Opportunities for Improving Care in Opioid Treatment Programs: Implementation of Updated 42 CFR Part 8

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2024 Maryland OTP Providers Meeting

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Faculty Disclosures

- Yngvild Olsen, MD, MPH, has no conflicts of interest or financial disclosures relating to the subject matter of this presentation.

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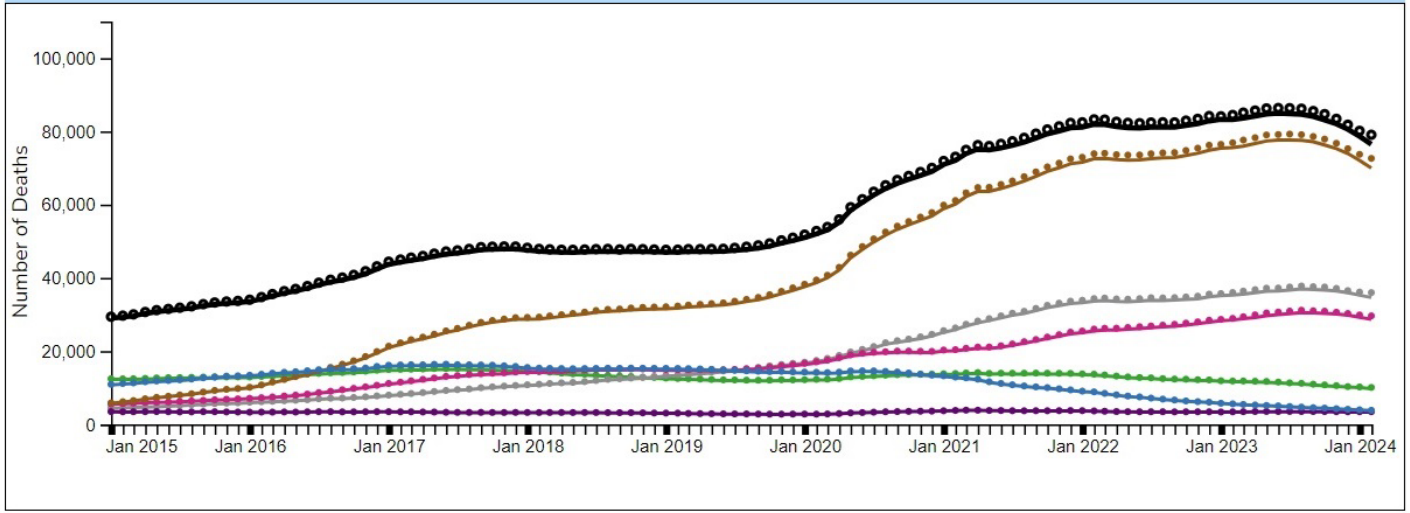
Learning Objectives

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

Purpose: The objective of this announcement is to notify public health, harm reduction, first responders, clinicians, medical examiners and coroners, forensic an 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 o 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

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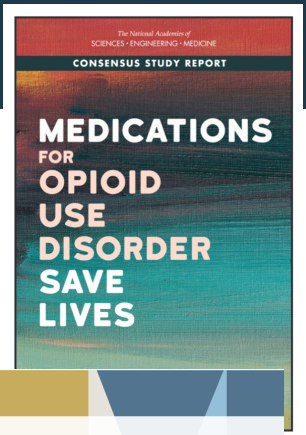
Compelling Published Evidence

	Naltrexone	Buprenorphine	Methadone
Reduces craving	✓	✓	✓
Reduces misuse	✓	✓	✓
Increases treatment retention	✓	✓	✓
Prevents recurrence	✓	✓	✓
Reduces overdose		✓	✓
Treats opioid withdrawal		✓	✓
Reduces infectious disease		✓	✓
Reduces mortality		✓	✓
Increases employment		✓	✓
Recommended in pregnancy		✓	✓
Reduces criminality			✓



Wednesday, July 13, 2022

Percentage of overdose deaths involving methadone declined between January 2019 and August 2021

National data indicate COVID-era treatment expansion was not associated with harms, add evidence to support take-home treatment for opioid use disorder.

Institute/Center

National Institute on Drug Abuse (NIDA)

Contact

NIDA Press Office
301-443-6245

Treatment with effective medications is not addiction by another means.

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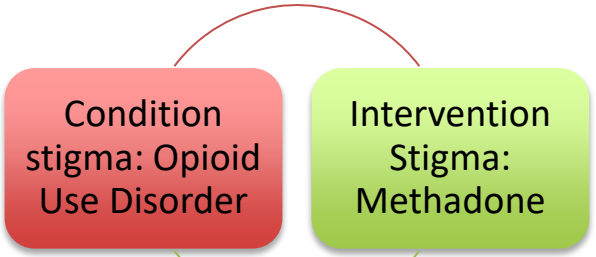
Stigma and Methadone



opioid overdose.[11] Similarly, Anstice et al[12] and Harris and McElrath[13] both reported that institutional stigma is commonly found in MMT programs; institutional stigma refers to when negative attitudes and beliefs toward methadone are reflected in organization's policies, practices, or cultures. For instance, patients reported hearing condescending or distrusting remarks from pharmacists and other health care workers, whereas dispensing spaces often made patients feel humiliated and exposed under the public gaze.[13] Finally, a survey of 114 MMT patients found moderate to high levels of self-stigma and perceived stigma among patients, with higher experiences of stigma associated with unemployment, intravenous drug use, incarceration, and heroin use.[14]

Woo J, Bhalerao A, Bawor M, et al. "Don't Judge a Book Its Cover": A Qualitative Study of Methadone Patients' Experiences of Stigma. Subst Abuse. 2017 Mar 23;11.

More addiction patients can take methadone at home, but some states lag behind

Only 19% of the roughly 2.1 million U.S. adults who have opioid use disorder receive methadone treatment.

BY: **ANNA CLAIRE VOLLERS** - MAY 8, 2024 5:00 AM

to curb the epidemic of overdoses from ... Continue reading

Stateline

One pregnant patient in a 2021 study reported being required to remain in line at her methadone clinic even after her water broke. Other patients said they were refused take-home doses for family emergency situations or were randomly required to make additional clinic visits. Ten states require methadone providers to observe patients during urine sample collection, according to a 2021 analysis by The Pew Charitable Trusts.

"There's no other medical condition where we feel like patients need to earn the right to treatment," said Ximena Levander, an addiction medicine physician and researcher at Oregon Health & Science University. "What SAMHSA has done with these new rules is to try to shift that paradigm from a punitive, 'you need to earn this' model to a patient-centered, individualized treatment plan.

"But it's going to take time for that culture change to happen."

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Opportunity for A New Approach

- Person-centered and supportive treatment environments that promote trust, recovery and patient engagement
  - OTPs should be a great place to work and to receive care
- Responsive and flexible OTP services that are grounded in evidence
  - The opioid overdose epidemic is changing, and so must we
- Acknowledgment of the skill and patient-centered understanding of treating practitioners
  - You know your patients! Just as you trust your patients, we trust you to create plans of care that are person-centered, safe and effective
- Promoting MOUD as a treatment for a chronic medical condition
  - We must all work to overcome stigma through application of evidence-based practices and skills

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.
- The medical director role must still be filled by an MD/DO
  - Responsible for all medical and behavioral health services provided and administered by the OTP

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

- Take-home supply limits:
  - Up to 7 days of medication for the first 14 days of treatment
  - Up to 14 days of medication for days 15-30 in treatment
  - Up to 28 days of medication for days 31+ in treatment
- Criteria for practitioners to consider: risk of overdose or safety concerns minimal, absence of serious behavioral issues, no recent diversion, can safely store doses, practitioner discretion
  - This is a risk/benefit analysis, not adherence to rigid rules
  - An 'absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely' recognizes that individuals in treatment with methadone may intermittently use substances that do not necessarily impact the efficacy or safety of methadone, or increase the risk of overdose above that which may occur in the absence of methadone
  - Routine drug testing shall not be used punitively → the results contribute to the risk/benefit analysis and promote person-centered discussion and treatment planning
- Educate patients on safe storage, and transport; document in patient record
  - The rule does not discuss the provision or use of locked boxes
- Consider state law

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
- Expand the reach of the OTP with mobile units and other services
- Foster innovation in evidence-based, person-centered care
- Integrate primary care, infectious disease treatments, and mental health services

More Information

- The final rule is available in the Federal Register (89 FR 7528)
  - The last section (Part 8—Medications For The Treatment Of Opioid Use Disorder) is the text of the rule. Information before this describes and justifies the rule
  - The final rule is approximately twelve printed pages in length

- Updated Federal Guidelines will be published soon

- Frequently Asked Questions and other information is available on the SAMHSA Webpages

- You can email providersupport@samhsa.hhs.gov with any non-clinical questions that do not require fact specific legal analysis

OTP TECHNICAL ASSISTANCE (TA) CONTRACT

Goals of the TA: To expand and improve access to treatment, facilitate shared and evidence-based decision making, enhance the integration of services and care coordination, and assist programs in implementation of 42 CFR Part 8 and related accreditation standards.

Planned activities include:

- Provide training for OTP staff
- Provide targeted TA for OTPs and SSAs/SOTAs related to opioid treatment, including TA for certification and recertification
- Conduct workshops/TA targeted toward improving the quality of and access to treatment such as: integration of primary and mental health care, addition of medication units, and collaboration with criminal justice settings
- Assist OTPs and SOTAs in ensuring diversity, equity, inclusion, and accessibility inclusion in OTP care

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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.

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