February 13, 2023

Substance Abuse and Mental Health Services Administration (SAMHSA)
Department of Health and Human Services
Attention: SAMHSA – Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

Re: Comments on Notice of Proposed Rulemaking regarding Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)

Dear Assistant Secretary Delphin-Rittmon and Dr. Baillieu:

On behalf of the American Society of Addiction Medicine ("ASAM"), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction and co-occurring conditions, thank you for the opportunity to provide comments on proposed modifications to 42 C.F.R. Part 8 ("Part 8") in SAMHSA's notice of proposed rulemaking (87 Federal Reg. 77330) (the "NPRM"). ASAM advocates to reduce barriers to appropriate access to medications for opioid use disorder (MOUD) and optimize the quality of addiction care, including at opioid treatment programs (OTPs). Treatment with MOUD reduces illegal opioid use, the risk of overdose, symptoms of opioid use disorder (OUD), and risk of transmission of infectious disease. Treatment with MOUD also increases the chances a patient stays in treatment, which itself also reduces the risk of overdose, risk of transmission of infectious disease, and criminal legal involvement, and increases the chances of employment.[1] Therefore, ASAM strongly supports policy changes that facilitate effective treatment with MOUD, through patient-provider relationships that are an integrated core

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component of general healthcare and chronic disease management.[2]

The deadly role of fentanyl driving the rise of and disparities in overdoses and deaths in the United States demands urgency in policy responses, including expanding access to prevention, harm reduction, and addiction treatment services. The federal government's national drug control strategy aims to achieve universal access to MOUD throughout all health settings by 2025, including in federal prisons, and increase access by 50 percent in state prisons and local jails.[3] **Aligned with recent actions taken to achieve these goals, including the removal of the DATA 2000-waiver program in the Consolidated Appropriations Act, 2023 (the "CAA 2023"), ASAM urges SAMHSA to eliminate all references related to the former DATA 2000-waiver program; consider limiting the scope of its final rule to the dispensing of methadone for OUD (i.e., not "MOUD") as controlled medications in schedule III, IV, or V were explicitly carved out of Section 303(h) of the Controlled Substances Act under the CAA 2023; and adjust all cross-references, where appropriate, to account for all federal legislation passed in December 2022, prior to finalizing the rule.**

In this letter, ASAM also offers additional comments to the NPRM for SAMHSA's consideration, as further described below. These additional comments address areas where SAMHSA seeks comment and respond to the NPRM's stated objectives. If adopted, these comments will further encourage an approach to OUD within a chronic disease model of care and better align treatment with methadone for OUD with the practice of medicine by addiction specialist physicians.[4]

Executive Summary of Key Recommendations

With respect to SAMHSA's proposed continuation and enhancement of regulatory flexibilities beyond the COVID-19 public health emergency ("COVID PHE"), ASAM recommends in the first section that SAMHSA finalize proposals to remove time in treatment and abstinence requirements from unsupervised use criteria; allow for clinical consideration of unsupervised use of methadone when a patient enters treatment; allow for patient evaluations with audio-visual or audio-only telehealth for Schedule III addiction medications; and allow for patient evaluations with audio-visual telehealth for Schedule II addiction medications. ASAM further recommends that SAMHSA:

- Clarify that the unsupervised use criteria in § 8.12(i)(2) do not apply to buprenorphine and buprenorphine products;
- Permit patients in methadone treatment from 31 days of treatment to access up to a 30-day supply of methadone for unsupervised use, in lieu of 28 days;
- Modify § 8.12 so that it only applies to "unsupervised use" and "supply/doses of methadone for unsupervised use," considering the existence of technologies that allow for remote, supervised dosing; and
- Strike the proposal that would allow for audio-only devices for patient evaluations for treatment with Schedule II medications.

To expand access to and improve the quality of OTP treatment, in section three, ASAM recommends that SAMHSA finalize the proposals that provide that patient refusal of counseling shall not preclude them from receiving MOUD; allow for split dosing of methadone for pregnant patients; eliminate the one-year history of addiction prior to OTP admission; and allow for clinical consideration in initial dosing adjustments of methadone. ASAM additionally recommends that SAMHSA:

- Require initial physical health assessments to include universal or opt-out screening for hepatitis C virus;
- Clarify that additional laboratory testing and an administrative exception are not needed if the OTP practitioner has judged split dosing is clinically appropriate;
- Ensure that patients be informed that they have the right to refuse pregnancy testing and that the exercise of such right will not jeopardize their receipt of specialized services;
- Modify § 8.12(h)(3)(i) to ensure more availability of methadone formulation innovations (e.g., diskettes and tablets);
- Require OTPs to conduct patient surveys to assess patients' experiences; and
- Adjust the interim treatment period from 180 to 360 days and expand its use beyond public or nonprofit, private OTPs.

In section four, ASAM offers that the NPRM, as proposed, fails to provide access to MOUD for all individuals in confined settings who have a right to medically necessary care. Therefore, ASAM recommends that SAMHSA finalize the definition of long-term care facilities, with modifications to include local jails, and state and federal prisons, and further modify the proposals to expand the reach of these facilities. ASAM further recommends that SAMHSA finalize proposals to allow non-OTP practitioners and certain, other providers to provide various services, including allowing non-OTP practitioners to conduct the required initial medical examination of a patient.

To promote patient-practitioner relationships in an integrated system of collaborative care, ASAM recommends in section five that SAMHSA finalize the proposals to expand the definition of qualifying OTP practitioners, with modifications to account for the enactment of the CAA 2023. Importantly, ASAM strongly recommends that SAMHSA require OTP medical directors to have a minimum amount of experience in addiction treatment to ensure benefits and minimize harms to patients at OTPs. Further, ASAM recommends that SAMHSA:

- Clarify that a program remains eligible for OTP certification if it dispenses methadone in the treatment of OUD using **practitioners for prescribing, and appropriately licensed community pharmacists for administering or dispensing directly (but not prescribing), methadone from the stock of one or more community pharmacies that (i) will comply with standards established by the Attorney General respecting security of methadone stock and the maintenance of records on methadone and/or (ii) will obtain any necessary exceptions from the Attorney General.**

I. Continuing and Enhancing Regulatory Flexibility Beyond the COVID-19 PHE for Unsupervised Use of MOUD and Telehealth

Criteria for Unsupervised Use of MOUD (§ 8.12(i))

The NPRM recognizes that SAMHSA's regulations for OTPs have remained unchanged for over twenty years and that the COVID PHE has provided a growing body of research that demonstrates that certain regulatory flexibilities have facilitated greater access to methadone treatment for OUD. Part 8's current regulatory restrictions on unsupervised use of MOUD are a structural barrier to care as they require some patients to visit OTPs daily or nearly daily, disrupt employment[5] and other daily activities, and disproportionately impact individuals without access to transportation or with childcare responsibilities.

The NPRM notes that the flexibilities left patients feeling more respected as responsible individuals and references reports that there was no significant change in rates of diversion. In addition, the NPRM references a study showing increases in methadone-involved deaths during the COVID-19 pandemic were largely attributable to the increase in fentanyl-driven deaths.[6] **ASAM applauds the proposed revisions to the extent they remove from the unsupervised use criteria the required consideration of the length of time an individual has been in treatment, as well as absence of substance use, demonstrated by toxicology tests.[7] Similarly, ASAM supports SAMHSA's proposed revisions that would allow for unsupervised use of methadone when a patient enters treatment, based on the clinical judgment of the treating practitioner, and the requirement that patients be educated on safe transport and storage of medication.**

However, state regulators may easily misconstrue SAMHSA's proposed language to foreclose the clinical judgment of addiction specialist physicians and other practitioners well-trained in addiction medicine to calibrate when unsupervised use of buprenorphine should continue. Most buprenorphine is prescribed in office-based settings to patients who fill prescriptions at regular pharmacies in the U.S.,[8] and concerns over increased access to buprenorphine have been found to be largely unfounded.[9] Further, as noted above, the CAA 2023 has eliminated the x-waiver program and associated patient limits. **To align buprenorphine treatment in OTPs with buprenorphine treatment in other medical settings, ASAM recommends that the final rule make it clear that the unsupervised use criteria in § 8.12(i)(2) do not apply to buprenorphine and buprenorphine products; such clarification would be consistent with the existing exemption of buprenorphine and buprenorphine products from the dispensing restrictions in §8.12(i)(3)(i) through (iii).**

Schedule for Unsupervised Use of Methadone (§ 8.12(i)(3)(i) – (iii))

SAMHSA seeks comment on the proposed schedule for unsupervised use doses of methadone, which is, during the first 14 days of treatment, 7 days; from 31 days of treatment, 14 days, and from 31 days of treatment, 28 days, if clinical rationale is documented and consistent with good faith efforts to ensure patients are not receiving services at another OTP. ASAM submits that most states permit appropriately licensed practitioners to prescribe, dispense, and administer 30

days of Schedule II-controlled medications.[10] Thus, a reasonably foreseeable alternative[11] to the NPRM to improve patient engagement and retention in evidence-based treatment services would give patients of an OTP the opportunity to receive a supply of methadone for unsupervised use more like patients taking Schedule II medications do in other medical settings. **To that end, ASAM recommends that the final rule permit patients in methadone treatment from 31 days of treatment to access up to a 30-day supply of methadone for unsupervised use, in lieu of 28 days.** This recommended change would better align methadone treatment for OUD with the use of other prescription medications in a chronic disease model of care.

In addition, today, there are newer technologies that would allow for "take home" supply/use that is supervised. In other words, the terms "take home" and "unsupervised" are not necessarily synonymous. Furthermore, "unsupervised use" is the terminology used in applicable statute (21 U.S.C. 823(h)). SAMHSA, however, inconsistently uses the modifiers "take home" and "unsupervised" to describe the terms "use," "doses," and "supply," throughout the proposed §8.12. **Therefore, ASAM strongly recommends that SAMHSA explicitly acknowledge the existence of such technologies in the final rule; take their potential use into account when finalizing the final rule's language, and make global changes so that § 8.12 only applies to "unsupervised use" and "supply/doses of methadone for unsupervised use."**

Telehealth for Initiating Methadone and Buprenorphine Treatment (§ 8.2 (Definition of "Telehealth or telemedicine), § 8.12(f)(2)(B)(v))

The NPRM reviews evidence that telehealth is an important tool to integrate care, extends the reach of specialty providers, and results in patients receiving buprenorphine having a high level of satisfaction with telehealth services. ASAM concurs with SAMHSA that the evidence underlying the initiation of buprenorphine using telehealth translates, to some degree, to the treatment of OUD with methadone. Accordingly, ASAM largely supports permitting the use of telehealth to conduct the required two-part initial examination of a patient, including the screening and full examination, with appropriate guardrails as outlined in the proposal, and the inclusion of the proposed definition of telehealth in the NPRM.

Specifically, ASAM applauds SAMHSA's proposal to the extent it allows for audio-visual telehealth in evaluating patients for treatment with Schedule II addiction medications like methadone. However, ASAM does not support the proposal to the extent it would allow for audio-only devices for evaluating patients for treatment with Schedule II medications, even if the patient is in the presence of certain licensed practitioners, especially considering those practitioners can obtain access to audio-visual technologies.[12] If SAMHSA finalizes its audio-only proposal with respect to Schedule II medications, then, at a minimum, ASAM recommends that SAMHSA clarify what is exactly meant by "in the presence of a licensed practitioner who can *prescribe (including dispense) (emphasis added)* controlled medications," in § 8.12(f)(2)(B)(v)(A). For example, under the Controlled Substances Act, the term "dispensing" includes "prescribing." These terms can also mean different things under State law. **ASAM does support audio-only telehealth for patient evaluations for Schedule III addiction medications like buprenorphine.**[13]

II. Updating Certification and Expanding Medication Units (§ 8.2 (Definition of Conditional certification and Medication unit), § 8.11(a)(3)-(6), § 8.11(h)(2))

ASAM supports the proposed changes facilitating information sharing and updating the OTP certification process to reflect better practice, including the new proposed category creating a one-year temporary, conditional certification for an OTP that has sought certification renewal and received a temporary one-year accreditation, to address areas of non-conformance that are not immediate, high-risk health and/or safety concerns. As proposed, an OTP with such certification must obtain a standard three-year accreditation within one year. **ASAM also applauds the proposal to add one licensed physician with "experience treating OUD with MOUD," which would be added to accreditation body applicant's staff.**

ASAM notes that the proposed rule defines "Medication units" as "an entity that is established as part of, but geographically separate from, an OTP from which appropriate, licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit." **ASAM applauds that proposed definition, as well as the proposal to add that medication units can offer "any services that are provided in an OTP,"** "assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space."

III. Expanding Access to and Improving the Quality of OTP Services

Integrating Harm Reduction and Recovery Support Services (§ 8.2 (Definition of Harm reduction, Recovery support services), § 8.12(f)(4)(i), § 8.12(f)(5)(i))

The NPRM recognizes that definitions and paradigms of care for OUD have evolved over the past twenty years to become more multimodal and patient-centered, and successful treatment interventions are individualized and incorporate harm reduction and recovery support services. Accordingly, ASAM supports SAMHSA's proposed definitions and integration of harm reduction and recovery support services into the proposed rule, including the incorporation of such services into the required patient care plan, counseling and psychoeducational services of OTPs, and in the definition of "comprehensive treatment." **ASAM specifically applauds the proposed provision that provides that "Patient refusal of counseling shall not preclude them from receiving MOUD,"** as requiring that these services be accepted by all patients, especially early in care, can present a barrier to accessing OTP services for some patients.[14]

ASAM recommends that the definition of harm reduction be modified to reflect that the proposed regulatory definition specifies types of harm reduction interventions, rather than reflecting the philosophy of harm reduction. Thus, in § 8.2, the definition would be modified as follows, **"Harm reduction services include, but are not limited to,** practical, evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted

infections, and bacterial and fungal infections; 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."

The NPRM also provides that OTPs must provide specific counseling on HIV, hepatitis C virus (HCV), and other sexually transmitted infections (STIs), and linkage to treatment, for patients with positive OTP test results. A patient's admission to an OTP is an opportunity to maximize the benefit to public health, and incidence and prevalence of HCV infection have increased significantly because of increasing rates of injection drug use.[15] Universal or opt-out screening policies that test everyone allow individuals to choose whether to participate rather than self-disclose as a member of a risk-based group, and have been shown to result in earlier detection, reduced stigma, and increase the number of screened individuals.[16] **Accordingly, ASAM requests that SAMHSA include in OTP's initial physical health assessment required services,** "Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, **and universal or opt-out screening for hepatitis C virus (HCV)**," in § 8.12(f)(4)(i).

Including Housing, Shared Decision Making, and Split Dosing in OTP's Required Services (§ 8.2 (Definition of Split dosing), § 8.12(f)(3), § 8.12(f)(4))

ASAM's public policy statement on advancing racial justice in health care through addiction medicine recommends "healthcare settings should consider and address the social determinants of health—including housing, education, transportation, employment, and racism itself."[17] Accordingly, ASAM applauds SAMHSA's proposal to include "housing" as a key area to be addressed as part of treatment by OTP medical practitioners and the OTP multi-disciplinary team, as well as the proposal to include "shared decision making" in patient care plans, to improve care.

ASAM applauds the NPRM's proposals that provide a definition and the opportunity for split dosing of methadone for pregnant patients;[18] however, ASAM recommends that SAMHSA clarify that additional laboratory testing demonstrating a patient is a "rapid metabolizer" and the submission of administrative exception documentation are not required for the provision of split dosing to a patient. ASAM also applauds the proposal to require OTPs to provide reproductive health services for pregnant and postpartum patients.[19] It is important to recognize, however, that that the decision in *Dobbs v. Jackson Women's Health Organization* to overturn *Roe v. Wade* bears a disproportionate impact on pregnant people who use substances and that requiring documentation of pregnancy confirmation in one's medical record could cause fear among certain patients. **Therefore, ASAM recommends that SAMHSA make it clear in the final rule that patients be informed that they have the right to refuse pregnancy testing and that the exercise of such right will not jeopardize their receipt of specialized services.**

Revising Patient Admission Criteria and Individualizing Initial Dosing (§ 8.12(e)(4), § 8.12(f)(1), § 8.12(g)(1), and § 8.12(h)(3)(i))

The NPRM proposes amending certain elements of current regulations considering quickly changing trends in illegal substance supply and use, including the proliferation of fentanyl, methamphetamine, xylazine, and other substances, which impact treatment. **ASAM applauds the elimination of the one-year requirement for OUD before admission to an OTP when the patient "meets diagnostic criteria for moderate or severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose."** ASAM also supports the proposed rule's elimination of the requirement for two documented unsuccessful attempts at treatment within one year for individuals under 18 to be admitted to an OTP, as well as the requirement for their parents' consent to treatment in the absence of a requirement of state law.

ASAM applauds the proposal allowing for the use of clinical judgment in initial dosing adjustments above 40mg of methadone for patients if such a decision is documented in the patient's record. ASAM recommends further modification to accommodate OTPs that already utilize methadone formulated in diskettes or tablets,[20] and to allow for more OTPs to adapt to formulation innovations and for practitioners to individualize medication formulations for patients, by amending language in § 8.12(h)(3)(i) as follows: "Methadone shall be administered or dispensed only in oral form ~~and shall be formulated in such a way as to reduce its potential for parenteral misuse~~." **Further, ASAM recommends that SAMHSA clarify language in §8.12(h)(3)(ii) as follows:** "Should ~~this~~ **the initial 30 mg dose or total daily 40 mg dose be determined** not **to** be sufficient to suppress symptoms of withdrawal~~,~~ **by** the OTP practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, **they** must document in the patient's record a specific rationale indicating ~~that 40 milligrams did not adequately suppress opioid withdrawal symptoms, and~~ that a higher dose was clinically indicated and thus provided to the patient." ASAM also supports the proposed changes that tapering be provided to patients with informed consent and "at a mutually agreed-upon rate that minimizes taper-related risks," in § 8.12(e)(4).

ASAM submits that patient experience surveys[21] can inform policymakers' efforts to help build meaningful patient-provider relationships, establish effective and constructive communication, and develop care that is grounded in empathy and compassion.[22] **Therefore, ASAM further recommends that OTPs be required to conduct patient surveys to assess patients' experiences**. Furthermore, not all OTPs utilized, and not all states applied for, SAMHSA's blanket exemptions during the COVID-19 pandemic to provide methadone for unsupervised use and ease patients' access to treatment. **Thus, ASAM requests that the finalized rule include the following language**: "The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients, **and the program sponsor must ensure that patients are surveyed annually to assess their experiences with the OTP's required services, and the OTP's provision of methadone for unsupervised use**," in § 8.12(f)(1), and "OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care **and survey and evaluate patient experiences with the OTP's required services, and the OTP's provision of methadone for unsupervised use**," with the parallel reporting and confidentiality requirements, in § 8.12(g)(1). SAMHSA should ensure appropriate funding for, and develop a methodology and framework for, the OTP patient experience surveys and draw on the expertise

of the Centers for Medicare and Medicaid Services' (CMS) Outpatient and Ambulatory Survey (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) family of surveys for such development.[23]

Optimizing Interim Treatment with Methadone (§ 8.2 (Definition of Interim treatment), § 8.11(f)(1), § 8.11(f)(2)(iv), § 8.12(j)(1), § 8.12(j)(4))

Interim treatment with methadone has been found in randomized controlled trials to reduce illegal opioid use, criminal activity, and arrests, as well as increase engagement in comprehensive services, compared to wait list control groups,[24] yet interim treatment is still relatively uncommon in clinical practice.[25] **ASAM applauds the proposals to update the definition of interim treatment, remove the prohibition on unsupervised use for patients in interim treatment, and permit interim treatment for patients "if comprehensive services are not readily available," rather than "cannot be placed in a public or nonprofit private program."** ASAM further supports the newly proposed requirements for OTP practitioners treating patients in interim treatment with respect to patient transfers, documented plans for patient's treatment continuation, and the provision of crisis and ancillary services.

SAMHSA's specific request for comment on its proposed revision of the interim treatment period from 120 to 180 days indicates that the agency is contemplating a change to this period.[26] The NPRM's stated objective is to accommodate OTPs and states in addressing addiction care workforce shortages that are not easily resolved in 120 days and add an opportunity to the care continuum. The NPRM offers a one-year period for conditional certification and temporary accreditation for OTPs, to provide them an opportunity to resolve low-risk non-conformance issues. ASAM submits that addiction care workforce shortages are neither easily resolved, nor are OTPs opened, accredited, or certified, in 180 days. In fact, OTPs have expanded much more slowly than the growth of the prevalence of OUD and most U.S. counties have no OTPs.[27]

Reasonably foreseeable alternatives[28] to the NPRM would further extend the interim treatment period to align it with the conditional certification and temporary accreditation period for OTPs, and not continue to limit interim treatment to public or non-profit, private OTPs. **As such, ASAM recommends that SAMHSA adjust the interim treatment period from 180 to 360 days, to maximize the net public health and safety benefit of the final rule**, in § 8.2, § 8.11(f)(2)(iv), § 8.12(j)(1), and § 8.12(j)(4), respectively. **In addition, ASAM recommends SAMHSA remove the phrase "public or nonprofit, private"** from § 8.11(f)(1) and § 8.12(j)(1). Further, ASAM recommends to avoid redundancy, that SAMHSA remove the following language from § 8.12(j)(1), "Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws~~, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11)~~.

IV. Increasing Access to MOUD for Individuals in Confined Settings Who Have a Right to Medically Necessary Care (§ 8.2 (Definition of Long-term care facility); § 8.11(h)(3))

There is a growing recognition that the OTP certification process is a regulatory barrier for some institutions to implement methadone treatment for OUD for individuals who reside in confined settings and must be on premises to receive medically necessary care. The NPRM further acknowledges the heightened costs of overdoses and deaths in the absence of treatment with MOUD, which, if criminal legal costs are included, rise to savings of $25,000 to $105,000 in lifetime costs per person, compared with no treatment.[29]

The nearly two million individuals who are incarcerated in the U.S. have high rates of chronic diseases, including substance use disorder (SUD), yet only an estimated 12 percent of jails and prisons offer treatment with any MOUD.[30] Plaintiffs who are incarcerated have been granted injunctive relief by federal courts from inflexible policies that deny them access to medically necessary treatment, including methadone and buprenorphine for OUD, given likely violations of the Americans with Disabilities Act (ADA) and/or the Eighth Amendment to the U.S. Constitution's prohibition of cruel and unusual punishment,[31] yet a lack of access to methadone and buprenorphine treatment for OUD continues to be a challenge in many jails and prisons.[32]

Large numbers of disproportionately racially and ethnically marginalized individuals confined in jails and prisons are at high risk for overdose and death and have the right to medically necessary care.[33] The risk for overdose and death is particularly high for individuals when returning from incarceration,[34] and, in jails, is likely shortly after incarceration begins.[35] Alongside the federal government's goal to expand access to treatment with MOUD in jails and prisons, the Drug Enforcement Administration (DEA) has made recent regulatory changes that aim to expand MOUD in jails and prisons, through OTP mobile medication units,[36] but the expansion of said treatment is especially slow with methadone—in part due to SAMHSA's regulations. Further, jails and prisons frequently have substantial experience handling and preventing the diversion of controlled medications,[37] and salient to their budgets is that methadone is more cost effective as a generic medication than buprenorphine.

The NPRM proposes to define long-term care facilities by listing a range of facility types that can forgo the OTP certification requirement to provide treatment with MOUD for a patient who requires it and is admitted for a primary medical condition other than OUD. The NPRM fails to list local jails and state and federal prisons or specifically seek comment on the inclusion of certain institutions in the proposed definition of "long-term care facilities" that provide "rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living." **Thus, to correct this procedural harmless error,[38] ASAM recommends that SAMHSA finalize that definition in § 8.2 as follows, "those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; ~~and~~ chronic care hospitals, local jails, and state and federal prisons."** In addition, the final rule should make it clear

that if such facilities are registered with the DEA as a "hospital/clinic," then they do not need to obtain separate registration under 21 U.S.C. 823(h) to treat OUD with methadone for people admitted to a hospital or long-term care facility (including a jail or prison) for the treatment of medical conditions other than OUD.

Further, the NPRM states that SAMHSA intends to depart from the prescriptive model of care in its current regulations and revise them to align with the chronic disease model of care. However, the proposed rule fails to recognize that a patient with OUD can be admitted to a hospital or long-term care facility (including a jail or prison) for reasons other than the treatment of a medical condition secondary to OUD (e.g., incarceration for an alleged or committed crime). **Therefore, to correct the procedural harmless error,[39] ASAM recommends that the final rule also recognize that a patient with OUD can be admitted to a hospital or long-term care facility (including a jail or prison) for reasons other than the treatment of a medical condition secondary to OUD (e.g., incarceration for an alleged or committed crime) and that the Department of Health and Human Services (HHS) Secretary has the statutory authority to determine if an applicant is qualified to engage in methadone treatment of OUD as the primary medical condition and certify it as an OTP, even if the applicant does not meet all the requirements of § 8.12, subject to applicable DEA regulations regarding the security of such medications and related maintenance of records (or DEA-granted exceptions thereto).**

V. Promoting Patient-Practitioner Relationships in a System of Integrated, Collaborative Care

Ensuring Appropriate Training in Addiction Care at OTPs (§ 8.2 (Definition of Practitioner), § 8.12(b)(2), § 8.12(d))

Laws and regulations for MOUD have dramatically changed in the last twenty years, including the recent enactment of the CAA 2023, which expands the range of practitioners who can dispense (including prescribe) buprenorphine treatment for OUD. **ASAM applauds the NPRM's proposed expansion of the definition of a qualifying OTP practitioner, while recommending, below, codification of additional qualifications for OTP medical directors and reiterating the need to eliminate all references related to the former DATA 2000 waiver program.** ASAM also supports the proposed addition that all OTP healthcare providers maintain licensure and/or certification requirements of their respective professions.

ASAM concurs that it is likely that methadone-involved deaths during the COVID-19 pandemic were largely attributable to the increase in fentanyl-driven deaths.[40] Although ASAM notes (and raises questions[41] about) studies of methadone-involved deaths before and after the COVID-19 pandemic published subsequent to the NPRM, which point to a potential role of regulatory changes in the increase in methadone-involved deaths, ASAM agrees that proposed regulatory changes, as modified herein, should be finalized, albeit with continued monitoring for unintended consequences, in the absence of direct evidence of risk. **A reasonably foreseeable alternative[42] to the NPRM would consider sufficient training needed to oversee the provision of addiction care if a final rule were to expand who qualifies as an OTP practitioner, as proposed. Thus,**

ASAM requests that SAMHSA require such sufficient training in addiction treatment in regulation, rather than in SAMHSA's 2015 Federal Guidelines for Opioid Treatment Programs.[43] **Thus, at a minimum, ASAM recommends that SAMHSA finalize § 8.12(b)(2) to read as follows:** "The medical director shall assume responsibility for administering all medical and behavioral services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations. **The medical director must have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is strongly preferred."**

Integrating Non-OTP Providers to Create Patient-Centered Treatment (§ 8.12(f)((2))

Patients with SUD often encounter a siloed health care system that can impede access to care, requiring efforts to integrate services across the care continuum for effective treatment. As part of past pilot projects, some hospitals have accomplished a patient's OTP admission by having the OTP physician review the patient's physical examination performed by an addiction medicine consult physician seeing the patient in the hospital.[44] Therefore, **ASAM applauds the proposals in this section to allow non-OTP practitioners and other providers, with documented agreements with OTPs, to provide various services, including allowing non-OTP practitioners to conduct the required initial medical examination of a patient**, comprised of two parts: the screening examination and the full history and examination, with the proposed guardrails outlined in the NPRM. Further, ASAM recommends that SAMHSA, to facilitate timely patient transitions between other settings and OTPs, further clarify in § 8.12(f)((2)(B)(ii) that, "Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. **The intent is for patient transitions from other settings to OTPs to be timely and for treatment with MOUD to be continuous**."

Dispensing Methadone at Community Pharmacies (§ 8.11(a)(1) and § 8.12(h)(1))

The NPRM specifies that "OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law." **As the NPRM explicitly states, "to accommodate variations among states," the NPRM proposes to eliminate the requirement in the current § 8.12(h)(1) that the agent be a "pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs."** ASAM submits that states allow for most controlled medications, including methadone for pain, to be dispensed at pharmacies from pharmacy stock.

To better achieve SAMHSA's objectives to so accommodate states, promote patients' recovery behaviors like sustained employment, and support patients who live long distances from OTPs, **a reasonably foreseeable alternative**[45] **to the NPRM's proposals would be to permit a pharmacist**

to dispense methadone for OUD to patients from community pharmacy stock if certain standards were met.[46] Therefore, ASAM recommends SAMHSA finalize § 8.11 (a)(1) to read as follows, which includes language that would help avoid an overinclusive final rule:[47]

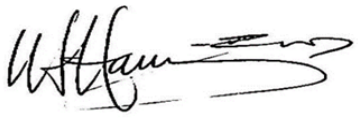
"An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(~~g~~h) of the Controlled Substances Act (21 U.S.C. 823(~~g~~h)) to dispense methadone ~~MOUD~~ in the treatment of OUD, **which, for the avoidance of doubt, may include a program that dispenses methadone in the treatment of OUD using practitioners for prescribing, and appropriately licensed community pharmacists for administering or dispensing directly (but not prescribing), methadone from the stock of one or more community pharmacies that (i) will comply with standards established by the Attorney General respecting security of methadone stock and the maintenance of records on methadone and/or (ii) will obtain any necessary exceptions from the Attorney General.** An OTP must be determined to be qualified under section 303(~~g~~h)~~(1)~~ of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(~~g~~h)~~(1)~~, to be registered by the Attorney General to dispense methadone ~~MOUD~~ to individuals for treatment of OUD."

VI. Global Changes to Language in the Proposed Rule

The NPRM proposes to use language in the final rule that reflects modern medical terminology and person-first language. **ASAM applauds the proposed terminology changes from "medication-assisted treatment" to "medications for opioid use disorder"; from "maintenance" to "continuous medication treatment," and from "detoxification" to "withdrawal management."** However, the NPRM also proposes global changes to language regarding from whom necessary approvals of various items are required. **ASAM strongly recommends that SAMHSA reviews these proposed changes and ensures that the final rule is consistent with references that designate from whom various approvals must be obtained and explains the rationale for such changes**.

In conclusion, ASAM is grateful for SAMHSA's thoughtful NPRM. The NPRM presents an unprecedented vision for expanding access to MOUD and improving the quality of addiction care, especially care that is provided by OTPs. ASAM will continue to advocate for cautious policy changes that facilitate effective treatment with MOUD and reduce structural barriers to care for individuals made vulnerable by inequities created by personal, institutional, and systemic mechanisms. If you have any questions or concerns, then please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org or at 301-547-4111.

Sincerely,



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President, American Society of Addiction Medicine

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[11] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
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[24] See ASAM, "Regulation of the Treatment of Opioid Use Disorder with Methadone."
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[26] Courts will uphold a final rule if the NPRM expressly asks for comment on a particular issue and the agency modifies its final rule based on comments – this is the simplest expression of the logical outgrowth doctrine. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
[27] See ASAM, "Regulation of the Treatment of Opioid Use Disorder with Methadone."
[28] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
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[38] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. In some cases, a court will affirm an agency's final rule, even when the final rule is not a logical outgrowth if the result of the final rule is a harmless error. Harmless error stems from the judicial review

provision in section 706 of the Administrative Procedures Act (5 U.S.C. § 3 706). A party claiming error on the part of an agency must state a prejudicial harm has flown from the error for a harmless error to have occurred. A harmless error is not substantive or does not affect parties' "substantial rights." See Lifton, Henry. (2017). "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92. 2(943). https://scholarship.law.nd.edu/ndlr/vol92/iss2/9. See also: Jurrens, Cannon. (2021). "The Not-so Harmless Error Rule: Applying 706 of the APA in A More Effective Matter." Administrative Law Review Accord. 6:4 (289-314). https://administrativelawreview.org/wp-content/uploads/sites/2/2021/11/Accord_6.4_Jurrens_Final.pdf.

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[40] Jones, et al., find that methadone-involved overdose deaths remained similar before and after March 2020, and that an increase in methadone-involved overdose deaths in March 2020 was largely attributable to the increase in fentanyl driven deaths, rather than regulatory changes to OTP practices. See Jones, Christopher M., Wilson M. Compton, Beth Han, Grant Baldwin, and Nora D. Volkow. "Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs." JAMA Psychiatry 79, no. 9 (September 1, 2022): 932–34. https://doi.org/10.1001/jamapsychiatry.2022.1776.

[41] Two recent studies highlight that there were increases in methadone-involved deaths in 2020 and raise questions about the role of the regulatory changes to OTP practices in the increase in methadone-involved deaths. However, both studies' authors identify significant limitations of their study in demonstrating direct causality. Kleinman, et al., highlights that there were increases in methadone-involved overdose deaths both with and without synthetic opioid co-involvement in the 12-month period after March 2020, compared with prior trends. Another study by Kaufman, et al., also identifies an increase in methadone overdoses in 2020 relative to 2019, while examining the methadone-involved unintentional overdose rate from 1999 to 2020. Kleinman, et al.'s study has several limitations, including that its model may be biased, because the study examines data from a significant time period from before the beginning of the pandemic (January 2007- March 2020), and a small time period from after the beginning of the pandemic (March 2020- March 2021). This is despite the availability of additional provisional overdose death data after March 2021, when methadone-involved deaths stabilized. Kaufman, et al. offer in their study that confounding policy changes could account for the increase in overdoses, including reduced urinalysis and the use of telehealth, or that methadone's long half-life could result in it being increasingly preferentially listed on death certificates, instead of more rapidly eliminated, or more obscure substances. The Kleinman, et al. and Kaufman et al. studies both also generate a statistic from SAMHSA's 2019 and 2020 National Survey on Substance Abuse Treatment Services (N-SSATS) Data on Substance Abuse Treatment Facilities, to indicate that the number of patients receiving methadone in the U.S. was reduced by 24% from 2019 to 2020, from 408,550 to 311,531. However, the N-SSATS surveys gathered data on March 29, 2019, and March 31, 2020, respectively, in other words, the 2020 N-SSATS survey census was taken on one day at the height of the beginning of the pandemic. Furthermore, a census of OTPs conducted by the National Substance Abuse and Drug and Alcohol Dependence (NASADAD) and American Association for the Treatment of Opioid Use Disorder (AATOD) between April and December 2021, found 476,763 patients treated with methadone at OTPs in 2021. See Kleinman, Robert A., and Marcos Sanches. "Methadone-Involved Overdose Deaths in the United States before and during the COVID-19 Pandemic." Drug and Alcohol Dependence 242 (January 1, 2023): 109703. https://doi.org/10.1016/j.drugalcdep.2022.109703. See also Kaufman, Daniel E., Amy L. Kennalley, Kenneth L. McCall, and Brian J. Piper. "Examination of Methadone Involved Overdoses during the COVID-19 Pandemic." Forensic Science International 344 (January 31, 2023): 111579. https://doi.org/10.1016/j.forsciint.2023.111579. See also National Association of State Alcohol and Drug Abuse Directors, and American Association for the Treatment of Opioid Dependence. "TECHNICAL BRIEF: CENSUS OF OPIOID TREATMENT PROGRAMS | NASADAD," December 5, 2022. https://nasadad.org/2022/12/technical-brief-census-of-opioid-treatment-programs/.

[42] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.

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[47] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a logical outgrowth failure when the final rule covers a broader scope than originally proposed. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.