Methadone in the Modern Era

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- No financial disclosures or conflicts of interest to report

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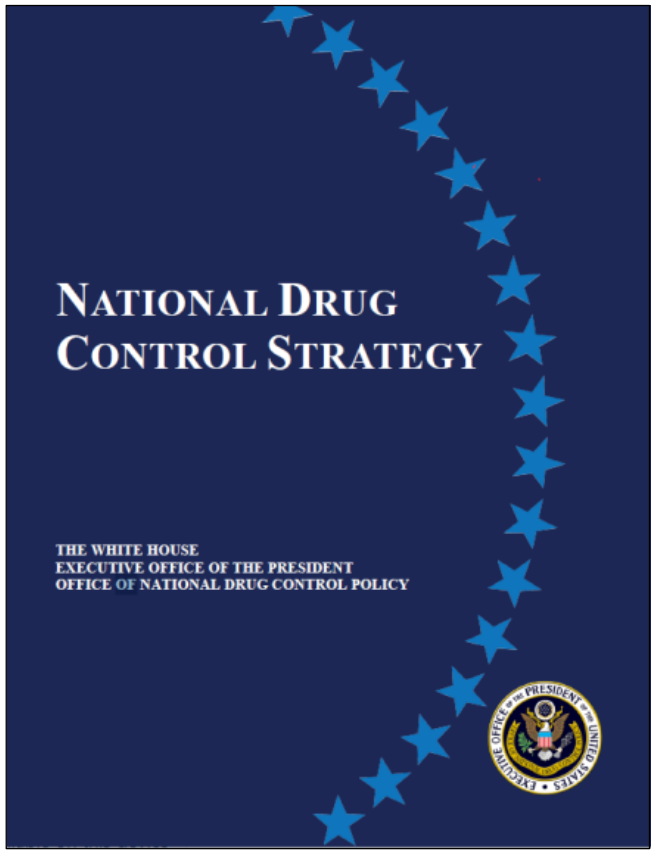
Guiding Frameworks

HHS Overdose Prevention Strategy

https://www.hhs.gov/overdose-prevention/

White House Strategy



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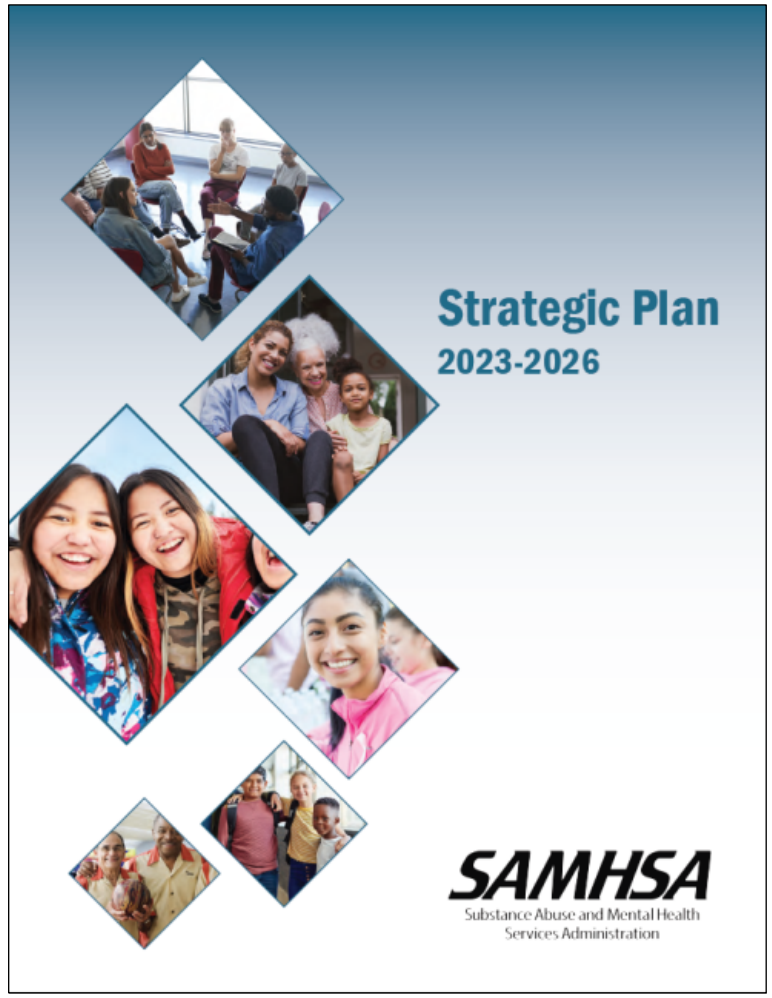
SAMHSA's Overarching Priority Areas and Guiding Principles



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Expanding Access to MOUD

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

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

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Until now:

Criteria retained from the experimental model of methadone initiated in 1960's was carried into the 2001 regulations:

- One year of OUD history for adults and two 'failed' attempts at withdrawal for patients younger than 18
- Daily visits to the clinic
- Stigmatizing language that goes back to the Harrison Act

These rules posed barriers to treatment engagement by:

- Hampering patients' schedules for work, school and health care.
- Hindering travel – for vacations, work, or to spend holidays with family.
- Increasing the likelihood of debilitating withdrawal if they were unable to visit a clinic or arrange alternate medication (e.g., jail, nursing home).

A Need To Address Barriers

- The COVID-19 pandemic necessitated regulatory flexibilities to protect OTP providers and patients:
  - Expanded parameters of unsupervised “take-home” methadone dosing
  - Initiation of buprenorphine via telehealth
- The ongoing overdose crisis calls for patient-centered, accessible care.
- Feedback from stakeholder groups requested and/or endorsed continuation of the flexibilities and other changes to the rules.
- Studies examining the impact of the COVID-19 flexibilities found:
  - No increase in methadone overdose rates
  - Low diversion of methadone
  - Positive impacts on retention and patient-reported outcomes

Making Flexibilities Permanent

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

- Revises criteria for unsupervised “take-home” methadone doses by:
  - Reframing from rule-based to clinical judgment-based metric, using benefits and risk framework,
  - Emphasizing patient education on safe transportation and storage of medication, and
  - Allowing patients eligibility for take-home doses upon entry into treatment.

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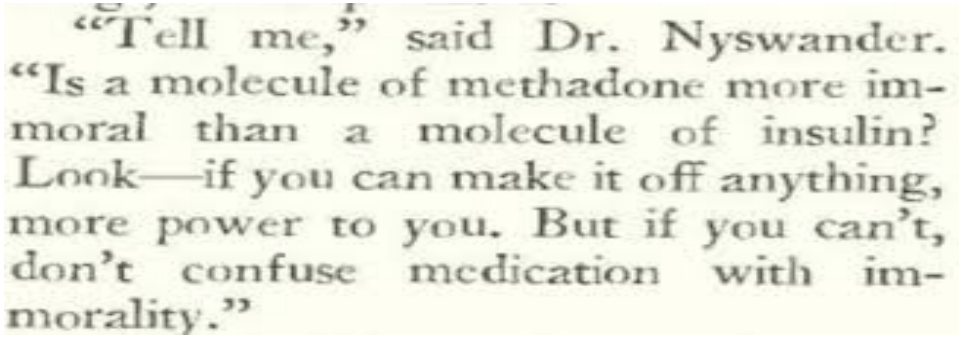
Underlying Values and Principles of the Revised Rule

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



"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."

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Further Changes to Part 8

- Remove from admissions regulations the one-year OUD requirement for adults and two "failed" attempts at withdrawal for patients younger than 18.

- Add new definitions, such as for "split dosing," to support evidence-based practice.

- Expand access through incorporation of telehealth and integration of care among OTPs:
  - Initiation of methadone using audiovisual technology
  - Potential for medical screening by practitioners external to the OTP.

- Incorporate harm reduction and recovery principles.

- The proposed rule is neither applicable to, nor authorizes, the prescribing of methadone for OUD or makes permanent the prescribing of buprenorphine via telehealth outside of an OTP

Other Highlights – Expanding Access

Access expanded by:

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

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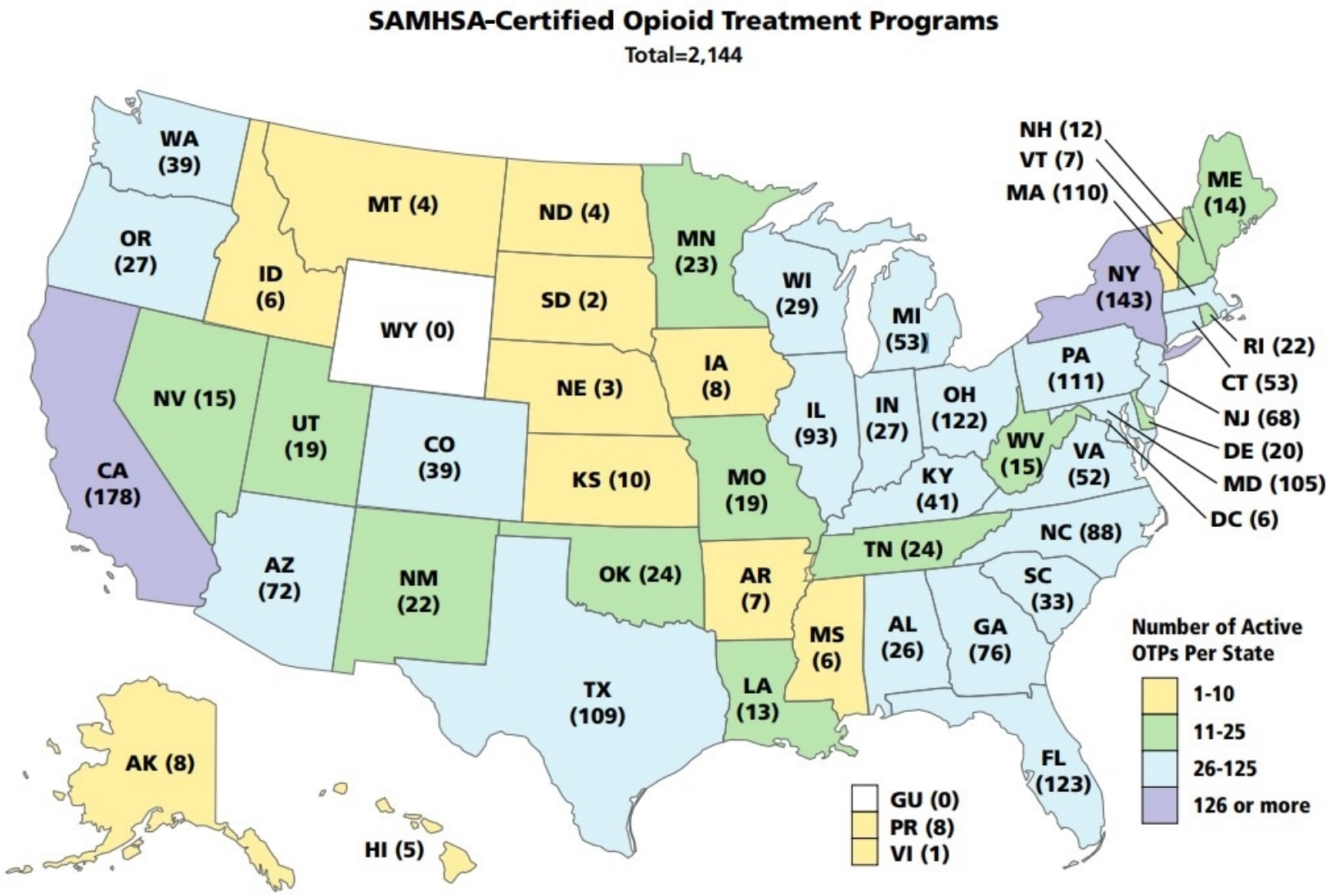
Opioid Treatment Program Landscape in the U.S.



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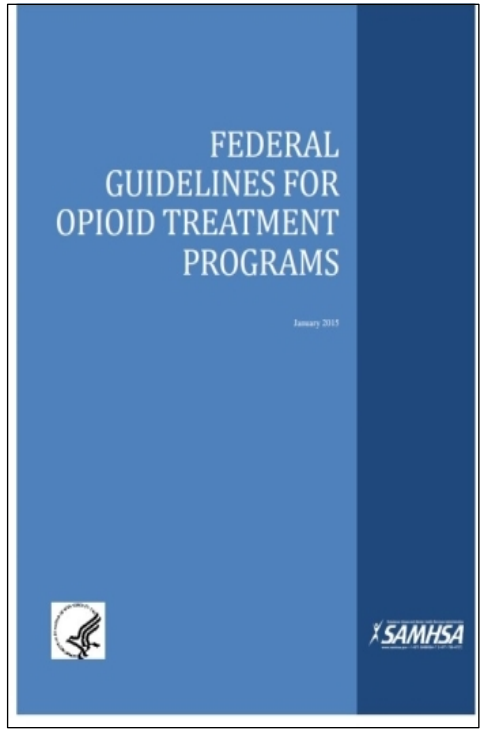
Implementation

- The effective date of the final rule is April 2, 2024, and the compliance date is October 2, 2024.
  - This allows time for OTPs and Accreditation Bodies to implement changes.

- The rule can be viewed in the Federal Register: Medications for the Treatment of Opioid Use Disorder, February 2, 2024.

Implementation Activities

- SAMHSA webpages and documentation have been updated.
- Revisions to the *Federal Guidelines for Opioid Treatment Programs* are in progress.
- SAMHSA will provide webinars for stakeholder groups, and meetings with implementation partners including:
  - OTP Sponsors, Medical Directors and other representatives
  - State Opioid Treatment Authorities
  - Accreditation Bodies
  - Professional associations
- SAMHSA will continue to work with its federal partners to facilitate implementation.



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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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References

Figgatt, MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID–19, Journal of Substance Abuse Treatment, Volume 123, 2021.

Hatch-Maillette MA, Peavy KM, Tsui JI, Banta-Green CJ, Woolworth S, Grekin P. Re-thinking patient stability for methadone in opioid treatment programs during a global pandemic: Provider perspectives. J Subst Abuse Treat. 2021 May;124:108223.

Jones, C. M., Compton, W. M., Han, B., Baldwin, G., & Volkow, N. D. (2022). Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. JAMA Psychiatry, e221776. *https://doi.org/10.1001/jamapsychiatry.2022.1776*

Joseph G, Torres-Lockhart K, Stein MR, Mund PA, Nahvi S. Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID–19. J Subst Abuse Treat. 2021 Mar;122:108219.

Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. "The idea is to help people achieve greater success and liberty": A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Subst Abus. 2022;43(1):1143–1150.

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