditation bodies to include all eligible licensed professionals, specifically APRNs. We further recommend the language read "staff physician(s) and other licensed professionals with experience in treating OUD, including Advanced Practice Registered Nurses (APRNs)." Given the vital role APRNs with experience in OUD treatment are to the solution, their direct recognition reinforces the agency's commitment to increasing access to those seeking OUD treatment.

The Academy supports the removal of the X-waiver and the 275-patient limit in the proposed rule. We also commend SAMHSA for including additional definitions to expand and promote harm reduction services to OTP patients, exposure to and transmission of sexually transmitted diseases (STDs), and HIV,

¹⁰ American Academy of Nursing offers comments to CMS regarding the FY2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) Proposed Rule (2022)

https://higherlogicdownload.s3.amazonaws.com/AANNET/c8a8da9e-918c-4dae-b0c6-6d630c46007f/UploadedImages/Academy_CMS_FY_2023_Proposed_Rule_Comment_Letter.pdf

¹¹ Duff, N., E. Freiling, H. Burstin, K. J. Clark, and A. Salman, rapporteurs. 2022. NAM Action Collaborative on Countering the U.S. Opioid Epidemic Telehealth and Virtual Care Meeting Series: Introduction to Improving Telehealth and Virtual Care for Pain Management and Opioid/Substance Use Disorder. Discussion Proceedings, National Academy of Medicine, Washington, DC

¹² Naegle MA, Finnell DS, Kaplan L, Herr K, Ricciardi R, Reuter-Rice K, Oerther S, Van Hook P. *Opioid Crisis through the Lens of Social Justice. Nursing Outlook.* 2020 Sep-Oct;68(5):678-681. <https://doi.org/10.1016/j.outlook.2020.08.014>

¹³ H.R.2617 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2023. (2022, December 29). <https://www.congress.gov/bill/117th-congress/house-bill/2617>

¹⁴ Substance Abuse and Mental Health Service Administration. (n.d.). *Removal of data waiver (X-waiver) requirement.* SAMHSA. Retrieved January 24, 2023, from <https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>

¹⁵ National Academies of Sciences, Engineering, and Medicine. 2021. *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity.* Washington, DC: The National Academies Press. <https://doi.org/10.17226/25982>.

¹⁶ Salman, A., E. Freiling, R. Bottner, A. Boulton, R. Cooper, and M. Stefanko, rapporteurs. 2022. Stigma of Addiction Summit: Lessons Learned and Priorities for Action. Discussion Proceedings, National Academy of Medicine, Washington, DC.

¹⁷ American Academy of Nursing. (2020, August 18). *Academy comments to the US Department of Health and Human Services (HHS) in response to the final rule "Nondiscrimination in Health and Health Education Programs or Activities."* www.AANNET.org. https://higherlogicdownload.s3.amazonaws.com/AANNET/c8a8da9e-918c-4dae-b0c6-6d630c46007f/UploadedImages/FINAL_HHS_Final_Rule_Health_Nondiscrimination.pdf

including drug overdoses related to fentanyl. These forms of harm reduction measures not only put the power of choice in the hands of patients in OTPs, but it grants patient autonomy. Further, creating a patient-centered as well as culturally safe and supportive perspective will reduce barriers to receiving care. We support these important changes in the proposed rule to combat stigma and normalize MOUD and treatments for individuals to increase health equity.

Additionally, the Academy is concerned with language contained in the proposed rule amending recordkeeping that would change the word “review” to “determine” if a patient is enrolled in another OTP. The proposed rule states this change avoids simultaneous enrollment in other OTPs (which curves substance abuse) and allows instances for patients to obtain treatment at another OTP when there is an inability to access care at the OTP of record. However, it is unclear if this change in wording indicates a change in OTP functional requirements. Specifically, if it places additional requirements on the OTP, this could place onerous demands on already stressed OTPs without associated timelines to accomplish that determination. We recommend SAMHSA ensure OTPs have the technical or systems support needed with this amendment to recordkeeping.

Finally, while we applaud the loosening of OTP restrictions with an emphasis on patient-centered care and improved access, we overall feel these proposed changes do not go far enough to stem the ever-rising tide of opioid-related morbidity and mortality in the US. Opioid overdose deaths have continued to rise precipitously, even in the context of considerable federal treatment expansions that have included the Drug Addiction Treatment Act of 2000 (DATA 2000)¹⁸, Comprehensive Addiction and Recovery Act of 2016 (CARA)¹⁹, and SUPPORT for Patients and Communities Act²⁰, the 2016 “Final Rule” on office-based opioid treatment (OBOT) treatment limits²¹, and now the Mainstreaming Addiction Treatment Act of 2021 (MAT)²² and the Medication Access and Training Expansion Act of 2021 (MATE Act of 2021).²³ Keeping MOUD treatment siloed and sequestered from other treatments is not providing sufficient support for the citizens that need better access to care. While there may always be a place for OTPs for a subset of patients who require wraparound medical, nursing, counseling, and psycho-social support for OUD, implementation of evidence-based broader applications of MOUD must occur. For example, since the 1990s methadone MOUD in Scotland and England has included pharmacist-supervised dosing, with resulting improvements in treatment rates and reduced deaths from overdose.²⁴ We recommend SAMHSA consider these types of strategies to fully address drug-related morbidity and mortality.

The Academy appreciates the opportunity to provide input on SAMHSA’s proposed rule to revise and expand access to MOUD and OTPs that would improve health care access and behavioral health services throughout all communities. We are eager to work with you to continue to identify and implement

¹⁸ H.R.2634 - 106th Congress (1999-2000): Drug Addiction Treatment Act of 2000. (2000, July 27).

<https://www.congress.gov/bill/106th-congress/house-bill/2634>

¹⁹ S.524 - 114th Congress (2015-2016): Comprehensive Addiction and Recovery Act of 2016. (2016, July 22).

<https://www.congress.gov/bill/114th-congress/senate-bill/524>

²⁰ H.R.6 - 115th Congress (2017-2018): SUPPORT for Patients and Communities Act. (2018, October 24).

<https://www.congress.gov/bill/115th-congress/house-bill/6>

²¹ Office of the Secretary, Department of Defense (DoD). (2016, September 2). *61068 federal register /vol. 81, no. 171/Friday, September 2, 2016 ...* FederalRegister.gov. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2016-09-02/pdf/2016-21125.pdf>

²² S.445 - 117th Congress (2021-2022): Mainstreaming Addiction Treatment Act of 2021. (2021, February 25).


<https://www.congress.gov/bill/117th-congress/senate-bill/445>

²³ H.R. 2067 - 117th Congress (2021-2022): MATE Act of 2021. (2021, October 19). <https://www.congress.gov/bill/117th-congress/house-bill/2067>

²⁴ Strang, J., Hall, W., Hickman, M., & Bird, S. M. (2010). Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland. *BMJ*, 341(sep16 2), c4851–c4851. <https://doi.org/10.1136/bmj.c4851>

policies that close this gap. Please contact the Academy's Senior Director of Policy, Christine Murphy at cmurphy@aannet.org or 202-777-1174 if you have any questions or need additional information.

Sincerely,



Kenneth R. White, PhD, AGACNP, ACHPN, FACHE, FAAN
President