NC Department of Health and Human Services

The Evolving Role of OTPs in Addressing the Opioid Crisis

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MOUD Conference 2025

Objectives

- **Understand the Evolution**

Review the history and regulatory evolution of opioid treatment programs, focusing on the impact of updated federal 42 CFR regulations.

- **Explore Patient-Centered Changes**

Highlight significant shifts in patient care before and after the regulatory updates.

- **Promote Clinical Cultural Shift**

Explore outcomes measurements and data that support a clinical cultural shift to better align with the new regulations and improve patient outcomes.

- **Seek out Partnership Opportunities**

Explore ways that OTPs are positioned to be great partners in the community wide approach to address the opioid crisis

This is NOT Your Parents' OTP.

History of Opioid Treatment

Prior to 1919

- **Morphine treatment clinics**: Morphine was prescribed and dispensed in treatment clinics across the U.S. for those struggling with addiction.

1920s

- **Closure of morphine clinics**: The Federal Bureau of Narcotics, part of the U.S. Department of the Treasury, successfully shut down morphine treatment clinics, labeling them “another form of drug trafficking.”

1929

- **Narcotics farms established**: Congress allocated funds for "narcotics farms," which were hospitals providing treatment services, including detoxification. However, the environment was very "prisonlike," limiting their therapeutic effectiveness.

1950s-1960s

- **Heroin crisis**: Death rates from heroin overdose soared
- **Hepatitis B surge**: Along with the heroin crisis, cases of Hepatitis B increased
- **Overcrowded jails**: Jails overcrowded with no effective system in place to ease detoxification for inmates.

Opioid Treatment Programs 1960s-1970s

1960s
Dole and Nyswander began researching treating patients who were addicted to opioids with methadone using the FDA's Investigational New Drug (IND) designation

1972
Methadone was approved by the FDA for the treatment of opioid use disorder

1970s
OTPs gained popularity as the Nixon Administration's primary weapon in the War on Drugs.

Bureau of Narcotics and Dangerous Drugs (formerly known as the Federal Bureau of Narcotics, and later known as the Drug Enforcement Agency) was made an equal partner with the FDA in the federal effort to control Opioid Treatment Programs

Opioid Treatment Programs Regulatory Revisions 1980

- Reduced admission standard: from 2 years of addiction to 1 year with physiological dependence
- Allowed individuals under 16 to receive maintenance treatment.
- Urine testing: 8 tests in the first year, quarterly thereafter, unless patient had 6 take-home doses, then testing was monthly.
- Counselor-to-patient ratio set at 1:50.
- Initial dosage: capped at 30 mg, with an additional 10 mg allowed within 4-8 hours if necessary.
- 100 mg dose cap: state and federal notification required if exceeded, and no take-home doses allowed over this limit.

Opioid Treatment Programs Regulatory Revisions 1989

- Counselor ratio was deleted
- Testing for drug abuse was no longer limited to urine testing
- Notification requirement for doses over 100mg was eliminated, but written justification as still required
- Annual reviews of patient treatment plan no longer required after 3 years for “model” patients
- Syphilis testing no longer required if veins were too damaged to obtain blood
- Required counseling for pregnant women

Take Homes in the 1980s

Time in Treatment	# of take homes	Conditions
< 3 months	No more than 1 take home per week	Take homes restricted to “responsible” patients
3 months	2 take homes	“Good behavior” for 2 years
2 years	3 take homes	“Good behavior” for 3 years
3 years	6 take homes	Take homes are not permitted for anyone over 100mg

Restriction or “probationary withdrawal” of take homes were required if patients missed a scheduled clinic appointment or if a urine test was positive for an opioid or negative for methadone

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Oversight Shift in the 2000s

- Oversight shifted from FDA to SAMHSA in 2001
- The 1972 FDA regulations were repealed and an accreditation-based regulatory system was created
- New regulations set forth general certification requirements
- Best-practice guidelines and accreditation elements were developed by SAMHSA approved accreditation bodies
- Maintained tripartite system of oversight involving State Authority, DHHS/SAMHSA, and US DOJ/DEA

8-Point Criteria Pre-Covid Era

42 CFR, Part 8 § 12(i) listed 8 criteria that must be considered when the medical director decides whether patients can have take homes.

1. Absence of recent drug and alcohol abuse
2. Regular OTP attendance
3. Absence of behavioral problems at the OTP
4. Absence of recent criminal activity
5. Stable home environment and social relationships
6. Acceptable length of time in treatment based on federal regulation
7. Assurance of safe storage of medication
8. Determination that benefits of take homes outweighs the risk of diversion

Time In Treatment Requirement

Time In Treatment	# of Take Homes
First 90 days	One take home dose per week
Second 90 days	2 take home doses per week
Third 90 days	3 take home doses per week
Fourth 90 days	6 take home doses per week
After 1 year	2 weeks supply of take home medication
After 2 years	Monthly supply

States *could* be more stringent, and North Carolina was!

Time in Treatment	Min. Time in Compliance	Min./mo. Counseling	Min./mo. UDS	Take Homes	Doses in OTP
1-90 Days		2/mo.	1	1	6
91-180 (3-6 mo.)	90d L1	2/mo.	1	3	4
181-270 (6-9 mo.)	90d L2	2/mo.	1	4	3
271 Days (9-12 mo.)	90d L3	2/mo.	1	5	2
365 Days (1 year)	180d L4	1/mo.	1	6	1/wk.
2 years	1 yr. L5	1/mo.	1	13	1/14 d
4 years	3 yr.	1/mo.	1	27-max 30	1/mo.

Thought Experiment: Liquid Handcuffs

A comparison between the OTP and the Carceral Setting*

*Despite similarities, it's important to recognize that OTPs aim to provide medical treatment and support for recovery.

Schedules

OTP

OTPs have strict schedules with mandated daily “dosing times”

Carceral

Carceral Settings have strict schedules with designated times for meals, work, exercise, and recreation

Security

OTP

OTPs use surveillance cameras, security personnel, and controlled access points

Carceral

Carceral Settings use surveillance cameras, security personnel, and controlled access points

Behavioral Control

OTP

OTPs have behavioral rules regarding interactions and dress codes, with violations leading to disciplinary actions

Carceral

Carceral Settings have behavioral rules regarding interactions and dress codes, with violations leading to disciplinary actions

Privileges

OTP

OTPs have classifications for take home privileges based on perceived diversion risk

OTPs may revoke patient's take home privileges based on violations of conditions of treatment

Carceral

Carceral Settings have classifications for housing and other privileges based on perceived security risk

During supervised release, parole officers may revoke parolee's conditional freedom based on violations of terms of parole

Organizational Hierarchies

OTP

OTPs have structured hierarchies where authority figures (counselors, nurses, medical providers) enforce rules and oversee their compliance, including regular drug screen monitoring

Carceral

Carceral Settings have structured hierarchies where authority figures (guards or officers) enforce rules and oversee compliance and progress

Personal Autonomy

OTP

OTPs restrict personal autonomy by requiring daily or frequent attendance, with processes to request take homes for things like vacations that often involve state and federal approval

Carceral

Carceral Settings restrict personal autonomy necessarily for punishment and inmate containment

Similarities between OTPs & Carceral Settings*

- Regimentation and Surveillance
- Controlled Environment
- Restricted Autonomy
- Stigmatization and Social Isolation
- Institutional Hierarchy
- Monitoring Compliance
- Regular Check Ins
- Documentation and Reporting

*This is an exercise in critical thinking - Despite similarities, it's important to recognize that OTPs aim to provide medical treatment and support for recovery.

The Thought Experiment has Concluded
We will now return to our regularly scheduled programming.

COVID-19

The COVID-19 Pandemic significantly impacted the operation of OTPs

- OTPs needed to quickly reduce the number of patients attending the clinic to protect vulnerable patients and staff
- Social distancing, lack of public transit, required quarantines and isolations made it difficult for patients to attend programs daily
- The risk of COVID-19 transmission had to be weighed in the decisions to provide take homes

COVID-19

Regulatory bodies, including SAMHSA and the DEA temporarily relaxed certain regulations to accommodate the challenges posed by the pandemic

- Extended the use of telehealth
- Flexibility of take home medication requirements
- Scope of practice expansion for nurse practitioners and physician assistants to complete admissions and make determinations about take homes in the OTP setting

Hats Off to Our OTPs!

OTPs shifted quickly to get through an unprecedented public health emergency themselves, while taking care of the essential needs of their patients!

- Expansion of take-home dosing required adjustment to clinic workflow
- Telehealth equipment set up in extra offices to ensure access to patients even if counselor was working off site

What Did We Learn?

- Greater access to treatment
- Greater retention in treatment
- Enhanced patient-centered care
- Improved patient-provider rapport
- Increased patient autonomy and engagement
- Stable patients receiving more take homes was associated with higher retention and lower rates of opioid positive drug tests
- Patients reported increased time spent on work and recreation
- Several studies indicated that prior concerns about methadone diversion related problems and methadone overdose death DID NOT INCREASE

New Federal Time in Treatment Standards

- In treatment 0-14 days, up to 7* unsupervised take-home doses of methadone may be provided to the patient
- Treatment days 15-30, up to 14* unsupervised take-home doses of methadone may be provided to the patient
- From 31 days in treatment, up to 28* unsupervised take-home doses of methadone may be provided to the patient

**In all instances, it is within the clinical judgement of the OTP practitioner who is treating the patient directly to determine the actual number of take-home doses within these ranges.*

New 6-Point Criteria

OTP decisions regarding dispensing methadone for unsupervised use under this exemption ***shall be determined by an appropriately licensed OTP medical practitioner*** or the medical director. In determining which patients may receive unsupervised doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate whether the therapeutic benefits of unsupervised doses outweigh the risks, the following SIX criteria:

New 6-Point Criteria

a. 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;
b. Regularity of attendance for supervised medication administration;
c. Absence of serious behavioral problems that endanger the patient, the public or others;
d. Absence of known recent diversion activity; and
e. Whether take home medication can be safely transported and stored; and
f. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

Such determinations and the basis for such determinations consistent with the criteria outlined in a – f, above, shall be documented in the patient's medical record.

Admissions

OLD RULE

Required that the person be "currently addicted to an opioid drug" and that they had at least one year of documented addiction prior to admission

NEW RULE

Requires that the person meets criteria for a moderate or severe OUD, either active, or in remission, or is at high risk for recurrence or overdose.

Adolescents

OLD RULE

Patients under the age of 18 had to have 2 documented “failed” or “unsuccessful” attempts at drug-free treatment within a 1-year period

Programs had to obtain state and federal approval, in additional to parental consent for adolescent admissions to OTP

NEW RULE

Patients under the age of 18 NO LONGER need to fail at abstinence-based treatment prior to entering treatment at an OTP

Parental consent is still required, but can be electronic

Initial Dose

OLD RULE

The initial dose could be no more than 30 mg, and the provider could give up to an additional 10 mg in the same day after they re-evaluated the patient.

The total first day's dose could be no more than 40 mg.

NEW RULE

Total dose for the first day shall not exceed 50 mg…UNLESS the OTP medical practitioner finds sufficient rationale, including but not limited to if the patient is transferring on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

More patient centered, individualized determination

Split Dosing

OLD RULE

State and federal approval was required for split dosing, along with evidence that the patient was a “rapid metabolizer”

NEW RULE

Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated

State and federal approval is no longer required, though rationale should be documented in the patient chart

Telehealth Admissions

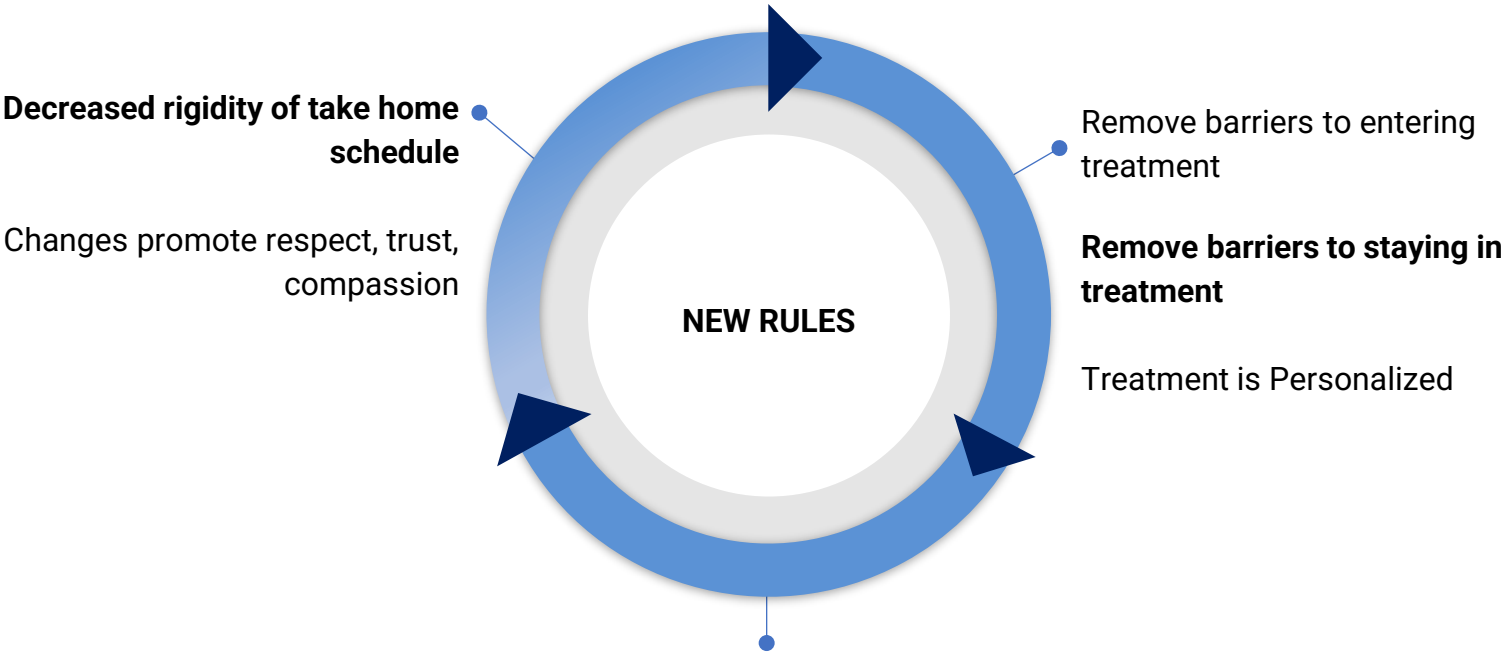
BUPRENORPHINE:

- For patients being treated with buprenorphine, telehealth is permitted for the initial (medical) screening examination, the full examination, and the initiation of buprenorphine.

METHADONE:

- For patients receiving methadone, audio-visual telehealth can be used for the initial medical screening examination, and the initiation of methadone.
- A full in-person physical examination must be completed within 14 calendar days following the patient's admission to the OTP

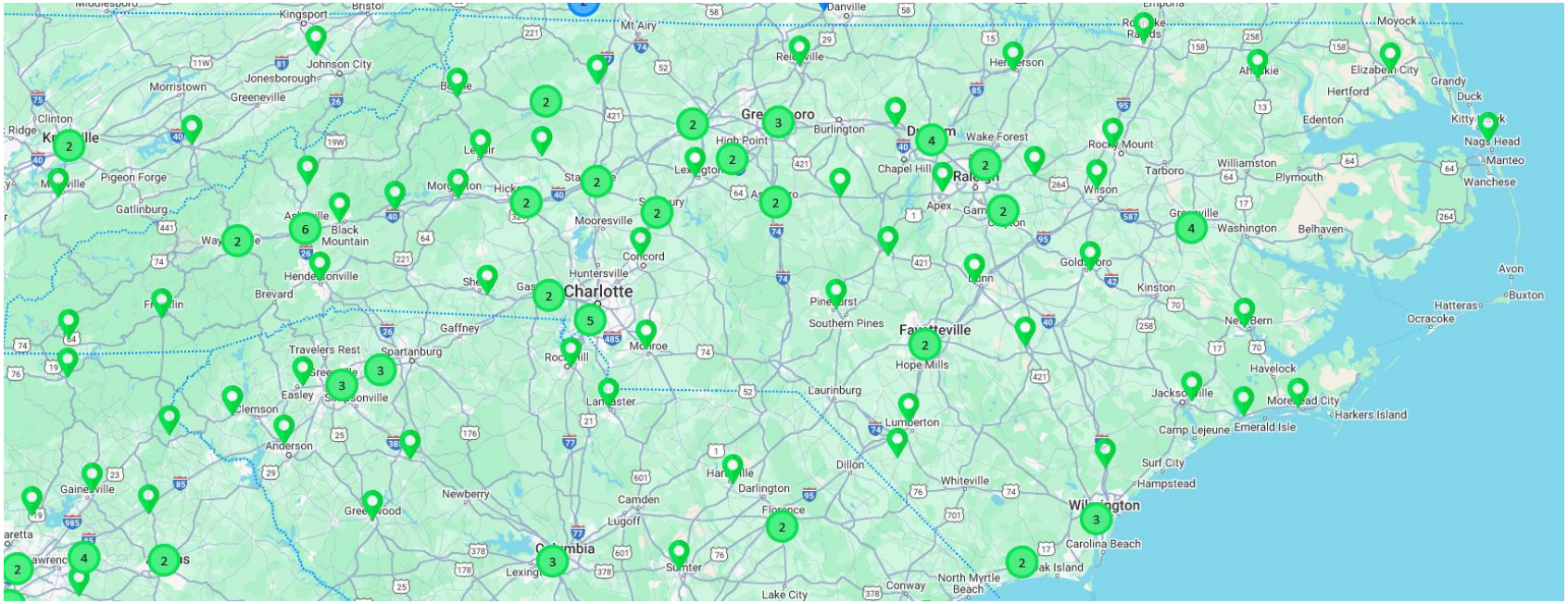
Embracing the “New Normal”



Back to the Basics: What is the OTP Landscape in NC?

OTPs in NC

- 96 OTP Programs across 55 counties in North Carolina
- OTP patients reside in all 100 counties
- Our OTPs served 31,641 unique patients in 2024



Visit https://www.thecentralregistry.com/map/ to find contact information for the OTP in your area

Opioid Treatment Programs

- State and federally licensed facilities where comprehensive opioid treatment services are provided by a multidisciplinary treatment team
  - Physicians
  - Physician Assistants
  - Nurse Practitioners
  - RNs, LPNs
  - Counselors specializing in addiction and mental health treatment
  - Peer Support Specialists
  - Case Managers
- **OTPs are the only level of care where all FDA approved medications for the treatment of opioid use disorder can be provided**

Medications for Opioid Use Disorder

Methadone - Agonist

Buprenorphine (Subutex®, Suboxone®, Sublocade®) – Partial Agonist

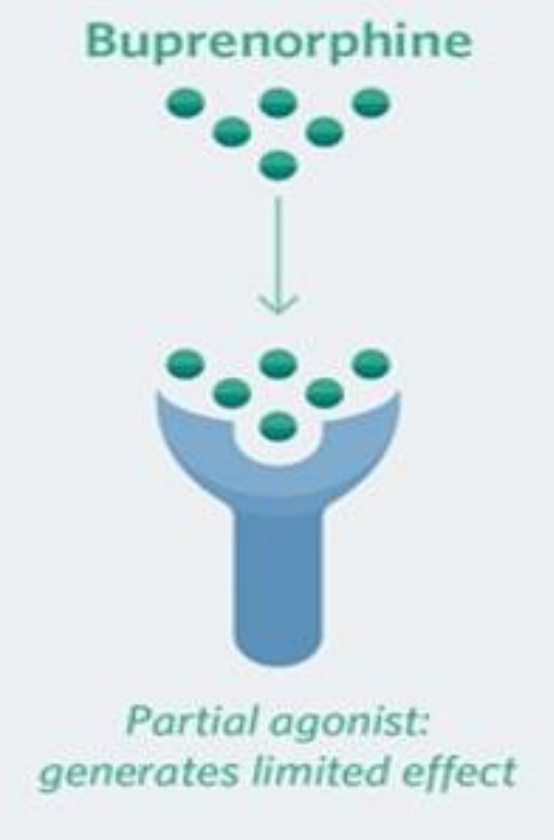
Naltrexone - Antagonist

Methadone

- Oral medication available in liquid or dissolvable diskettes
- Full Opioid Agonist
- Synthetic opioid that fully binds to the same receptor sites as other heroin and other prescription opiates
- Produces the same effects as other opiates including some pain relief
- Has a long half life and slow onset of action, so when taken as prescribed, does not produce euphoria or sedation
- An adequate daily oral dose of methadone suppresses withdrawal and drug craving for 24-36 hours
- Therapeutically appropriate doses of methadone block the euphoric effects of heroin and other shorter acting opiates

Buprenorphine

- Sublingual tablet available in mono-therapy (buprenorphine/Subutex®), combination buprenorphine/naloxone (Suboxone®)
- Available as injectable extended-release subcutaneous injection (Sublocade®)
- Partial Opioid Agonist
- Synthetic opioid that partially binds to the same receptor sites as other heroin and other prescription opiates
- Has a greater affinity for the opioid receptor sites in the brain, so will push other opioids off if taken, which can lead to withdrawal
- Produces most of the same effects as other opiates including some pain relief, but has a ceiling effect, so larger doses are ineffective making overdose uncommon
- Has a long half life and slow onset of action, so when taken as prescribed, does not produce euphoria or sedation



Naltrexone

- Available as oral tablet taken daily or as a long-acting monthly injectable (Vivitrol®)
- Opioid Antagonist
- Tightly binds to opioid receptor sites in the brain and displaces them, precipitating withdrawal
- Produces no narcotic effect
- Produces no withdrawal symptoms when use is discontinued
- Produces no relief from opioid withdrawal symptoms
- Highly effective in preventing relapse when taken as directed, but has had little impact on treatment of opioid addiction due to very low patient compliance rate

Services Offered at OTPs

- Counseling, case management, and linkage to resources
- Coordination of care between medical providers
- STI screening, testing, and referrals for treatment
- Specialized services for pregnant people
- Naloxone distribution
- Some programs may offer integrated psychiatric and/or primary medical care

Other Benefits of an OTP

- **OTPs are the recommended level of care** for patients who are not successful in the OBOT setting
- **OTPs are the recommended level of care** for patients that would benefit from methadone over buprenorphine
- **OTPs are the recommended level of care** for patients that need to switch between medications
- Multidisciplinary treatment team offers wrap-around support for patients
- Greater access to counseling, case management, and peer support services
- Medicaid fully covers treatment at an OTP and state block grant funding is available for people who are uninsured
- Open access with same day onsite medication availability

Mobile Units & Medication Units

Mobile Unit: A motor vehicle (van, RV) from which Opioid Treatment Program (OTP) services are provided at one or more predetermined locations.

Example: jails, residential facilities, shelters

Medication Unit: A stationary unit established as part of an OTP that operates at a geographically separate location from the OTP facility.

Example: rural areas, jails

Strategic Partnerships That Just Make Sense: Enhancing OTP Services in NC

Why Partnerships Matter

- OTPs are most effective when integrated into a broader system of care.
- Strategic partnerships improve:
  - Access and retention
  - Continuity of care
  - Stigma reduction
  - Holistic support for recovery
-

Justice System Partners

Partner	Why It Matters
Jails	Continuity of methadone/buprenorphine during and after incarceration
LEAD Programs	Divert individuals into treatment instead of jail
Drug/Specialty Courts	Support treatment over incarceration with judicial oversight

Healthcare Providers

Partner	Why It Matters
FQHCs	Integrated care for underserved populations
Emergency Rooms	Initiate treatment and refer after overdose
Primary Care	Manage co-occurring conditions
Behavioral Health	Address trauma and mental health
VA Clinics	Serve veterans with OUD

Harm Reduction/Outreach

Partner	Why It Matters
SSPs	Trusted access points for harm reduction and referrals
Mobile Health Units	Bring services to rural or hard-to-reach areas
Pharmacies	Naloxone access and potential methadone pilots
Post Overdose Response Teams (PORTs)	Provide rapid outreach after non-fatal overdoses, connecting individuals to treatment, including OTPs, at a critical moment of readiness.

Community Based Support

Partner	Why It Matters
Faith-Based Communities	Reduce stigma and offer emotional support
Peer Support Orgs	Lived experience and recovery navigation
Housing Services	Address housing instability
Workforce Programs	Support employment and reintegration

Public Health and Coordination

Partner	Why It Matters
Health Departments	Align with public health strategies
Community Task Forces	Coordinate local efforts
MCOs	Facilitate care coordination and funding
Academic Institutions	Research, training, and workforce development
Transportation Services	Overcome access barriers

Call To Action

- Identify gaps in your local OTP partnership network.
- Start small: build trust with one new partner.
- Use existing community coalitions to align efforts.
- Share success stories to inspire replication.

Paradigm Shift Toward Innovation

The new rules have created a paradigm shift in the way we think about the services provided in the OTP. It's been a huge shift away from rule-based and dictated treatment to a more individualized approach. The old way of doing things reinforced the stigma for our patients AND our OTPs. In a lot of ways, our OTPs were victims of the silos that the system created.

Our new rules are about breaking down the barriers to treatment and recovery. Our OTPs are their community's resident experts on the treatment of opioid use disorder. They are positioned to be amazing community partners and a larger part of the health care continuum.

Links

Federal Regulation 42 C.F.R., Part 8

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8

SAMHSA's Federal Guidelines

https://library.samhsa.gov/sites/default/files/federal-guidelines-opioid-treatment-pep24-02-011.pdf

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