# Making a Transformation (MAT) Conference 2024





# Keynote 1: Updates in Methadone 2024: Increasing Access, Decreasing Stigma, and New Directions

Transforming California's Medications for Addiction Treatment System







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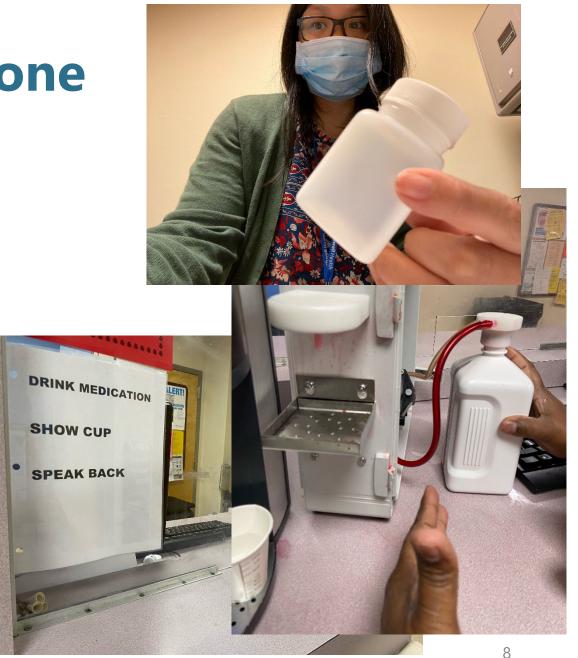






## My Journey in Methadone

- » "A pain medication": Methadone for chronic pain, primary care clinic, MGH Charlestown, MA
- » Rikers Island KEEP program: 30 years of methadone provision in NYC jail
- » Methadone during COVID: Canarsie, Brooklyn, OTP medical director
- » Methadone + primary care at Apt Foundation, New Haven, CT









# Medication for Opioid Use Disorder: US Snapshot

- Estimated burden of OUD in the US: NSDUH 2021 estimate 2.0% of the population or 5.6 million people
- » Past year OUD, 35.6% received any SUD tx and 22.3% MOUD (Jones 2023)
- » Those less likely to receive MOUD were Black, women, unemployed, rural areas

~4,351,200 million people with OUD did not access MOUD.







## Sociohistorical Perspectives on Methadone in the United States

#### Why does this history matter?

- » Developed in WWII as alternative analgesic to morphine, studied at at Lexington "Narcotic Farm" for opioid withdrawal management 1946
- » Marie Nyswander, Vincent Dole, Mary Jean Kreek: early research on methadone to treat heroin use disorder met with disapproval from Bureau of Narcotics, according to Don DesJarlais, tried to revoke Dole's license. 1965: Dole publishes on maintenance.
- » Approved by FDA in 1972 for treating heroin addiction
- » OTPs and methadone maintenance born of the US' inherent politics of medicine and clinical research; carcerality baked in







#### F.D.A. Sets Severe Restrictions on Use of Methadone

today by the Food and Drug use in the city.

methadone maintenance pro- and under close surveillance.

The drug will not be avail- narcotic frequently enough to grams are expected to expand

He said he believed they able to persons under the age be classed as addicts, however. cept those of hospitals.

frees the patent of a craving use methadone. for the other drug but does not A preliminary version of the maintain supplies of it.

tial quantities have been divert- others.

been expected for several of the drug. months, Dr. Robert G. Newman. The new regulations were In remarks prepared for a director of New York City's published today in the Federal news conference to be held

Under the new regulations, were generally well operated provide the following:

substantially, but they will be were largely free of the kinds of 18 except in special cir- A news conference to explain much more tightly controlled of abuse reported from other cumstances. The prescribing of methadone cities, including Washington. The prescribing of methadone cities, including Washington to a maintenance program must Government agencies involved out. Except in special and re-pensing the drug without proper years.

The new regulations place tight restrictions on the types of patient able to get methadone and on their use of it.

Methadone is a synthetic chemical developed in Germany during World War II to cope with a shortage of morphine. In procent years, the programs, of whom the programs and programs and programs and the program and the progr

produce the "high" the addict Federal regulations made pub. The maintenance programs However, methadone is also a in April and has evoked a great Federal agencies. narcotic and can produce the deal of comment from doctors. In answer to a query today, "high" when injected. Substan-industry representatives and the Bureau of Narcotics and

The new regulations, most of an unwarranted intrusion into federally sponsored methadone which become effective in 90 medical practice and the doc-maintenance programs in Ocdays, are designed to allow ex-tor-patient relationship. Gov-tober, 1971, and that the figure pansion of methadone's legiti-ernment spokesmen have re-had risen to 20,000 in Septemmate uses, while curbing illicit plied that such intrusions have an estimated 34,000 were re-The new regulations have mum required for the safe use ceiving methadone on doctors'

By HAROLD M. SCHMECK Jr. methadone maintenance pro-special to The New York Times, said today he was not Dr. Charles C. Edwards, Com-director of the bureau, said that WASHINGTON, Dec. 15—Sefamiliar with the details of the missioner of Food and Drugs. the 34,000 represented an estivere restrictions on the use of pect there would be much efEdwards said that maintenance legitimate users. methadone were made public fect on legitimate methadone programs had expanded greatly The White House's special in recent years.

the programs in New York observed. The new regulations users of heroin in the country

doctors not involved in such reports here that some indi-programs will be virtually ruled vidual doctors have been dis-drug-dependent for at least two Dr. Jaffe's office.

The new regulations place estimated 100,000 to 150,000 tered only in liquid form, and heroin addicts. It is also used

recent years it has been used the Health Service Administra- who demonstrably need it, but widely in maintenance pro-grams for heroin addicts be-000 are under treatment in prescriptions filled either cause, when taken by mouth, it various programs that do not through approved methadone programs or hospitals that

lic today was made public here must be approved by state and

Dangerous Drugs said there ec into illicit channels in recent Numerous critics said the were an estimated 10,000 perproposed regulations would be sons in the United States on been kept to the absolute mini- ber, 1972. As of that later date. prescriptions.

action office for drug abuse Administration in an effort to Dr. Newman, who is also Astronect better control over this sistant Commissioner of Health widely used substitute for her- for addiction programs, said lem of abuse and diversion," he there are 500,000 to 600,000 today. Not all of them use the

the new regulations is planned

There are believed to be 435 stricted cases, the drug will not supervision of the persons rebe carried by pharmacies exceiving it.

4All participation must be federally approved maintenance programs throughout the coun-New York, which has an The drug will be adminis- try using methadone to help



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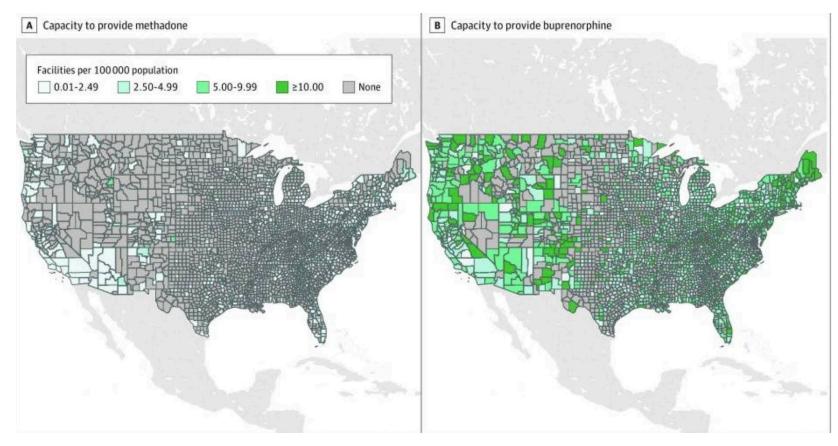






## Structural Racism and MOUD Access

- » Black pts much less likely to access buprenorphine
- » Methadone access higher in counties w/ Black and Hispanic patients, bupe access higher in counties w/ white residents
- » White Out (Hansen, Netherland, Herzberg)





Goedel WC, Shapiro A, Cerdá M, Tsai JW, Hadland SE, Marshall BDL. Association of Racial/Ethnic Segregation With Treatment Capacity for Opioid Use Disorder in Counties in the United States. JAMA Netw Open. 2020 Apr 1;3(4):e203711. doi: 10.1001/jamanetworkopen.2020.3711. PMID: 32320038; PMCID: PMC7177200.



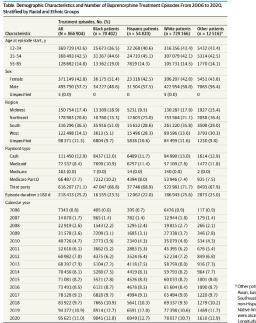






#### From: Racial and Ethnic Disparities in Buprenorphine Treatment Duration in the US

JAMA Psychiatry. 2023;80(1):93-95. doi:10.1001/jamapsychiatry.2022.3673



Other patients include Central Asian, East Asian, South Asian, Southeast Asian, Caribbean non-Hispanic, Polymesian, and Native American. Race and ethnic were ascertained from IQVIA Longitudinal Prescription Data.

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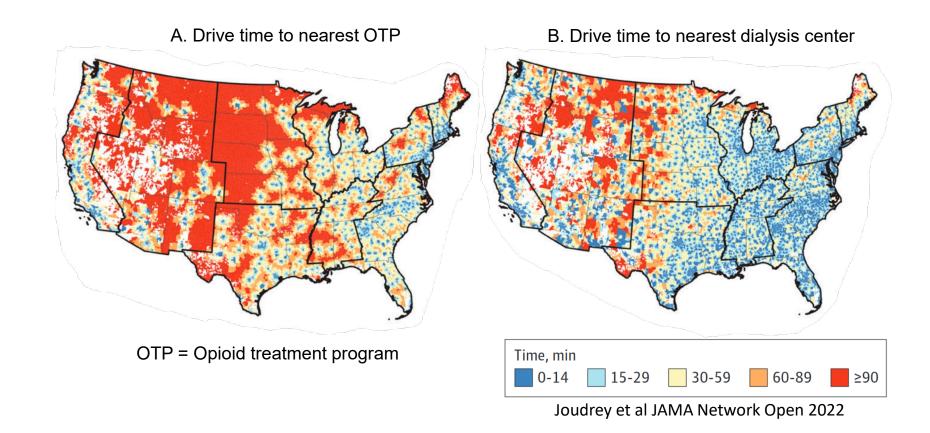
Demographic Characteristics and Number of Buprenorphine Treatment Episodes From 2006 to 2020, Stratified by Racial and Ethnic Groups<sup>a</sup> Other patients include Central Asian, East Asian, South Asian, Southeast Asian, Caribbean non-Hispanic, Polynesian, and Native American. Race and ethnicity were ascertained from IQVIA Longitudinal Prescription Data.







## **Methadone Access in the US**









## **OTPs: A Litany of Problems**

- » Drive/travel time
- » No flexibility with take-homes
- » Punishment with dose or insufficient dose to blockade; punishment for polysubstance use
- » Not therapeutic whole person care
- » Harassment and stigma from staff/guards/admins/HCWs
- » Inflexible hours
- » Frequent urine toxicology
- » Counseling requirements
- » Lev Facher Stat News "War on Recovery"
- » National Survivors Union: "A culture of cruelty"



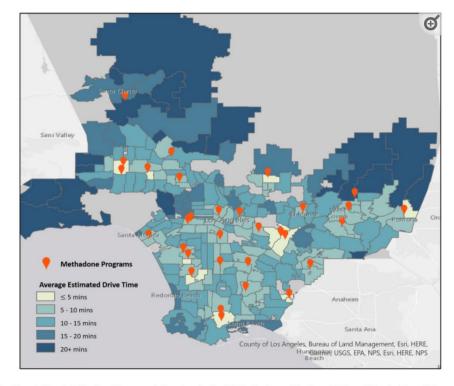




# Drive Time to OTPs and Outcomes: Los Angeles Case Study

Fig. 1

- Discharge data analysis of 22,587 OUD treatment episodes in LA
- On average, 10.88% of episodes resulted in completion of treatment goals. The completion rate of counseling episodes was 23.6% whereas the completion rate for methadone was notable lower, at 8.1%
- Findings show an average driving time of
   11.32 min and an average distance of 11.18 km
- Found that an EDT of 10 to 20 min was associated with a 33% (CI = 12.2, 40.1%) drop in the odds of completing a methadone episode compared to an episode where the client had an EDT of less than 10 min.



Average Estimated Drive Time to Reach Methadone Programs in Los Angeles by ZIP Code. A combination of GIS and Google Maps API was used to calculate the average time (in minutes) it would take for clients from Los Angeles County ZIP code in the study sample to drive to the methadone programs they attended. For robustness, only ZIP codes with at least 10 episodes are shown

Alibrahim A, Marsh JC, Amaro H, Kong Y, Khachikian T, Guerrero E. Disparities in expected driving time to opioid treatment and treatment completion: findings from an exploratory study. BMC Health Serv Res. 2022 Apr 11;22(1):478. doi: 10.1186/s12913-022-07886-7. Erratum in: BMC Health Serv Res. 2022 May

9;22(1):620. PMID: 35410215; PMCID: PMC8996398.







## **California OTP Regulations >> Fed Regs**

Figure 1

### 19 States and the District of Columbia Impose Barriers on Opening New OTPs

Restrictions on new OTPs as of June 1, 2021

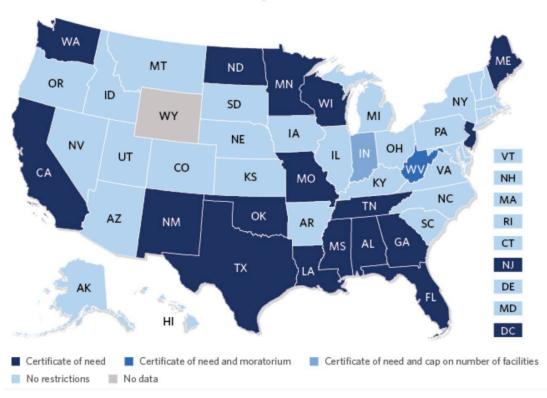
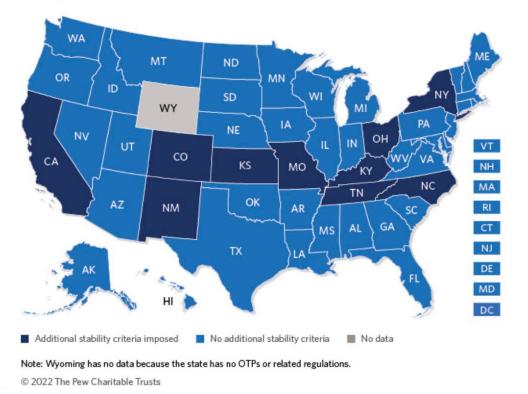


Figure 10

#### State Stability Requirements Make It Harder to Obtain Take-Home Medication

States with a definition of stability beyond what is described in federal rules as of June 1, 2021









# Love people on methadone









## **SAMHSA Final Rule Updates 2024**

#### Overall moving to promote use of clinical judgment and patient-centered care

#### » Stigma

1. Removes stigmatizing language "abuse" "detoxification" "MAT", etc.

#### » Telehealth

- 1. Allows OTPs to initiate buprenorphine treatment via audio-visual or audio only
- 2. 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)

#### » Eligibility

- 1. Removes 1-year minimum diagnosis of OUD criteria to expand to any mod/severe OUD, OUD remission, or risk of recurrence/overdose, and removes 1-year history of OUD for individuals leaving corrections, pregnant, or previously enrolled
- 2. Removes requirement of 2 failed attempts at detox for minors <18 to enter OTP

Summary by Noa Krawczyk







## **SAMHSA Final Rule Updates 2024**

#### » Interim Treatment

- 1. Definition expanded from 120 to 180 days, and gives priority to pregnant individuals
- 2. Expands the circumstances in which a patient may obtain treatment at another OTP to include instances when there is an inability to access care at the OTP of record.

#### » Non-OTP methadone administration

- 1. Correctional settings can be designated LTC facility if registered as a hospital with DEA "Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law."
- 2. Lowering Barriers

#### Lowering barriers

- 1. Does not make medication continuity contingent upon involvement in counseling services but fosters greater shared decision-making. Also expands definition of counseling to include harm reduction, psychoeducational services, and recovery-oriented services.
- 2. Facilitates initial screening to allow for medication to commence at time of intake
- 3. Serology optional: "Patient's refusal to undergo lab testing should not preclude them from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications".







## **SAMHSA Final Rule Updates 2024**

#### » Accreditation

- 1. Changes around OTP accreditation procedures as well as compliance oversight for Accreditation Bodies state and federal
- 2. Expanded definition of practitioner to "a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP"

#### » Drug testing

1. Still require minimum 8 random tests per year, criteria around take homes do not explicitly mention drug testing

#### » Take homes:

- 1. Patients new to tx can receive up to max 7 days of take-home doses during the first 14 days of treatment, up to max 14 take home doses from 15 days of treatment, and up to max 28 take-home doses from 31 days in treatment (OTPs must maintain procedures to protect take-homes from theft and diversion, and patient education on safe transport/storage)
- 2. The following criteria are listed as guiding but ultimately rely on determinations by "an appropriately licensed OTP medical practitioner or the medical director"
  - 1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
  - 2. Regularity of attendance for supervised medication administration;
  - 3. Absence of serious behavioral problems that endanger the patient, the public or others;
  - 4. Absence of known recent diversion activity;
  - 5. Whether take-home medication can be safely transported and stored; and
  - 6. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

Summary by Noa Krawczyk







## **Changes in Dosing SAMHSA Final Rule 2024**

#### **Dosing**

- 1. Allows greater flexibility for split dosing, including in take homes and without additional documentation needed
- 2. Allows for higher induction doses of methadone, but requires rationale to be documented in patient's record "For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.







## **How Can Change Happen?**

- » Movement building and community mobilization
- » Education, enforcement, accreditation levers, payers
- » Work with and action at state level
- » There is a huge treatment gap need. Building more flexible and lower barrier OTPs can help more patients stay in treatment for longer
- » MOTA-A bill to allow addiction medicine physicians to prescribe, pts to pick up at pharmacies, not OTPs









## Methadone Treatment Working Group Recommendations (Liberating Methadone Conference, NYU, Fall 2023)

- 1. Centering Living and Lived Experience in Policy and Practice
- 2. Shifting Public Thinking and Normalizing Methadone as Standard Healthcare
- 3. Improving Practices within Opioid Treatment Programs including Grounding in Person-centeredness
- 4. Creating Alternatives to the OTP System
- 5. Increasing Accountability In and Through Research, Data Collection, Reporting, and Monitoring

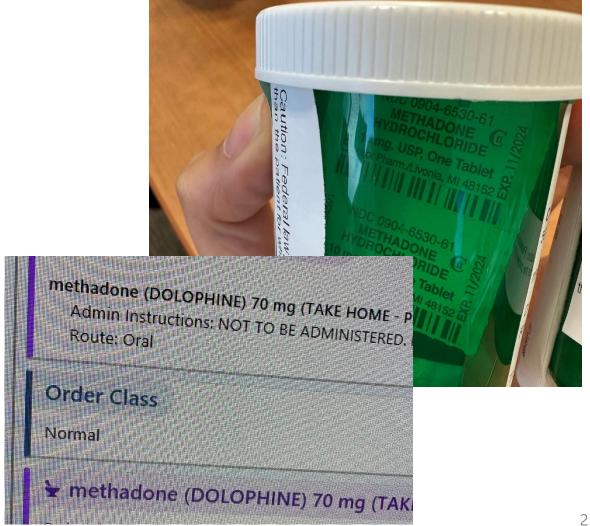






## Methadone 72 Hour Rule

- » Methadone for OUD administered by non-OTP provider to treat opioid withdrawal for up to 72 hours while arranging ongoing care/linkage to OTP
- » Currently not permitted in CA

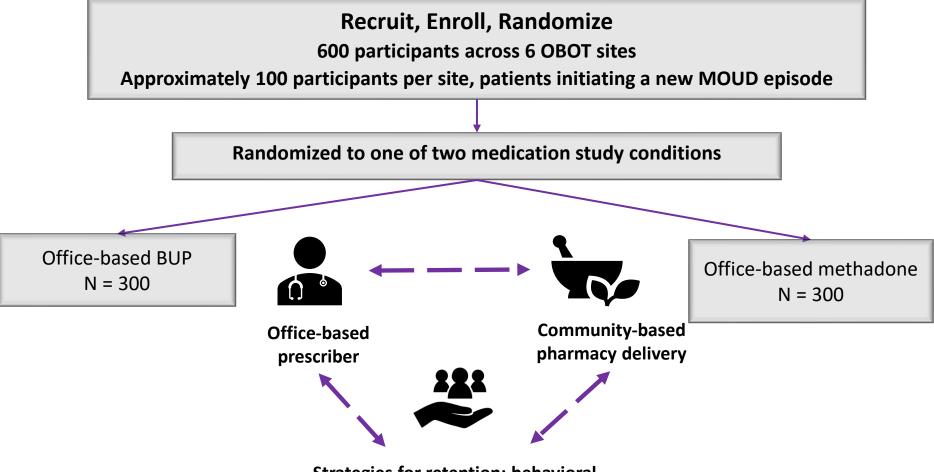








## Methadone in Primary Care? CTN 0131 Office based methadone vs bupe to address retention for MOUD treatment









Strategies for retention; behavioral treatment, addressing adherence, more frequent monitoring

## **International Methadone Models**

- » Canada
- » Australia
- » UK

Overview of Methadone Delivery in Australia, Canada, the U.K., and the U.S.

	Allows prescribing outside of specialty treatment settings	Requires specialized training to prescribe	Allows pharmacy dispensing	Limits on take-home doses
Australia	Yes	Yes, training varies by state	Yes	Federal guidelines discourage more than four take-home doses per week. States set specific policies.
Canada	Yes	Yes, training varies by province	Yes	Rules vary by province.
United Kingdom	Yes	No	Yes	Limited to seven doses (a one-week supply) at a time.
United States	No	N/A*	No	Under current rules, the phased schedule increases from one per week in the first 90 days of treatment to a potential maximum of one month after two years' treatment. Recently proposed rules would allow up to 28 doses for clinically stable patients after just one month in treatment.





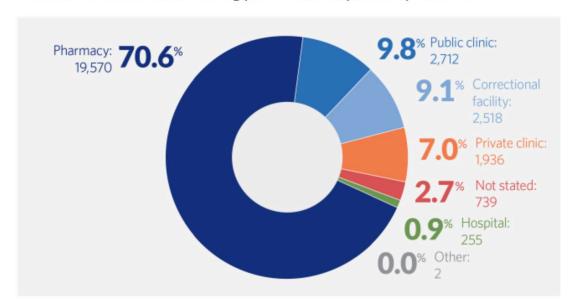


## **International Models**

Figure 1:

### Most of the 47,500 Methadone Patients in Australia Receive the Medication at a Pharmacy

Patients served at various dosing points on a snapshot day in 2021



Notes: Data for 2021 excludes Queensland. Each state and territory reports data for a single "snapshot day," usually in June, although the exact date varies across jurisdictions.

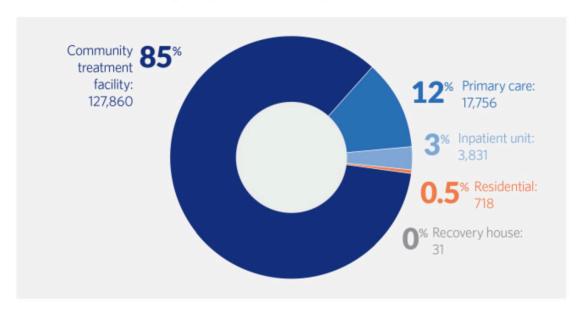
Source: Australian Institute of Health and Welfare, National Opioid Pharmacotherapy Statistics Annual Data collection, https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/national-opioid-pharmacotherapy-statistics/contents/about

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#### Figure 1

### Most MOUD in England Is Prescribed in Community Addiction Treatment Settings

Treatment data from April 1, 2020-March 31, 2021



Note: Data includes prescriptions for all forms of MOUD: methadone, buprenorphine, and naltrexone.

Source: UK Office for Health Improvement and Disparities, "Substance Misuse Treatment for Adults: Statistics 2020 to 2021," Table 9.1, https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2020-to-2021

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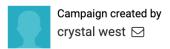




# Stigma Associated with Methadone Treatment/OTP System

TO: President Donald Trump, The North Carolina State House, The North Carolina State Senate, Governor Roy Cooper, The United States House of Representatives, and The United States Senate

#### **Shut Down Methadone Clinics**



Methadone clinics are allowing the government to legally dose heroine addicts, and allow them to drive away under the influence! On top of dosing patients with legalized narcotics, they don't lower the dosage to help them get clean; they UP the dosages each week!

#### Why is this important?

I am a recovering heroine addic,t as is my husband. We run 2 addictions recovery ministries. We see 30 out of 50 people walk through our doors weekly. The majority of them hate that they ever got on methadone because now it is in their bones and are deathly sick when they try to come off. The clinic gets \$80 to \$100 per week per client that walks through their doors! Not only that but as soon as these addicts get their dose, they meet their dealer within 5 miles of the clinic to get the ultimate high! Our lives, our children's lives, and these addicts lives are all at risk. Please help me get these clinics out of our cities.



## Stigma: New Haven, CT case study

#### New Haven mayoral hopeful calls for clos Congress Avenue methadone clinic

By Mark Zaretsky March 7, 2023



Tom Goldenberg holds a news conference on Congress Avenue in New Haven between an APT Foundation methadone clinic and the John C. Daniels School of International Communication Tuesday.



APT patient Jeffrey Culp: "What happens to the people where this place saved their lives?"



Arnold Gold/Hearst Connecticut Media





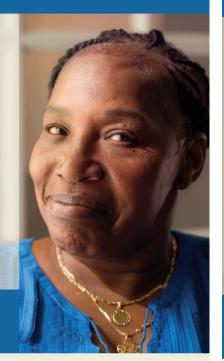
## **Methadone Saved My Life:** Sample public health campaign

#### I am living proof that methadone treatment works.

I had a horrible addiction to heroin. I didn't really care if I lived or died. My family wanted me to change, but I didn't know how. I started methadone treatment. It's medicine. It helped me stop craving and taking drugs. Today I have my family. Every Sunday I cook at home. My kids and grandkids come to visit. Thanks to methadone treatment. I'm living life.

- Camille

Opioid addiction treatment with methadone and buprenorphine is available in New York City.



If you or someone you know needs help, call 888-NYC-WELL



#### I am living proof that methadone treatment works.

I started using heroin when I was 20. I went from once in awhile to every day. When you wake up sick from withdrawal, all other needs and responsibilities are subordinate. It's only through methadone treatment that I was able to stop. Today, life is centered on my kids, my family, and my music. Methadone made it possible.

- Erik

Opioid addiction treatment with methadone and buprenorphine is available in New York City.

If you or someone you know needs help, call 888-NYC-WELL or visit nyc.gov/health/addictiontreatment for more information.



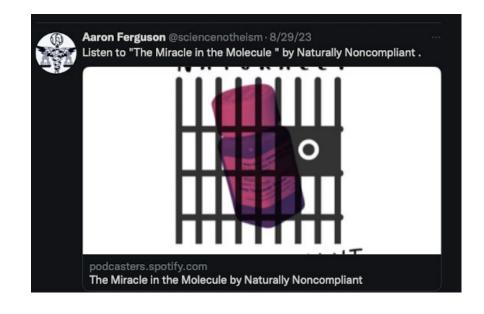






## What More Can We Do?

- » Yes In My Backyard
- » Better methadone research
- » Advocacy
- » National Coalition to Liberate Methadone
- » Work with patients in OTPS/ppl with lived and living experience, "Naturally Noncompliant" podcast









People on methadone are essential voices to inform the changes we need









# Questions? Email <u>Kimberly.sue@yale.edu</u> @DrKimSue

