Opportunities for Improving Care: Implementation of Updated 42 CFR Part 8

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PA OTP Providers
DDAP Meeting, Camp Hill, PA
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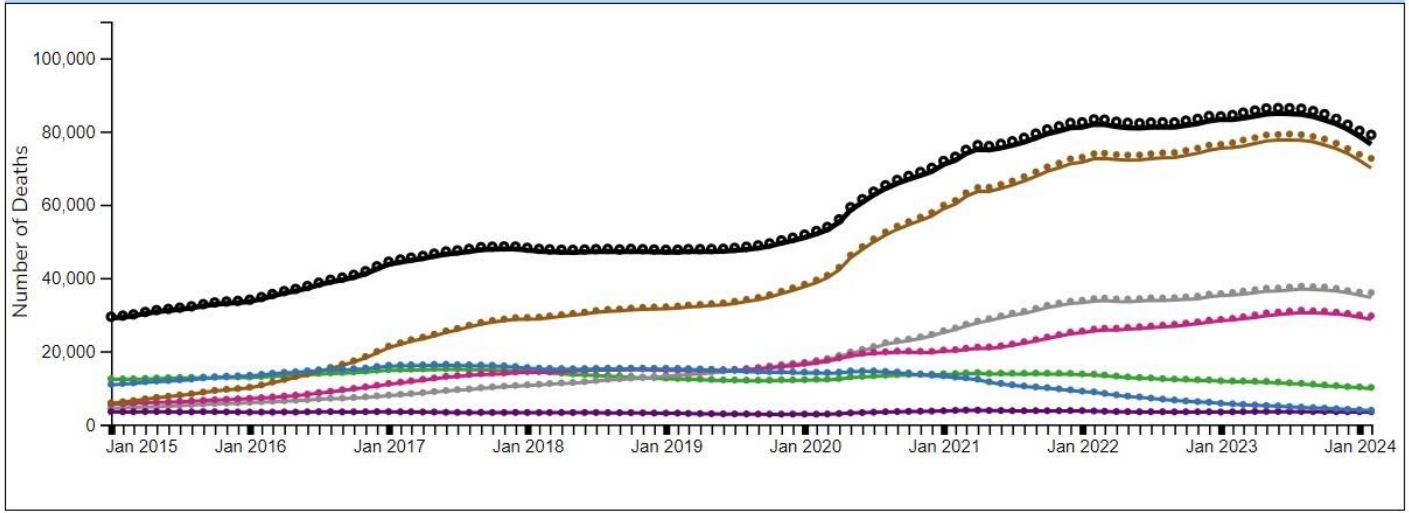
Learning Objectives

By the end of this session, participants should be able to:

- Describe the rationale behind the 42 CFR Part 8 changes
- Apply at least 3 federal changes related to opioid use disorder (OUD) treatment to care in Opioid Treatment Programs (OTPs).
- Summarize at least 3 benefits of the revised regulations for patients and OTPs.

Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Overdose deaths still claiming over 100,000 lives per year

Legend for Drug or Drug Class

- Cocaine (T40.5)
- Heroin (T40.1)
- Methadone (T40.3)
- Natural & semi-synthetic opioids (T40.2)
- Opioids (T40.0-T40.4,T40.6)
- Psychostimulants with abuse potential (T43.6)
- Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

O Predicted Value

Source: National Center for Health Statistics/Centers for Disease Control and Prevention. *Vital Statistics Rapid Release Provisional Drug Overdose Death Counts.*

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The Substance Use Landscape Is More Dynamic Than Ever Before

Illicitly Manufactured Fentanyl–Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022

Mbabazi Kariisa, PhD[1]; Julie O'Donnell, PhD[1]; Sagar Kumar, MPH[1]; Christine L. Mattson, PhD[1]; Bruce A. Goldberger, PhD[2]

Illicit Benzodiazepines Detected in Patients Evaluated in Emergency Departments for Suspected Opioid Overdose — Four States, October 6, 2020–March 9, 2021

Kim Aldy, DO[1,2]; Desiree Mustaquim, PhD[3]; Sharan Campleman, PhD[1]; Alison Meyn, MPH[1]; Stephanie Abston[1]; Alex Krotulski, PhD[4]; Barry Logan, PhD[4,5]; Matthew R. Gladden, PhD[3]; Adrienne Hughes, MD[6]; Alexandra Amaducci, DO[7]; Joshua Shulman, MD[8]; Evan Schwarz, MD[9]; Paul Wax, MD[1,2]; Jeffrey Brent, MD, PhD[10]; Alex Manini, MD[11]; the Toxicology Investigators Consortium Fentalog Study Group

May 20, 2024

Medetomidine Rapidly Proliferating Across USA — Implicated In Recreational Opioid Drug Supply & Causing Overdose Outbreaks


cfsre NPS DISCOVERY PUBLIC ALERT MAY 2024

MEDETOMIDINE RAPIDLY PROLIFERATING ACROSS USA — IMPLICATED IN RECREATIONAL OPIOID DRUG SUPPLY & CAUSING OVERDOSE OUTBREAKS

TIMEFRAME | DESCRIPTION OF MEDETOMIDINE IDENTIFICATIONS AND OVERDOSE EVENTS

Purpose: The objective of this announcement is to notify public health, harm reduction, first responders, clinicians, medical examiners and coroners, forensic and clinical laboratories, and all other related communities about new information surrounding the emergent adulterant medetomidine (also referred to as dexmedetomidine).

Background: Medetomidine is an alpha-2 agonist, belonging to the same family of drugs as xylazine and clonidine. Medetomidine is synthetically manufactured and exists in two enantiomeric forms: dexmedetomidine and levomedetomidine, the former being active and potent. Dexmedetomidine is approved for use in humans

RESEARCH Open Access

Signals of increasing co-use of stimulants and opioids from online drug forum data

Abeed Sarker[1*], Mohammed Ali Al-Garadi[1], Yao Ge[1], Nisha Nataraj[2], Christopher M. Jones[2] and Steven A. Sumner[2]

Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events

Print

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

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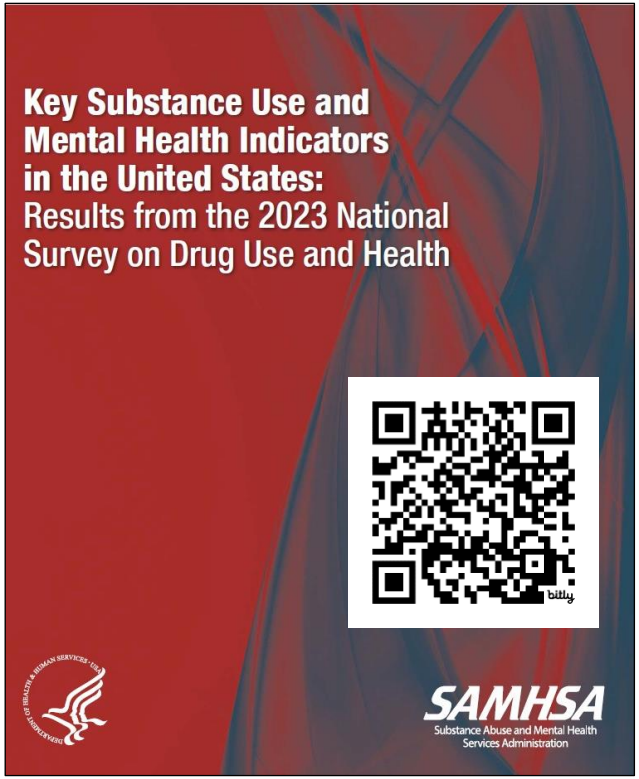
Large Treatment Gap for Common Conditions



- Substance Use Disorders (SUDs) are common -- 48.5 million people aged 12 or older (or 17.1%) had SUD in the past year.

- SUD treatment is not getting to everyone who may need it
  - Among people aged 12 or older, about 1 in 4 (23.6% or 12.8 million people) received it.
  - Among people aged 12 or older with OUD, only 18% received medications for opioid use disorder (MOUD) in past year

*Does not include OUD that exclusively involves illicitly manufactured fentanyl

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Multifront Advancements to Address Overdose Crisis and Reduce Stigma

Adopting, funding Harm Reduction

Revising federal guidelines for OTPs

Increasing grant funding

Updating regulations for OTP care

Updating regulations for information privacy

Equipping and expanding the Workforce

Elimination of the DATA 2000/X-Waiver

Low Barrier Care Advisory

Overdose Prevention and Response Toolkit

Expanding access to medications for opioid use disorder in correctional settings

Collaborating with states to advance Naloxone Saturation

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MOUD Expansion Through Improved Policy

Mainstreaming Addiction Treatment (MAT) Act	Medication Access and Training Expansion Act (MATE)
Removed the DATA-2000 Waiver to prescribe buprenorphine	Requirement for a non-recurring, 8-hour training on SUD for practitioners applying for registration from the DEA
Lifted caps on number of patients who can be treated; removes counseling and reporting requirements	Met through addiction board certification, as part of or post-healthcare professional degree training

Implementation of MAT and MATE is close collaboration and coordination between the Department of Justice/Drug Enforcement Administration, and Health and Human Services/SAMHSA

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Current Status

"All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law and SAMHSA encourages them to do so."

https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement

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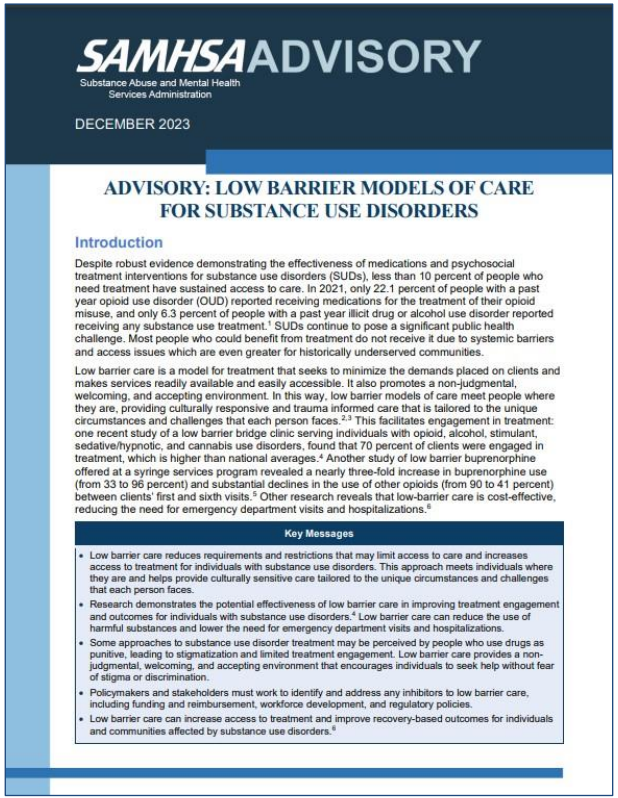
Eroding Barriers to Care



SAMHSA ADVISORY

Substance Abuse and Mental Health Services Administration

DECEMBER 2023

ADVISORY: LOW BARRIER MODELS OF CARE FOR SUBSTANCE USE DISORDERS

Introduction

Despite robust evidence demonstrating the effectiveness of medications and psychosocial treatment interventions for substance use disorders (SUDs), less than 10 percent of people who need treatment have sustained access to care. In 2021, only 22.1 percent of people with a past year opioid use disorder (OUD) reported receiving medications for the treatment of their opioid misuse, and only 6.3 percent of people with a past year illicit drug or alcohol use disorder reported receiving any substance use treatment.[1] SUDs continue to pose a significant public health challenge. Most people who could benefit from treatment do not receive it due to systemic barriers and access issues which are even greater for historically underserved communities.

Low barrier care is a model for treatment that seeks to minimize the demands placed on clients and makes services readily available and easily accessible. It also promotes a non-judgmental, welcoming, and accepting environment. In this way, low barrier models of care meet people where they are, providing culturally responsive and trauma informed care that is tailored to the unique circumstances and challenges that each person faces.[2,3] This facilitates engagement in treatment: one recent study of a low barrier bridge clinic serving individuals with opioid, alcohol, stimulant, sedative/hypnotic, and cannabis use disorders, found that 70 percent of clients were engaged in treatment, which is higher than national averages.[4] Another study of low barrier buprenorphine offered at a syringe services program revealed a nearly three-fold increase in buprenorphine use (from 33 to 96 percent) and substantial declines in the use of other opioids (from 90 to 41 percent) between clients' first and sixth visits.[5] Other research reveals that low-barrier care is cost-effective, reducing the need for emergency department visits and hospitalizations.[6]

Key Messages

- Low barrier care reduces requirements and restrictions that may limit access to care and increases access to treatment for individuals with substance use disorders. This approach meets individuals where they are and helps provide culturally sensitive care tailored to the unique circumstances and challenges that each person faces.
- Research demonstrates the potential effectiveness of low barrier care in improving treatment engagement and outcomes for individuals with substance use disorders.[4] Low barrier care can reduce the use of harmful substances and lower the need for emergency department visits and hospitalizations.
- Some approaches to substance use disorder treatment may be perceived by people who use drugs as punitive, leading to stigmatization and limited treatment engagement. Low barrier care provides a non-judgmental, welcoming, and accepting environment that encourages individuals to seek help without fear of stigma or discrimination.
- Policymakers and stakeholders must work to identify and address any inhibitors to low barrier care, including funding and reimbursement, workforce development, and regulatory policies.
- Low barrier care can increase access to treatment and improve recovery-based outcomes for individuals and communities affected by substance use disorders.[6]

In December 2023, SAMHSA published an advisory: Low Barrier Models of Care for Substance Use Disorder

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A Change In How OTPs Deliver Care

February 2024: SAMHSA finalized updates to 42 CFR Part 8, the federal rule that sets standards for services provided in Opioid Treatment Programs (OTPs).

Goals: Enhance services provided in OTPs, improve collaboration with partner services and facilitate access to medications for opioid use disorder (MOUD).

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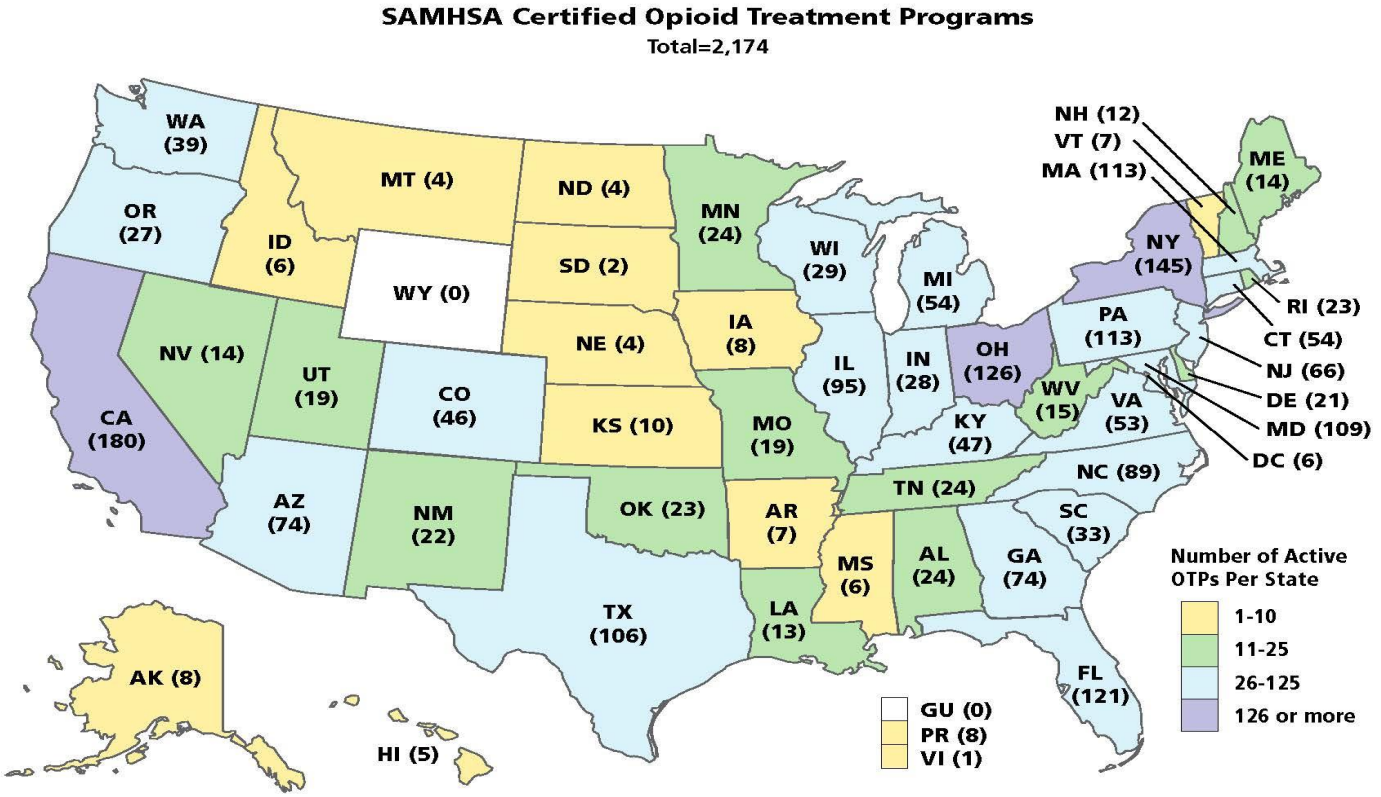
Opioid Treatment Program Landscape in the U.S.



Source: SAMHSA, CSAT, OTP Database. November 2024

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A Need To Address Barriers

- The COVID-19 pandemic necessitated regulatory flexibilities to protect OTP providers and patients:
  - Expanded parameters of take-home methadone dosing
  - Initiation of buprenorphine via telehealth
- The ongoing overdose crisis calls for patient-centered, accessible care:
  - Incorporation of harm reduction principles
  - Promoting use of clinical judgment
- Feedback from multiple stakeholder groups requesting and/or endorsing continuation of the flexibilities and other changes to the rules.
- Aspects of the 2001 rules were outdated.

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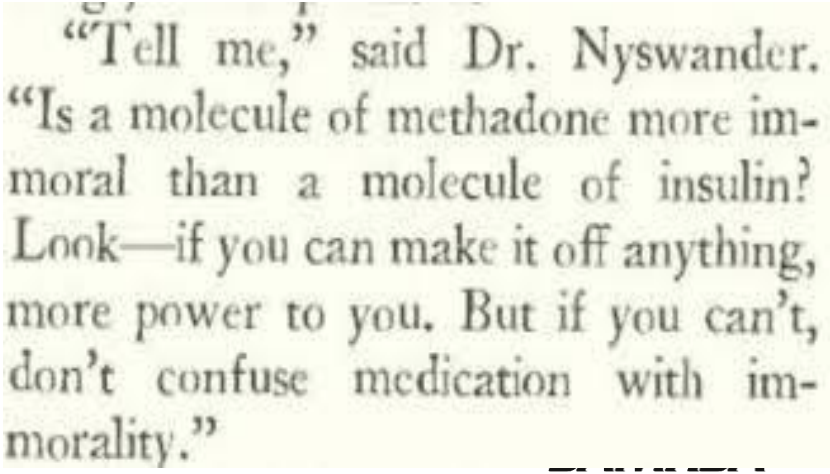
Opportunity to Enhance OTP Services

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



"Tell me," said Dr. Nyswander. "Is a molecule of methadone more immoral than a molecule of insulin? Look—if you can make it off anything, more power to you. But if you can't, don't confuse medication with immorality."

And Expand Access to MOUD

- Acknowledging the skill and understanding of NPs and PAs as qualified practitioners
- Expanding the range of services allowed in medication and mobile units
- Extending the use of interim treatment
- Recognizing long-term care facilities and jails with DEA hospital/clinic registrations can dispense methadone when OUD is adjunct to a primary health condition

Data supports these changes as a safe approach

- Expanded use of telehealth for provision of MOUD during the pandemic was associated with improved retention in care and reduced odds of medically treated overdose.[1]

- Surveys found diversion of methadone was low among patients receiving take-home doses under the COVID-19 flexibility and retention improved.[2]

- Deaths involving methadone declined overall between Jan 2019 and Aug 2021.[3]

1. Jones CM, Shoff C, Blanco C, Losby JL, Ling SM, Compton WM. Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* 2023;80(5):508–514.
2. Krawczyk, Noa et al. Synthesising evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. The Lancet Public Health, Volume 8, Issue 3, e238 - e246.
3. Jones CM, Compton WM, Han B, Baldwin G, Volkow ND. Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. *JAMA Psychiatry.* 2022;79(9):932–934.

Key Changes to 42 CFR Part 8

- The final rule makes permanent flexibilities for the provision of take home doses of methadone and the use of telehealth, including audio-only telehealth, in initiating buprenorphine

- Revises criteria for take-home methadone doses by:
  - Reframing from rule-based to clinical judgment-based using benefits and risk framework
  - Emphasizes patient education on safe transportation and storage of medication
  - Allowing consideration of take-home doses upon entry into treatment

Use this QR Code to link to further information

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Admission Criteria Under 42 CFR Part 8

- 1-year history of OUD, or previous attempts at treatment, is no longer required for admission
  - People under 18 years of age may be admitted to OTP treatment with the written consent of a parent, legal guardian, or responsible adult designated by the relevant State authority
- Focus on DSM-5 diagnosis:
  - Meets diagnostic criteria for a moderate to severe OUD; **or**
  - OUD in remission; **or**
  - The individual is at high risk for recurrence or overdose
- Admission decisions must be documented, along with consent to treatment
- Revised rule expands the definition of a practitioner to include NPs or PAs.

Admission to the OTP

- Two-part exam: initial screening, then a full assessment within 14 days
  - The screening exam establishes the diagnosis of OUD, rules out contraindications to methadone or buprenorphine and determines initial dose
  - While the maximum initial dose is up to 50mg, practitioner discretion can be applied with the appropriate clinical justification and documentation.

- The full assessment includes history, physical, lab tests, psychosocial assessment, and treatment plan (elements can be obtained during the screening exam)

- Telehealth allowed for methadone (audio-visual) and buprenorphine (audio-only or audio-visual) initiation
  - Must document OTP practitioner determination that telehealth exam is adequate
  - While much of the full assessment can be completed via telehealth, some elements (such as key parts of the physical examination and lab testing) will need to be completed in person

Involvement of Non-OTP Practitioners

- A non-OTP practitioners' examination can be used to expedite the screening process, if the exam was performed within seven days prior to the individual's admission to the OTP
- With proper patient consent, the non-OTP practitioner's examination findings can be transmitted to the OTP, where the examination can be reviewed, verified, and integrated by the OTP practitioner into the patient's records
- A full physical examination and history completed by a non-OTP practitioner can also be used, with the patient's consent. The OTP practitioner should verify the accuracy of the H&P, and add to it if needed.
- Serology testing and other testing, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination
- A periodic physical examination should occur at least one time each year and be conducted by an OTP practitioner

Counseling and Other Services

- Medications cannot be withheld if the client refuses to engage in counseling
- OTPs must offer 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
- OTPs must provide counseling on preventing HIV, viral hepatitis, and sexually transmitted infections
  - Where an individual is found to have an infectious disease, OTPs must either directly provide services and treatments or actively link to treatment
- OTPs must provide directly, or through referral, adequate and reasonably accessible community resources, vocational training, education, and employment services
- Care coordination, case management, and recovery support services are critical care components
- Drug testing:
  - OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances
  - No fewer than 8 random drug tests each year unless extenuating circumstances exist
  - The FDA marketing authorization requirement does not preclude distribution of harm reduction supplies for drug checking

Take Home Doses of Methadone

Days in Treatment	# Take-homes – up to:
Up to 14	7
15-30	14
31+	28

- Risk/benefit analysis, not specific criteria
- Educate patients on safe storage, and transport; document in patient record
  - The rule does not discuss the provision or use of locked boxes
- State law needs to be considered as well

Special Populations

- Admit and treat pregnant patients with MOUD on priority basis, provide/refer for OB care
  - Split dosing allowed under the rule (and can be provided as a take home in split aliquots)

- When comprehensive services are not readily available within 14 days, and with state approval, offer interim maintenance (methadone only) for up to 180 days → Prioritize pregnant patients

- Consider the needs of youth, LGBTQIA+ people, older adults and local populations

- Mobile units can reach isolated or underserved populations in encampments (for example)

Documentation

- Maintain a diversion control plan, program-wide quality assurance plan

- Clearly document in patient record: exam findings, clinical rationale, shared decision-making and patient progress
  - Reliance on blanket, rigid or standing order protocols or policies does not align with individualized standard of care
  - Evidence-based patient management, and continuity of care, relies on individualized assessments and plans and documentation that reflects this

- For take-home dose decisions: document individualized justification with risk-benefit analysis

- Retain all records in compliance with federal/state regulations

What Does This Mean for OTPs?

Integration of these changes is an opportunity to:

- See more patients
- Improve retention in care
- Foster innovation in evidence-based, person-centered care
- Integrate primary care, infectious disease treatments, and mental health services

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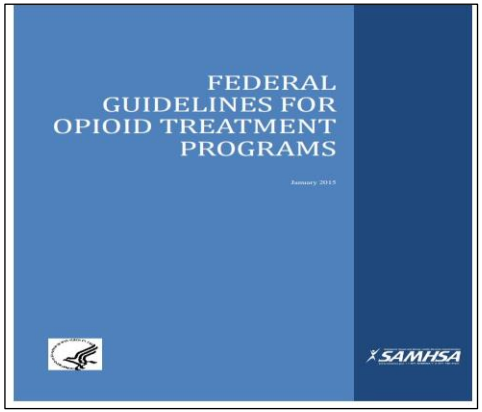
And expand the reach of OTPs

- beyond traditional OTP settings
  - Establishing medication units and mobile units in diverse locations
  - Collaborating with emergency rooms, jails, prisons, and other institutions

- Integrating OTPs into the broader healthcare and human services ecosystem
  - Building partnerships to provide comprehensive, coordinated care
  - Advocating for policies that support OTP integration and expansion
  - Using telehealth and digital platforms to expand reach and to promote collaboration

What is SAMHSA Doing to Support Implementation?

- In-person presentations and meetings
- Updated the Federal Guidelines for OTPs - will be published soon
- Frequently Asked Questions and other information is available on the SAMHSA Webpages
- Additional guidance to follow!



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Question 1

What challenges of implementation are you having to address, and how are you addressing them?

Question 2

What local agencies or institutions might benefit from collaboration and what might be barriers to developing partnerships with them?

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.

DPT Helpdesk
dpt@samhsa.hhs.gov

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