

The Regulatory Situation for Treatment of Opioid Use Disorder with Methadone: Where Are We?

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Disclosures

- No relevant disclosures or conflicts of interest to report
- Note: Former Medical Director of Opioid Treatment Program (OTP) for 10 years

Areas of Historic Concern Related to OTP Regulations (42 CFR Part 8)

- Restrictions on take-home methadone doses
- Perceived counseling requirement
- Restrictions on access to methadone

2020: COVID-19 Pandemic Changes Regulatory Landscape

3/11/20:
WHO
declares
COVID-19
pandemic

4/19/20: SAMHSA
releases guidance
on 42 CFR Part 2
confidentiality of
patient records

6/19/20: CMS
clarifies allowance
under Medicare for
OTPs to use
telehealth platforms
for periodic patient
assessments

3/16/20: SAMHSA releases
blanket methadone take-home
exceptions to states

And

3/16/20: HHS and DEA
designate telehealth
exceptions for all schedule II-V
controlled medications

4/21/20: SAMHSA clarifies
exemption from requirement
for an in-person physical
examination for new patients
starting buprenorphine in an
OTP (but not methadone)

2021: Building on Changes

7/28/21: DEA
releases guidance
on mobile
medication units

9/21/21: SAMHSA
releases guidance
on mobile and
non-mobile
medication unit
establishment and
allowable services

8/4/21: SAMHSA
releases guidance to
states on use of
substance use
treatment block grant
funds for mobile units

11/18/21: SAMHSA
releases guidance on
extension of blanket
methadone take-home
exceptions for one year past
end of COVID Public Health
Emergency (PHE)

Collective Challenges and Opportunities

- Stigma of methadone
- Healthcare professional training needs
- Optimize access and quality

Thank You

SAMHSA's mission is to reduce the impact of substance use and mental illness on America's communities.

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