

Updates to 42 CFR Part 8 Opioid Treatment Regulations: General and Administrative Issues

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OTP Administrators Session – Overview
March 20, 2024, 2-3pm



SAMHSA
Substance Abuse and Mental Health
Services Administration

A Change In How OTPs Deliver Care

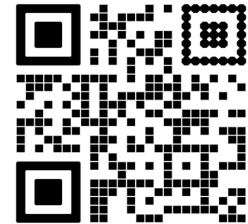
SAMHSA finalized updates to 42 CFR Part 8, the federal rule that governs Opioid Treatment Programs (OTPs), in February 2024.

The effective date of the final rule is April 2, 2024, and the compliance date is October 2, 2024.

The revised rule will enhance OTPs, improve collaboration with partner services and facilitate access to medications for opioid use disorder (MOUD).



Use this QR Code to link to the SAMHSA webpages on Part 8



Underlying Values and Principles of the Revised Rule

- Patient-centered care
- Shared practitioner-patient decision-making
- Practitioners' clinical judgment
- Responsive, flexible OTP services
- Evidenced-based practice
- Non-stigmatizing language

These Changes Promote:



Fostering trust and recovery
in a patient-centered
environment



Acknowledging the skill and
patient-centered
understanding of treating
practitioners



Creating responsive, flexible
OTP services that are
grounded in evidence



Promoting MOUD as a
treatment for a chronic
medical condition and
reducing stigma

Cultural Shifts In Care And Service Delivery

Fostering trust and recovery in a patient-centered environment

- The final rule makes permanent flexibilities for the provision of take-homes and revises the criteria for unsupervised “take-home” methadone doses.
 - Changes from rule-based to clinical judgment using risk/benefits framework
 - Allows eligibility for take-home doses upon entry into treatment
- Removes participation in counseling as a contingency for medication access.
- Continues to require the OTP to offer adequate treatment services to meet patient needs.

Fostering trust and recovery in a patient-centered environment

- Removes from admissions regulations the one-year OUD requirement for adults and two unsuccessful attempts at withdrawal for patients less than 18 yrs old.
- Allows patients to begin treatment with MOUD after the screening examination has been completed.
- Completion of physical and behavioral health assessment within 14 calendar days following admission, and periodically thereafter.
- Revises the language for drug testing from identifying misuse to a strengths-based approach, such as “allowing for extenuating circumstances”.

Acknowledging the skill and understanding of practitioners

- Includes NPs and PAs as practitioners able to order and manage methadone (Medical Director still must be a physician)
- Potential for medical screening by practitioners external to the OTP.
- Accepts examination results of non-OTP practitioners, if the exam is verified by an OTP practitioner (e.g. MD, NP, or PA).
- Total dose for the first day is now up to 50 mgs, unless the practitioner determines that a higher dose was clinically indicated and documents that in the patient's record .

Expanding Access to Care

- Expands access through incorporation of telehealth and integration of care among OTPs:
 - Initiation of methadone using audiovisual technology
 - Initiation of buprenorphine through audio-only or audio-visual technology
- Incorporates harm reduction and recovery principles.
 - Remove participation in counseling as contingency for medication.
 - Revises the language for drug testing from identifying misuse to a strengths-based approach, such as “allowing for extenuating circumstances”.
 - Allows for distribution of supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.
 - Incorporates overdose education and distribution of opioid overdose reversal medications

Expanding Access

Access expanded by:

- Expanding the range of services allowed in medication and mobile units
- Extending use of interim treatment from 120 to 180 days, if comprehensive services are not readily available in the area within 14 days. Requires moving patients from interim to comprehensive treatment during the interim period.
- Recognizing long-term care facilities and jails with DEA hospital/clinic registrations can dispense methadone when OUD is adjunct to a primary health condition
- Encouraging collaboration with other services



Changes to Certification and Accreditation Content

The final rule:

- Extends the time allotted for corrective action to 180 days (following receipt of the survey report)
- Distinguishes between “minor” and “significant” non-compliance.
- Introduces a three-year accreditation for OTPs that are required to correct minor non-compliant conditions and
- One-year accreditation for those required to correct significant non-compliant conditions. Corrections must be made within one year.
- Adds rules detailing procedures for severe non-compliance.

Changes to Certification and Accreditation Content

Changes in categories of certification:

- Transitional certification was removed (extinct)
- Conditional certification was established (one year certification)
- OTPs are expected to apply for certification renewal during the final year of the OTP's certification period and before the OTP's certification expires.
- Extension may be requested by submitting to the Secretary a statement justifying the extension
- Lapsed programs seeking re-certification will be considered "new" programs and will be required to apply for provisional certification (one year)

Changes to accreditation

Clarification of SAMHSA's expectations of ABs:

- Requires written notice to the OTP and SAMHSA of areas of non-compliance, distinguishing between minor and significant noncompliance.
- Requires verification of the implementation of the corrective measures by the OTP within the specified schedule.
- In cases of severe non-compliance that pose immediate risks to patient health and safety, the AB is expected to inform the OTP and Secretary within 48 hours.
 - In case of severe non-compliance, the OTP is given 30 days from the date of the report to correct the issue(s), and the AB is expected to conduct a follow-up survey within 30 days of the expected correction date to ensure successful correction.

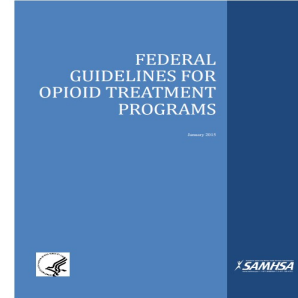
What does this mean for OTPs

Opportunity to:

- See more patients
- Improve retention in care
- Expand the reach of the OTP with mobile units
- Expand the reach of OTPs with med units in other services
- Integrate primary care, infectious disease treatments, and mental health services

Implementation Activities

- SAMHSA webpages and documentation have been updated.
- Revisions to the *Federal Guidelines for Opioid Treatment Programs* are in process.
- SAMHSA has scheduled webinars and meetings with implementation partners including:
 - OTPs (March 20 and 27)
 - State Officials (March 18)
 - Accreditation Bodies (March 25 and April 4)
- SAMHSA will continue to work with its federal partners to facilitate implementation.



Thank You!

SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

Grant Opportunities

www.samhsa.gov/grants
www.grants.gov/web/grants

988 Suicide and Crisis Lifeline Toolkit

www.samhsa.gov/find-help/988/partner-toolkit

