Changes to Federal Regulations For Opioid Treatment Programs: Part 2

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Last Updated: 7/24/2024

Disclosures

No conflicts of interest or relationships to disclose

Disclaimer

Funding for this presentation was made possible by 1 TR7HA53202-01-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*

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N.B.

- I want to acknowledge that the fentanyl overdose crisis is often syndemic with HIV and other conditions such as homelessness and mental health disorders.
- Detailed knowledge of the treatment landscape for opioid use disorder among HIV providers is important in order to counsel patients effectively and pragmatically about treatment options.

OUTLINE

- Brief review of changes to 42 CFR Part 8, which regulates Opioid Treatment Programs (OTPs).
- Mobile Medication Units
- “72 hour rule”
- X-ing the X waiver
- Telehealth buprenorphine
- 42-CFR Part 2 (Privacy regs)
- ? Modernizing Opioid Treatment Access Act ?

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42 CFR Part 8 changes

Major substantive changes to regulations for Opioid Treatment Programs enacted in April 2024.

- More emphasis on provider autonomy and patient-centered care
- Much more flexible guardrails around the provision of unsupervised (“take-home”) doses of medication
- Lower barrier to treatment entry
- Counseling not required for continued medication treatment
- Allowance of more aggressive methadone initiation strategies
- Allowance for telehealth visits
- Allowance for “split dosing” (BID dosing) when indicated and safe
- Long-term care and carceral setting can dispense methadone, like hospitals, for folks admitted for another reason

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Mobile Medication Units (MMUs)

- MMUs (“methadone vans”) emerged in the late 1980s to respond to the spread of HIV infection among people who use drugs, to facilitate access to care in rural communities and in urban areas when communities opposed the opening of a fixed site OTP.
- DEA authorized units on an ad-hoc basis, utilizing the same regulatory approval process as a fixed site OTP.
- In 2007, citing concerns about potential diversion, DEA issued a moratorium and stopped approving MMUs.

Mobile Medication Units (MMUs)

- On July 28, 2021, the DEA published a final rule that lifts the moratorium and permits OTPs to add a “mobile component” to their existing registration – eliminating the separate registration requirements.
- SAMHSA has allowed block grant funds to go to MMU purchase and upkeep.
- As of April, there were 42 MMUs in operation in the US (8 of them in Washington state).

Mobile Medication Units (MMUs)

Mobile Medication Units (MMUs)

- MMUs can offer all the core services of an OTP (medical evaluation, medication dispensing, counseling, case management) in the community.
- No additional federal siting requirements.
- Dearth of evidence: Recent Scoping Review: Three cohort analyses (one prospective) and one before and after analysis of individuals using mobile medication services. Mobile services were associated with enhanced retention in care (relative to patients in fixed site programs) and mobile units appeared to facilitate access for underserved populations with opioid use disorders.

Chan et al. 2021

Fixed site medication units?

- Federal Rules also allow for formation of fixed site Medication units which are “part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services.”
- Has not been implemented anywhere to my knowledge.
- These medication units under federal law can be (1) located as a free-standing facility; (2) co-located within in a variety of community settings such as but not limited to hospitals/medical primary care systems/pharmacies/FQHCs etc.
- WA DOH undergoing rule-making process to promote implementation.

“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).”

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“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.

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BMC Bridge Clinic Study

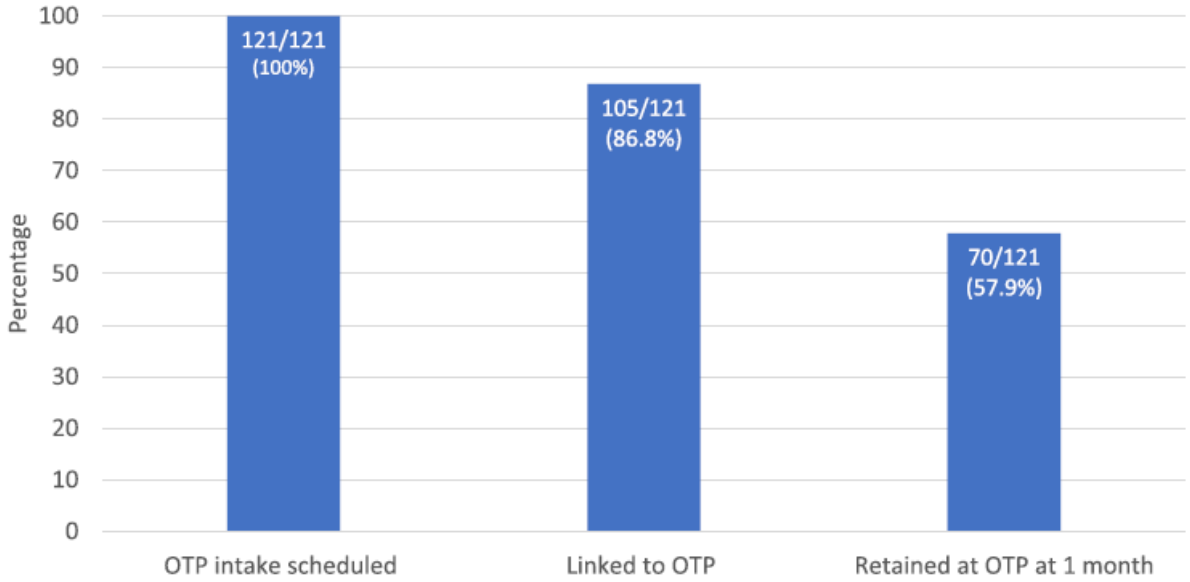

Fig. 4. Scheduled intake appointments, attendance within 1 month of scheduled intake, and 1-month retention in care at two primary collaborating OTPs. Acronyms: OTP, opioid treatment program.

- Methadone was administered during 150 episodes of care for 142 unique patients.
- Among 121 referrals to two primary OTP partners, 87% (105/121) linked and 58% (70/121) were retained at one month.

Taylor et al, 2022

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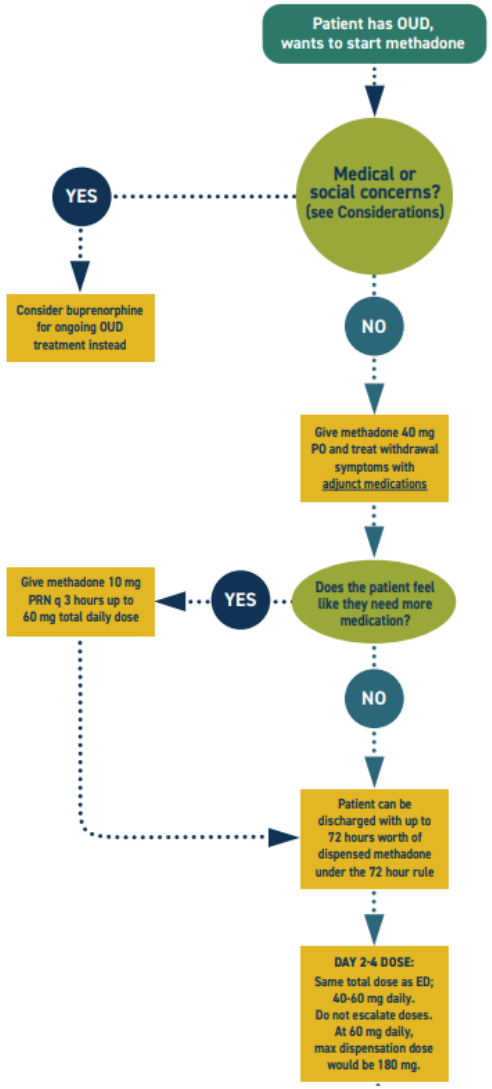
ED-initiated methadone

Methadone Initiation



Methadone dispensation

Patient may be discharged with up to 72 hours worth of methadone while awaiting connection to an OTP per the 72 hour rule per 21 CFR 1306.07(b). Connecting the patient to an OTP is required if dispensing medication.

Considerations

- Age over 65
- Concurrent sedative use
- COPD with oxygen requirement
- Underlying heart disease (potential for QT prolongation)

It is vital to determine whether the patient can successfully connect to an OTP. Consider the daily dosing requirement, distance from and transportation to the OTP, and if the OTP is taking new patients. It is best to schedule the OTP appointment before discharge, and the patient must be linked to the OTP within 72 hours. Fully inform patient of OTP process and expectations.

Communicate with the OTP. At a minimum, the OTP needs documentation of what date/time the patient was given their dose and what their dosing regimen is. Call, if possible, and fax and provide the info to the patient to bring to the OTP.

Consider screening for HIV, HCV, STIs, and mental health comorbidities.

Methadone can have significant drug-drug interactions, which should be reviewed prior to initiation.

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.

Telehealth bup

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42 CFR Part II: Privacy Rule

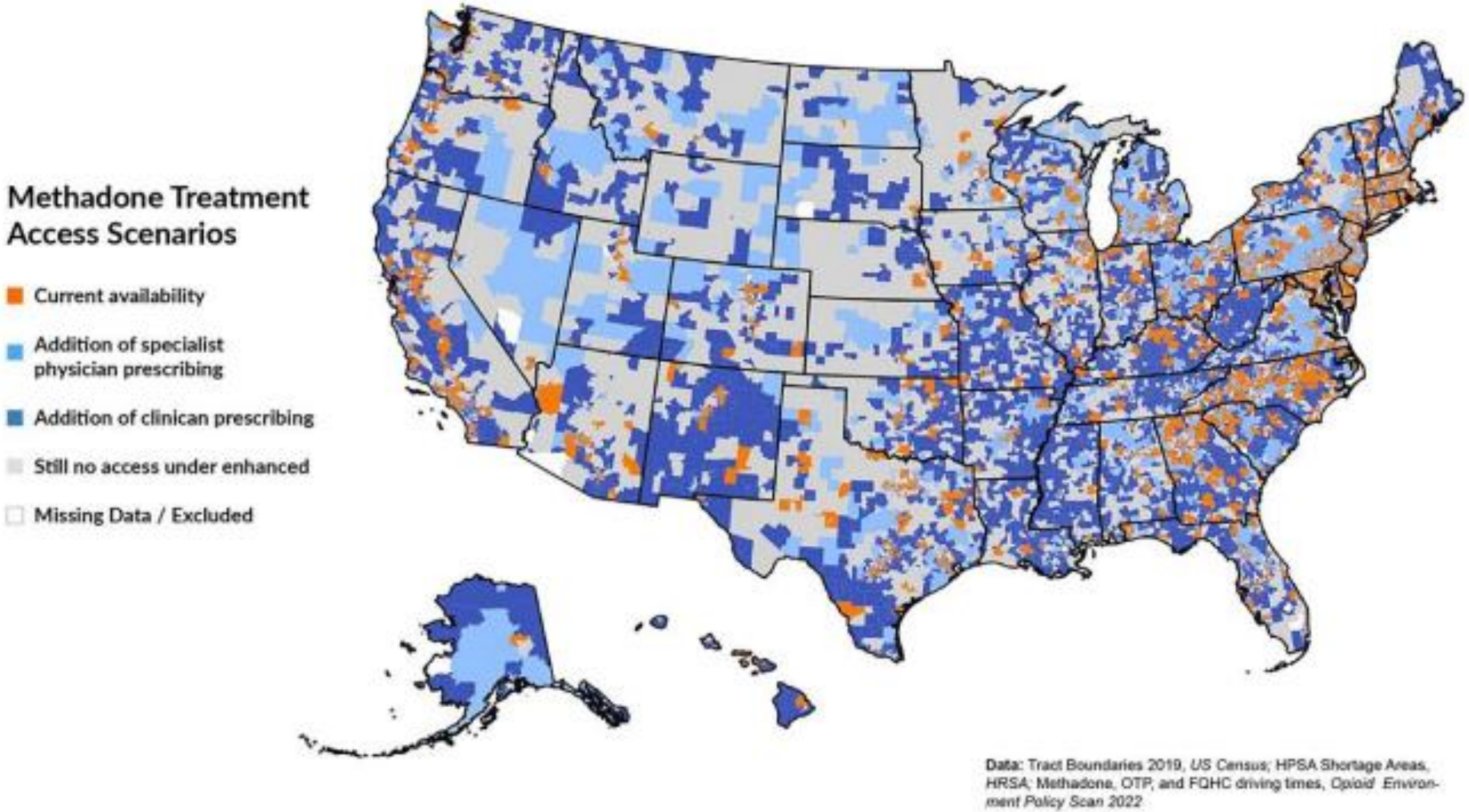
Former: “Part 2 programs” – programs that provide alcohol and drug abuse diagnosis, treatment or referral for treatment, are subject to more intensive regulations around privacy than HIPAA.

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.



Joudrey, et al 2023

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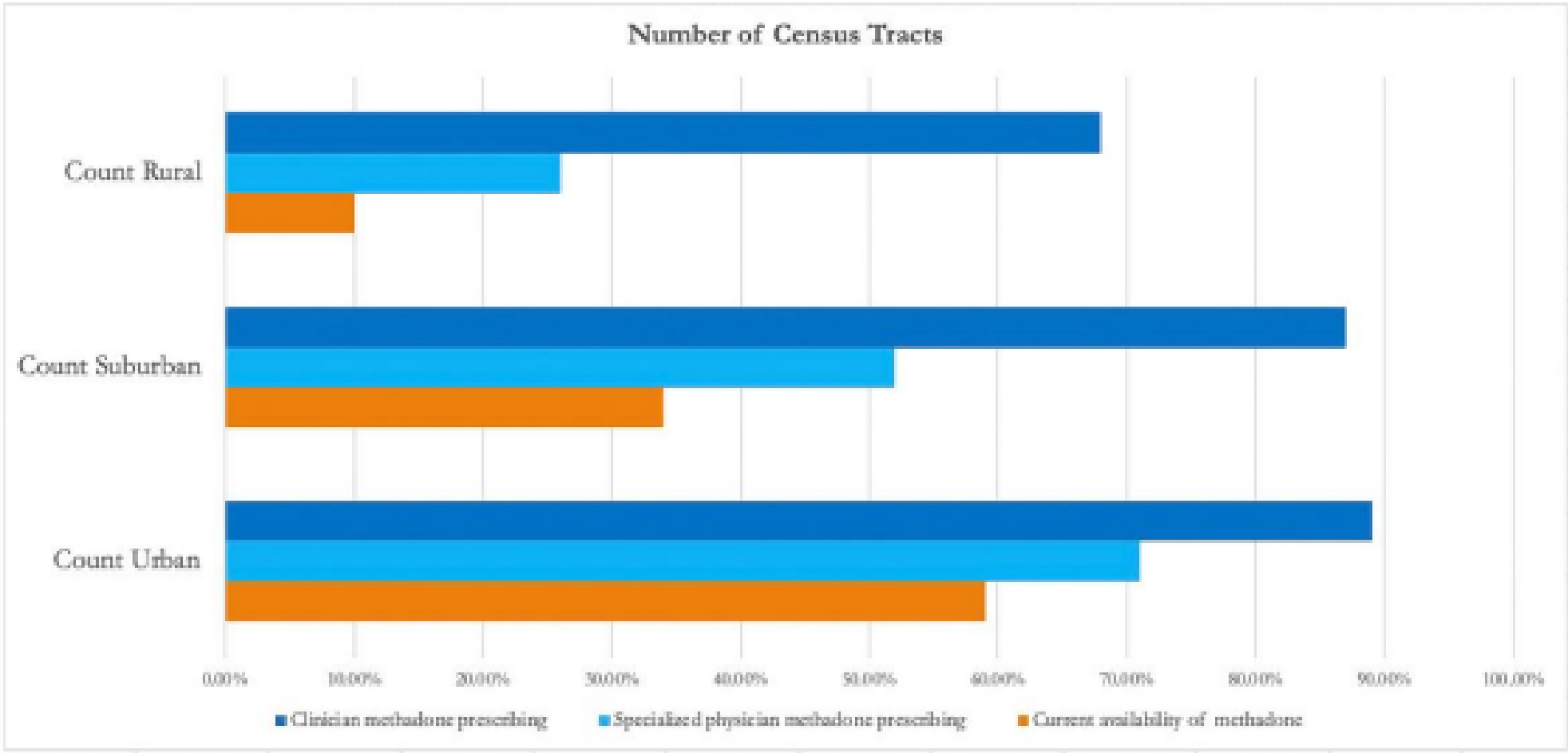

Figure 3. The total population, overdose deaths between 2009 and 2019, and census tracts with and without available methadone treatment with specialist physician and clinician prescribing compared with current availability in populated US census tracts in 2022. Source: Authors' analysis. Methadone was currently available if the census tract was within a 20-minute drive time of an OTP providing methadone treatment for urban census tracts and a 30-minute drive time for suburban and rural census tracts. Methadone was available with specialist physician prescribing in census tracts with either an available OTP or outside of an area with a mental health professional shortage score of 14 or greater. Methadone was available with all clinician prescribing in census tracts with either an available OTP or FQHC using the same 20- and 30-minute drive-time thresholds or outside of an area with a mental health professional shortage score of 14 or greater. Abbreviations: FQHC, federally qualified health center; OTP, opioid treatment program.

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Questions

Acknowledgment

This Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of award 1 TR7HA53202-01-00 totaling $2,982,063 with 0% financed with non-governmental sources.

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