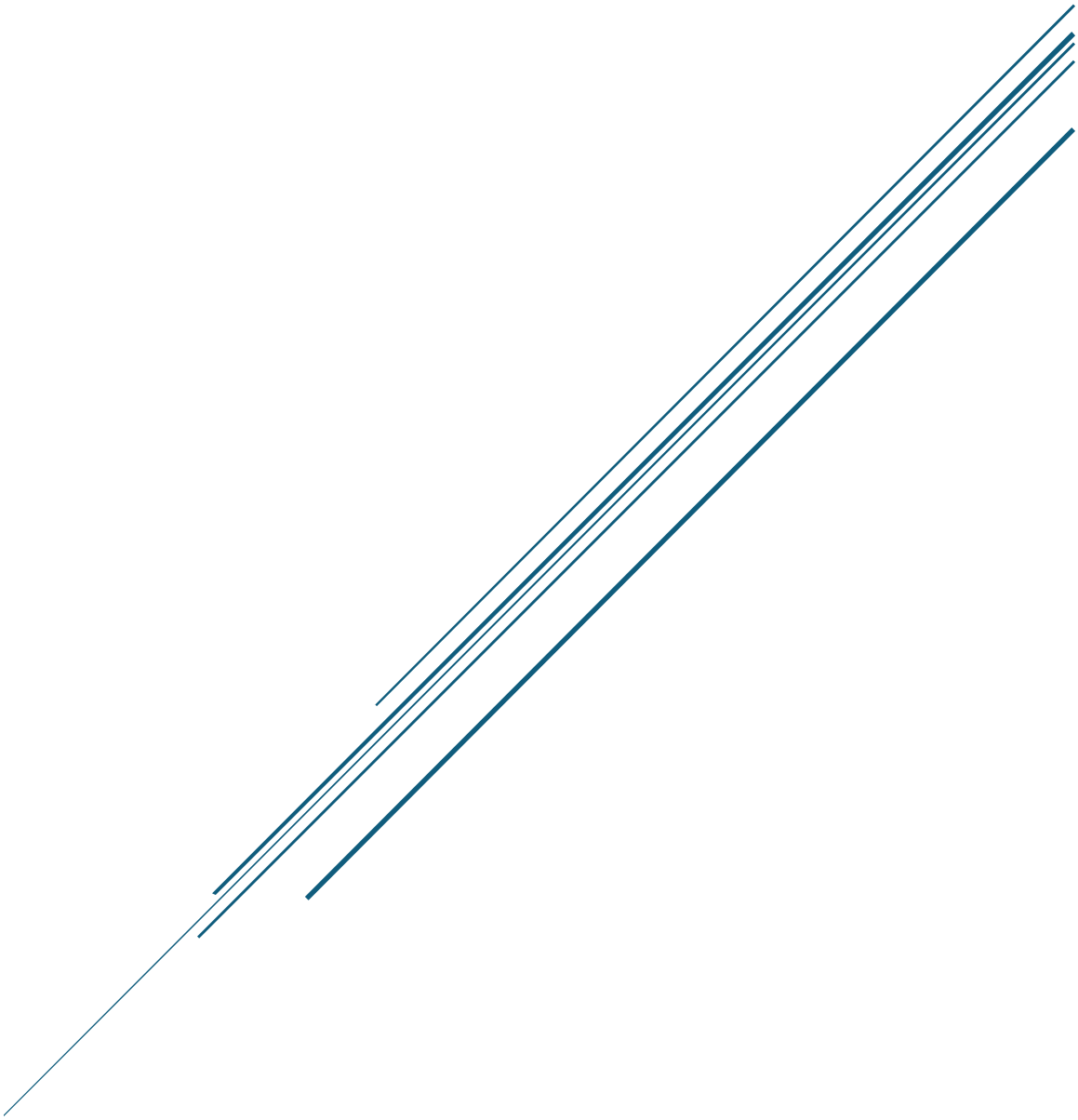
TECHNICAL REVIEW OF SAMHSA'S FINAL REGULATIONS



March 8, 2024

Introduction

AATOD is providing an overview of the final regulations, which were issued by SAMHSA on February 13, 2024. The following comments follow along the text of the final rule and we also reference our correspondence to Dr. Robert Baillieu (Physician and Senior Advisor to SAMHSA/CSAT) dated February 10, 2023 (see attached). This correspondence responds to the Notice for Proposed Rulemaking, which SAMHSA released on December 16, 2022.

In commenting on the final rule, you should note that SAMHSA responded favorably to a number of field responses including our own.

We will also work with SAMHSA on two technical training webinars during March 2024 in order to provide interpretive analysis of the final rule and respond to Frequently Asked Questions (FAQs), which SAMHSA is collecting at the present time.

In order to simplify an analysis of a fairly complex rulemaking document, we have chosen to focus on what I perceive to be the most significant regulations affecting opioid treatment programs (OTPs).

Areas of Focus

1. **Removing the one-year requirement for opioid use prior to admission**

The final rule eliminates the one-year requirement for opioid use disorder prior to admitting the patient. This has been a significant barrier and we identified it as such in our letter to SAMHSA of February 10, 2023.

2. **Removing the prior requirement of minors having two documented unsuccessful attempts at short term withdrawal management or drug free treatment within a 12-month period before entering an OTP**

This has been a long-standing barrier in admitting minors into OTPs especially with the use of methadone maintenance treatment.

> "The final rule removes the requirement, previously at 8.12(e)(2), that minors are required to have had two documented unsuccessful attempts at short-term "detoxification", or withdrawal management, or drug-free treatment within a 12-month period to be eligible for maintenance treatment, and that those seeking withdrawal management, previously under 8.12(e)(4), cannot initiate methadone treatment more than twice per year. Instead, OTPs shall ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: the

person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose."

The issue here is that OTP admitting personnel need to exercise good clinical judgment in determining if such an individual (minor) meets the criteria to be admitted to an OTP. It is important for OTPs to understand that they could be adapting their services to accommodate a younger population.

3. Removing the Consideration of the Length of Time in Treatment for a Patient in Granting Take Home Medication

The final rule removes the length of time for a patient to have been in treatment before eligibility for take home medication.

"Based on the clinical judgment of the treating provider, patients may be eligible for unsupervised, take-home doses of methadone upon entry into treatment. This change recognizes the importance of the practitioner-patient relationship and is consistent with modern substance use disorder treatment standards."

There will be an additional reference later in this review concerning take-home medication. Once again, it will be based on the clinical determinations made by OTP personnel.

4. Initiation of Buprenorphine and Methadone Induction Through Telehealth Allows for Audio only for Buprenorphine and Audio-Visual for Methadone

The final rule responds to our concerns stated over the course of the past several years, through the beginning of COVID-19 and its impact on the patients we treat.

SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in person examination flexibilities to treatment with methadone in OTPs.

However, SAMHSA also acknowledges that there are differences between these two medications.

Accordingly, this “final rule allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone if a program physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via audio or audio-visual platform."

The striking issue here is that the only way that a methadone-maintained patient can be inducted with methadone through an OTP will be through an audio-visual experience. Once again, SAMHSA will provide training webinars with references to how OTPs may interpret this audio-visual related methadone induction particularly when significant barriers exist for in person or audiovisual induction.

5. Interim Treatment

- For the first time, SAMHSA is allowing all OTPs, both public and private (for-profit) OTPs. We had requested that this be enacted, and SAMHSA has so approved.
- It adds that active plans need to be developed to move the person into regular, ongoing services during the interim treatment period.
- It is also important to keep in mind that a state officer needs to approve the use of interim care in an OTP until more comprehensive care is made available and that is within the 180-day period of time. The interim care option remains if a patient waiting list exists.

6. The Development of Mobile Van Units and Bricks and Mortar Medication Units

AATOD has been advocating for the expansion of mobile vans since the DEA approved the new regulations during June 2021. We have offered training webinars as a method of enhancing such mobile van expansion but at the present time and according to SAMHSA, there are fewer than 40 mobile vans in the United States. This is in spite of the fact that SAMHSA has provided funding to the states so that all of the OTPs, public and privately financed, would be able to get access to federal funds through their State Alcohol and Drug Abuse Directors.

In effect, some states have served as barriers in this mobile van extension, and we are working with our associates at NASADAD and in the states to encourage the expanded use of such mobile vans. It is important to note that the final rule contains a reference to this matter. "Some commentators reference specific state regulations that limit mobile van units, but federal OTP regulations do not pre-empt separate state requirements."

SAMHSA fully encourages and facilitates additional OTP applications. In effect, OTP's need to be the entities that express an interest in purchasing and operating mobile vans in their respective states. All of these applications need to be carefully documented so that we are in a position to demonstrate an interest on the part of the OTPs to increase access to such mobile vans.

We are also referencing our correspondence to the Drug Enforcement Administration (see attached), which discusses the use of mobile vans as a method of extending the reach of OTPs into rural and underserved communities, engaging correctional facilities in providing access to medication assisted treatment for opioid use disorder in such correctional environments and in reaching out to other residential facilities that do have methadone on their respective formularies.

As indicated in a number of communications with SAMHSA personnel over the years, the only effective way of increasing access to mobile vans is to also have third party ongoing reimbursement for the services that are provided through such van units. This was also discussed in SAMHSA guidance to the field about the services that can be provided through such vans. We are attaching this correspondence as a reference point for OTPs. It is also important to expand the use of bricks and mortar medication units and such units are also able to provide the full range of services that are provided in an OTP. The regulations promote collaboration with other services such as federally qualified health centers, jails/prisons, in addition to other entities referenced in the final rule.

7. Definition of Practitioner

"The final rule expands the definition of practitioners to include nurse practitioners, physician assistants, certified nurse managers and pharmacists to order methadone." The final rule also pointed out that not all states allow for the expanded definition of practitioners.

Once again, it will be up to the OTPs to utilize this newly expanded definition and work with the individual states.

8. Counseling Services to be Provided by the OTP

On the one hand, the final rule eliminates the terminology of medication assisted treatment (MAT) in favor of medications for opioid use disorder (MOUD). As many individuals know, AATOD requested that the terminology MAT be retained while understanding that there is a broader policy issue that comes about in reference to providing counseling. :

> "OTPs are expected to offer adequate medical counseling, vocational, educational and other assessment, in treatment services either on site or by referral to an outside agency or practitioner. The revision in this final rule promoting patient centered approach to care that does that does not make medication continuity contingent upon involvement in counseling services but fosters greater shared decision making".

The matter of counseling services is also referenced later on in the final rule.

> "The proposed rule expands the definition of `counseling services' to include psychoeducational services, harm reduction and recovery-oriented services, and counseling and linkage to treatment for anyone with positive test results on human immunodeficiency virus (HIV), viral hepatitis, and other sexually transmitted infection (STI) panels, or from OTP-provided medical examinations. Language about services that must be provided directly or through referral is revised to promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters shared decision-making for all care plans."

9. OTPs Increasing the Initial Dose of Methadone

In recognition of the fact that most of the patients being admitted to OTPs are using fentanyl, the final regulations make an important change. "The regulation of an initial dose of methadone has been increased to 50 milligrams on first day, with the clarification left of allowance for higher doses if clinically indicated and documented in the person's record." As OTP practitioners know, the maximum initial dosage of 30 milligrams on the first day of medication has been in place for many years. While there have always been opportunities for clinical judgment to increase the initial dose as needed by the patient the final rule provides greater clarity.

Once again, it is important for admitting personnel to carefully document in the patient's medical record the need for a more rapid increase of methadone maintenance dosage during the initial stabilization period. This must be balanced against objective findings in toxicology reports in addition to observations in dispensing by the OTP personnel.

This new final rulemaking is intended to more rapidly engage the patient to achieve stability at the earliest possible opportunity, also keeping in mind the ultimate safely of individual patients.

10. Specific Reference to Take Home Medication Amounts

The final rule makes permanent the emergency take-home guidance at the beginning of the COVID-19 impact epidemic when it was having its earliest impact on patients in OTPs. Accordingly, OTPs were using much broader clinical authority and providing greater amounts of take-home medication to the patients.

“Rules on the provision of unsupervised (or take home) doses of methadone are finalized as per the NPRM, to incorporate flexibilities issued in response to the COVID-19 epidemic. In general, the final criteria allow for up to seven days of take home doses during the first 14 days of treatments, Up to 14 doses up from 15 days of treatment and 28 take home doses from 31 days in treatment.”

"The requirement that OTPs maintain procedures to protect take home from theft and diversion is finalized as well as patient education on safe transport and storage of take home doses, including documentation of the provision of this education and the patient's clinical record."

To be clear, the OTP clinician makes the final determinations of who is eligible to receive take home medication. While toxicology reports should not be used punitively, they should be employed in providing objective information to the clinician within the OTP as to best ascertain who is most capable of handling take home medication at such early stages of treatment.

We have stated this throughout our commentary on regulatory oversight of take home medication. There must be a balance in providing flexibility to the patients in order to retain the patients in treatment against the safety of providing such take home medication to an unsupervised individual. While we have learned that there is increased safety in providing such take home to patients as a result of the COVID-19 experience, it does not relieve the OTP using careful balancing standards in order to provide safety and flexibility.

The rule finalizes the removal of the requirement of observation of all daily doses during interim treatment, it also finalizes the expectation that crisis services and information pertaining to locally available community-based resources to ancillary services be made available to individual patients if requested.

Summary

While the final rule provides more nuanced decision making in the OTP environment, it is critical that there be increased alignment of policymaking between SAMHSA/DEA and state regulatory authorities, which govern OTPs in the United States. This is a critical matter and one that will need greater coordination at all levels of federal and state government relations. In addition, there need to be revisions with state Medicaid/Medicare authorities and how OTP services are reimbursed given the flexibilities that have been provided. In other words, the only way that these rules will be effectively promulgated is if state authorities are better aligned with federal agencies and if third party reimbursors are also better aligned with the provisions of the final rule.

If these issues do not get resolved, barriers will continue against the flexibilities of how the patients are treated in the OTP.