The Network for Public Health Law

Regulatory Opportunities to Remove Current Barriers to Methadone

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Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws

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No conflicts to declare

All opinions my own

Law is a barrier to methadone for OUD

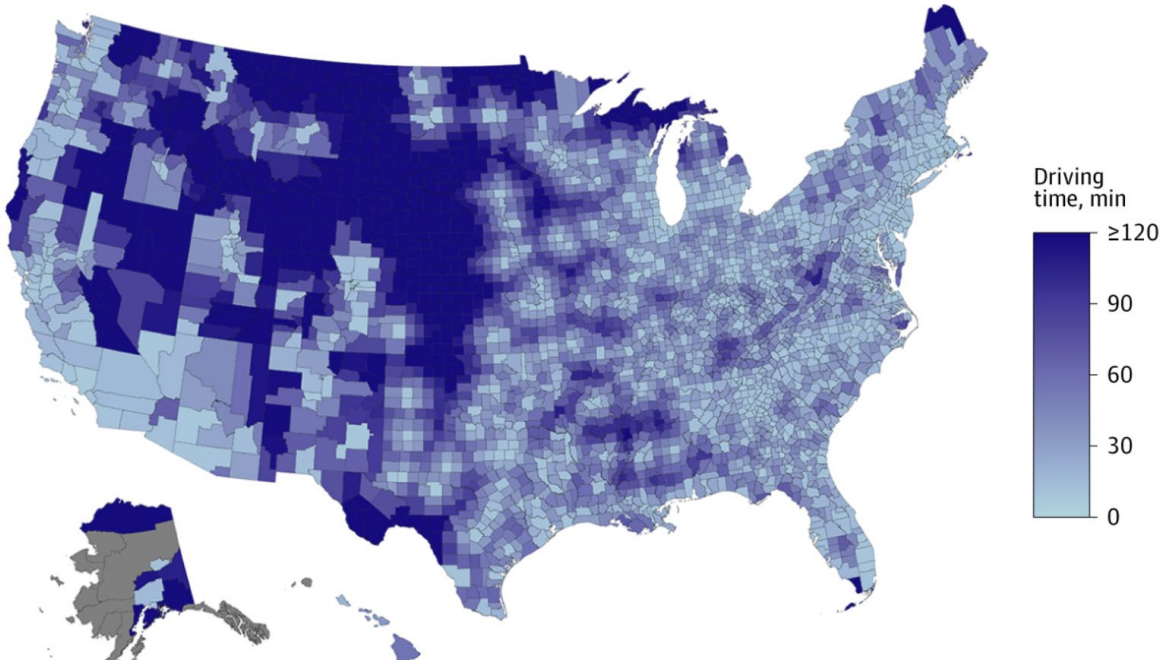
- **Many federal regulatory barriers to methadone access**
  - Only federally certified Opioid Treatment Programs (OTPs) may dispense methadone for OUD treatment
  - Only patients w/ certain characteristics are eligible for treatment
    - Must generally have had OUD for one year; those <18 must have tried detox twice in 12 months
  - Prospective patients must have an initial in-person visit
  - Initial doses are limited
  - Counseling on specific subjects required
  - Periodic urinalysis (generally 8x/year) required
  - All patients required to come to the OTP daily initially for observed dosing
  - "Take-home" doses extremely limited by regulation - not provider expertise, patient characteristics, or patient need

These barriers reduce access

Table 1. Driving Times to the Closest Opioid Treatment Program and Pharmacy[a]

Outcome	One-way driving time, mean (95% CI), min	
	Opioid treatment program	Pharmacy
Primary outcome		
Total US	20.4 (20.3-20.6)	4.5 (4.4-4.5)
Secondary outcomes		
Metropolitan counties		
Large central metro	9.8 (9.8-9.9)	2.8 (2.8-2.8)
Large fringe metro	15.8 (15.6-15.9)	4.2 (4.1-4.2)
Medium metro	15.9 (15.7-16.1)	4.5 (4.4-4.5)
Small metro	24.4 (23.7-25.1)	5.5 (5.4-5.7)
Nonmetropolitan counties		
Micropolitan	48.4 (47.5-49.4)	7.0 (6.7-7.2)
Noncore	60.9 (59.8-62.0)	9.1 (8.8-9.5)

[a] Population-weighted mean driving times (95% CIs) were calculated from census tract mean centers of population to the opioid treatment program and pharmacy with the shortest driving time. Census tract population estimates and mean centers of population were obtained from the 2010 US Census. The primary and secondary outcomes were defined a priori as the population-weighted mean driving times. Weighted 1-sample *t* tests on the differences between driving times to OTPs and pharmacies were calculated. Bonferroni corrections were used for secondary outcome testing. The 2-tailed *t* test $P < .001$ was used for all comparisons.



Kleinman, et al. Comparison of driving times to opioid treatment programs and pharmacies in the US. *JAMA Psychiatry*. 2020.

Some recent flexibilities

- **During COVID emergency:**
  - SAMHSA permits states to request blanket exemptions to permit
    - 28 day take-homes for “stable” patients
    - 14 day take-homes for “less-stable” patients
  - DEA permits some OTPs to provide doses in off-site locations w/o separate registration
  - DEA permits authorized OTP employees, law enforcement, and national guard to deliver methadone to patients (mailing is still forbidden)
  - Neither permitted OTPs to initiate treatment via telemedicine, even though that flexibility was extended to buprenorphine patients - who, on average, are whiter and wealthier than MMT patients

Some recent flexibilities

- **Ongoing**
  - DEA created pathway for mobile delivery of methadone to OTP patients
    - Note that this didn't require regulatory change – DEA decided in 2007 that it didn't like them and wouldn't permit any more, despite evidence that theft and loss were practically zero
  - SAMHSA will extend take-home flexibility after expiration of COVID public health emergency
    - but, per guidance, only for patients who are "stable" or "less stable" – as defined (very restrictively) by SAMHSA
    - and only after 30 or 60 days of in-person visits
    - and only if states "concur" with the change

Some recent flexibilities

» **"Stable" patients are those whose medical record demonstrates:**

(a) that the benefits of providing unsupervised doses to an individual outweigh the risks;
(b) that the individual demonstrates **total adherence** per the OTP's discretion with their treatment plan for at least 60 days;
(c) negative toxicology tests for 60 calendar days;
(d) an absence of serious behavioral problems;
(e) stability in their living arrangements and social relationships;
(f) an absence of substance misuse-related behaviors;
(g) an absence of recent diversion activity; and
(h) assurance that the medication can be safely stored.

Under the guidance, none of these can be waived or modified by the provider.

Actions that can be taken immediately

- As an obvious and immediate first step, current flexibilities that rely on PHE can be tied to the opioid emergency declaration instead of the Covid emergency declaration
- DEA has authority (21 CFR 1307.03) to grant exceptions to many relevant regulations
- SAMHSA has similar authority (42 CFR 8.11(h)) with regard to the OTP regulations
- As a practical matter, both agencies have nearly unlimited enforcement discretion, even if not explicitly granted

Much more can be done relatively quickly

- **Barriers that can be modified or removed solely by regulation**
  - Only federally certified Opioid Treatment Programs (OTPs) may dispense methadone for OUD treatment
  - Only patients w/ certain characteristics are eligible for treatment
    - Must generally have had OUD for one year; those <18 must have tried detox twice in 12 months
  - Prospective patients must have an initial in-person visit
  - Initial dose limits
  - Required counseling
  - Periodic urinalysis (generally 8x/year) is required
  - All patients required to come to the OTP daily initially for observed dosing
  - “Take-home” doses extremely limited by regulation, not provider expertise, patient characteristics, or patient need

Much more can be done relatively quickly

- To belabor the point, the statute only requires that "practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose." 21 U.S.C. § 823(g)(1).

- Everything else can be removed or modified by notice-and-comment regulation, by agency action, or both.

Incentives matter

» **Federal government can amend regulations not directly related to methadone access to align incentives of providers, states, and other actors**

- **Modify Medicaid/Medicare regulations and incentives to encourage states to make state law no more restrictive than federal law**
- **Ensure that Medicare-funded resident physicians receive training in OUD diagnosis and treatment**
- **Condition Medicare funding on hospitals providing MOUD in the ED and elsewhere**
- **Condition criminal-legal funding on corrections providing MMT**
- **Require Medicaid funding for supports such as transportation**
- **Direct all USAs to make ADA and other violations that restrict access to MMT a priority**

The bigger picture

- **Methadone improves outcomes and saves lives**
  - However, it remains more heavily restricted than nearly every other medication – including the *exact same medication* when prescribed for pain
  - This reflects an outmoded framework that prioritizes social control, diversion prevention, and criminalization of (some) people who use (some) drugs over evidence-based and evidence-informed practice

- **In other words, we're optimizing for the wrong things**: Diversion control, social control, structural racism, and stigmatization over patient needs and desires, improved health, productivity, and longevity
  - Statutes can and should be modified to change this framework, but in the meantime regulatory agencies have huge opportunities to make change

My suggestions

- **Go now, go big**
  - We lost **100,000 people – mothers, fathers, daughters, and sons -** in the US in the last year alone
  - Agencies can and should modify take-home requirements, initial dosing, etc. Those reforms are necessary, but they are not sufficient

- **Methadone should be available to everyone who would benefit from it**
  - That necessarily means removing the OTP-only requirement
  - Anything less is letting people – disproportionately people of color, poor people, and other people who are already underserved – suffer preventable disability and death

Conclusions

- Must treat OUD as a public health and not criminal-legal issue
- Everyone who wants MMT should be able to access it – quickly, affordably, and with dignity
- Need to address stigma, financial barriers, and structural inequities
- Federal government has many levers to increase access to methadone for OUD treatment
- Failure to do so is knowingly and intentionally increasing risk of overdose and other harms
- Assuming the agencies have the will, the way is clear, and can happen quickly