

Changes to Federal Regulations For Opioid Treatment Programs

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Last Updated: 3/15/2024

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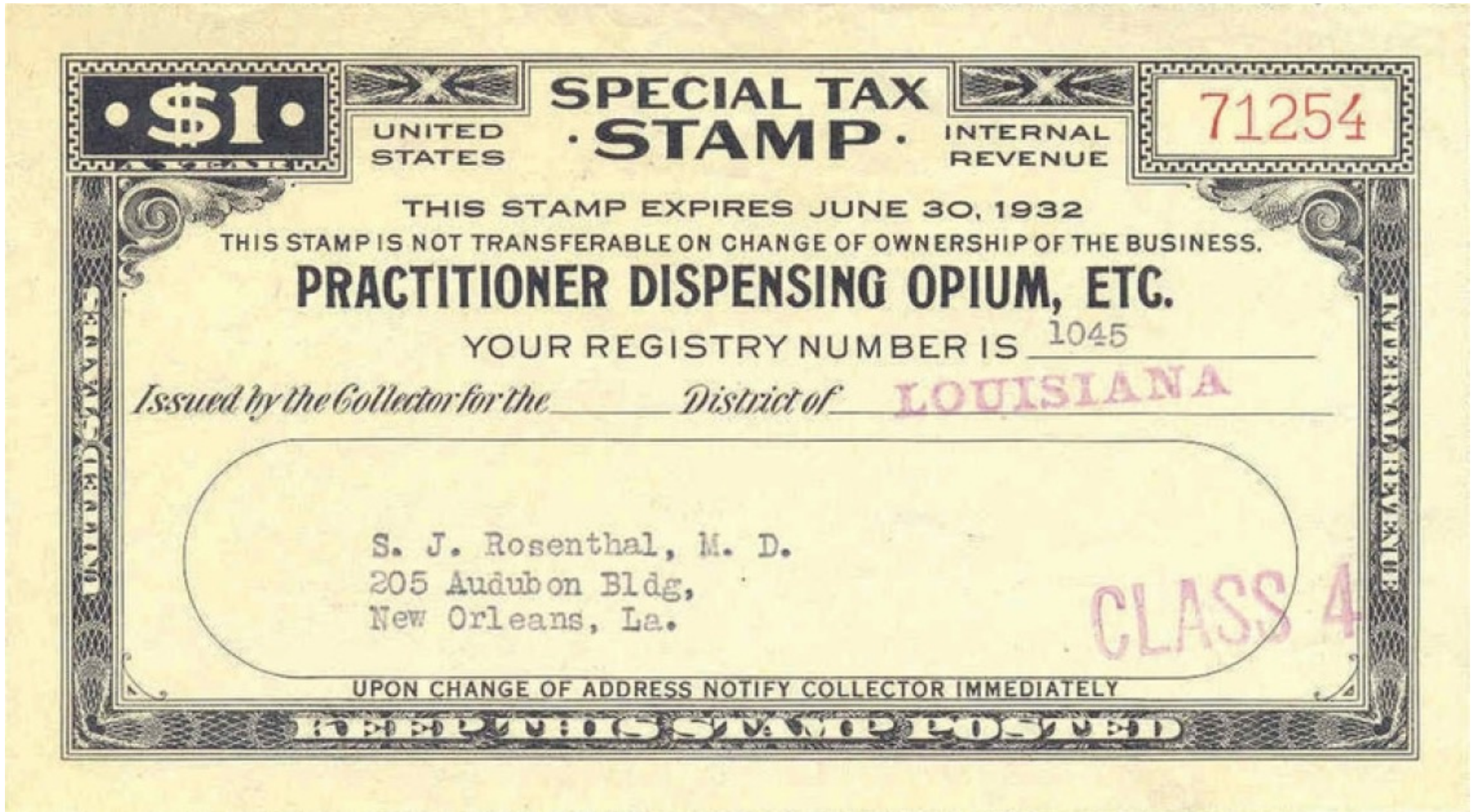
Disclosures

No conflicts of interest or relationships to disclose

OUTLINE

- Brief History of OTP regulations
- Changes to Federal OTP regulations
- Other regulatory changes affecting provision of medical care for patients with OUD.

Criminalization of Addiction



Nyswander and Dole



The rise of methadone and the regulatory “counter-revolution”

- Veterans returning from Vietnam
- Political winds
- Bureau of Narcotics
- 1972: First version of today’s methadone regs in CFR.
- Expanded in 1973 methadone diversion control act
- 1974 Narcotic Addict Treatment Act (which gave DEA authority of storage and security of methadone).

42 CFR Part 8

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

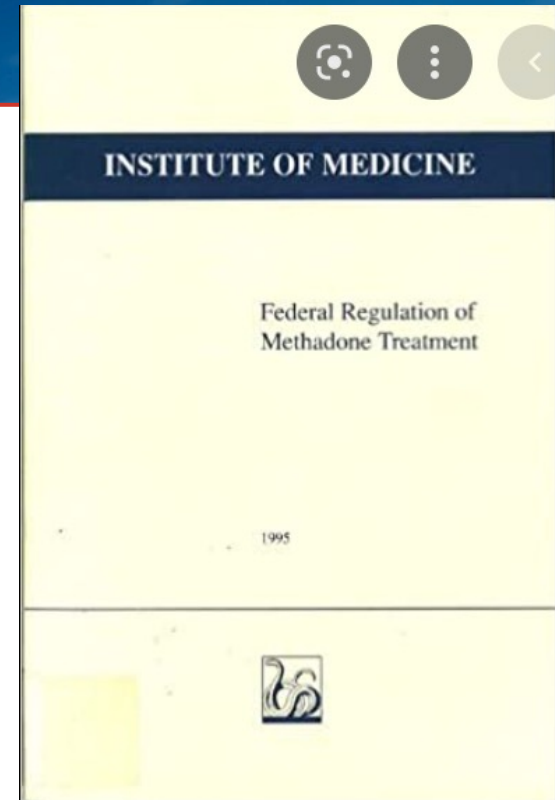
EDITORIAL NOTE: Nomenclature changes to chapter I appear at 67 FR 36549, May 24, 2002.

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Institute of Medicine, 1995

- 1. Current regs over-emphasized dangers of methadone diversion.
- 2. They burdened programs with unnecessary paperwork
- 3. Constrained clinical judgement
- 4. Reduced access to treatment
- 5. Contributes to premature termination of treatment.

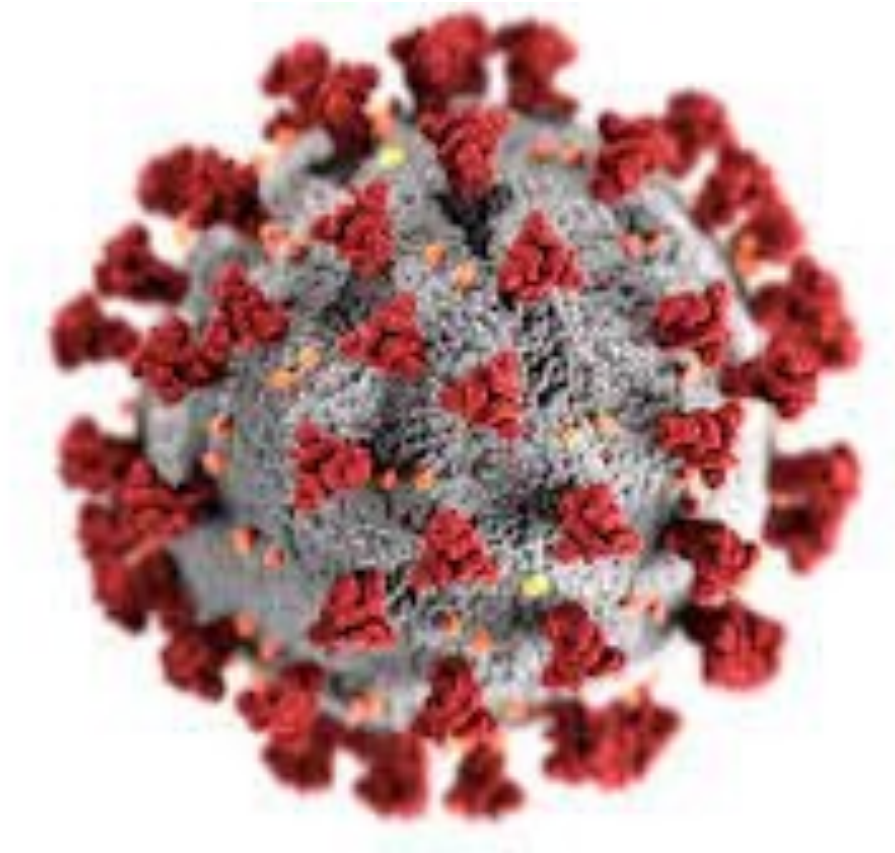


Recommend fundamentally reducing regulatory burdens and changing them to guidelines.

42 CFR regulations (holdovers from 1974)

- Only approved clinics (OTPs) and hospitals.
- Age 18 and above
- Evidence of an OUD of one year's duration
- Regular urine drug testing
- Maximum initial dose of 30 mg
- Counseling must be made available
- Specific limitations on Take home dosing

2020



42 CFR Part 8 Revision, 2/2/2024

HEALTH

Methadone treatment gets first major update in over 20 years



By [Lev Facher](#) Feb. 1, 2024

[Reprints](#)



“PRACTIONER” DEFINITION

CHANGE:

- Expand Definition of Practitioner to include any “health care professional who is appropriately license by a State to prescribe and/or dispense medication for OUD and, as a result, is authorized to practice within an OTP.”

“PRACTIONER” DEFINITION

IMPLICATIONS:

- Easier for programs to hire advanced practitioners to staff their programs and expand the medical provider workforce.
 - ? Shorter waiting lists, more walk-in and transfer access.
 - ? OTPs could provide more medical care (primary care, wound care, HCV treatment etc).
 - ? OTPs could change doses every day.
- In states that allow exemptions for advanced practitioners, less paperwork for programs.

TELEHEALTH

CHANGE:

- Allow OTPs to initiate buprenorphine via audio-visual or audio only telehealth platform.
- Allows OTPs to initiate methadone treatment via audio-visual only or audio-only if in the presence of a licensed controlled-substances practitioner (with dosing at OTP)

TELEHEALTH

IMPLICATIONS:

- Could programs coordinate with jails, residential treatment facilities, to perform remote OTP intakes?
- Leverage provider time to support performing intake via telehealth supported by a field-based team?
 - The medication itself must still be accessed through the OTP, so the logistics of this are complicated.

TREATMENT ELIGIBILITY

CHANGE:

- Removes 1 year minimum diagnosis of OUD criteria to expand to any mod/severe OUD, OUD in remission, or risk of recurrence/overdose.
- Removes requirement of 2 failed attempts at detox for minors <18; continues to require written consent of parent or guardian.

TREATMENT ELIGIBILITY

IMPLICATIONS:

- Simplify intake process (and align it with FDA label indication for treatment with buprenorphine products).
- More feasible to treat patients who have developed complications and risks associated with OUD within a one year period of time.
 - Increasingly common in the fentanyl era.
- More feasible to treat adolescents.

LOWERING BARRIERS

CHANGE:

- Does not make medication continuity contingent upon involvement in counseling services.
- Expands definition of counseling to include harm reduction and recovery-oriented services.
- More explicit about allowing initiation of medication after a “screening” exam at intake, as long as a “comprehensive” exam occurs within 14 days.

LOWERING BARRIERS

IMPLICATIONS:

- Patients not interested in or ready for traditional SUD counseling could have access to other resources early in treatment like case management, care navigation, harm reduction specialist, peer counseling.
- Could intake be streamlined?

INITIAL DOSE

CHANGE:

Allows for higher induction dosing. Total dose on the first day should not exceed 50mg, unless the OTP practitioner finds and documents sufficient medical rationale.

INITIAL DOSE

Implications:

- Opens the door for more aggressive initial dosing strategy for people with high tolerance and low risk for med toxicity.
 - Particularly people with prior methadone treatment experience, no advanced age, no comorbid cardiac/pulmonary disease, no concurrent use of other CNS/respiratory depressants
 - This may be helpful to support early retention (editorial comment).

SPLIT DOSING

CHANGE:

- New regs state that BID dosing may be initiated among, but not limited to,
 - high metabolizers
 - people taking other meds/substances that induce rapid metabolism
 - pregnant individuals
 - individuals with chronic pain.

SPLIT DOSING

IMPLICATIONS:

More access to split dosing for folks who many benefit.

TAKE-HOMES

CHANGE:

Ultimately rely on determinations by “an appropriately licensed OTP medical practitioner or the medical director” who may consider

- Conditions that might increase the risk for overdose or ability to function safely
- Regularity of attendance
- Absence of serious behavioral problems
- Absence of known recent diversion
- Ability to safely transfer and store medications

TAKE-HOMES

“Interim Rules,” in effect for about a year, were continued verbatim. Dramatic difference compared to pre-2020 regarding time in treatment:

In-clinic dosing	Length of time in Tx	
	Former	New
6 days/wk	0 days	
5 days/wk	90 days	
4 days/wk	180 days	
1 day/wk	270 days	0 days
Every 14 days	1 year	15 days
Every 28 days	2 years	31 days

TAKE-HOMES

IMPLICATIONS:

- Allows for dramatic change in how care is delivered and the patient experience.
- Early studies show no increase in methadone related overdose deaths among patients or the general population (as proportion of overall deaths).¹
- One cohort study (non-randomized) suggests improved treatment retention and less treatment interruption.²
- Qualitative studies indicating more autonomy, normalcy, and flexibility to meet treatment goals, but that individualized care is key.³

Non-OTP Methadone Access

Change:

Correctional settings and long-term care facilities can continue or initiate methadone if registered as a hospital/clinic with DEA, similar to the way hospitals can, for patients who are admitted “for the treatment of medical conditions other than OUD, and who require treatment of OUD with methadone during their stay . . .”.

- NB: Definition of LTC includes “rehabilitation centers, skilled nursing facilities, permanent supportive housing, assisted living facilities, and chronic care hospitals.”

Non-OTP Methadone Access

Implications:

Jails/Prisons and Long-term care facilities with DEA hospital/clinic licensure can initiate or continue methadone without involvement of an OTP (just like a hospital).

Correctional Access to MOUD

Providing Methadone in Jails and Prisons: An explanation of a new approach to increase access to methadone in carceral settings



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

OTHER NOTES

- Rule will become effective April 2, 2024
- SAMHSA will complete a “revision of the Federal OTP guidelines” following this rulemaking that will include more guidance on quality metrics and decision making within OTPs
- These rules do not mandate that States promulgate less restrictive rules to match provisions of Federal law that may provide more flexibility.
 - But Washington SOTA and DOH have indicated they DO intend to align state rules with the Federal.

WHAT DIDN'T CHANGE

- Methadone cannot be prescribed for OUD, only dispensed in the outpatient setting from federally registered Opioid Treatment Programs.
- Drug testing: At least 8 random drug tests required each year.
- Relies on credentialing agencies to enforce.

It's not just the Federal Regs.

- Many STATE regulations are more restrictive than federal
 - 19 states and DC have imposed barriers on opening new OTPs
 - 8 states require a government ID to access OTP treatment
 - 10 states impose additional stability criteria for THs
 - Nearly half of states have a set counseling requirement.
- DEA licensure has many requirements
- Board of Pharmacy oversight
- Opioid Treatment Programs themselves
 - Many programs have imposed rules through clinic policies that impose additional barriers on patients.
 - In some states, payment structures may influence a clinic's policies around, for example, provision of take-home medication.

BIG PICTURE IMPLICATIONS

It is hard to know what treatment in an OTP will look like in the coming years and will likely vary greatly depending on the state and from clinic to clinic.

I think we can be confident that, in general, there will be increased access to admission, decreased barriers to remaining in treatment, and increased access to unsupervised doses of medication when medically appropriate.

How can I counsel about treatment options?

- In discussing treatment options for OUD, while differences in the pharmacology of different MOUD is important, arguably more important is the treatment setting.
- Patients – especially those who have tried treatment through an OTP before – should understand that some of these rule changes may translate into lower-barrier care that allows for more patient-centered medical decision-making.
- Try calling the OTPs in your catchment area to get an understanding of what patients can expect from those specific clinics.

Other regulatory changes re: OUD treatment

“72 hour rule”

X-ing the X waiver

Telehealth buprenorphine

42-CFR Part 2 (Privacy regs)

? Modernizing Opioid Treatment Access Act?

“72 hour rule”

- There has long been a provision in federal regulations (21 CFR 1306.079(b), allowing non OTP practitioners to dispense (but not prescribe) one day’s worth of narcotic drugs, for not more than three continuous days, to relieve withdrawal while referrals are being made for treatment.
- As of August 8 2023: **3 days worth of medication can be dispensed at one time** “for the purpose of initiating maintenance treatment or detoxification treatment (or both).”

“72 hour rule”

- In neither the old or new version of this provision, is the site of care specified, and there is increasing interest in utilizing this provision to initiate methadone in different treatment settings. Could this be a means of initiating methadone in
 - Emergency rooms
 - Withdrawal management facilities
 - Clinics
- BMC published a study looking at initiating methadone at a hospital-based clinic, titrating the dose rapidly, and linking to an OTP.

X-ing the X waiver

- December 29, 2022, The Consolidated Appropriations Act eliminated the DATA-waiver requirement to prescribe buprenorphine.
- No patient caps
- Need to attest to 8 hour SUD education to renew (or obtain) DEA license.

Telehealth bup

- DEA and HHS extended full set of telehealth flexibilities put in place during COVID emergency through December 31, 2024 (in response to overwhelming public response to plans to roll it back).
- This extension authorizes all DEA-registered practitioners to prescribe schedule II–V controlled medications via telemedicine.
- Can prescribe buprenorphine on the basis of audio-only encounter.

42 CFR Part II: Privacy Rule

Former: “Part 2 programs” – programs that provide alcohol and drug abuse diagnosis, treatment or referral for treatment, are subject to more intensive regulations around privacy than HIPAA.

Change: On February 8th, 2024, final rule announced. Now a single consent can be obtained for all future uses and disclosures for treatment, payment and health care operations.

Implication: Brings the regs more into alignment with HIPAA and should facilitate sharing information for the purposes of care coordination.

Modernizing Opioid Treatment Access ACT (MOTAA)

- Would allow for Physicians Board Certified in Addiction Medicine or Addiction Psychiatry, to prescribe methadone for OUD to be picked up at retail pharmacy
- Bound by SAMHSA Time in Treatment regulations.
- Passed the Senate Committee on Health, Education, Labor and Pensions (HELP) in December '23.

References

- Amram, O., Amiri, S., Panwala, V., Lutz, R., Joudrey, P. J., & Socias, E. (2021). The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. *The American journal of drug and alcohol abuse*, 47(6), 722-729.
- Bao, Y., Williams, A. R., & Schackman, B. R. (2020). COVID-19 could change the way we respond to the opioid crisis—for the better. *Psychiatric services*, 71(12), 1214-1215.
- Brothers, S., Viera, A., & Heimer, R. (2021). Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19. *Journal of substance abuse treatment*, 131, 108449.
- Figgatt, M. C., Salazar, Z., Day, E., Vincent, L., & Dasgupta, N. Take-Home Dosing Experiences among Persons Receiving Methadone Maintenance Treatment During COVID-19 Authors: Mary C. Fig. *Substance Abuse*, 2887, 1.
- Frank, D. (2021). A chance to do it better: Methadone maintenance treatment in the age of Covid-19. *Journal of Substance Abuse Treatment*, 123, 108246
- Jaffe, Jerome H., and Charles O'Keeffe. "From morphine clinics to buprenorphine: regulating opioid agonist treatment of addiction in the United States." *Drug and alcohol dependence* 70.2 (2003): S3-S11.
- Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment. *Federal Reg*
- Courtwright DT. Preventing and Treating Narcotic Addiction--Century of Federal Drug Control. *N Engl J Med*. 2015 Nov 26;373(22):2095-7. doi: 10.1056/NEJMp1508818. PMID: 26605925.

- “Characterizing Variability in StateLevel Regulations Governing Opioid Treatment Programs,” *Journal of Substance Abuse Treatment* 115 (2020): #ASAMAnnual2022 108008, <https://doi.org/10.1016/j.jsat.2020.108008>
- Courtwright; *Dark Paradise: A History of Opiate Addiction in America*;
- Hatch-Maillette, M. A., Peavy, K. M., Tsui, J. I., Banta-Green, C. J., Woolworth, S., & Grekin, P. (2021). Re-thinking patient stability for methadone in opioid treatment programs during a global pandemic: Provider perspectives. *Journal of Substance Abuse Treatment*, 124, 108223.
- Gomes T, Campbell TJ, Kitchen SA, et al. Association Between Increased Dispensing of Opioid Agonist Therapy Take-Home Doses and Opioid Overdose and Treatment Interruption and Discontinuation. *JAMA*. 2022;327(9):846-855. doi:10.1001/jama.2022.1271
- 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. doi:10.1001/jamapsychiatry.2022.1776

Questions



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