



Models for Mobile Opioid Treatment Programs

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Debbi Witham, JD, LMSW	Ms. Witham discloses that she is an employee of Health Management Associates, a national research and consulting firm providing technical assistance to a diverse group of health care clients. Ms. Witham conducted research and analysis for Indivior.
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Presenters



Anika Alvanzo, MD, MS, FACP, DFASAM
Physician Principal
Health Management Associates
(HMA)



Debbi Witham, JD, LMSW
Principal
Health Management Associates
(HMA)

Agenda

- » Overview of Evolution of Opioid Treatment Program (OTP) Services and Mobile OTP
- » Increasing Engagement and Low-Barrier Treatment using Mobile OTPs
- » Barriers to and Benefits of Implementation
- » Question & Answer

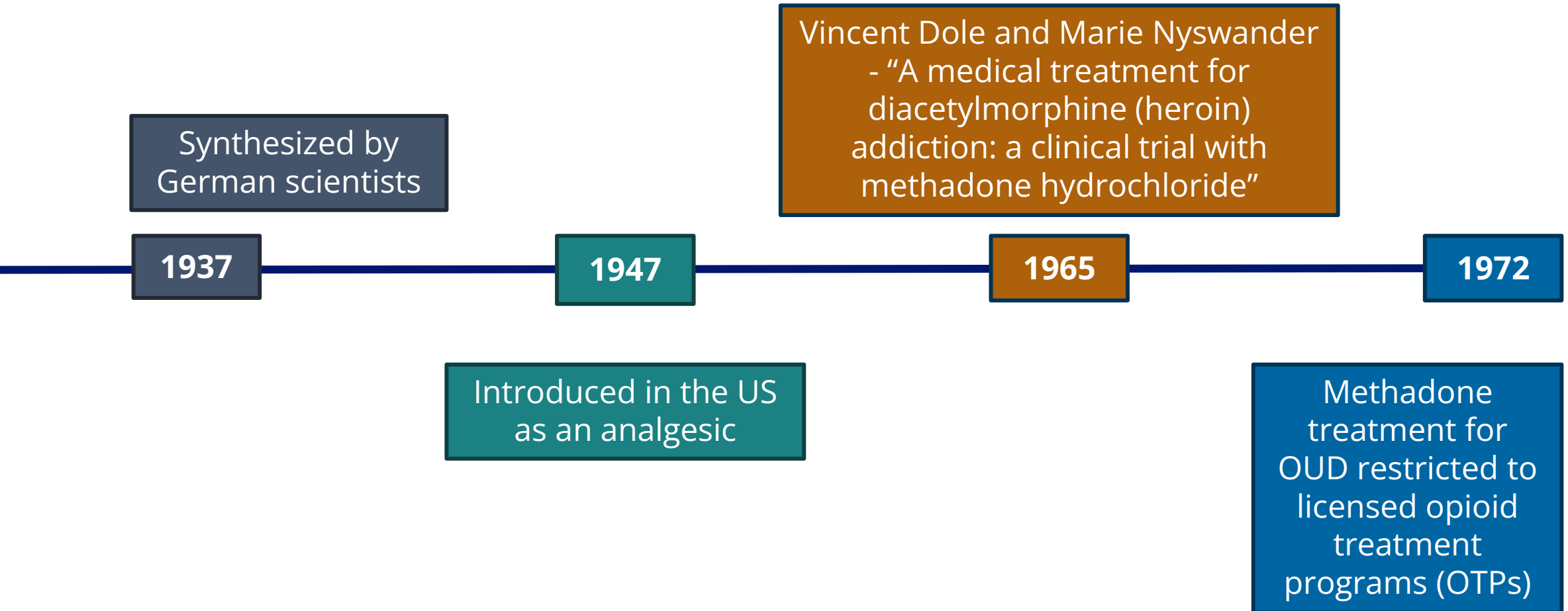
Learning Objectives

At the end of the session, participants will be able to:

- » Identify at least two major milestones in the evolution of Mobile OTP services.
- » List at least three tenets or principles of low-barrier treatment.
- » Identify at least two common barriers and strategies for addressing those barriers.
- » Identify at least two potential benefits of implementing mobile OTP approaches.

Overview of Evolution of OTP Services and Mobile OTP

History of Methadone



SOURCE(S): Colorado Behavioral Health Administration, n.d.; National Academies of Sciences, Engineering, and Medicine, 2022; Payte, J. T., 1991.

Benefits of Methadone in Treating Opioid Use Disorder (OUD)

- » Decreased illicit opioid use
- » Increased treatment engagement
- » Decreased mortality
 - 2 – 3 times reduction in risk of mortality
 - Those who receive medications for opioid use disorder (MOUD) are 75% less likely to have an addiction-related death than those who do not receive MOUD
- » Decreased transmission of infectious diseases (HIV, Hepatitis)
 - 3.5% vs. 22% HIV seroconversion rate
- » Decreased criminal recidivism
- » Increased employment
- » Improved birth outcomes among pregnant persons with OUD

Benefits

Methadone is Highly Regulated

- » Can only be dispensed in a federally certified opioid treatment program (OTP).
 - Called a narcotic treatment program or NTP in California.
- » OTPS must be accredited by SAMHSA-approved accrediting body:
 - CARF
 - Joint Commission
 - Council on Accreditation
 - National Commission on Correctional Health
- » Must be certified:
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
- » Must be licensed by the state in which they operate:
 - State Opioid Treatment Authority (SOTA)
- » Must be registered with the Drug Enforcement Administration (DEA).

SOURCE(S): Colorado Behavioral Health Administration, n.d.; National Academies of Sciences, Engineering, and Medicine, 2022; Payte, J. T., 1991.

OTPs are more than just Methadone

“... a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication” that is also “registered under 21 U.S.C. 823(h)(1)” is described as an “Opioid Treatment Program” (OTP).

- » Dispense opioid agonist medications for treatment of opioid use disorders.

Required Services

- » Supervised dosing.
- » Toxicology testing.
- » “Adequate medical, counseling, vocational, educational, and other screening, assessment and treatment services to meet patient needs...”
 - Combination of services and frequency of delivery individually tailored on shared decision-making treatment/recovery planning process.
 - Services must be provided onsite, except when a formal agreement exists with another organization to provide the services.

SOURCE(S): Substance Abuse and Mental Health Services Administration (SAMHSA), n.d.

Updates to OTP Standards: The Final Rule

“The Final Rule”

Code of federal regulations Title 42, Part 8 originally in effect as of 2001 contains standards for OTPs:

- » Review of record-keeping.
- » Site for storage of methadone and buprenorphine.
- » Inspection and testing of the safe where medication will be stored.
- » Verification of state licensure.
- » Verification of SAMHSA certification.

February 2, 2024, updated final rule published.

- » Went into effect April 2, 2024.
- » Programs allowed until October 2, 2024, to be compliant.

Final Rule Changes: Treatment Standards

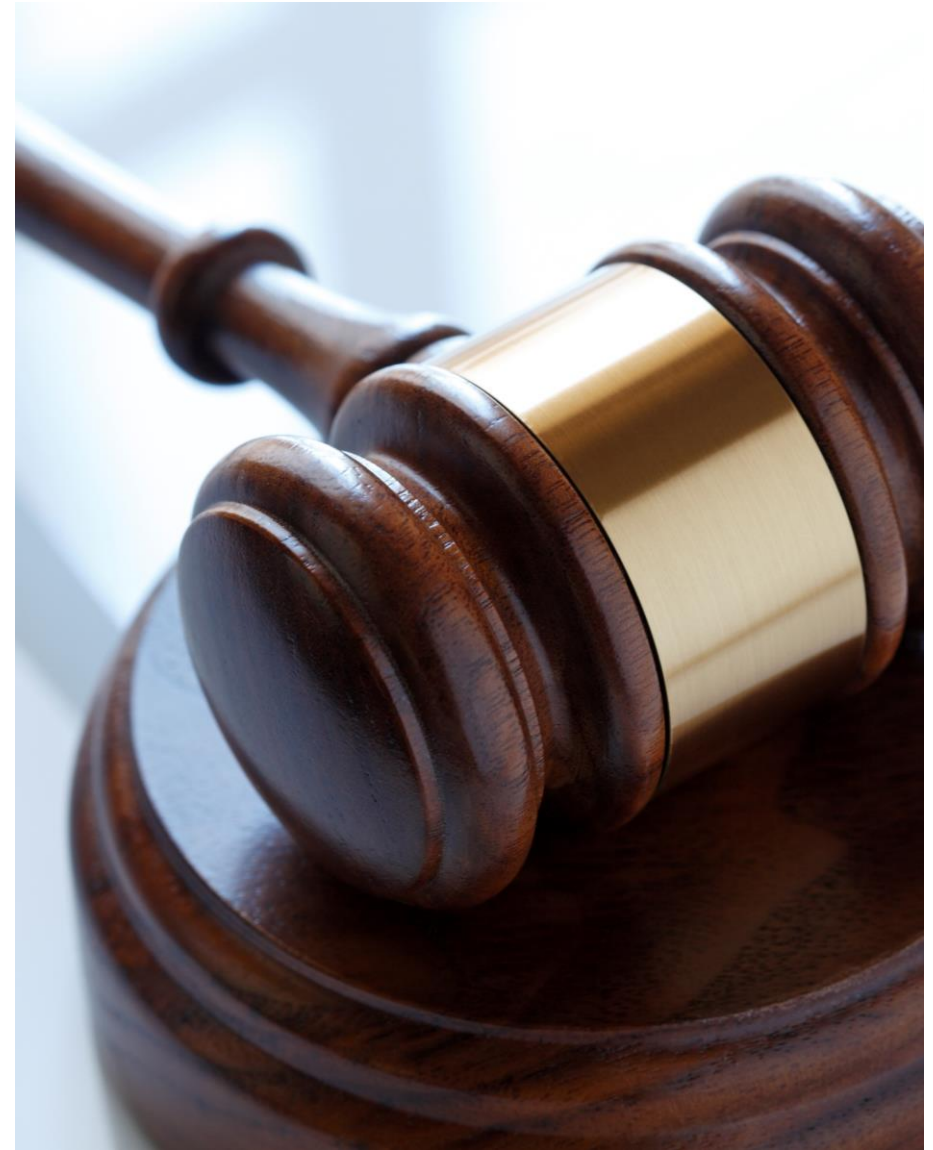
- » Emphasizes shared decision-making.
- » Promotes individualized treatment.
- » Encourages use of clinical judgment.
- » Incorporates principles of harm reduction.

Rationale: “Recognizes the need to meet patients where they are with their opioid and other substance use disorders, and help patients make positive change, reducing harm along the way.”

SOURCE(S): Substance Abuse and Mental Health Services Administration, n.d.

Final Rule Changes: Admissions

- » Removes **requirement for 1-year** history of opioid addiction.
- » Removes the **requirement for two documented instances** of unsuccessful treatment for people under age 18.
- » Promotes priority treatment for **pregnant individuals**.
- » Allows consent for treatment to be **obtained electronically**.
- » Allows for initiation of methadone after a screening examination and **does not require delay** of initiation until comprehensive examination is completed.



Final Rule Changes: Admissions (Continued)

- » Allows for screening examination to be conducted via audio-visual telehealth.
- » OTPs can accept screening examinations performed by other practitioners, if done within seven days of admission, with verification by OTP practitioner.
- » Full in-person physical examination to be completed within 14 calendar days.
- » While there is an expectation that counseling be offered, denial of medication to people who decline counseling is discouraged.

Rationale: “Removes unnecessary barriers to medication access by focusing on individual patient needs. Adds protections for vulnerable groups.”

SOURCE(S): Substance Abuse and Mental Health Services Administration, n.d.

Final Rule Changes: Methadone Initiation

Old	New
Maximum initial dose of 30mg on first day.	Initial dose up to 50mg on first day.
Could give additional 10mg for persistent withdrawal symptoms. Maximum Day 1 dose of 40mg .	Provider can use clinical judgment to give higher starting dose with appropriate documentation.

Old Methadone Take-Home Dose Rules



Any patient may receive a single take-home dose for a day that the clinic is closed for business.



First 90 days of treatment: limited to one take-home dose each week.



Second 90 days of treatment: up to two doses per week.



Third 90 days of treatment: up to three doses per week.



Remainder of first year: up to six doses per week.



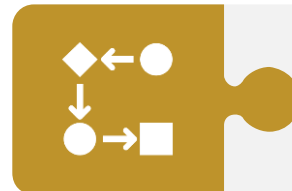
After one year of continuous treatment: up to two-week supply.



After two years of continuous treatment: up to one-month supply.



Anything outside of these parameters requires formal request to SAMHSA and SOTA.



Eight-point criteria for consideration.



Changes: Take-Home Doses

With the COVID-19 public health emergency, relaxed take-home restrictions.

- » Made COVID-19 flexibilities permanent:
 - Up to 7 days of take-homes in the first 14 days of treatment.
 - Up to 14 days of take-homes from day 15 of treatment.
 - Up to 28 days of take-homes from day 31 in treatment.

Rationale: “Makes permanent the COVID-19 flexibilities which demonstrated that wider access to methadone improves outcomes, without increasing rates of diversion, when paired with individualized, clinical judgment, safeguards, and patient education.”

SOURCE(S): Substance Abuse and Mental Health Services Administration, n.d.

Mobile Opioid Treatment Unit

- » 1988: Mobile methadone units first approved with goal of expanding access to marginalized communities.
- » 2007: Moratorium on new units due to concerns about potential diversion.
- » July 2021: DEA issued new regulations related to mobile methadone.
 - Must be part of a fixed-site OTP.
 - Waived requirement of separate registration.
- » Advancements in technology allow for engagement in counseling as well as medication dispensing.

SOURCE(S): Colorado Behavioral Health Administration, n.d.; Office of the Federal Register, 2023.

Models for Mobile OTP Operation

Facilities with Higher OUD Prevalence

- » One model for operating a mobile OTP unit is to identify and partner with facilities that may have a higher prevalence of individuals with opioid use disorder such as:
- Correctional facilities
 - Skilled nursing facilities/Long-term care facilities
 - Residential addiction treatment facilities



SOURCE(S): Office of the Assistant Secretary for Planning and Evaluation, n.d.

Partners Already Serving Those with OUD

» Another approach is to partner with organizations that are already actively serving people who use drugs, such as:

- Harm-reduction organizations (e.g., syringe services programs)
- Recovery organizations



SOURCE(S): Office of the Assistant Secretary for Planning and Evaluation, n.d.

Targeting Populations with High Need

- » Lastly, some models include intentional targeting of populations and communities with some of the highest need:
- Rural residents
 - Urban residents with limited transportation access
 - Tribal communities
 - People experiencing homelessness (e.g., shelters, encampments)



SOURCE(S): Office of the Assistant Secretary for Planning and Evaluation, n.d.

Mobile OTP Services

- » Medication maintenance to those already on methadone.
- » Initiation and maintenance treatment.
- » Counseling.
- » Case management.
- » Telehealth linkage to medical providers and counselors.
- » Vocational counseling.
- » Housing support.
- » Medical services (e.g., HIV, hepatitis testing and treatment, wound care).

SOURCE(S): Office of the Assistant Secretary for Planning and Evaluation, n.d.

Ideas in Action

- » When you think about AFBSS:
- Who are the populations you most want to reach?
 - Where are some key locations?
 - How will you use “Data Driven Outreach” to determine this?



**What are the rules and how
do we do this?**

DEA Requirements for Mobile OTPs

- » **“The intent of the rule is to ensure that there is greater access to treatment for those who are suffering from OUD, and who are unable to access treatment because of rural or geographic limitations, mobility issues, etc.”**
- » Must operate in the same state as the brick-and-mortar OTP.
 - Cannot cross state lines.
- » Must return to registered location at the end of the day.
 - For OTPs unable to accommodate due to space:
 - Mobile unit can be parked in a secure fenced-in location, as long as all DEA security requirements are met:
 - Controlled substances removed from the mobile component at end of the day.
 - Local DEA office notified of the location where unit will be parked overnight.
- » All controlled substances must be removed and secured within registered location.

SOURCE(S): Federal Register, 2021; 21 Office of the Federal Register, 2023.

DEA Requirements for Mobile OTPs (Continued)

- » **“The intent of the rule is to ensure that there is greater access to treatment for those who are suffering from OUD, and who are unable to access treatment because of rural or geographic limitations, mobility issues, etc.”**
- » Safe must be installed and used to secure controlled substances.
 - Substances secured in safe during transportation.
- » Mobile unit must have an alarm system.
- » If seating or a reception area is not separate from the storage and dispensing area, patients must wait outside.
- » Decision on armed or unarmed security left to the OTP.
- » Must have standard operating procedures for contingency plan if the unit becomes inoperable.
 - Includes how controlled substances will be removed and secured at registered location.

SOURCE(S): Federal Register, 2021; 21 Office of the Federal Register, 2023.

Mobile Narcotic Treatment and Medication Units RFA Program Goal

Department of Health Care Services (DHCS)

- » DHCS' primary objective for this funding opportunity is to expand the availability of medication units (MUs) and mobile narcotic treatment programs (MNTPs), to increase MOUD access for rural areas, justice-involved populations, Indigenous and Native communities, patients without transportation, and areas that do not have a Narcotic Treatment Program (NTP) within close proximity to patients in need of NTP services.



Behavioral Health Information Notice (BHIN) 24-005: Application and Protocol Requirements

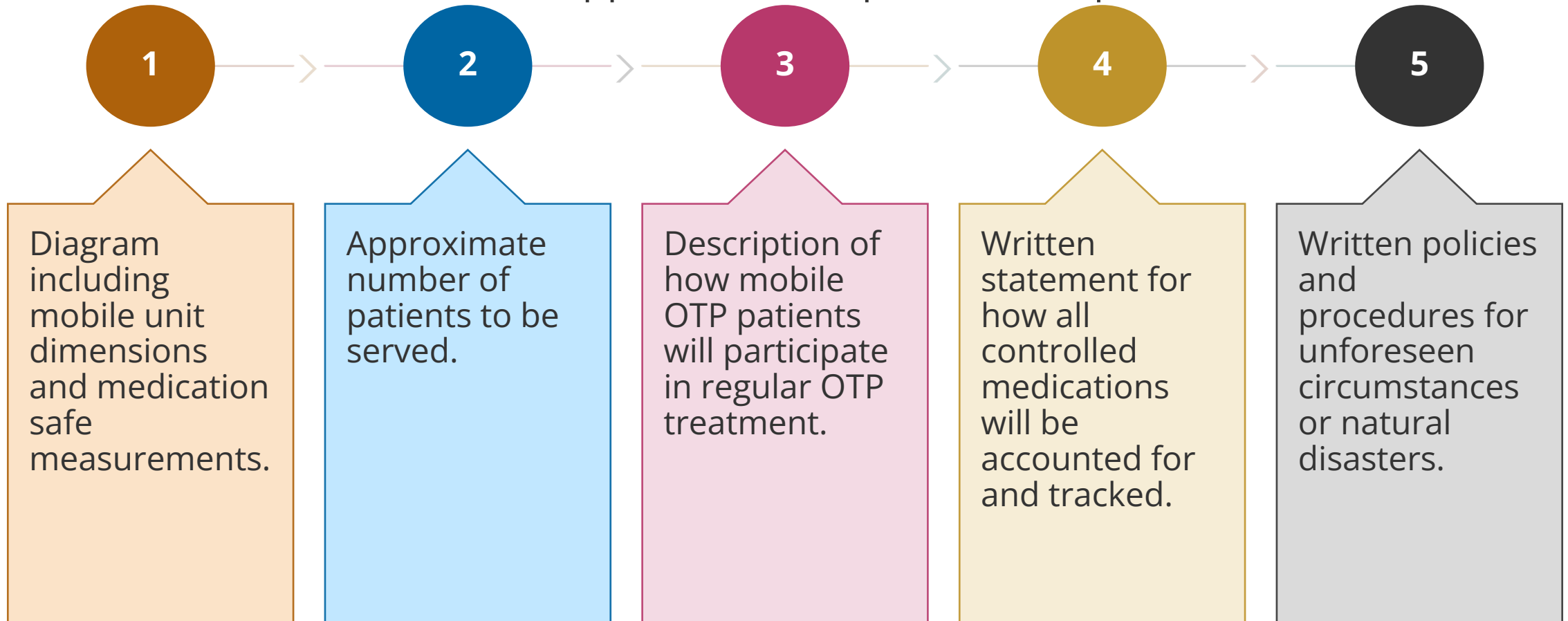
DHCS Requirements for Mobile OTPs

- » Statement explaining geographical areas served, including specific addresses.
- » Statement explaining population to be served.
- » List of names and job titles of mobile OTP staff members and staff who will have access to the medication safe.
- » Resume for every mobile OTP staff member.
- » Description of methods for transporting medication from brick-and-mortar OTP to mobile OTP.
- » Schedule of operations.
 - Including days and hours of medication dispensing.
- » Written statement and map describing standard route to and from dispensing locations.

DHCS Mobile OTP Requirements

DHCS Requirements for Mobile OTPs

(BHIN) 24-005: Application and protocol Requirements



Ideas in Action

» Consider the following:

- What opportunities does having a mobile OTP unit present for your county?
- What makes you most excited about adding a mobile OTP unit?
- What makes you the most nervous?



Increasing Engagement and Low-Barrier Treatment using Mobile OTPs

SAMHSA's Previous Definition of Harm Reduction

SAMHSA Definition of HARM Reduction

» “a practical and transformative approach that incorporates **community-driven public health strategies**—including prevention, risk reduction, and health promotion—to **empower people who use drugs (PWUD) and their families with the choice to live healthier, self-directed, and purpose-filled lives**. Harm reduction centers the lived and living experience of PWUD, especially those in underserved communities, in these strategies and the practices that flow from them.”



SOURCE(S): Substance Abuse and Mental Health Services Administration, 2023.

Harm Reduction in OTPs: Updated Final Rule 42 CFR Part 8

Expanded integration of harm reduction

Includes:

- Overdose education
- Distribution of overdose reversal medication
- Distribution of legal drug-checking supplies
- Infectious disease testing and intervention
- Counseling and risk mitigation
- Linkage to other public health services
- Connection to peer and recovery support services
- Addressing basic needs (e.g., food, hygiene, housing)

SOURCE(S): Substance Abuse and Mental Health Services Administration, n.d.

Harm Reduction in OTPs: Updated Final Rule 42 CFR Part 8 (Continued)

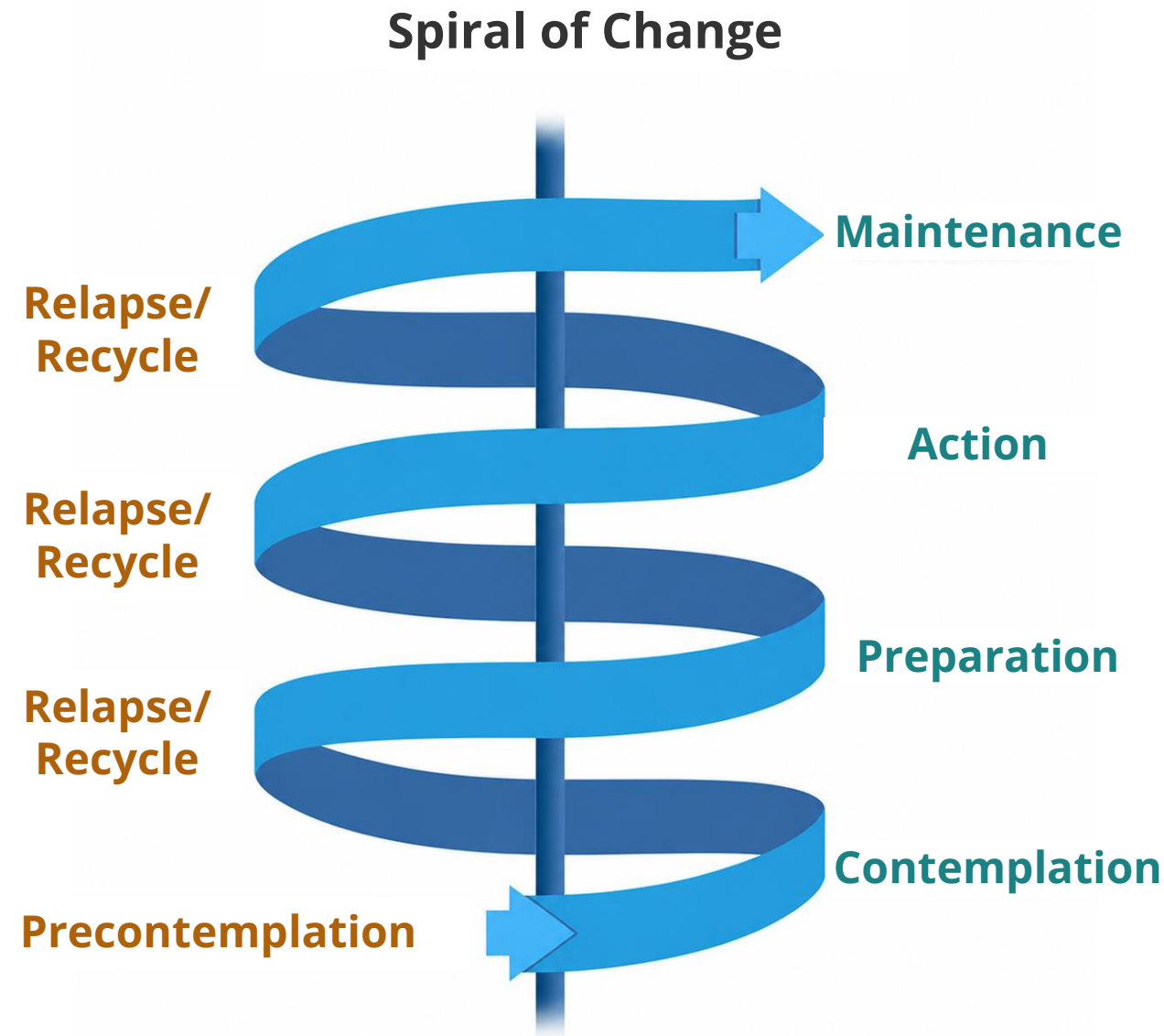
- » Goes beyond overdose and risk reduction services
- » Includes:
 - Cultivation of relationships
 - Engagement and listening
 - Treating individuals with dignity and respect
 - Meeting people where they are

SOURCE(S): Substance Abuse and Mental Health Services Administration, n.d.

Framework for Engaging Patients

Stages of Change/ Transtheoretical Model

- » Change is **gradual**.
- » Change is **cyclical and constant**.
- » Change is **progressive and sequential** through stages.
- » Recurrence is likely and still progress.
- » Meet people at their stage, not yours.



SOURCE(S): Prochaska, DiClemente, & Norcross, 1992.

Core Principles of Engagement

Safety of person-served first

Respect and dignity for all

Informed consent and shared decision-making

Individualized pathways to recovery

Non-punitive, supportive engagement

Collaboration with community resources

Applying the Framework in Clinical Care

Creating an Engaging Environment

Create a nonjudgemental environment in which drug use is acknowledged and accepted.



Write and enact program policies that reflect this reality and so are supportive and not punitive.



There is a safe dialogue between providers and people served, strong feedback loops that inform programs, service delivery, and resources available (including harm reduction resources).



People are more involved in their own care, they spread the word about your services and feel more supported to take steps to improve well-being.

Low-Barrier Treatment

Tenets of Low-Barrier Treatment

- » When we think of low barrier treatment we put a harm reduction focus in the middle.
- » We don't require total abstinence but engage the person in how we can help them to reduce the harms of their use.



Principles of Low-Barrier Treatment

Same day admission to treatment and access to medication.

Access to life-saving medication **should not be withheld or discontinued** based on participation in other services.

Counseling and other ancillary support services (care coordination, case management, etc.) should be offered **but not required** to receive medication for opioid use disorder (MOUD).

MOUD reduces harm. Discontinuation of MOUD based on continued opioid use leaves patients at increased risk for overdose.

SOURCE(S): Jakubowski, & Fox, 2020.

Principles of Low-Barrier Treatment (Continued)

MOUD should not be denied or discontinued based on use of other substances.

- **MOUD should only be expected to treat opioid use disorder.**

Treatment scheduling should be flexible and allow patients to meet other obligations, such as work, school, or childcare.

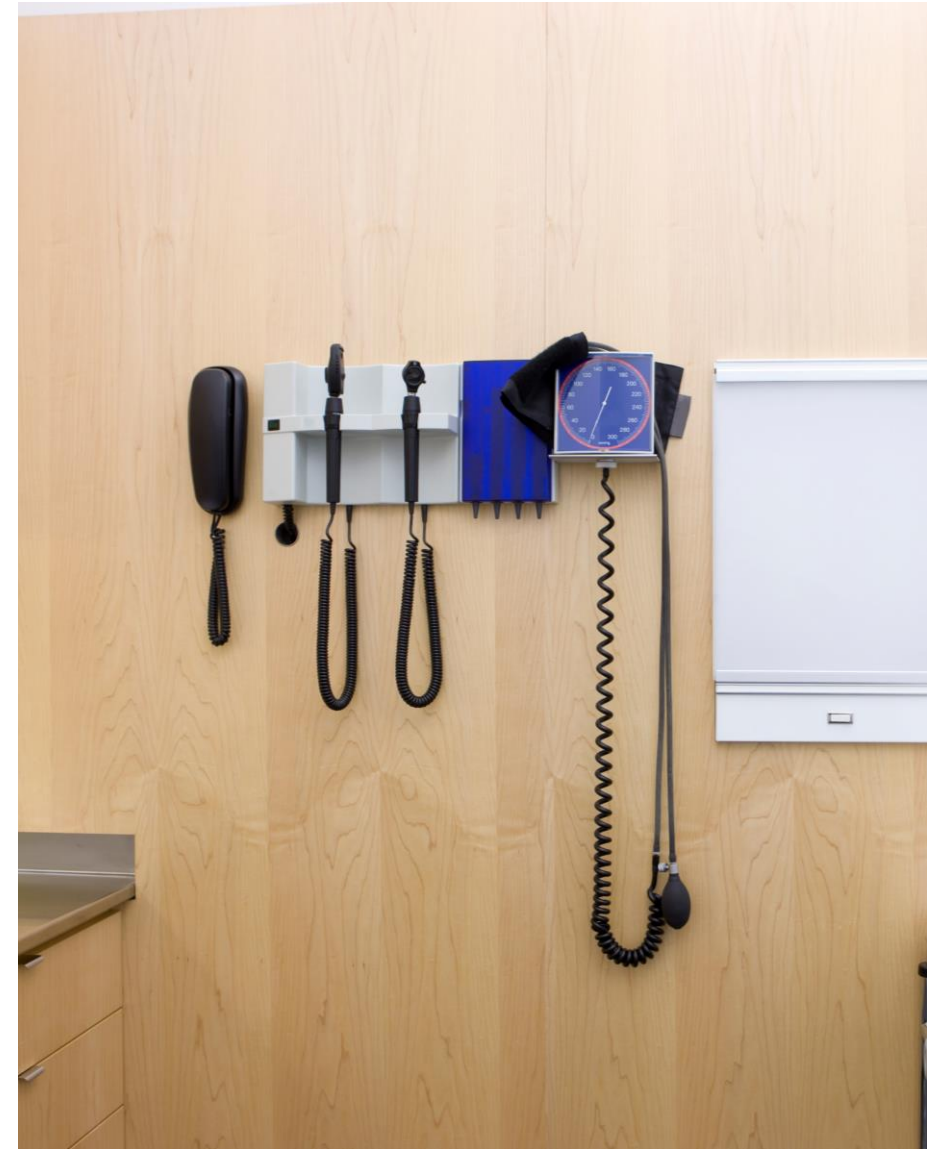
Length of time for MOUD treatment is based on the needs of the individual.

- For many, it may be indefinite.

SOURCE(S): Jakubowski, & Fox, 2020.

Services Beyond Medication and Counseling

- » Excellent Opportunities for:
- Engagement in HIV and Hep C testing and connection to care.
 - Initiation of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).
 - Direct observation therapy (DOT) for medications for chronic conditions.
 - Connection to primary care and ongoing behavioral health care.
 - Long-Acting Injectable (LAI) for psychiatric medications, etc.
 - Vaccinations (e.g. Hepatitis, influenza).



Ideas in Action

- » What services would you want to see provided by a mobile OTP unit operating in your community?



Barriers to and Benefits of Implementation

Barriers to Implementation



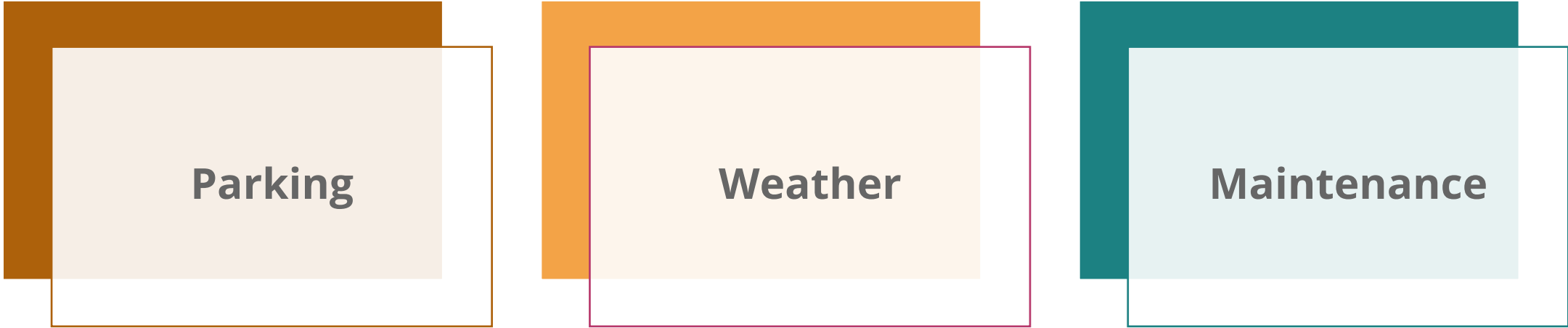
**Power
Dynamics**

**Regulations
and Program
Policies**

Ego

NIMBYism

Barriers to Implementation



Parking

Weather

Maintenance

Clinical Impacts



Improved clinical relationships.



Strengthened trust between patients and members of the treatment team.



Increased access to education and harm reduction resources.



Expansion of resources to support patients' treatment outcomes.



Patients achieve milestones at their own pace.



Increased patient retention.

Strategic Approach and Planning

Identifying Need

- Geography
- Population
- Service cohort

Community Partnerships

- Social service
- Law enforcement
- Health care
- Syringe Service

County Levers and Barriers

- Contracting and service payment
- Opportunities for value

Increasing Access

Open Access

Steps from first request to first dose

Where is the biggest need

Strategic partners

- Placement of mobile unit
- Access into brick and mortar
- Who will be advocates for their use

Ideas in Action

- » What is your vision for increasing access to hard-to-reach populations in your county?



Questions?

info@afbsstraining.org

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