

Decreasing Barriers to Methadone Access: Lessons from Jail and COVID-19

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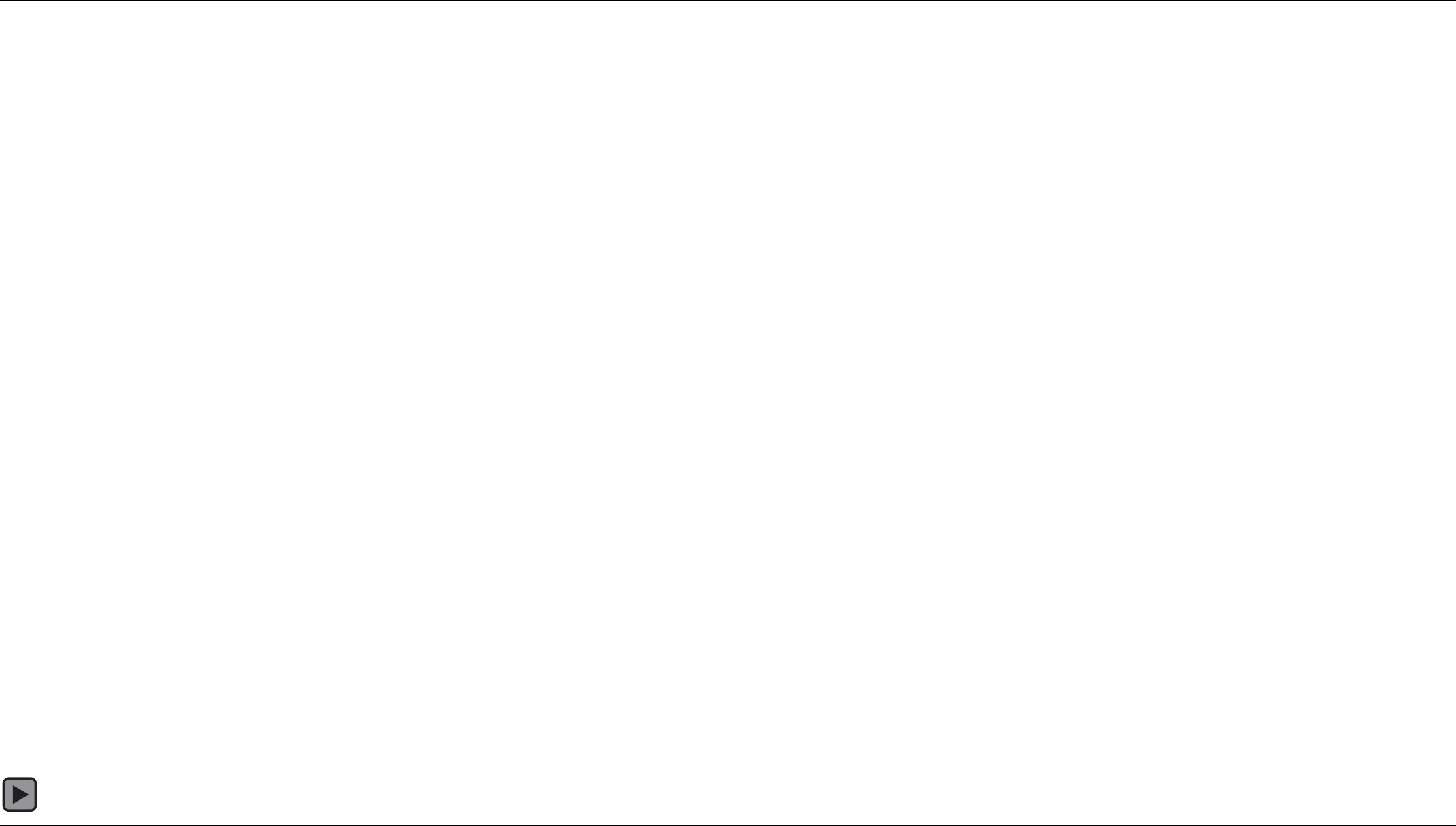
Disclosure Information

- ◆ I have no disclosures.



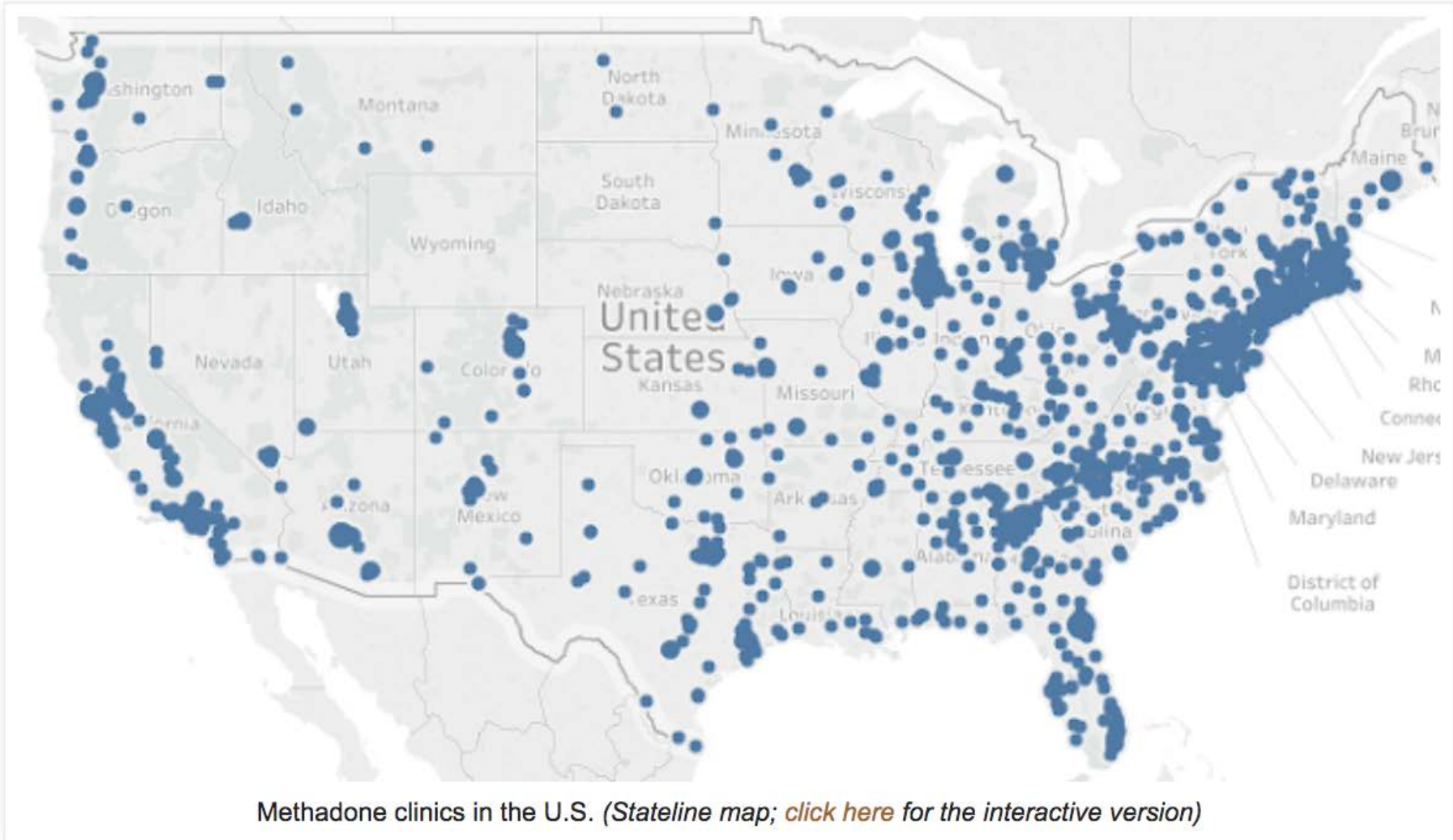
Learning Objectives

- Outline the steps needed to obtain an OTP license as a correctional facility
- Recognize the different carceral systems in the United States and how medical care is delivered in those settings
- Summarize the history of federal oversight in methadone administration

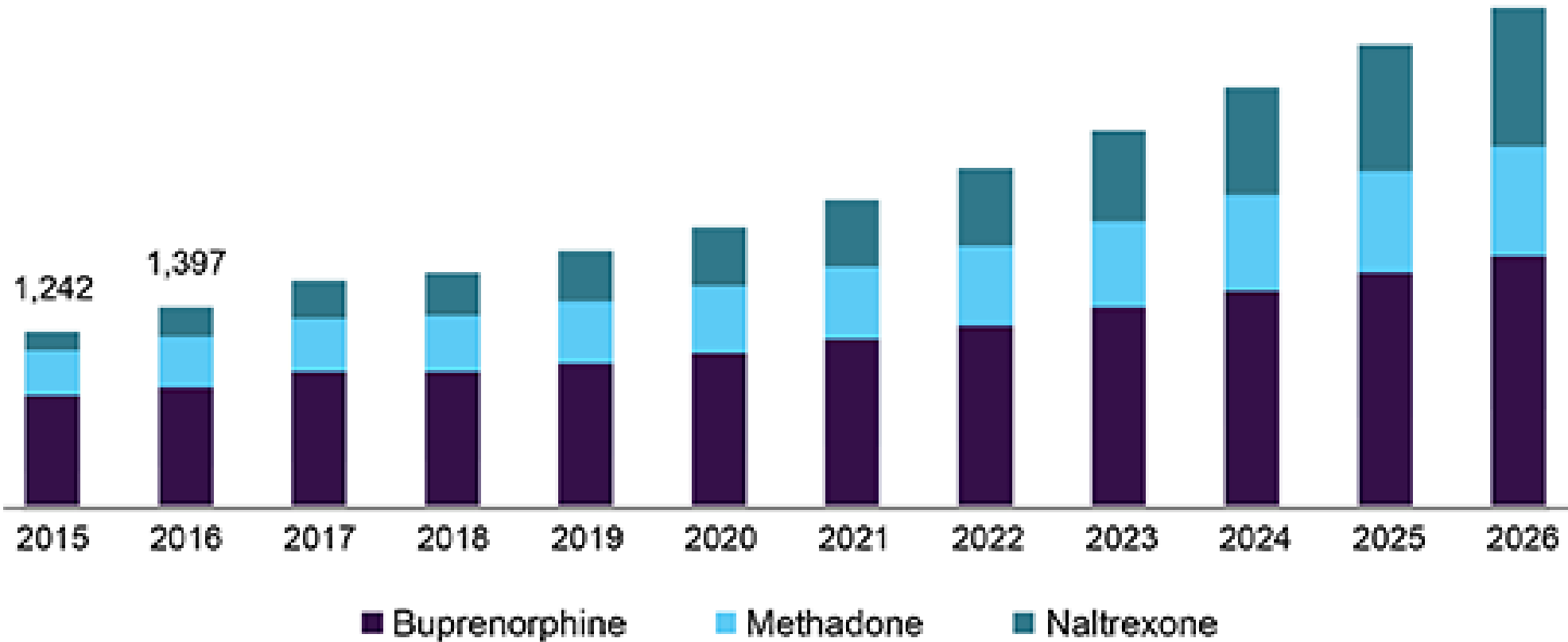




Medication-assisted treatment expands as stigma decreases and more states cover treatment under Medicaid



U.S. opioid use disorder market size, by drug, 2015 - 2026 (USD Million)



Source: www.grandviewresearch.com







Evaluated by the
State for the
Appropriateness of
your Application

Application to
SAMHSA-CSAT

Accreditation by national
organization

Apply for DEA
Number
to be OTP

Apply for state prescribing
Authority to be OTP



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SAMHSA – CSAT

Online Form SMA-162 for Provisional Certification of a New Opioid Treatment Program

Instructions

On the following pages you can fill out and submit to SAMHSA an on-line form SMA-162, and supporting documents, for Provisional (initial) Certification of a new Opioid Treatment Program (OTP).

Note: Only SMA-162s for **provisional certification** of a new OTP can be submitted at this site. Existing OTPs wishing to submit Form SMA-162 for **renewal of certification**, or other purposes, must submit via their account on the SAMHSA OTP Extranet Website at <http://otp-extranet.samhsa.gov>. All OTPs have an account on the site. For help accessing your program's account, contact the SAMHSA OTP Extranet Information Center at OTP-Help@jbsinternational.com, or 1-866-348-5741.

The instructions below will help you prepare a complete SMA-162 submission that can be processed expeditiously by SAMHSA. You may wish to [print](#) these instructions for use as a checklist in obtaining and preparing all required information and supporting documents for your SMA-162 submission. When ready, click 'Continue' at the bottom of the page to begin completing your online SMA-162.

Who May Submit an SMA-162 Form?

An SMA-162 may only be submitted/signed by an OTP Program Sponsor. The Program Sponsor's name and contact information, including telephone number and e-mail address, are required on the form. After submitting an online SMA-162, a confirmation e-mail will be sent to the Sponsor. The Sponsor will need to click a link supplied in that e-mail within 3 days to electronically sign the SMA-162 and complete the submission process. The submission process will not be complete until the Sponsor clicks the link in that e-mail. SAMHSA will contact the Sponsor after receipt of a completed SMA-162 if additional information is required.

Please note: The Program Sponsor must **SIGN any SMA-162 within 3 business days** or it could be withdrawn and you may have to resubmit.



FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

INTRODUCTION

The *Federal Guidelines for Opioid Treatment Programs* (Guidelines) describe the Substance Abuse and Mental Health Services Administration's (SAMHSA) expectation of how the federal opioid treatment standards found in Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8) are to be satisfied by opioid treatment programs (OTPs). Under these federal regulations, OTPs are required to have current valid accreditation status, SAMHSA certification, and Drug Enforcement Administration (DEA) registration before they are able to administer or dispense opioid drugs for the treatment of opioid addiction. As stated in 42 CFR § 8.12(i)(2), these regulations apply to “opioid agonist treatment medications that are approved by the Food and Drug Administration.” Currently, these drugs are methadone and pharmaceutical products containing buprenorphine, hereafter referred to as buprenorphine. The regulations apply equally to both of these medications, with the only difference being the time and treatment requirement for unsupervised dosing spelled out in 42 CFR § 8.12(i)(3). Other pharmacotherapies may be provided in a manner consistent with the best medical practices for each drug. For example, the use of naltrexone has a place in OTPs but is not subject to these regulations.





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**The Rockefeller
University Hospital**

Acknowledgments

The First Pharmacological Treatment for Narcotic Addiction: Methadone Maintenance

Heroin abuse surged in the United States in the early 1960s, becoming a major public health problem. At the time, most people attributed addiction to a lack of willpower, or to antisocial or criminal behavior. The urgency of dealing with these issues came to the attention of Rockefeller researcher Vincent P. Dole (1913-2006) in 1962, when he was acting chairman of the Health Research Council of the City of New York's committee on unresolved health problems, which was grappling with the heroin problem in New York. Dole proposed that addiction was an illness, a "metabolic" disease with behavioral manifestations. He was so committed to understanding this problem that he changed the focus of his laboratory, where he had studied obesity and metabolism, to heroin addiction and new pharmacological approaches for chronic treatment.

In late 1963 Dole recruited two additional researchers to the project: clinical investigator Mary Jeanne Kreek and psychiatrist Marie Nyswander (1919-1986). In early 1964, this team began studies with heroin addicts at the Rockefeller Hospital which, within six months, established the mode of action and potential effectiveness for maintenance treatment of methadone, a synthetic drug that had been used for short-term detoxification in a few clinics. The researchers also contrasted methadone's effects to the action of short-acting opiates such as heroin and morphine.



Dole, Vincent; Nyswander, Marie; Kreek, Mary Jeanne.

Methadone

1967-1970 - Investigational New Drug

FDA doubted efficacy

Clinics Profiteering – No Standards

Harry Anslinger Influence – Get Rid of the “Addict”

Treatment of people with unclear OUD

Push back from communities of color that this was Government mind-control

Reports of unlimited quantities of methadone

“Drug Free” treatment preference

Reports of children overdosing on methadone

Reports of diverted methadone



March 1973 Regulations

Unprecedented Departure from Allowing Licensed Physicians to Use Judgement

- ◆ Age (18)
- ◆ Length of Use (at least one year)
- ◆ Maximum initial doses (30 mg)
- ◆ Minimum amount of counselling
- ◆ Specifics limitations on take home doses
- ◆ Closed system: approved clinics and hospital pharmacies

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

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(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions with a documented history of opioid use disorder (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification (medical withdrawal) treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

PATIENT ADMISSION CRITERIA

42 CFR 8.12(e) *Patient admission criteria.* (1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

SAMHSA – CSAT

- ◆ Organizational structure of the program
- ◆ Diagram of the facilities
- ◆ Plan for how the program will provide all the required vocational, medical, educational, behavioral programming
- ◆ Medical director licensure and CV
- ◆ Staff licensure
- ◆ Funding sources
- ◆ Numbers of people to be treated
- ◆ Hours of operation



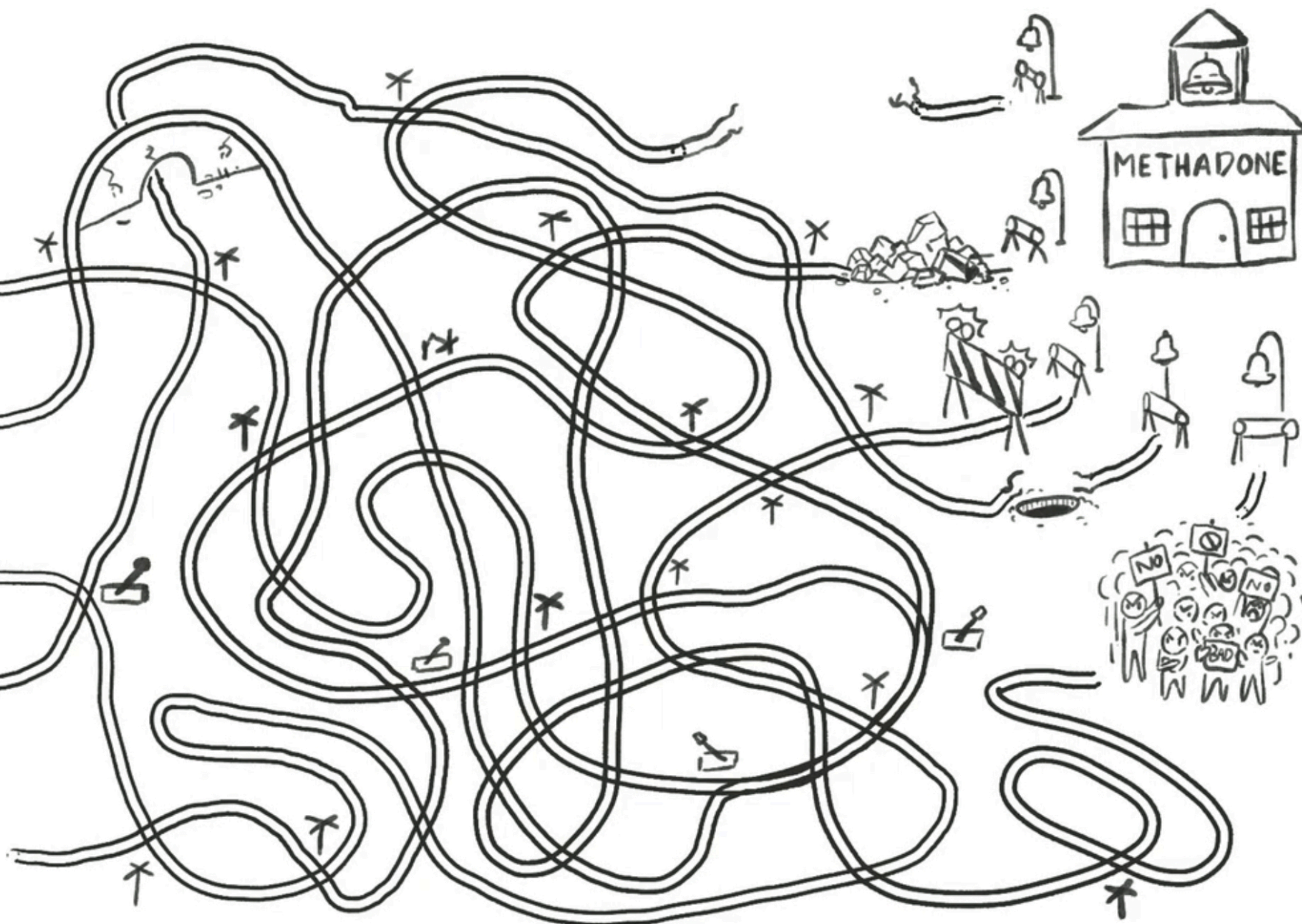
FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.”

The program sponsor is the person ultimately responsible for the operation of the program, and most importantly, ensuring the program is in continuous compliance with all federal, state, and local laws and regulations. If there is a change of program sponsor, SAMHSA requires formal notification within 3 weeks of the change.

While the program sponsor retains the ultimate responsibility for an OTP’s operations, the day-to-day management of the program often is assigned to the program director or manager who assumes the duties assigned by the program sponsor. It is important to note that the regulations do not require OTPs to have program directors or managers on staff nor define the role of a program director; therefore, the program sponsor in some OTPs also serves as the program director.

The medical director is responsible for monitoring and supervising all medical and nursing services provided by the OTP. The medical director should have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is preferred. All OTP physicians are urged to complete the training in the use of buprenorphine required by the Drug Addiction Treatment Act 2000 (DATA 2000), even if they do not plan to provide buprenorphine under office-based opioid treatment (OBOT) rules. In some cases, the one individual may be both medical director and program sponsor but only a physician may serve as the medical director of an OTP. (See 42 CFR § 8.2.) If there is a change of medical director, SAMHSA requires formal notification within 3 weeks of the change.



Accreditation



HOME CONTACT LOGIN

NCCHC National Commission on Correctional Health Care

Facility Accreditation Professional Certification (CCHP) Education and Conferences Standards and Resources Publications

Accreditation Programs

- Health Services
- Mental Health Services
- Opioid Treatment Programs**
 - Overview
 - Survey
- Accreditation FAQs
- Applying for Accreditation
- Accreditation Surveyors
- Technical Assistance

Opioid Treatment Programs

SHARE/PRINT    

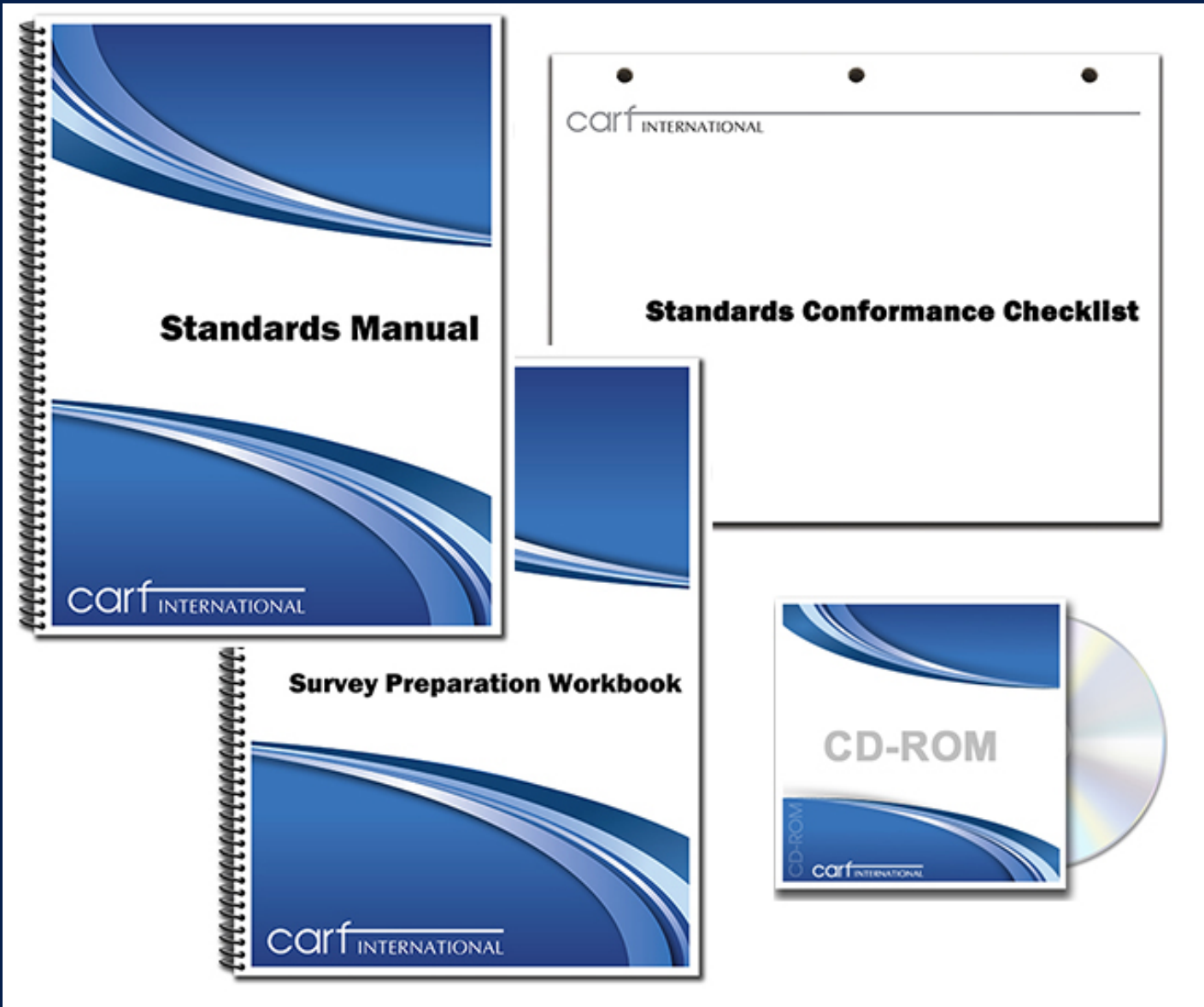
Opioid treatment programs in correctional facilities are fairly rare due, in part, to the regulatory red tape and institutional resistance that have often stymied attempts to establish them. But with the help of NCCHC and the federal Substance Abuse and Mental Health Services Administration, OTPs aiming to serve correctional populations stand a better chance.

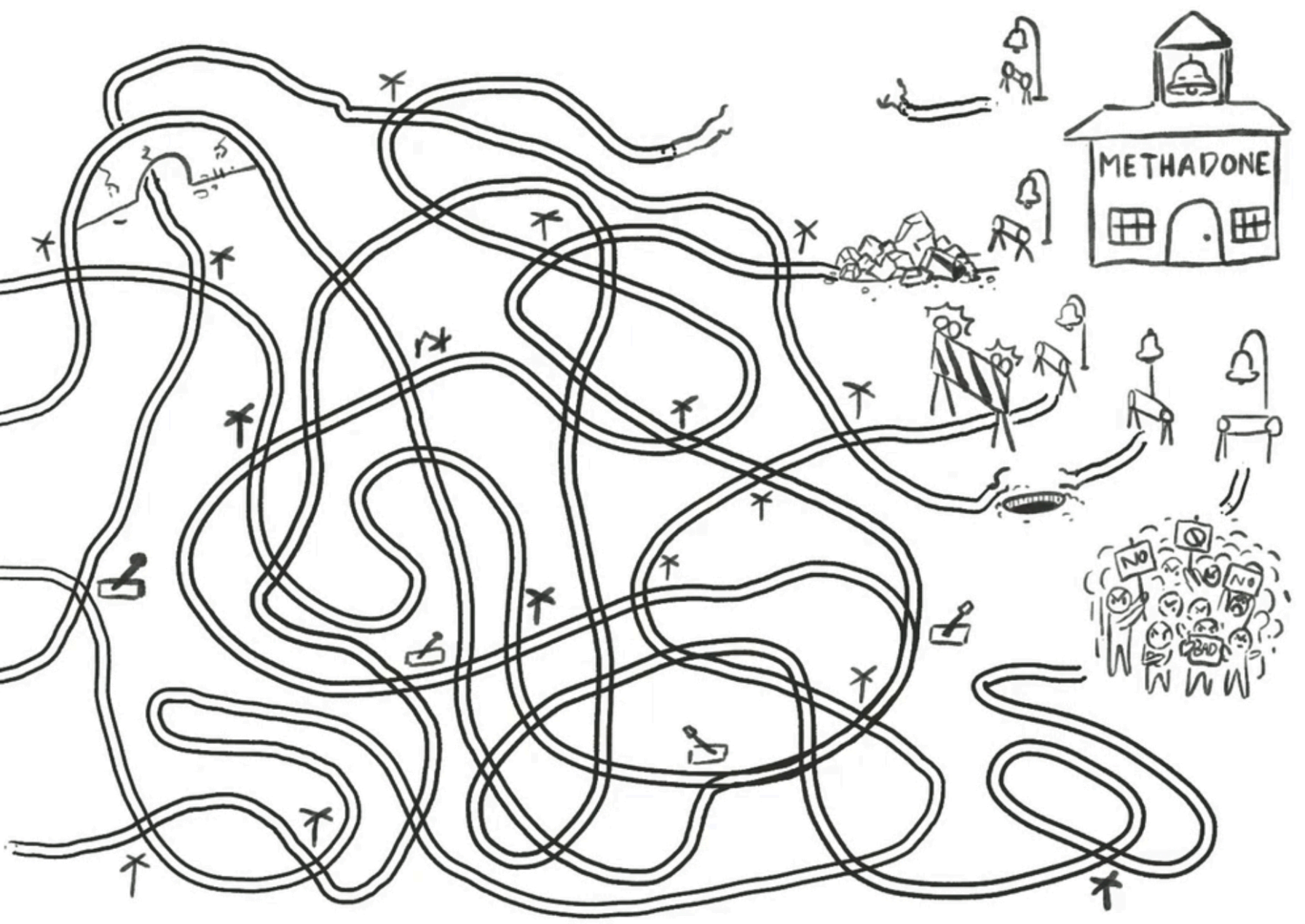
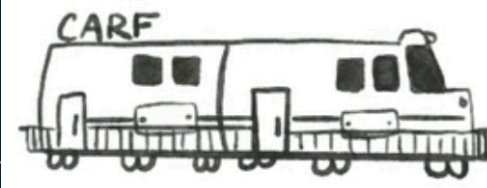
By federal law, corrections-based OTPs must obtain certification from SAMHSA, an agency of the U.S. Department of Health and Human Services, but to become certified, the OTPs first must be accredited by a federally approved body. In February 2004, SAMHSA granted NCCHC the authority to accredit OTPs, making it one of only six bodies so authorized and the only one specializing in corrections.



<https://www.ncchc.org/opioid-treatment-programs-accreditation>

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Narcotic Addict Treatment Act of 1974

DEA Jurisdiction Over Methadone

- ◆ Specific licenses for clinics and providers
- ◆ Restrictive storage rules
- ◆ Specific safes size, weight, alarming to police stations or 24 hour security system alarming to central authority.
- ◆ Specifics of who can distribute methadone and all of their personal data (social security numbers, home addresses, etc)
- ◆ Clearly delineated “reverse distribution”
- ◆ Strong preference for using computerized dispensing through expensive software programs



Massachusetts Dept of Public Health

105 CMR 164.000 = 156 pages

Licensing Procedures and Requirements

164.007: Applications Required

(A) Application for a license, approval, substance abuse treatment license for a Department of Mental Health licensed facility [hereinafter reference to license shall include substance abuse treatment license for a Department of Mental Health licensed facility where referenced in 105 CMR 164.012(D)(3)], or for renewal of a license or approval shall be filed on forms provided by the Department and accompanied by all supporting documents required by 105 CMR 164.000.

(B) No entity, except a general hospital or clinic licensed by the Department, or a department, agency or institution of the federal government or of the Commonwealth, or any subdivision of those listed above, shall operate a substance abuse treatment program without a substance abuse treatment license from the Department.



State Regulations Can Be More Onerous

Statutory Limits on Numbers of Methadone Clinics

Ohio
Wyoming
Indiana
Georgia

West Virginia
Louisiana

Some states don't allow any take-homes

Some states don't allow any private companies to open OTPs

No Medicaid Reimbursement for Methadone Treatment

Alabama
Arkansas
Idaho
Louisiana
Illinois

Wyoming
Texas
North Dakota
Kentucky

Tennessee
South Carolina
Nebraska
Iowa



REQUIRED SERVICES

42 CFR 8.12(f) *Required services.* (1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. Any assessments or treatments not directly provided at the facility must be assured via a formal documented agreement with the appropriate community providers.

Adequacy of services is manifest by a plan to manage and follow up each problem identified in the patient's history, physical exam, psychiatric evaluation, health risk assessments, and social support evaluations within 30 days of admission. An OTP should have appropriate information-sharing agreements with other providers, in accordance with federal regulations, in order for these services to be considered fully available to patients.

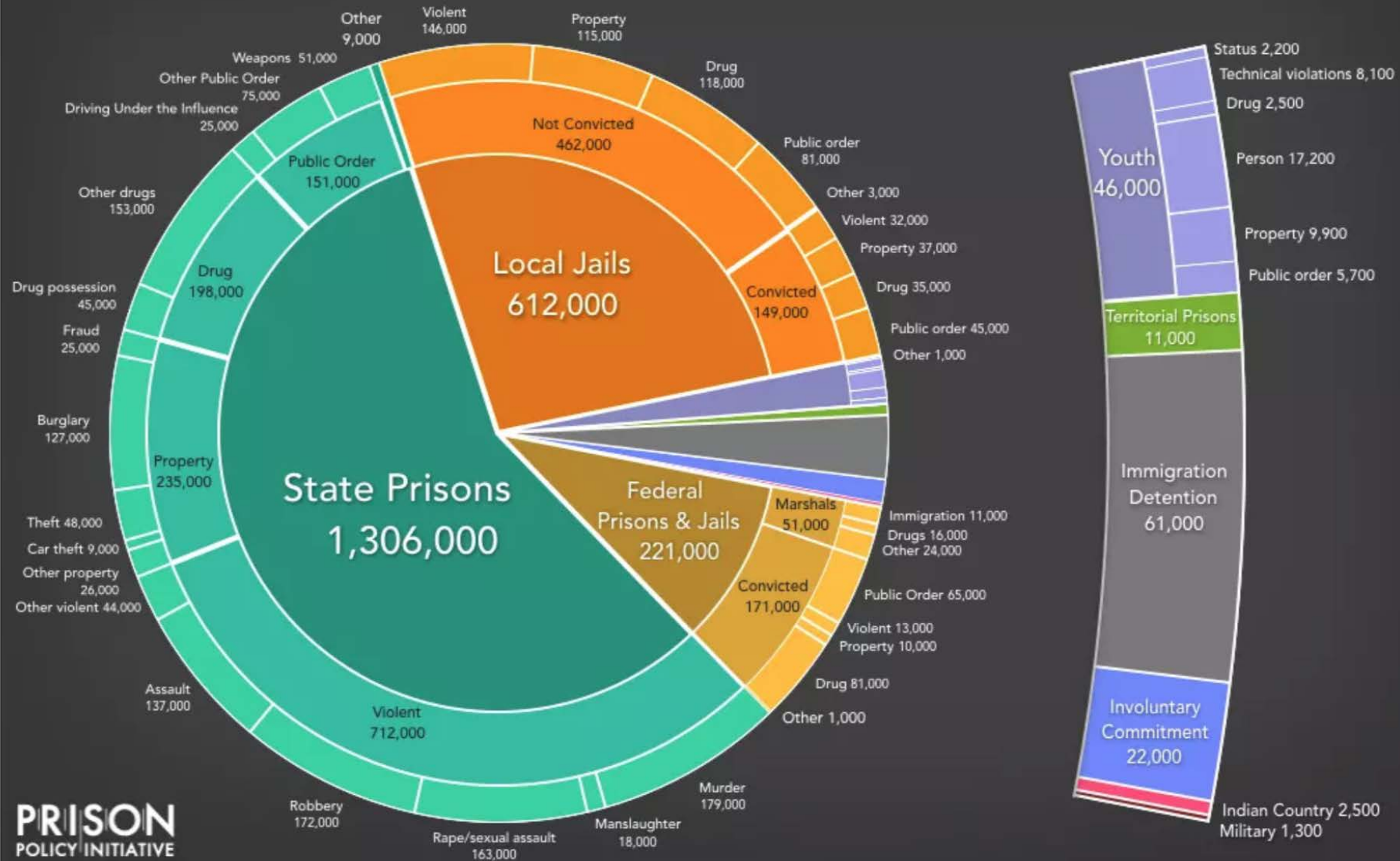
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An individual patient record should contain:

- Documentation of compliance with the approved central registry system (if applicable) or an alternative mechanism to avoid dual registration.
- The initial assessment report.
- Narrative bio-psycho-social history prepared within approximately 30 days of the patient's admission or as required by state regulation.
- Medical reports, including results of the physical examination; past and family medical history; nursing notes; laboratory reports, including results of regular toxicology screens, a problem list, and list of medications updated as clinically indicated; and progress notes, including documentation of all medications and dosages. Information in the medical record is entered by physicians and authorized healthcare professionals, as appropriate.
- Dated case entries of all significant contacts with patients, including a record of each counseling session, in chronological order.
- Dates and results of patient case conferences.
- The treatment plan and any amendments to it; quarterly reviews; and updates of the assessment and treatment plan for the first year of continuous treatment; and in subsequent years, semiannual assessments; treatment plan updates; and counselor summaries, which include an evaluation of the existing treatment plan and the patient's response to treatment.
- Documentation that all services listed in the treatment plan are available and actually were provided or that the patient was referred to such services.
- A written report on the process used to make patient treatment decisions, such as privileges or changes in counseling sessions, frequency of drug tests, or any other significant treatment changes, either positive or negative, and the factors considered in the decisions.
- A record of correspondence with patient, family members, and other individuals.

How many people are locked up in the United States?

The U.S. locks up more people per capita than any other nation, at the staggering rate of 698 per 100,000 residents. But to end mass incarceration, we must first consider *where* and *why* 2.3 million people are confined nationwide.

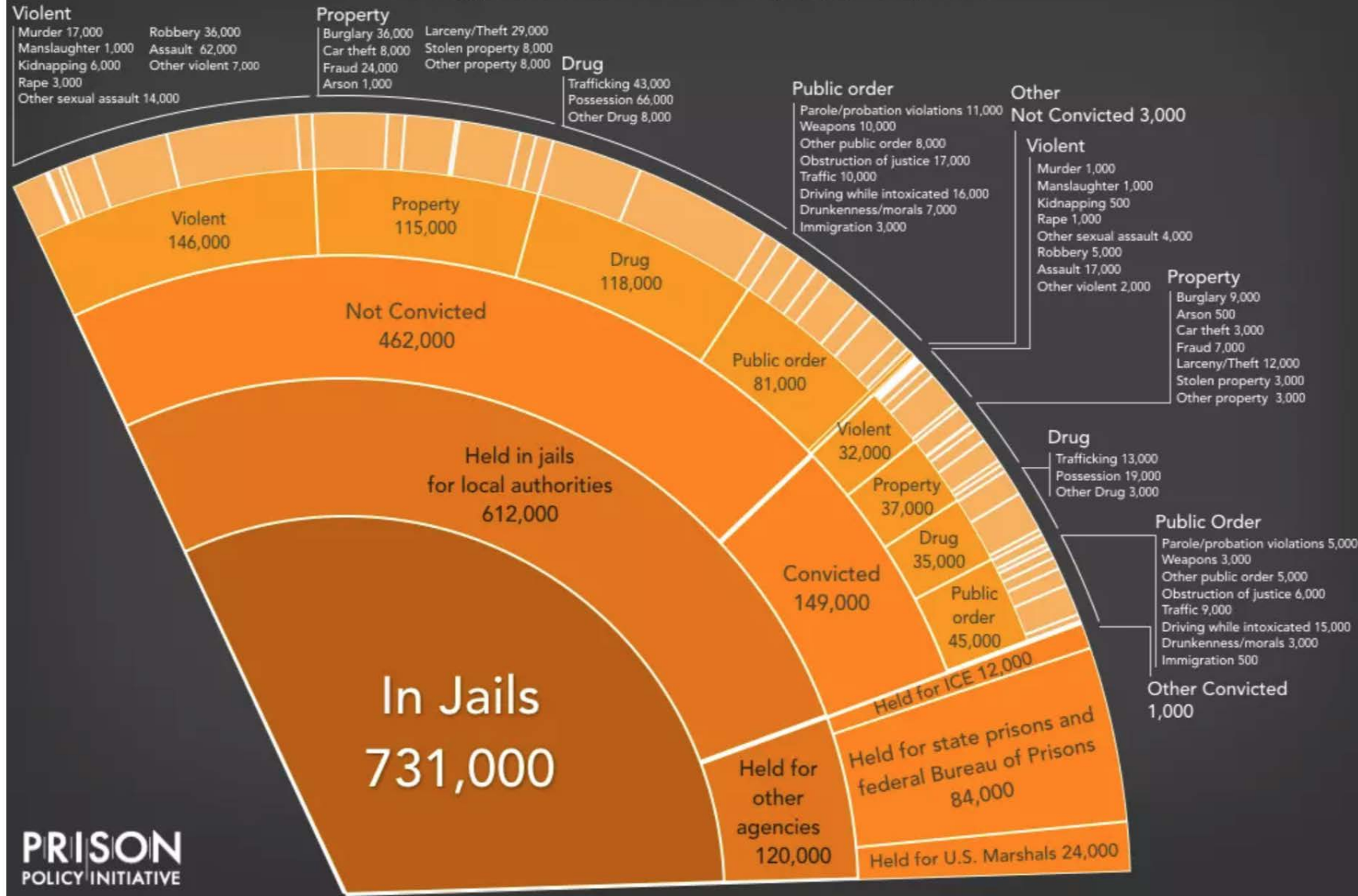


PRISON
POLICY INITIATIVE

Sources and data notes: See <https://www.prisonpolicy.org/reports/pie2019.html>

76% of people held by jails are not convicted of any crime

If you include the 120,000 people held in local jails that rent out space to other agencies, 63% are unconvicted.
 Either way, jail incarceration rates are driven largely by local bail practices.



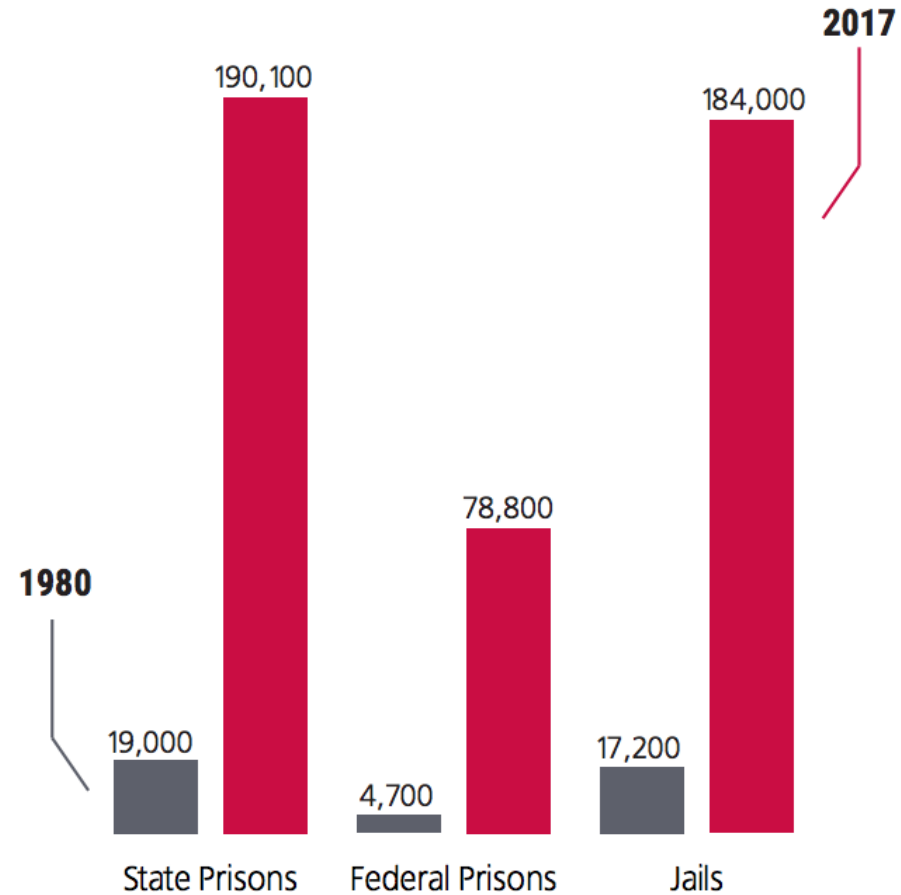
PRISON POLICY INITIATIVE



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Number of People in Prisons and Jails for Drug Offenses, 1980 and 2017

1980: 40,900 individuals
2017: 452,900 individuals



Sources: Bronson, J. and Carson, E.A. (2019). *Prisoners in 2017*. Washington, DC: Bureau of Justice Statistics; James, D.J. (2004). *Profile of Jail Inmates, 2002*. Washington, DC: Bureau of Justice Statistics; Zeng, Z. (2019). *Jail Inmates in 2017*. Washington, DC: Bureau of Justice Statistics.

Options and Steps to Implement MAT in Pilot Houses of Correction

All 3 Medications: Methadone, Buprenorphine, Naltrexone

OPTION 1 HOC/DOC Acquires OTP Certification

Provision of Methadone

- Obtain SAMHSA Certification (which include counseling, MAT and other required SUD services)
- Requires approvals from:
 - DEA
 - DPH DCP
 - DPH BSAS

Provision of Buprenorphine

- Once OTP Certified, can begin prescribing under OTP

Provision of Naltrexone

- Prescribed by onsite healthcare professional with MCSR

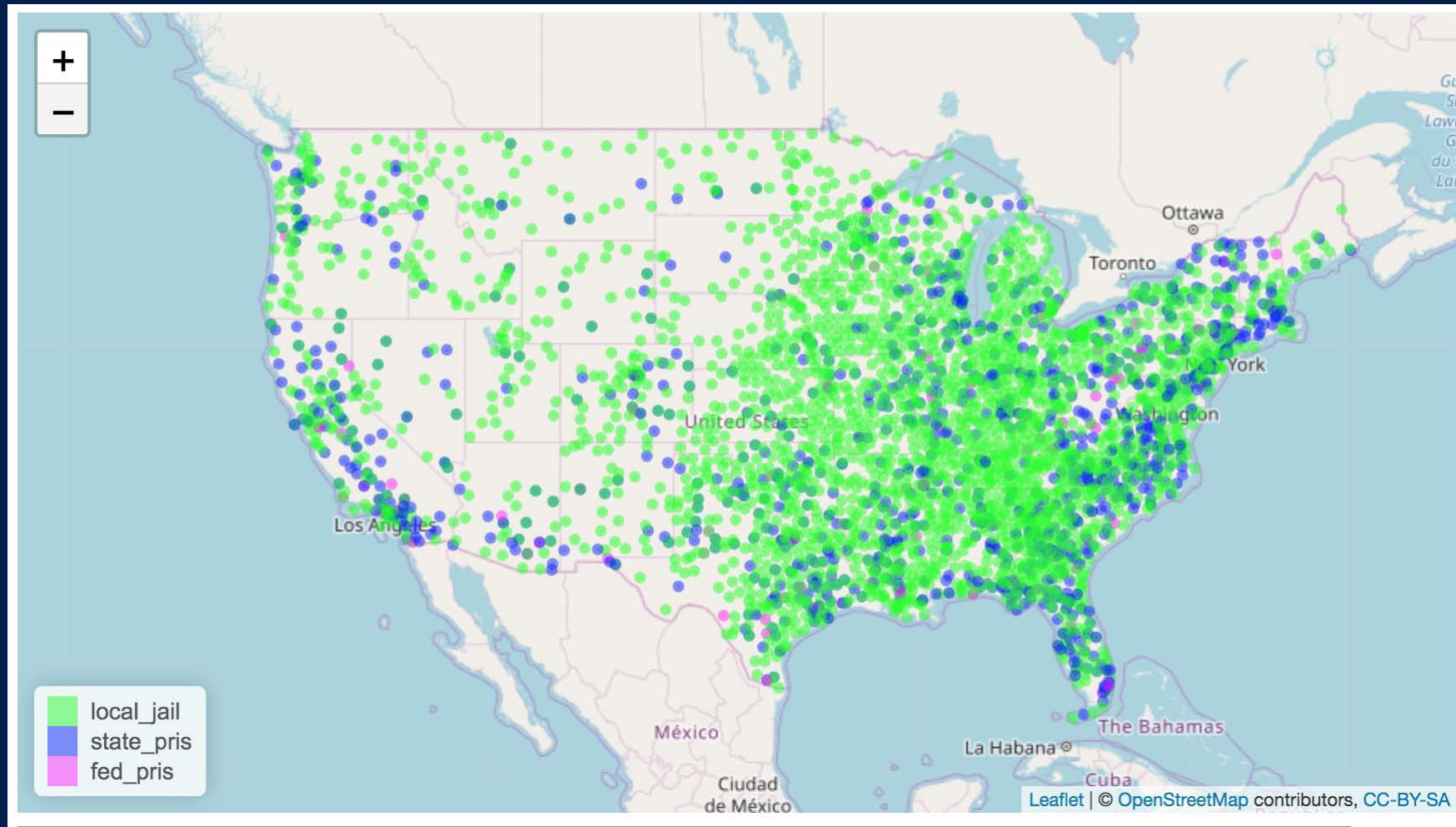
OPTION 2 HOC partners with an existing OTP who provides onsite Meds

- OTP must hold SAMHSA Certification (which include counseling, MAT and other required SUD services)
- OTP obtains additional approvals to operate at corrections location:
 - SAMHSA
 - DEA
 - DPH DCP
 - DPH BSAS
- QSOA Qualified Service Organization Agreement (QSOA) executed by OTP and HOC

OPTION 3 HOC partners with an existing OTP who provides offsite or transports meds daily

- OTP must hold SAMHSA Certification (which include counseling, MAT and other required SUD services)
- Methadone may not be stored at the DOC or a HOC.
- Qualified Service Organization Agreement (QSOA) executed by OTP and HOC

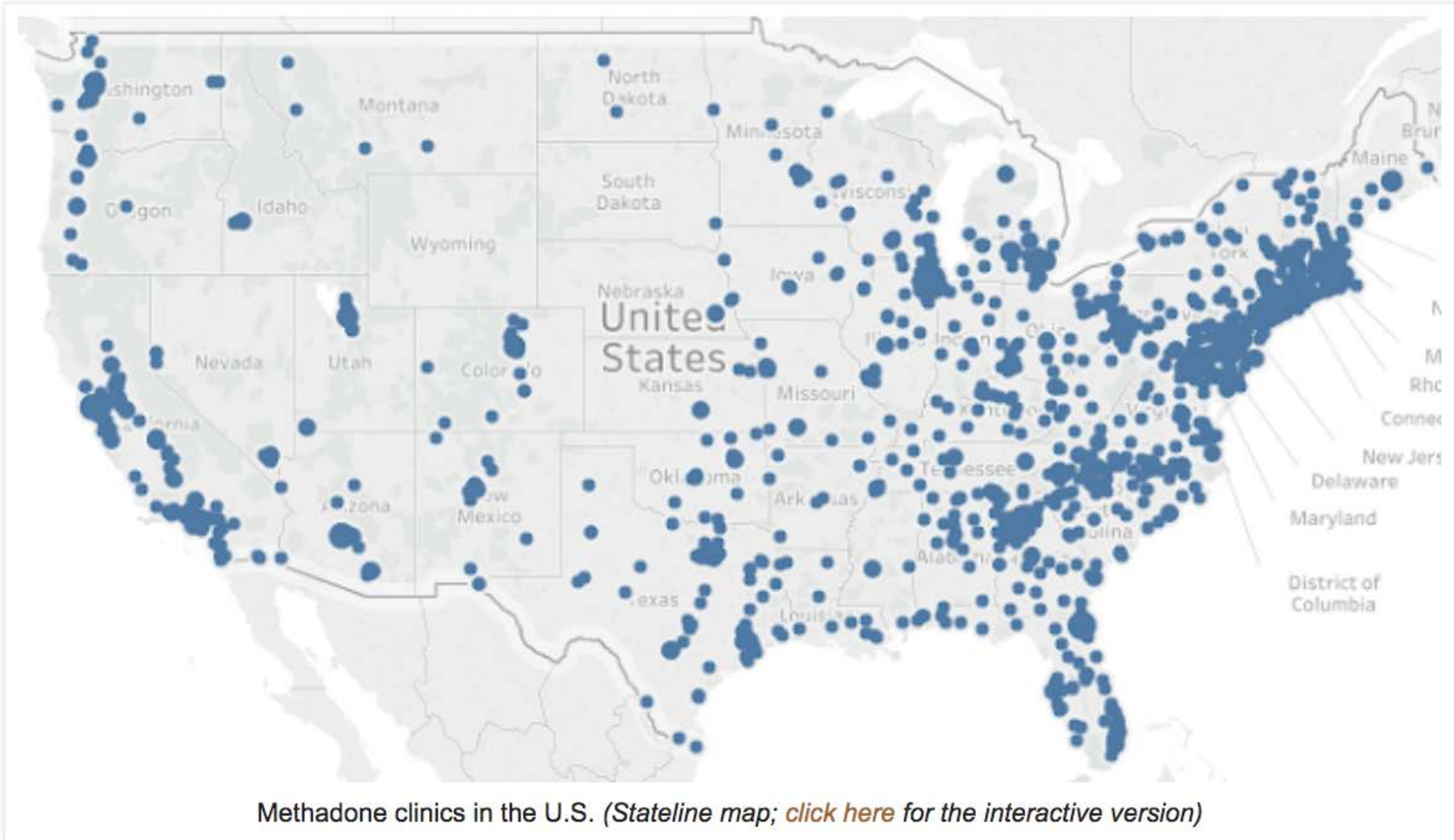
Jails and Prisons in the United States

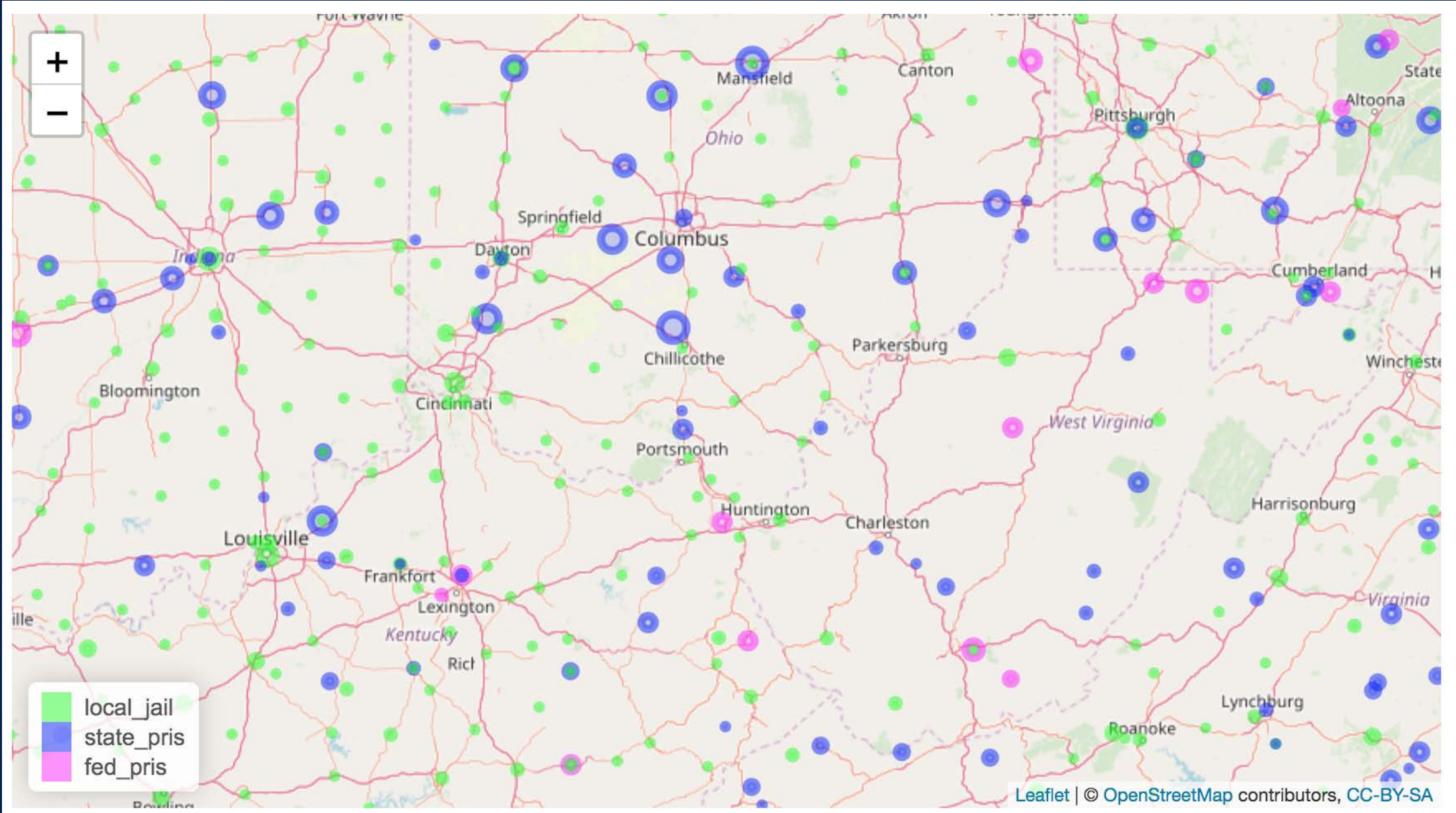


<https://www.gl-li.com/2018/02/05/map-prisons-in-the-united-states/>

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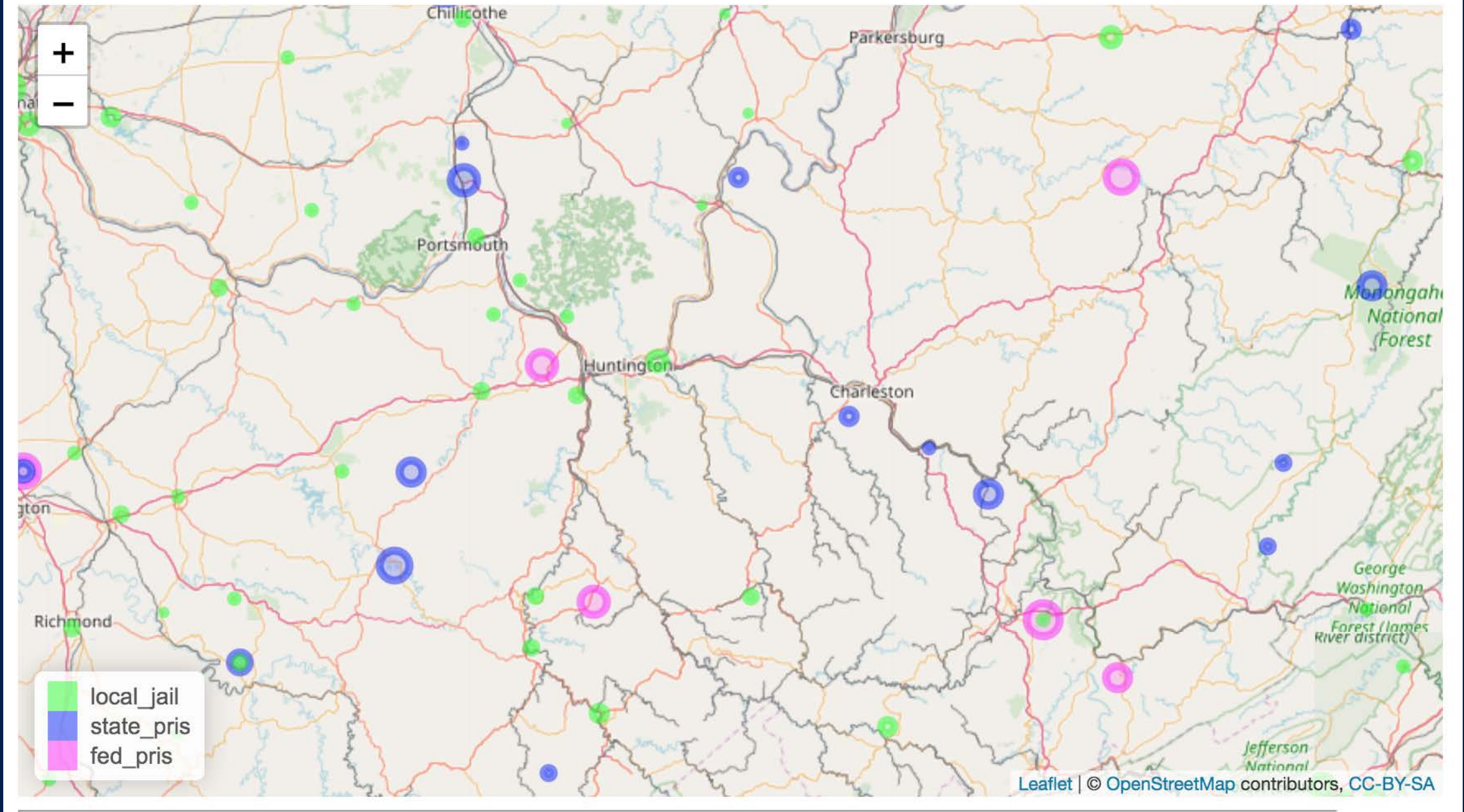
Medication-assisted treatment expands as stigma decreases and more states cover treatment under Medicaid





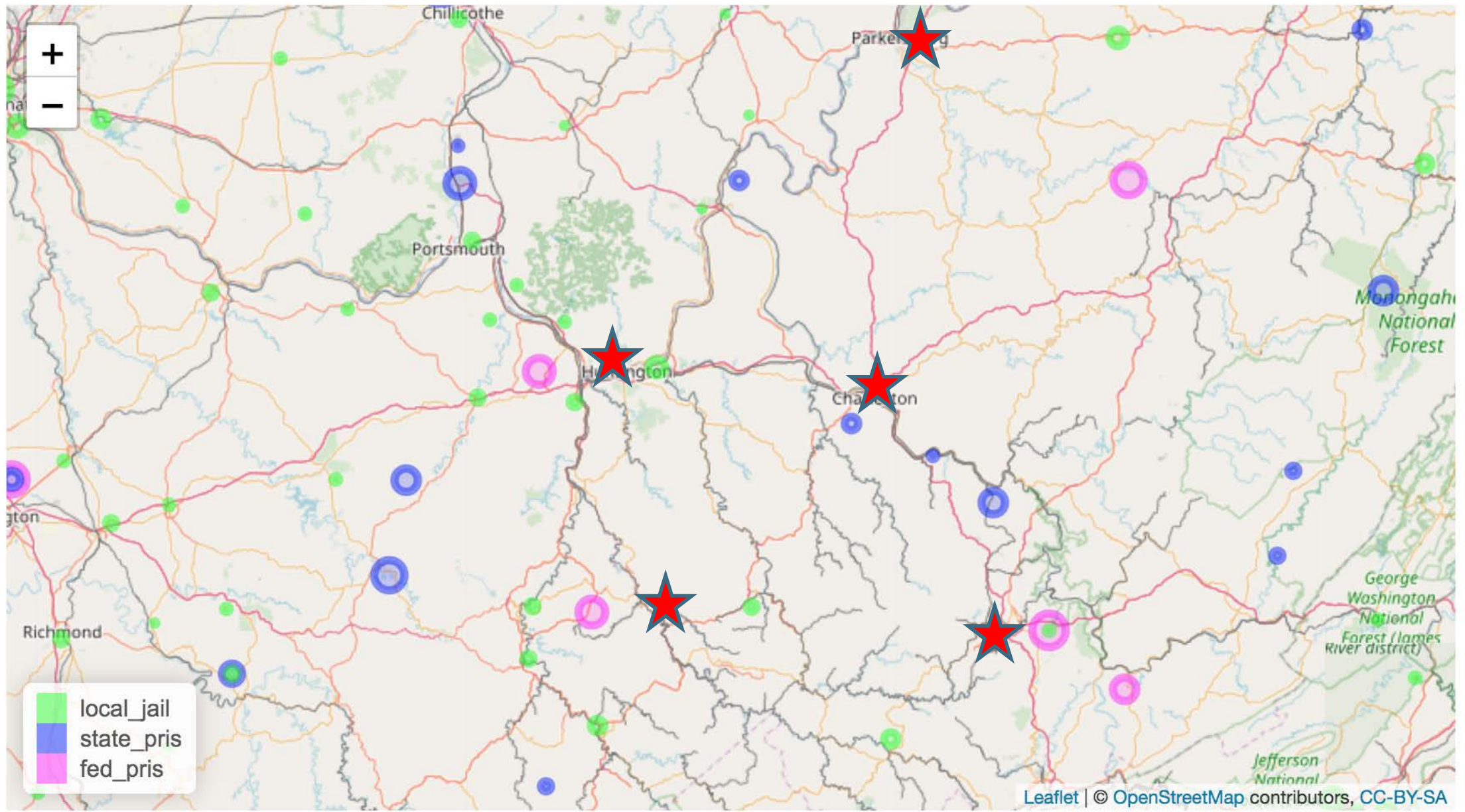
<https://www.gl-li.com/2018/02/05/map-prisons-in-the-united-states/>

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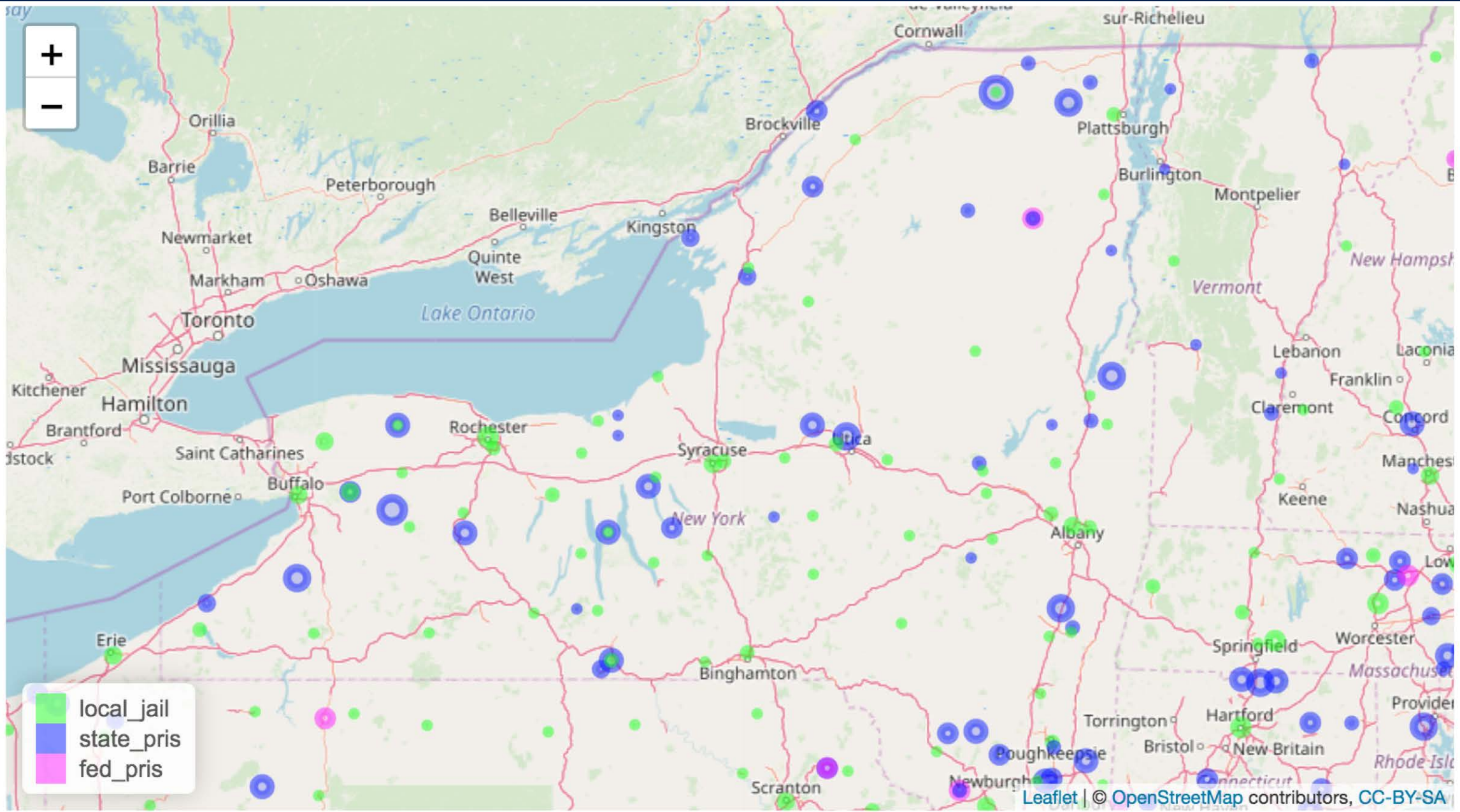


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<https://www.gl-li.com/2018/02/05/map-prisons-in-the-united-states/>
<https://dpt2.samhsa.gov/treatment/Home/map.aspx>

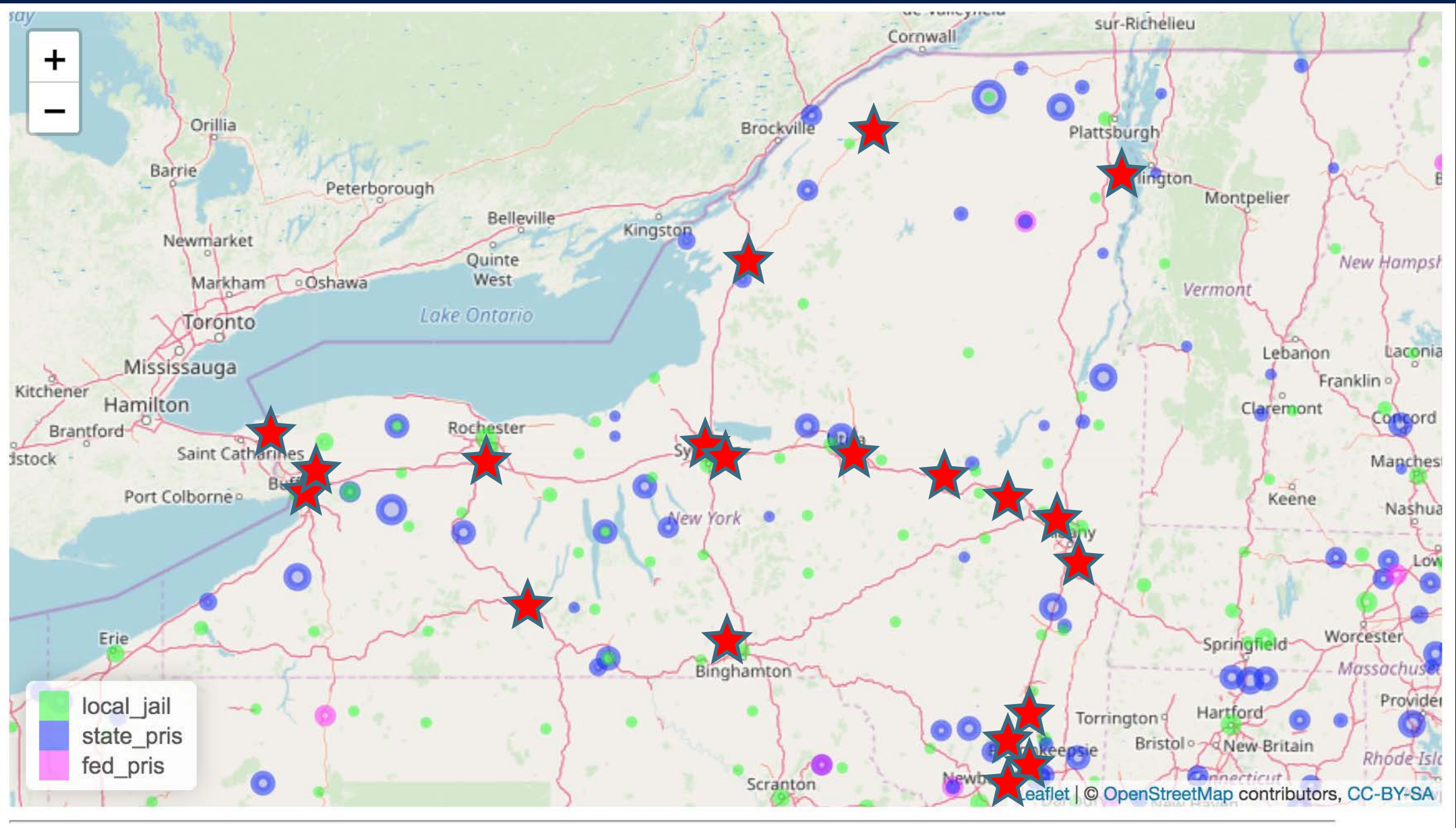
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EVIDENCE-BASED RESOURCE GUIDE SERIES

Use of Medication-Assisted Treatment in the Criminal Justice System

SAMHSA
Substance Abuse and Mental Health
Services Administration

Promising Programs and Practices That Support the Use of Medication-Assisted Treatment

There are several promising practices that have been used within criminal justice settings and during transition into the community that can facilitate successful outcomes.

Ensure Linkages to Treatment

According to a 2009 publication, only 45% of criminal justice facilities provided any community linkages to methadone treatment clinics.⁵⁰ Treatment with MAT and brief drug counseling integrated into the probation and parole system have shown positive results in terms of opioid use and re-arrest rates.⁵⁹

Support Police Officer-led Diversion Programs

Some police departments have engaged in training their officers to identify and divert non-violent opioid dependent individuals into MAT programs. One such program is the Angel Program in Massachusetts.⁶¹

Embed MAT Within Drug Court Programs

Many drug courts do not recommend (or even allow) the use of MAT for opioid dependence.⁶⁰ Approximately half of drug courts surveyed in one study offered any form of MAT to participants.³²

Change Organizational Policies to Reflect the Science

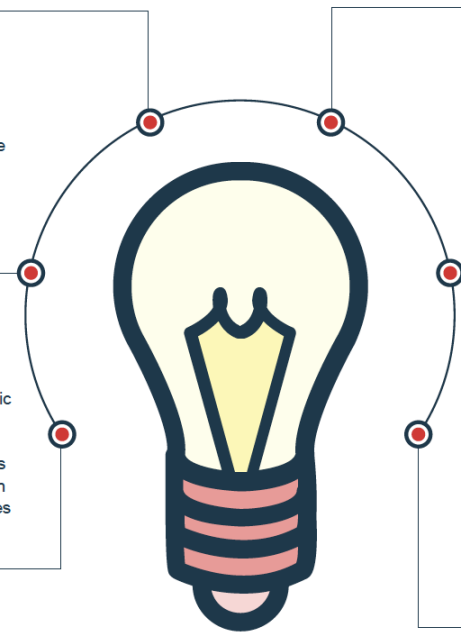
Based on the overwhelming evidence base for MAT, many jails, prisons, parole, probation, and diversion programs are changing policies that prohibit the use of MAT medications.

Partner with Community Providers

Correctional facilities can develop partnerships with registered narcotic treatment providers. Incorporating jails and prisons into a system of care allows incarcerated individuals to continue MAT upon incarceration and/or to connect with MAT services once they reenter the community.

Register as a Narcotic Treatment Provider

Some jails and prisons have registered to become treatment providers. For example, the Key Extended Entry Program (KEEP) is a methadone treatment program initiated in 1987 for incarcerated individuals. KEEP participants receive MAT behind bars, and when returning into the community, they are discharged to outpatient KEEP programs.⁶²



Substance Abuse and Mental Health Services Administration: Use of Medication-Assisted Treatment in the Criminal Justice Settings.
HHS Publication No. PEP19-MATUSECJS Rockville, MD: National Mental Health and Substance Use Policy Laboratory.
Substance Abuse and Mental Health Services Administration, 2019.

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FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

The full regulatory language describing medication units can be found in 42 CFR § 8.12 (<http://www.ecfr.gov/cgi-bin/text-idx?SID=b7de4cc92bf0a4d977929a4978c64e30&node=42:1.0.1.1.10.2.1.1&rgn=div8>).

Medication units are not required to be free-standing entities. For example, a medication unit can be located at a hospital or community pharmacy.

To open a medication unit, a program must submit the online SMA-162, available on SAMHSA's Extranet at <http://otp-extranet.samhsa.gov>, with all requested attachments and signed documents to SAMHSA. In Item 14, "Purpose of Application," "Medication Unit" must be checked off. SAMHSA will process the form and forward it for approval to the DEA, which will arrange an inspection. The program also should submit all required materials to the State Opioid Treatment Authority (SOTA) to seek state approval, as appropriate. Once approved by the DEA, the medication unit will be assigned a new DEA registration number. For further information please refer to the FAQs section of the Guidelines.





Canada – 6 Settings

- Addiction Clinic
- Primary Care Office
- Correctional facilities
- Pharmacies
- Home
- Hospitals



UK

- Pt stabilized in specialty methadone clinic and then prescribing is taken over by a GP
- Pharmacies can do daily and direct-observed administration



Keen, Jenny, et al. "Does methadone maintenance treatment based on the new national guidelines work in a primary care setting?." *Br J Gen Pract* 53.491 (2003): 461-467.

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Calcaterra, S. L., et al. "Methadone matters: what the United States can learn from the global effort to treat opioid addiction." *Journal of general internal medicine* 34.6 (2019): 1039-1042.

Primary care clinic prescribing of methadone for opioid use disorder could reduce drive times to methadone in rural counties

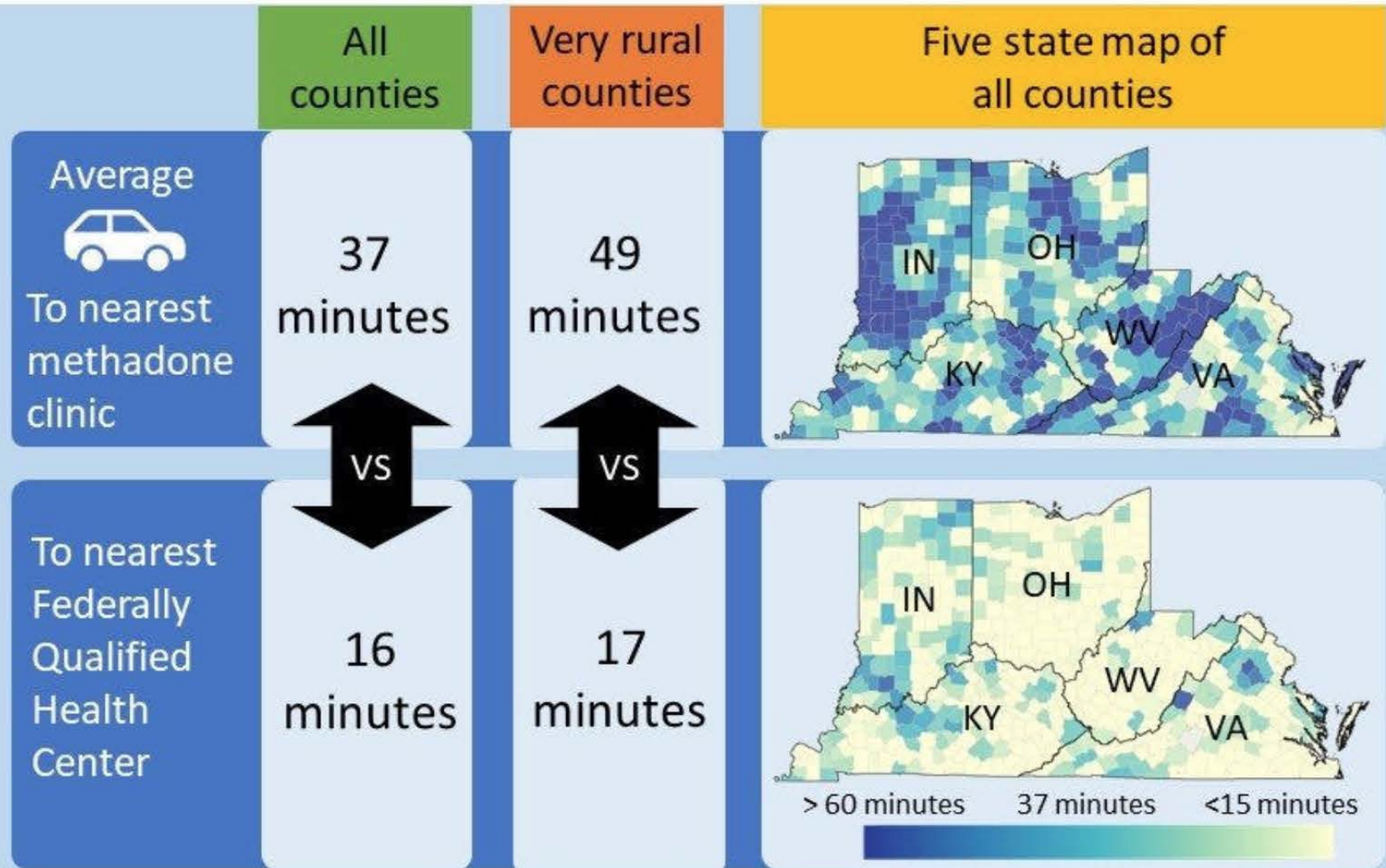
Question: How would prescribing methadone in Federally Qualified Health Centers impact drive time to methadone in rural counties?

Design: Cross-sectional geospatial Analysis

Sample: 487 counties (55% rural) in five states heavily impacted by the opioid epidemic

Outcome: drive time from county population center to nearest facility

Data sources: SAMHSA and Health Resources Services Administration data warehouse 2017







It takes 50 years to get a wrong idea out of medicine, and 100 years a right one into medicine.

~ John Hughlings Jackson

AZ QUOTES



Hall, John C., and Cameron Platell. "Half-life of truth in surgical literature." *The Lancet* 350.9093 (1997): 1752.

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COVID-19 Risk Mitigation in Franklin County

- ◆ Immediate lock down of facility to decrease exposure
- ◆ No admittance of non-violent detainees
- ◆ Regular testing and quarantine of inmates and staff
- ◆ Rapid release of non-violent pre-trial inmates (25% reduction)
- ◆ Telehealth behavioral health treatment
- ◆ Provided take home doses for released inmates when needed
- ◆ No internal spread of COVID-19 within facility. Fewer than 5 inmates COVID-19 positive at intake



Trauma Informed Jail

- ◆ Previous and continuing trauma is highly present for individuals involved in the criminal justice system
- ◆ Jail/Prison puts them in an environment where they have little control over; they are surrounded by individuals who have either victimized, or have been victims themselves, there is little expectation of privacy and emotional safety while incarcerated
- ◆ The impact of trauma can be experienced throughout life and affect various aspects of functioning and behavior
- ◆ Trauma frequently results in problematic behavior, poor relationships, and justice involvement
- ◆ When people are in a fight/flight/freeze response, their executive functioning decreases, and people make choices in order to survive (they do what they have done in the past to survive)

It is important that systems

- ◆ Ensure interpersonal interactions with officers and staff be grounded in respect, providing information, ensuring safety, and offering choice
- ◆ Make reasonable accommodations to keep the nervous system grounded
 - ◆ Informed consent to treatment with full disclosure of what the patient should expect
 - ◆ Approach people from the front (don't walk up behind people)
 - ◆ Explore triggers and make accommodations (e.g., keys jiggling, racking the doors, separating people who have victimized people from people who have been victimized)
 - ◆ Offer embodied practices that treat the whole body: yoga, gardening, exercise, music/art, sleep hygiene, healthy eating, other mindfulness based practices
- ◆ Seeing people as more than their worst moments and seek to clarify values and who/what is MOST important to the patient
- ◆ Create opportunities for community and positive peer connection
 - ◆ milieu based treatment
 - ◆ rituals and memorials
 - ◆ social empowerment model of treatment



COVID-19 Vaccination Rates



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