February 10, 2023

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

RE: RIN 0930-AA39, Notice of Proposed Rulemaking, 42 CFR Part 8

Dear Dr. Delphin-Rittmon:

The Pew Charitable Trusts (Pew) is an independent, nonpartisan research and policy organization. Through its Substance Use Prevention and Treatment Initiative, Pew works with states and at the federal level to address the nation's opioid overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

On December 16, 2022, the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed updating the regulations at 42 CFR part 8. (*See* RIN 0930–AA39). These proposed regulations advance practitioner autonomy, remove stigmatizing language, center patient perspectives, and work to reduce barriers to OUD treatment.

The 42 CFR part 8 rule changes will maintain and improve access to OUD treatment by promoting effective and expansive treatment in opioid treatment programs (OTPs). The proposed rule:

- Updates definitions to reduce stigma and clarify important terms;
- Extends the length of interim treatment and allows medication units to provide a full range of services;
- Changes several treatment standards to improve access to patient-centered care and support providers in exercising their clinical judgement; and
- Aims to improve how patients access and experience treatment by permanently allowing extended methadone take homes, adding flexibility to telehealth rules, centering individualized patient care plans, and removing counseling requirements for receiving medication.

Pew submits the following comments and recommendations on the proposed rules for consideration by SAMHSA.

§ 8.1 Scope – Pew supports changing "medication assisted treatment" to "medications for opioid use disorder."

As stated in the notice of proposed rulemaking, the term MOUD is more precise, less stigmatizing, aligned with treatment approaches for other conditions, and acknowledges MOUD as a critical part of treatment, not simply an adjunct or support in treatment. The National Institute on Drug Abuse (NIDA) endorses the use of the term MOUD to reduce stigma.[1] NIDA states that the term MAT suggests that these medications play a temporary or supplemental part in treatment, whereas the term MOUD highlights the importance of these medications and their central role in a patient's treatment.[2] Further, NIDA states that the term MOUD is in alignment with how other psychiatric medications are treated – as critical tools for treatment.[3]

§ 8.2 Definitions – SAMHSA should revise the definitions of comprehensive treatment, harm reduction and long-term care facilities.

The definition of comprehensive treatment should allow for medication alone

Pew recommends that SAMHSA add to the proposed definition a statement acknowledging that medication alone may constitute comprehensive treatment when needed based on an assessment of the patient and the establishment of a patient-centered care plan. This would complement interim treatment, discussed below, which offers medication alone even if the patient would benefit from other services which are not available due to insufficient treatment capacity.

Elsewhere in the proposed rule, SAMHSA clarifies that OTPs are required to "provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling" (8.12.(f)(5)). Further, the proposed rule states that "Patient refusal of counseling shall not preclude them from receiving MOUD" (8.12.(f)(5)).

Updating the definition would align with these other changes and prevent confusion from OTPs, state regulators and accreditation bodies regarding whether providers are considered compliant when serving patients who do not want or require services other than medication, such as counseling or recovery supports.

These proposed changes are based on a body of evidence which has found that medication alone can be effective for OUD, and that strict counseling requirements can reduce retention in care.[4]

The definition of harm reduction should be revised so that OTPs can offer a range of services to meet the needs of their clients

Pew recommends that SAMHSA revise the definition of harm reduction. It should start by defining the concept of harm reduction and then listing potential services. The definition should be clear that providers are not limited to offering those services explicitly named in the rule. This is the approach used when defining recovery elsewhere in the section.

Pew supports the addition of harm reduction to the services delivered in OTPs. However, the proposed narrow definition may be interpreted to restrict OTPs to providing only the services listed. This limits the ability of providers to offer new and necessary harm reduction services to their patients as the landscape of drug use changes. For example, fentanyl test strips and drug checking services are not included, and mitigation activities for viruses other than those explicitly mentioned in the rules are also omitted.

Elsewhere, SAMHSA has capably defined harm reduction as "an approach that emphasizes engaging directly with people who use drugs to prevent overdose and infectious disease transmission, improve the physical, mental, and social wellbeing of those served, and offer low-threshold options for accessing substance use disorder treatment and other health care services."[5] This definition should be incorporated into the OTP rules.

The definition of long-term care facilities should be expanded to include correctional settings.

SAMHSA should expressly allow jails and prisons to qualify as long-term care facilities and permit the dispensing of methadone for patients with OUD.

Under current regulations, correctional facilities must jump through bureaucratic hoops and pay significant costs to become designated and certified as OTPs, despite some facilities having staffing and service capabilities to provide medical care on site. Further, many correctional facilities lack the additional staff and time needed to complete the onerous process to become an OTP.

The most recent data available (2007-2009) showed that more than half of individuals in state prisons or those with jail sentences met the criteria for SUD.[6] Research also demonstrates that individuals who are incarcerated with OUD have higher rates of fatal overdose upon release than the general population, but providing MOUD during incarceration can dramatically reduce post-incarceration deaths.[7] Therefore, it is important to remove bureaucratic barriers so jails and prisons can easily provide MOUD. MOUD is the standard of care regardless of the treatment setting. The FDA approved medications include methadone, buprenorphine, and naltrexone, of which methadone has been used for decades to effectively treat opioid addiction. However, jails and prisons rarely provide methadone to individuals who need this treatment, and when they offer methadone, it is often only available to certain subsets of the population, such as pregnant individuals or people close to their release date.[8] In a survey of prison officials from 18 states, more than half cited [9]OBJ

SAMHSA could reduce this barrier and improve patient outcomes by allowing correctional facilities with existing medical service capabilities to dispense methadone in the same way as other long-term care facilities.

§ 8.11(f) Pew supports the extension of interim treatment from 120 to 180 days but recommends that SAMHSA revise the proposed rule to make for-profit OTPs eligible providers of interim treatment.

A 2018 survey found that over 1 in 10 OTPs had a waiting list at the time the survey was fielded.[10] Under current federal rules, these providers have the option of offering interim

treatment to individuals seeking care without requiring the delivery of comprehensive services, which multiple studies show to be safe and effective.[11]

Extending the duration of interim treatment will help patients living in areas served by OTPs with wait lists to access life-saving care in a timely manner.

However, the proposed rule, like the current regulations, lists only public and private nonprofit OTPs as eligible providers of interim treatment. Based on data from the SAMHSA treatment locator tool, for-profit OTPs make up the majority (67%) of all sites.[12] Prohibiting for-profit OTPs from offering interim treatment prevents people living in the areas they serve from accessing timely initiation of MOUD.

§ 8.11(h) - Pew supports language that allows medication units to provide the same services as OTPs

Pew supports the proposed definition of medication units found in § 8.2 and concurs with the clarification that medication units can be mobile units. Pew also supports § 8.11(h)(2) which states that medication units may provide any services that are provided in an OTP, assuming compliance with applicable laws and appropriate privacy and space.

These changes will help fill treatment gaps for people in rural areas and in other locations with limited access to treatment.

§ 8.12 – Pew supports changes to treatment standards which improve access to patient-centered care and allows providers to exercise their clinical judgement
§ 8.12(e)(1) Comprehensive Treatment: Pew supports the proposed changes to remove the requirements for a 1-year history of OUD prior to admission to an OTP

Delays in initiating opioid agonist treatment are associated with increased risks of multiple negative outcomes including death, infectious disease transmission, and criminal activity.[13] SAMHSA's proposed change will reduce these risks by removing an arbitrary barrier to care and substituting the more appropriate clinical judgement of the OTP provider.

§ 8.12(e)(2) Comprehensive treatment for persons under age 18: Pew supports the proposed removal of a requirement for two "failed" treatment attempts prior to admission

Both the American Academy of Pediatrics and the Society for Adolescent Health and Medicine have recommended MOUD as the standard of care for youth with OUD.[14]

Fatal overdoses among adolescents are rising, yet rates of MOUD receipt are low in this population.[15] Removing the requirement for two failed treatment attempts prior to admission for an OTP will remove one barrier to effective, evidence-based care for youth.

§ 8.12(f)(2)(v) – Pew supports the use of telehealth for initial medical examination at OTPs

Pew supports the addition of § 8.12(f)(2)(v) that allows screening and full examination for treatment with buprenorphine or methadone to be completed via telehealth. Further, Pew supports the use of audio-only platforms for evaluation of patients for treatment with schedule

III medications (such as buprenorphine). Pew also supports § 8.12(f)(2)(v)(A), which allows for the audio-only evaluation for schedule II medications (such as methadone).

For schedule II medications, § 8.12(f)(2)(v)(A) states that audio-only devices may be used when audio-visual telehealth platforms are not available to the patient and must be provided in the presence of a licensed practitioner registered to prescribe and dispense controlled medications. While acknowledging the lack of research on audio-only provision of schedule II medications, Pew asks the agency to consider alternatives to this requirement to maximize access to all types of MOUD, improve access parity for buprenorphine and methadone, reduce stigma around methadone use, and promote practitioner autonomy. For example, practitioners could be allowed to seek a waiver for individual cases in which audio-only evaluation is the only way the patient can access services and the lack of availability of a licensed practitioner registered to prescribe and dispense controlled medications in the patient's presence creates a barrier to access.

Providing MOUD via telehealth increases access to treatment for historically underserved populations and helps patients start and stay in treatment.[16] Audio-only telehealth is incredibly important in reaching the millions of Americans who do not have broadband internet access, many of whom are racial and ethnic minorities, people with limited English proficiency, and older adults.[17]

§ 8.12(f)(4)(i) – Pew supports inclusion of screening for imminent risk of harm to self in initial assessment at OTPs

Pew supports the addition of § 8.12(f)(4)(i) requiring that an individual starting treatment at an OTP to be screened for imminent risk of harm to self and referred to appropriate care.

Research shows that individuals with substance use disorders are often at increased risk for suicide mortality.[18] Data indicates that utilizing evidence-based screening tools can effectively help identify individuals experiencing suicidal thoughts or behaviors.[19] Evidence shows a combination of risk identification and follow up interventions can reduce suicide attempts.[20]

§ 8.12(f)(5)(i) - Pew supports SAMHSA's clarification that access to medication is not contingent upon receiving counseling

As discussed in § 8.2 above, medication alone can be effective for treating opioid use disorder. SAMSHA's proposed clarification will reduce confusion among providers and state regulators as to whether OTPs can continue to serve clients who do not participate in counseling services. This important clarification may also spur changes in the states – all of which currently allow programs to administratively discharge patients for not participating in ancillary services, and 23 of which impose a set counseling schedule.[21]

§ 8.12(h)(4)(i) SAMHSA's proposed take-home rules expand patient autonomy, but the requirement that patients not have an active substance use disorder to receive the take home medications should be removed

SAMHSA proposes rules which would permanently allow OTP patients to receive 14-28 days of take-home medication early in treatment – an extension of flexibility extended during the COVID-19 pandemic.

Studies on the effects of these emergency flexibility measures provide strong empirical support for making them permanent. A review of the literature recently published on a pre-print server and forthcoming in *Lancet Public Health* examined 29 relevant articles and found that:

- Despite some providers reporting concerns that the take home flexibilities would increase diversion and overdose risk, the studies examined did not find major changes in methadone non-compliance (as measured by urine drug screens) or methadone-related overdose fatalities.
- The additional take home doses benefited patients in multiple ways:
    - Study authors report that "many patients described that receiving increased take-homes and being given the responsibility to manage their medication resulted in feelings of pride, accomplishment and self-confidence that supported treatment goals and sobriety, and helped build a stronger relationship with their providers."
    - Patients experienced practical benefits as well. Not having daily clinic visits allowed them to better manage their other responsibilities like employment, education, and child-care.
- Many providers valued the flexibilities, citing the ability to establish patient-centered care plans that meet the needs of the individuals in their care.[22]

Given this research base, SAMHSA's proposed rule to permanently allow up to 28 days of take-home doses early in treatment will help OTPs better serve their clients.

However, while the proposed rules no longer prohibit people who have recently "abused" drugs from receiving take homes, the rule still restricts people with an active substance use disorder (SUD) from receiving these doses.

Polysubstance use disorder among people with OUD is common. One study of Medicaid enrollees in four states estimated that among people with OUD, more than half had a co-occurring substance use disorder.[23] While in some cases another active SUD may impede the ability of an individual to safely manage take homes, that will not be true for all patients.[24] Elsewhere in the criteria, SAMHSA defers to the clinical judgement of the OTP provider and urges care decisions to be based on the needs of the individual patient. The same standard should be used here.

Subpart F – Pew recommends updating this Subpart to reflect changes made by Congress
The practitioner eligibility requirement should be amended to reflect the changes mandated by Congress.

Sec. 1262. of the Consolidated Appropriations Act of 2023 (P.L. 117-328 (2022), also known as the Omnibus bill) eliminates the requirement that health care practitioners registered to dispense controlled substances must also apply for a separate waiver (known as the X Waiver) through the DEA to dispense buprenorphine for opioid use disorder maintenance or

detoxification treatment and eliminates the cap on the number of patients a prescriber can treat for opioid use disorder.

Recommendations for implementation:

SAMHSA should offer guidance on implementing the proposed rules

The proposed rules make significant, much-needed changes to how care is delivered in OTPs. Providers and their state regulators, the State Opioid Treatment Authorities, will need SAMHSA's support and guidance in understanding how the rules should be implemented at the clinic level.

To provide this support, SAMHSA should update the *Federal Guidelines for Opioid Treatment Programs*, last updated in 2015.

Pew recommends the following priorities for the updated guidelines:

1. **Extended take-homes:** The new guidelines should help providers understand the importance of offering extended take-home doses to patients who can manage them safely. A narrative review on the temporary COVID-era flexibilities found multiple studies showing that clinics did not always provide extended take home medication, and that patients sometimes regarded decisions about who received these doses as unfair.[25]
2. **Patient-centered care plans:** Guidance will also be needed to help providers understand the expectations for patient-centered care plans, including the need to continue medication without requiring burdensome daily visits simply because a patient declines counseling and other ancillary services or has positive drug screens.
3. **Screening and referral for self-harm and harm to others:** OTP providers will need guidance on how to screen and refer patients effectively and safely for risk of self-harm and harm to others. Pew urges SAMHSA to issue guidelines on evidence-based suicide screening tools, interventions, and referrals for care for individuals who are identified as experiencing suicidality.
4. **Harm reduction and recovery support services:** The updated guidelines should help providers understand how to incorporate harm reduction and recovery support services into clinical care, including through partnerships with other organizations.
5. **Providing services in jails and prisons:** Specific guidance is needed on how OTPs and others can effectively provide care to people who are incarcerated, and how these facilities can create partnerships and divide roles and responsibilities in a way that is compliant with federal law.

SAMHSA should evaluate the implementation and impact of the proposed rules

Research conducted on the COVID-related flexibilities found that not all clinics implemented them.[26] Given the uneven distribution of OTPs across the country, many clients do not have the option of finding another provider if their available OTP continues to require non-evidence-based practices like limited take-home doses and mandatory counseling.[27] Data collection and ongoing evaluation are needed to understand:

- The extent to which providers adopt the new approach to care;

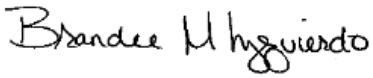
- Unequal access to patient-centered care, including extended take-homes, by race/ethnicity, geography, disability status, and other factors;
- Barriers to implementing new approaches, which may include provider attitudes, discrimination, state regulations, payment models, or accreditation standards; and
- The impact of the changes on initiation and retention in treatment and patient satisfaction.

SAMHSA should work with accrediting bodies to ensure that accreditation standards are updated to reflect the new rules

In both the current and proposed rules, SAMHSA delegates the responsibility for ensuring that OTPs offer care aligned with the standards set in regulation to accrediting bodies. To ensure that these bodies adjust their own standards appropriately, SAMHSA should work closely with them to help them understand the new guidelines and develop methods for assessing whether OTPs meet them.

Thank you for the opportunity to comment on these important regulatory changes. Should you have any questions, please contact David Wallace at dwallace@pewtrusts.org.

Respectfully,



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