

February 9, 2023

The Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD, 20857

RE: Proposed Rulemaking 42 CFR Part 8 Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)

To the Substance Abuse and Mental Health Services Administration (SAMHSA):

The Association for Multidisciplinary Education and Research in Substance use and Addiction (AMERSA) applauds SAMHSA's efforts to update federal regulations related to Medications for the Treatment of Opioid Use Disorder 42 Code of Federal Regulations (CFR) Part 8 Notification of Proposed Rule Making (NPRM).

AMERSA, founded in 1976, is a non-profit professional organization with a mission to improve health and well-being through interdisciplinary leadership and advocacy in substance use education, research, clinical care, and policy. Its membership consists of 450 experts in the field of addiction from multiple disciplines, including but not limited to, physicians, nurses, social workers, psychologists, dentists, pharmacists, and public health professionals. Many of us serve on the frontlines of the overdose crisis as federally funded scientists, teachers, treatment providers, and expert public health consultants, including to SAMHSA.

As an organization deeply committed to improving health and well-being among communities with substance use disorders, we have provided detailed comments on several topics related to the NPRM, as well as making several added considerations that are currently not included.

COMMENTS RELATED TO PROPOSED RULES BY TOPIC:

MAINTAIN AUDIO-ONLY TELEHEALTH FOR COUNSELING VISITS (42 CFR §8.12)

AMERSA supports the permanent provision of telehealth for both behavioral health and medical appointments in the OTP setting.

The new proposed changes require video-enabled telehealth for methadone treatments to avoid increasing methadone dosages for oversedated patients. As this concern is not applicable to counseling visits, we urge SAMSHA to support the permanent expansion for behavioral health appointments to take place by either audio- or video-based telehealth.

Under the state of emergency declared during COVID-19, a complex web of temporary changes enabled by payers, as well as by state and federal regulators, allowed OTP-based behavioral health (counseling) appointments to be conducted by video-based telehealth and, in some

cases, by audio-based telehealth.¹ However, federal regulations through the state of emergency maintained the requirement that medical intakes to OTPs for methadone treatment continue to occur in person, a requirement that curtailed enrollment into OTPs, especially during the early stages of the pandemic.² The provision of audio-only services (which do not require internet connectivity) for counseling has been documented to increase access to critical mental health services, especially for persons of color and low-income persons.³ Early studies of audio-only “telemental health” show similar effectiveness with face-to-face mental health care.⁴

In addition, we support regulatory changes to authorize medical intake and “annual physical” appointments at OTPs to take place by video-based telehealth platforms. The physical evaluation required to ensure safe methadone initiation is safety-oriented and need not be a comprehensive, head-to-toe, in-person exam. Practitioners can safely and effectively complete a medical intake for patients by video, while onsite staff gather vital sign and toxicology data, like visits in primary care settings. The results of research studies performed during the expansion of telehealth for MOUD services demonstrate decreased rates of opioid overdose and improved retention in care for those receiving telehealth services compared to those not receiving them.⁵ **We support the inclusion of OTPs in this expansion to further increase access to life-saving addiction services without undermining the quality of care.**

CLARIFY WHAT IS REQUIRED BY OTP PRACTITIONERS TO ENACT SPLIT DOSING (42 CFR §8.2 and §8.12)

AMERSA supports the expansion of split dosing for *all* OTP patients who, in the clinical judgment of the OTP practitioner, qualify for take-home doses. We further urge SAMSHA to clarify in its proposed changes that additional testing and submitting documentation for split dosing is not needed, as long as the OTP practitioner has made the clinical judgment and documented clearly in the medical record that the patient may benefit from split dosing.

Until now, split dosing has required the provider apply for an exception to SAMHSA, generally after having the patient undergo a peak and trough (P/T) laboratory measurement and then, only if the P/T demonstrates that they are a “rapid metabolizer” ($P/T > 2.0$). This process creates multiple barriers, including finding a laboratory that has the resources and expertise to perform this carefully timed measurement, the need for the patient to wait several hours while having two blood draws, and the administrative burden of applying for the exception. Pharmacokinetic studies support twice daily dosing in pregnant women based on their

¹ Busch AB, Sugarman DE, Horvitz LE, Greenfield SF. Telemedicine for treating mental health and substance use disorders: reflections since the pandemic. *Neuropsychopharmacol.* 2021;46(6):1068-1070. doi:10.1038/s41386-021-00960-4

² Joudrey PJ, Adams ZM, Bach P, et al. Methadone Access for Opioid Use Disorder During the COVID-19 Pandemic Within the United States and Canada. *JAMA Netw Open.* 2021;4(7):e2118223. doi:10.1001/jamanetworkopen.2021.18223

³ Kleinman RA, Sanches M. Impacts of Eliminating Audio-Only Care on Disparities in Telehealth Accessibility. *J GEN INTERN MED.* 2022;37(15):4021-4023. doi:10.1007/s11606-022-07570-w

⁴ Sugarman DE, Busch AB. Telemental health for clinical assessment and treatment. *BMJ.* 2023;380:e072398. doi:10.1136/bmj-2022-072398

⁵ Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* 2022;79(10):981-992. doi:10.1001/jamapsychiatry.2022.2284

increased metabolism and expanded blood volume.^{6,7} Studies show improved fetal measures⁸ and superior neonatal outcomes for pregnant women whose dose is split.⁹ Moreover, many non-pregnant patients also state they feel better when their dose is split,¹⁰ regardless of whether they are found by their peak/trough ratio to be “rapid metabolizers.”

In our clinical experience (including as frontline OTP practitioners), exemptions during COVID-19 that allowed split dosing improved patient care experiences, autonomy, and decreased the frequency and intensity of opioid withdrawal without leading to increased diversion or worse patient outcomes. The proposed changes clarify that split dosing is allowed but does not specifically state that OTP practitioners may prescribe split dosing for patients without the need for additional lab testing. This lack of clarity may function as an additional barrier if OTP practitioners mistakenly believe that additional testing is still required. **Further clarification should be added stating that additional lab testing and submission of paperwork to SAMHSA is not needed to approve split dosing.**

APPLY ENFORCEMENT MECHANISMS TO ENSURE EQUITABLE ACCESS TO TAKE-HOME DOSES (42 CFR §8.12)

AMERSA supports the removal of the eight take-home criteria to allow for clinician discretion if a patient may benefit from additional take-homes.

Researchers who evaluated the impact of methadone-related COVID-19 exemptions found that patients with increased take-homes had better treatment experiences and retention, while feared increases in diversion and methadone-related overdoses did not emerge.¹¹ However, not all patients experienced the benefit of increased take-homes during COVID-19, because not all clinics and states applied for these exemptions.

To ensure that all patients receive equitable access and support to take-homes, SAMHSA should re-examine their enforcement mechanisms and consider the addition of metrics examining take-home receipt in their OTP certification processes. For example, OTPs that have significantly low offerings of take-home doses could be flagged for additional auditing measures and to encourage OTPs to maintain equitable take-home access.

⁶ Bogen DL, Perel JM, Helsel JC, et al. Pharmacologic evidence to support clinical decision making for peripartum methadone treatment. *Psychopharmacology*. 2013;225(2):441-451. doi:10.1007/s00213-012-2833-7

⁷ Jarvis MA, Wu-Pong S, Kniseley JS, Schnoll SH. Alterations in methadone metabolism during late pregnancy. *J Addict Dis*. 1999;18(4):51-61. doi:10.1300/J069v18n04_05

⁸ Jansson LM, Dipietro JA, Velez M, Elko A, Knauer H, Kivlighan KT. Maternal methadone dosing schedule and fetal neurobehaviour. *J Matern Fetal Neonatal Med*. 2009;22(1):29-35. doi:10.1080/14767050802452291

⁹ McCarthy JJ, Leamon MH, Willits NH, Salo R. The Effect of Methadone Dose Regimen on Neonatal Abstinence Syndrome. *Journal of Addiction Medicine*. 2015;9(2):105. doi:[10.1097/ADM.0000000000000099](https://doi.org/10.1097/ADM.0000000000000099)

¹⁰ Haskew M, Wolff K, Dunn J, Bearn J. Patterns of adherence to oral methadone: Implications for prescribers. *Journal of Substance Abuse Treatment*. 2008;35(2):109-115. doi:10.1016/j.jsat.2007.08.013

¹¹ Krawczyk N, Rivera BD, Levin E, Dooling BCE. Synthesizing evidence on the impacts of COVID-19 regulatory changes on methadone treatment for opioid use disorder: Implications for U.S. federal policy. Published online December 16, 2022:2022.12.15.22283533. doi:10.1101/2022.12.15.22283533

EXPLICITLY DESCRIBE HOW NEW INTAKE RULES MAY BE APPLIED (42 CFR §8.12)

We applaud SAMHSA for clarifying the roles of screening and full examination for OTP intake in the proposed rule change (pasted below in italics). In addition, we further urge that SAMHSA explicitly describe how these rules apply to specific clinical scenarios such as care transitions from hospitals or non-OTP settings to OTPs.

Hospital-initiated methadone is an evidence-based strategy that can engage patients high-risk for overdose and other opioid-related death,¹² and more than double the likelihood of post-hospital treatment engagement.^{13,14} However, real-time linkages to methadone from hospital to post-hospital care are commonly hampered by long community wait-times for new patient intakes by an OTP-clinician. These delays happen despite current federal rules (42 CFR 8.12(f)) which permit OTPs to honor evaluations from “a primary care physician, or an authorized healthcare professional” (e.g., hospital physician). In states like Oregon, this means that a hospitalized patient who has started methadone during inpatient admission may have a 7-10 day wait-time to receive methadone after discharge, whereas in states like Massachusetts, patients routinely dose same- or next-day under a “direct admission status.” These disparities exist because of varied interpretations of current federal rules by State Opioid Treatment Authorities (SOTAs) across the country. **Clarifying how rules apply in these specific clinical scenarios will assure appropriate rule interpretation:**

“Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner. The above can facilitate timely care transitions from a hospital (or other non-OTP setting) to OTP, wherein a DEA-licensed hospital clinician performs initial OUD assessment and initiates methadone and supports same- or next-day linkage to OTP care wherein a patient can dose before completing full intake or OTP physician assessment. Another example of how this rule can support care transitions includes methadone initiation in withdrawal management or ambulatory settings, consistent with “72-hour rule” (21 CFR 1306.07).”

¹² King C, Cook R, Korthuis PT, Morris CD, Englander H. Causes of Death in the 12 Months After Hospital Discharge Among Patients With Opioid Use Disorder. *J Addict Med.* 2022;16(4):466-469. doi:10.1097/ADM.0000000000000915

¹³ Englander H, Dobbertin K, Lind BK, et al. Inpatient Addiction Medicine Consultation and Post-Hospital Substance Use Disorder Treatment Engagement: a Propensity-Matched Analysis. *J GEN INTERN MED.* Published online August 13, 2019. doi:10.1007/s11606-019-05251-9

¹⁴ Tierney HR, Rowe CL, Coffa DA, Sarnaik S, Coffin PO, Snyder HR. Inpatient Opioid Use Disorder Treatment by Generalists is Associated With Linkage to Opioid Treatment Programs After Discharge. *J Addict Med.* 2022;16(2):169-176. doi:10.1097/ADM.0000000000000851

EASE FIRST DAY DOSING RESTRICTIONS (42 CFR § 8.12)

We recognize that minimal changes were made to first day methadone dosing restrictions. We urge SAMHSA to address the subtherapeutic initial dosing of methadone in 42 CFR Part 8 by either eliminating restrictions on initial day dosing and deferring to clinician judgment, or providing further clarification in how higher doses, if clinically indicated and documented, could be enacted.

First day doses limiting to 40mg are not appropriate in the era with a ubiquitous fentanyl-contaminated drug supply. Many patients require higher initial and next day doses to avoid withdrawal and prevent treatment attrition.¹⁵ Rapid up-titration is also particularly important in later pregnancy, where patients initiating may need higher doses given their rapid methadone metabolism. The current proposed regulations, while clarifying that “*provision for higher doses if clinically indicated and documented in the patient’s record*”, are too vague and non-specific. It is unclear if higher than 30mg initial doses are allowed, or if “higher doses” means additional doses should be administered in 10-20 mg increments at several hour intervals. Lack of clarity will lead to higher doses being underutilized, leading to reduced treatment retention. The current practice at most OTPs is that patients, particularly pregnant patients, remain on subtherapeutic doses with a titration schedule that is not adjusted to meet the physiological needs of pregnancy, hence placing patients and pregnancies at risk. A complete abolition of any stated cap in any current or future rulemaking would empower providers to use their clinical judgment. If complete abolition is not possible, **SAMHSA should add further clarification to what is needed for OTP practitioners to provide higher first day doses to patients, as currently proposed changes are not sufficiently clear.**

ADDITIONAL SUGGESTIONS FOR PROPOSED CHANGES:

INCLUSION OF MEDICALLY LICENSED JAILS AND PRISONS AS LONG-TERM CARE FACILITIES (42 CFR §8.11(3))

Incarcerated individuals who use opioids have among the highest risk of overdose death,^{16,17} yet the proposed changes lack sufficient measures to facilitate methadone treatment within this population. Recent litigation and settlements by the Department of Justice have challenged inadequate access to OUD pharmacotherapy in jails, prisons, and long-term care facilities as a civil rights violation.¹⁸

Hospitals and long-term care facilities already have a waiver from OTP certification to administer methadone under 42 CFR §8.11. Extending that “hospital waiver” to correctional

¹⁵ Buresh M, Nahvi S, Steiger S, Weinstein ZM. Adapting methadone inductions to the fentanyl era. J Sub Abuse Treat. 2022 Oct;141:108832. doi: 10.1016/j.jsat.2022.108832. Epub 2022 Jun 27. PMID: 35870437.

¹⁶ Saloner B, Chang HY, Krawczyk N, et al. Predictive Modeling of Opioid Overdose Using Linked Statewide Medical and Criminal Justice Data. JAMA Psychiatry. 2020;77(11):1155-1162. doi:10.1001/jamapsychiatry.2020.1689

¹⁷ Jon Berg, Breaking The Cycle: Medication Assisted Treatment (MAT) In The Criminal Justice System, Substance Abuse and Mental Health Serv. Blog, 15 Mar. 2019, <https://blog.samhsa.gov/2019/03/15/breaking-the-cycle-medication-assisted-treatment-mat-in-the-criminaljustice-system>.

¹⁸ U.S. Attorney’s Office, District of Massachusetts, U. S. D. of J. (2022). U.S. Attorney Rollins Announces Correctional Facilities Statewide to Maintain All Medications for Opioid Use Disorder. [<https://www.justice.gov/usao-ma/pr/us-attorney-rollins-announces-correctional-facilities-statewide-maintain-all-medications>]

facilities (including prisons and jails) is an expedient and safe way to allow correctional facilities to provide legally compliant medical care.

To rapidly address the public health crisis of overdose mortality that disproportionately impacts justice-involved individuals, we recommend the following changes to the proposed rule (new language underlined):

42 CFR §8.11(3): Certification as an OTP under this part will not be required for the continuous medication treatment or withdrawal management of a patient who is admitted to a hospital or long-term care facility or an individual residing in a correctional facility (prison or jail) for the treatment of medical conditions other than OUD and who requires medication continuity or withdrawal management during the period of their stay in that ~~long-term care facility~~ when such treatment is permitted under applicable Federal law. The terms “long-term care facility” and “correctional facility” are is defined in § 8.2. Nothing in this section is intended to relieve ~~long-term care~~ these facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

A definition of qualifying correctional facilities should be added to 42 CFR §8.2, which would require the facility to have the necessary DEA registration to administer, store, and dispense scheduled prescription medications.

To align the waiver language for all three types of residential facilities, we removed the phrase “for the treatment of medical conditions other than OUD” regarding admitted patients and added “individuals residing” in qualifying facilities. Requiring that methadone administration inpatient be an “incidental adjunct” (secondary) to another medical condition does not make sense for a waiver expansion to jails and prisons. It is also unnecessary for long-term care facilities and hospitals. The DEA does not regulate the practice of medicine, so enforcing which patient condition is primary or secondary is simply not practical or feasible. A subsequent NPRM should eliminate references to this requirement also found in 21 CFR, Part 1306.07(c).

Much of the siloing of methadone treatment to OTPs was justified as being necessary to reduce diversion. Correctional facilities already have stricter diversion control infrastructure than hospitals as fully locked facilities with limited public access. Treating a jail differently than other facilities is not justified to reduce diversion.

Not all types of correctional facilities are expected to have the necessary staffing or structure to be able to administer all types of MOUD pharmacotherapy, and nothing in this rule change requires them to. They can still contract with a community OTP, or work with a mobile methadone unit to be able to offer MOUD in a collaborative arrangement. AMERSA supports reduced regulatory barriers to all those options as well. AMERSA also supports changes that will enable community pharmacies to collaborate with physicians, nurse practitioners, and physician assistants working in jails and prisons to offer all forms of OUD medication treatment. However, increasing OTP capacity in rural geographies through all these measures will take time as well as sufficient and sustained investments. Expanding the hospital waiver of OTP certification to jails and prisons is simply treating the people within these settings as deserving of the same medical care as those residing in other long-term care residential facilities.

Expanding the waiver of OTP certification will increase equitable access to OUD and opioid withdrawal treatment, deter the potential for civil rights violations, reduce the number of incarcerated people undergoing unnecessary forced tapers from evidence-

based treatment, all while decreasing the incidence of painful, untreated opioid withdrawal.

EASE PATHWAYS FOR OPENING NEW OPIOID TREATMENT PROGRAMS (42 CFR §8.3-8.6 and §8.11-8.15)

In the United States, where less than 20% of US counties have access to an OTP,¹⁹ the current limited supply of OTPs is insufficient to meet the demand for methadone treatment. Lack of access worsens patient outcomes, as patients accessing methadone treatment experience maximally disruptive care in OTP settings, such as having to drive long distances or face inclement weather to attend daily OTP visits with limited resources.²⁰

Existence of federal, state, and local regulations create extraneous barriers to opening and sustaining new OTPs and aspiring OTP clinics must apply for burdensome accreditation processes with SAMHSA, DEA, state regulatory health agencies, as well as often facing direct neighborhood opposition voicing “not in my backyard” sentiments. While SAMHSA and DEA have expressed interest in easing regulations for medication mobile units to expand access for existing OTPs, this pathway is insufficient. Implementation of mobile medication units are expensive, with costs for each unit estimated between \$250,000-500,000, plus additional requirements for the unit to return to/from the originating OTP daily, restricting community reach and impact.²¹

We urge SAMHSA to enact changes to ease or eliminate barriers for opening new OTP treatment programs.

For example, SAMHSA could extend the duration during which OTP certification is valid. SAMHSA could incentivize the opening of new OTPs through comprehensive federal funding opportunities and/or encourage operating new OTPs out of existing syringe service programs to help reduce costs of opening new facilities.

EXPAND METHADONE TREATMENT FOR OUD BEYOND OTP SETTINGS (42 CFR §8.12)

Allowing methadone treatment outside of OTP settings (e.g., allowing methadone prescribing in office-based settings or dispensing in community pharmacies) should be explored to further meet the urgent need of providing additional treatment access for patients with OUD.

As previously published, SAMHSA and the Drug Enforcement Administration (DEA) have the regulatory authority to allow methadone prescribing and dispensing to take place outside of OTPs.¹ Without expansion beyond the OTP setting, access to methadone for the treatment of OUD will remain limited due to geographic and rural disparities across the country, even with proposed changes in the above sections.

¹⁹ Duff JH, Carter JA. *Location of Medication-Assisted Treatment for Opioid Addiction: In Brief*. Congressional Research Service; 2019. <https://sgp.fas.org/crs/misc/R45782.pdf>

²⁰ Englander H, Gregg J, Levander XA. Envisioning Minimally Disruptive Opioid Use Disorder Care. *J Gen Intern Med*. Published online November 18, 2022:1-5. doi:10.1007/s11606-022-07939-x

²¹ El-Sabawi T, Baney M, Canzater SL, Weizman SR. The New Mobile Methadone Rules And What They Mean For Treatment Access. *Health Affairs Forefront*. doi:10.1377/forefront.20210727.942168

Central to a vision for a more accessible and equitable methadone treatment system are the principles that:

- 1) Methadone regulations should prioritize patient health over other concerns
- 2) Methadone should be available in all treatment settings and communities
- 3) The structure of methadone treatment should be determined by the patient in collaboration with their practitioner, with recommendations based on empirical evidence - consistent with how we approach other chronic diseases.

As such, we recommend the current methadone treatment system be expanded beyond OTP settings to include office-based methadone prescribing and dispensing in community pharmacies, as has been successfully implemented, standardized, and normalized in other countries including the UK, Australia, and Canada.^{22,23}

We urge SAMHSA to enact the following changes: 1) Work with the DEA to permit practitioners, including those in OTPs or in office-based settings, to prescribe methadone for OUD treatment. This should include any clinician authorized to prescribe controlled substances, as is the case with buprenorphine, or allow physicians with additional specialized addiction medicine training to do so in settings other than OTPs. 2) Permit methadone for OUD treatment to be dispensed by any pharmacy authorized to dispense controlled substances.

A model such as those described above would allow patients and clinicians to work together to determine the methadone treatment option that best fits a patient's needs, whether that means methadone dispensing and take-home doses at OTPs, methadone prescribing at OTPs, with pick up of doses at local pharmacies, or methadone prescribing by primary care and other non-specialist providers, with pick up of doses at local pharmacies.

CONCLUSION

Thank you again for your leadership and tireless work to finalize the proposed changes to 42 CFR Part 8, and for providing ongoing support to expanding treatment access which will affect hundreds of thousands of people across the country. If you have questions, or if our organization can be of further assistance, please contact Rebecca Northup at rebecca@amersa.org.

Sincerely,

Deborah S. Finnell, PhD, CARN-AP, FAAN
President, Association for Multidisciplinary Education and Research in Substance use and Addiction, on behalf of the 2022-2023 AMERSA Board of Directors

²² Calcaterra SL, Bach P, Chadi A, Chadi N, Kimmel SD, Morford KL and Samet JH. Methadone matters: what the United States can learn from the global effort to treat opioid addiction. *J Gen Int Med*. 2019. 34, 1039-1042.

²³ Board on Health Sciences Policy, Board on Health Care Services, Health and Medicine Division, Action Collaborative on Countering the U.S. Opioid Epidemic, National Academies of Sciences, Engineering, and Medicine. *Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop*. (Bain L, Norris SMP, Stroud C, eds.). National Academies Press; 2022:26635. doi:[10.17226/26635](https://doi.org/10.17226/26635)