PREMIER TRANSFORMING HEALTHCARE TOGETHER®

March 10, 2023

The Honorable Dr. Miriam Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically to: http://www.regulations.gov

Re: Medications for the Treatment of Opioid Use Disorder (Docket No. SAMHSA-2023-0001)

Dear Assistant Secretary Delphin-Rittmon,

Premier Inc. appreciates the opportunity to submit comments to the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) regarding the Notice of Proposed Rulemaking (NPRM) on Medications for the Treatment of Opioid Use Disorder (OUD) (Docket No. SAMHSA-2023-0001). The proposed rule seeks public comment on SAMHSA's proposals to update opioid treatment program (OTP) accreditation and certification standards, treatment standards for medications for OUDs and requirements for individual practitioners eligible to dispense certain types of OUD medications. SAMHSA also proposes to update regulation text to reflect the removal of the Drug Addiction Treatment Act of 2000 (DATA-2000) waiver requirements, consistent with statutory requirements in the Consolidated Appropriations Act of 2023 (CAA 2023).

Premier appreciates SAMHSA's commitment to enabling access to high-quality, equitable care for OUDs, as evidenced by the proposed policies in this rule. In our detailed comments below, Premier specifically recommends the following:

- Finalize removal of DATA-2000 waiver (also known as the "X waiver") from the Code of Federal Regulations, consistent with current law;
- Finalize proposals to codify pandemic-era flexibilities that allow take-home doses of methadone and the use of telehealth in initiating buprenorphine for OTPs;
- Collaborate with the Drug Enforcement Agency (DEA) to permanently codify practitioners' ability to prescribe controlled substances via telehealth;
- Expand the definition of an OTP "practitioner" to include advanced practice pharmacists with board certification and/or residency training in OUD;
- Finalize proposals to expand OTP services to include evidence-based care delivery models aligned with public health goals;
- Work alongside other federal agencies to standardize the collection and use of social determinant of health (SDOH) data in order to identify and scale the most appropriate evidence-based public health solutions for health disparities among individuals with OUDs; and
- Finalize proposals to expedite access to OTP services by removing arbitrary admission criteria and empowering clinically appropriate, joint decision-making between providers and patients.

Based on Premier's data[1], approximately 66 million emergency department outpatient visits and 760,000 inpatient admissions in the U.S. annually are for patients with a diagnosis of OUDs. Patients with an OUD diagnosis had 32.5 percent higher cost per emergency department visit and 8 percent higher cost per inpatient visit than those without an OUD diagnosis. In total, the annual cost of care for OUD-associated emergency department outpatient visits and inpatient admissions is estimated to be $95.4 billion nationally.

[1] https://premierinc.com/newsroom/blog/pinc-ai-data-opioid-use-disorders-cost-u-s-hospitals-more-than-95-billion-annually

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

Premier believes that it is paramount that the Department expeditiously finalize these regulations to empower providers to better integrate and coordinate care to combat the costly and deadly opioid epidemic. Additional details on our recommendations are included below.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. CONTINUING EXPANDED ACCESS TO METHADONE AND BUPRENORPHINE

In March 2020, as a result of the COVID-19 pandemic, SAMHSA allowed state regulatory authorities to request blanket exceptions to allow patients to take home additional doses of methadone. Specifically, SAMHSA allowed OTPs to dispense 28 days of "take home" methadone doses to "stable" patients for the treatment of OUD, and up to 14 doses of "take home" methadone for "less stable" patients "who the OTP believes can safely handle this level of take home medication."[2] SAMHSA notes that 43 states and the District of Columbia utilized these flexibilities.

Although the duration of this allowance was not initially specified, a SAMHSA frequently-asked questions (FAQ) document published in April 2020 indicated that the flexibility was tied to the duration of "the current national health emergency." Recognizing the importance of this flexibility, SAMHSA subsequently released guidance in November 2021 that extended the methadone take-home flexibility for one year past the end of the COVID-19 public health emergency (PHE). This extension was intended to accommodate the notice-and-comment rulemaking process to make the more flexible policies permanent. In this proposed rule, SAMHSA proposes to permanently codify the take-home methadone flexibility in regulation.

Additionally, the pandemic spurred use of telemedicine for the treatment of OUD using buprenorphine, a schedule III partial opioid receptor agonist. In March 2020, the Secretary of Health and Human Services (HHS), with the concurrence of the Acting DEA Administrator, designated that the telemedicine exception under 21 U.S.C. 802(54)(D) applied to all schedule II-V controlled substances. Accordingly, DEA-registered, DATA-waived practitioners may issue buprenorphine prescriptions through telemedicine to new patients for whom they have not conducted an in-person medical evaluation, provided certain conditions are met, during the COVID-19 PHE. Additionally, Section 1262 of the Consolidated Appropriations Act,

[2] https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf

2023 removed the federal requirement for practitioners to submit a Notice of Intent (have an "X waiver") to prescribe medications, like buprenorphine, for the treatment of OUDs.

In April 2020, SAMHSA exempted OTPs from the requirement to perform an in-person physical evaluation (under 42 CFR 8.12(f)(2)) for any patient who will be treated by the OTP with buprenorphine if a program physician, primary care physician or an authorized healthcare professional under the supervision of a program physician determines that an adequate evaluation of the patient can be accomplished via telehealth. The duration of this exemption was specifically tied with the "period of the national emergency declared in response to the COVID-19 pandemic."[3] In this proposed rule, SAMHSA also proposes to permanently codify this flexibility for initiating buprenorphine in regulation.

Premier applauds SAMHSA's efforts to expand access to medically-necessary treatment for patients with OUDs and supports the proposed policies. Premier previously expressed our support for the use of telehealth for intake appointments for buprenorphine treatment as part of the calendar year (CY) 2023 Medicare Physician Fee Schedule rulemaking. ***It is also critically important that SAMHSA and HHS work in close collaboration with the DEA to permanently codify practitioners' ability to prescribe controlled substances via telehealth, with appropriate guardrails in place to protect patients and ensure program integrity.*** Current DEA telehealth prescribing flexibilities for controlled substances will cease at the end of the PHE, and in-person visits will be required for the prescription of many FDA-approved medications for the treatment of OUDs While recent DEA proposed rules[4] begin to address these post-COVID challenges, the DEA proposal would limit telehealth prescriptions for buprenorphine to 30 days and prohibit telehealth prescriptions for methadone, potentially greatly limiting access to OUD treatments. ***Harmonization between SAMHSA, HHS and DEA requirements for the treatment of OUDs is paramount to ensuring continued patient access to necessary treatments, especially in light of the pandemic's toll on mental health and OUD rates.***

III. ENSURING A HOLISTIC POLICY APPROACH TO EXPANDING OUD TREATMENT ACCESS

As demonstrated by the rapid increase in telehealth utilization over the course of the COVID-19 public health emergency, allowing remote access to healthcare services dramatically increases access. A recent report from the HHS Office of the Inspector General (OIG) found that in the Medicare program alone, approximately 28 million beneficiaries used telehealth during the first year of the pandemic, which was 88 times the volume of telehealth services used the prior year.[5] OIG also found that a small proportion of providers billing telehealth services demonstrated concerning billing practices that threatened Medicare program integrity requirements. As with any new benefit expansion, it is important to consider the potential downstream effects on providers and payers, supply chains and program integrity monitoring programs. Specifically, Premier urges SAMHSA, HHS and other federal partners to consider the following in ensuring a holistic policy approach to implementation of these proposals:

- **Barriers to care in health plan coverage.** HHS should consider additional regulatory requirements for health plans' provider directory content to ensure that patients seeking in-network OUD care do not face obstacles to identifying in-network providers and facilities.
- **Supply chain considerations.** SAMHSA should consider how this increase in telehealth utilization may lead to drug shortages. Premier continues to advocate for increased transparency and communication to serve as an early warning system for potential drug shortages and other scenarios that may warrant proactive action from the Food and Drug Administration (FDA) and DEA to increase aggregate production quotas (APQs) for methadone and buprenorphine to mitigate impact to patient care.

[3] https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf
[4] https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities#:~:text=WASHINGTON%20-%20Today%2C%20the%20Drug%20Enforcement,COVID-19%20public%20health%20emergency
[5] https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf

- **Program integrity among providers and prescribers.** SAMHSA and HHS should consider applying OIG's recommendations for targeted oversight of telehealth services in Medicare to create a program integrity monitoring strategy as part of the implementation of the policies proposed in this rulemaking. Premier recommends that SAMHSA and HHS invest in developing an oversight and monitoring strategy, providing additional education to providers on billing federal programs for telehealth services and more closely monitor providers who put OUD patients at risk through inappropriate prescribing practices. Further, Premier recommends that SAMHSA and HHS develop a particular monitoring strategy for telehealth companies that may qualify to prescribe buprenorphine via telehealth, given recent Department of Justice investigations into possible violations of the Controlled Substances Act by online-only prescribers of controlled substances.

IV. EXPANDING DEFINITION OF OTP TREATMENT PRACTITIONER

In this proposed rule, SAMHSA seeks to expand the definition of an OTP treatment practitioner to include any practitioner who is appropriately licensed to dispense and/or prescribe approved medications. Current regulations under 42 CFR Part 8 strictly define "practitioner" as "a physician who is appropriately licensed by the state to dispense covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2)." During the PHE, this definition of "practitioner" was expanded to include "physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a State to prescribe covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2)." SAMHSA notes that OTPs have reported that this change was essential in supporting provider workflow and patient access during the PHE.

Premier strongly supports SAMHSA's proposal to expand the definition of "practitioner." This represents a critical flexibility for healthcare providers amidst labor shortages that further exacerbate existing workforce shortages among behavioral health specialties***. Premier further recommends that SAMHSA ensure that to the extent allowable under federal and state law, the definition of "practitioner" include advanced practice pharmacists with board certification and/or residency training in OUD .*** Currently 10 states allow pharmacists to obtain DEA authorization to prescribe controlled substances such as buprenorphine, expanding access to new treatment models.[6] Recent pilot programs have shown promise in pharmacy-based buprenorphine induction, with such programs showing substantially higher retention.[7]

V. ELIMINATION OF THE DATA-2000 WAIVER ("X WAIVER")

The CAA 2023 removed a number of requirements that limited providers' ability to prescribe controlled substances for maintenance treatment or withdrawal management, including:

- Eliminating a requirement for healthcare practitioners registered to dispense controlled substances to apply for a separate waiver through the DEA to dispense buprenorphine for opioid use disorder maintenance treatment or withdrawal management, known as the "X waiver;" and
- Removing the DATA 2000 cap, which restricted prescribers to prescribing buprenorphine to a limited number of patients.

The CAA 2023 also implemented new training requirements, including the requirement that any physician registered to dispense controlled substances II to V must either be board certified in a relevant specialty, complete at least eight hours of training, or have graduated from medical school within five years of their DEA license and/or had at least eight hours of training. For nonphysician practitioners, to dispense

[6] https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf
[7] https://www.nejm.org/doi/full/10.1056/NEJMc2208055

controlled substances II to V, they must either complete at least eight hours of training or have graduated from a physician assistant or nurse practitioner school within the last five years of their first DEA license and have at least eight hours of training.

In this rulemaking, SAMHSA proposes to remove the regulatory text that codifies X waiver requirements, consistent with current law. SAMHSA notes that these changes will have no practical or legal effect on medical provider practices under existing law, as the waiver process has been ended in practice in accordance with the CAA 2023. ***Premier supports the codification of the X waiver removal, which ensures that the regulatory code complies with Congressional intent to improve access for medically necessary care. Further, Premier urges the Administration to work as expeditiously as possible to release guidance related to the new training requirements in the CAA 2023 for healthcare professionals registered to dispense controlled substances.***

VI. EVIDENCE-BASED DELIVERY AND DECISION-MAKING MODELS

SAMHSA proposes to update OTP requirements to add evidence-based delivery models of care, such as split dosing, telehealth and harm reduction activities, as clinically necessary and mutually agreed-upon. SAMHSA further proposes to define "harm reduction" activities for OTPs as practical, evidence-based strategies, including overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities to help address human immunodeficiency virus (HIV); distribution of opioid overdose reversal medications; linkage to other public health services and connecting those who have expressed interest in additional support to peer services.

Premier strongly supports SAMHSA's proposals to expand OTP services to include evidence-based care delivery models aligned with public health goals. Premier's data shows significant health disparities among patients diagnosed with OUD. For example, patients with OUD diagnosis are more likely to live below the poverty line than those without OUD (e.g., 66.9 percent versus 40.8 percent of ED outpatients and 47.5 percent versus 21.4 percent of inpatients were on Medicaid or uninsured).[8] Studies also show that 87 percent of people with OUD do not receive evidence-based treatment,[9] and there are significant demographic disparities in pain management and development and management of OUD.[10]

As new evidence-based care delivery models are implemented in the field, SAMHSA must work alongside other agencies across HHS to drive better standardization in the collection and use of SDOH data. In addition to leveraging our data capabilities to identify key health disparities among patients with OUD for targeted public health strategies, Premier's PINC AI Applied Sciences works with more than 4,400 health systems and the life sciences industry to support the collection and use of accurate equity-related data. Premier and our partners have witnessed firsthand how standardizing the collection and use of robust equity-related data has helped public health officials, clinical researchers and health systems to learn more about SDOH, including the impact on health outcomes, costs and healthcare resource utilization. Once we know what works to address health disparities among patients with OUD, we can work to scale solutions. Premier's PINC AI Health Equity Collaborative, for example, is just one learning collaborative model aimed at identifying best practices and then testing and scaling nationally.

VII. EXPEDITING PATIENT ACCESS TO OTPs

In the proposed rule, SAMHSA proposes revisions to treatment standards aimed at improving access to treatment, improving patient satisfaction and engagement in services and supporting use of clinical

[8] https://premierinc.com/newsroom/blog/pinc-ai-data-reveals-significant-health-disparities-among-patients-diagnosed-with-opioid-use-disorder
[9] https://www.sciencedirect.com/science/article/pii/S0955395922002031?via%3Dihub
[10] https://pubmed.ncbi.nlm.nih.gov/35179723/

judgment in decision-making. Among its proposals, SAMHSA removes from OTP admission criteria references to the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV and eliminates the requirement for patients to have a one-year history of OUD before admission. Instead, the proposed rule specifies that the individual should meet diagnostic criteria for active moderate to severe OUD, or be at high risk for recurrence or overdose. SAMHSA also proposes to remove the requirement that individuals under age 18 have two documented unsuccessful attempts at short-term withdrawal management ("detoxification") or drug-free treatment to be eligible for OTP treatment, and instead proposes to allow consent of a parent, legal guardian or responsible adult.

Premier supports the policies as proposed, which remove arbitrary barriers to care and allow more clinical autonomy for providers to chart a clinically appropriate treatment plan alongside the patient. Premier urges SAMHSA to provide clear guidance and technical assistance to providers during the regulatory implementation period – providers should feel comfortable discussing the most clinically appropriate course of treatment with patients with OUDs, rather than waiting for their disease state to worsen so that they will "qualify" for an OTP.

VIII. CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments on the Notice of Proposed Rulemaking modifying SAMHSA's regulations regarding medications for the treatment of OUD. If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the agency in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com or 334.318.5016.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.