

HCV/Opioid Agonist Therapy Co-localization: Lessons Learned



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September 12, 2023

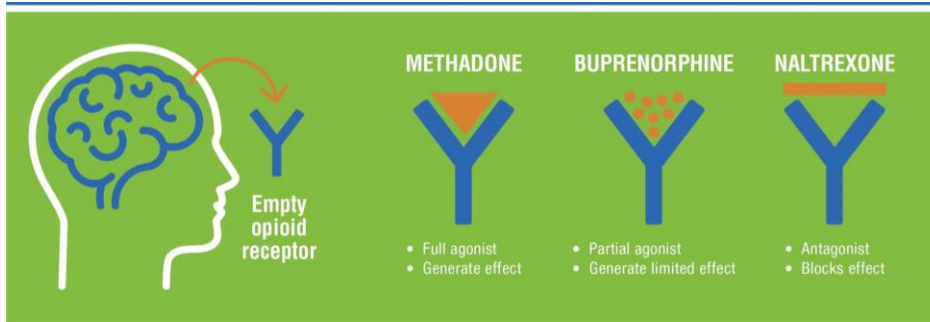
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**No relevant financial relationships with ACCME
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Opioid Use Disorder (OUD):

Treatable illness with extensive body of evidence supporting effective treatment, particularly use of Medications for OUD (MOUD)

- 2 types: Opioid Agonist Therapy (OAT, methadone, buprenorphine) *copies* effects of heroin/other opioids vs Opioid Antagonist (naltrexone) *blocks* effects.

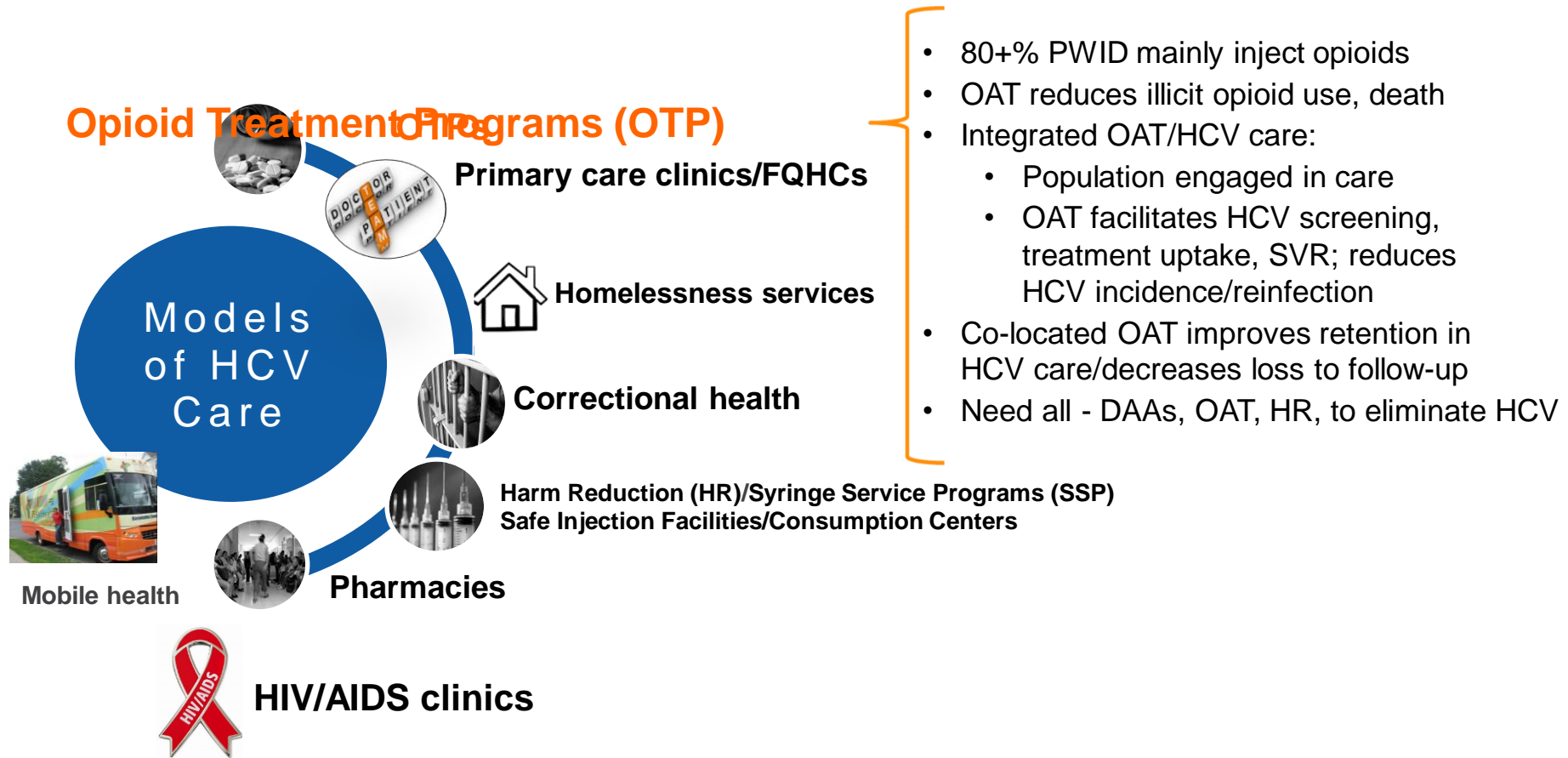


OAT is the most effective method for treating OUDs, reducing opioid overdose deaths, all-cause mortality.

- OAT: synthetic, long-acting opioids that reduce craving & withdrawal while blocking euphoric effects of other opioids.
- OAT reduces:
 - illicit opioid use, injection drug use, suicide, risk of HIV, HCV
- OAT improves:
 - retention in addiction treatment, quality of life
 - in pregnancy, adherence to prenatal care, maternal nutrition, infant birth weight

HCV Co-Location

- Many successful models of HCV care for people who inject drugs (PWID) on-site at accessible venues



Characteristics of Opioid Agonist Therapy

Agent	Mechanism	Location Available in U.S.	U.S. Federal Regulations
Methadone	μ receptor full agonist	OTP (methadone program)	Must be provided at federally licensed specialty OTP DEA-registered & SAMHSA-approved
Buprenorphine	μ receptor partial agonist (often paired w antagonist naloxone)	Office-based/primary care and other, OTP	

- U.S. 1974: Narcotic Addict Treatment Act
 - Methadone delivery requires patients attend designated clinic organizationally and often physically separate from medical system.
- OTPs highly structured
 - Physician evaluates patients; nurses administer methadone daily under observation.
 - Take-home doses contingent on toxicology tests, attendance, other criteria.

Leveraging OTP Infrastructure for On-site HCV Care

Medical Care

- Primary Care, Psychiatry

ID Care

- HIV/HBV/STI/wound care

HCV Universal “Test to Treat”

- Universal, opt-out HCV screening
- Accelerated, streamlined care
 - Minimal blood work
- Serum biomarkers in place of elastography
- Education
- Post-treatment care

Prevention

- HR (SSP services, naloxone), PrEP, vaccination

Services

- Counseling, peer support, housing/employment assistance

Supportive environment for HCV treatment

- Staff familiar with psychosocial needs

Frequent attendance

- Daily/frequent contact



1-Stop Shopping Providence RI



- Started on-site HCV clinic 2014 RI's non-profit OTP
- Provide comprehensive HCV care in gentle, accepting manner
 - Universal HCV test to treat, HIV/HBV/STI testing/care
 - Education, Counseling, Harm Reduction
- Accessible, responsive, flexible
 - Can miss 50 visits, always return to care
 - Low-threshold: walk-in/same day visits
 - Scale up/down intensity of visits as desired/needed
 - Hold DAAs if unstably housed (safe med storage)
 - Collaborate with RI Department of Corrections
- Built patient-centered research program

Candidacy



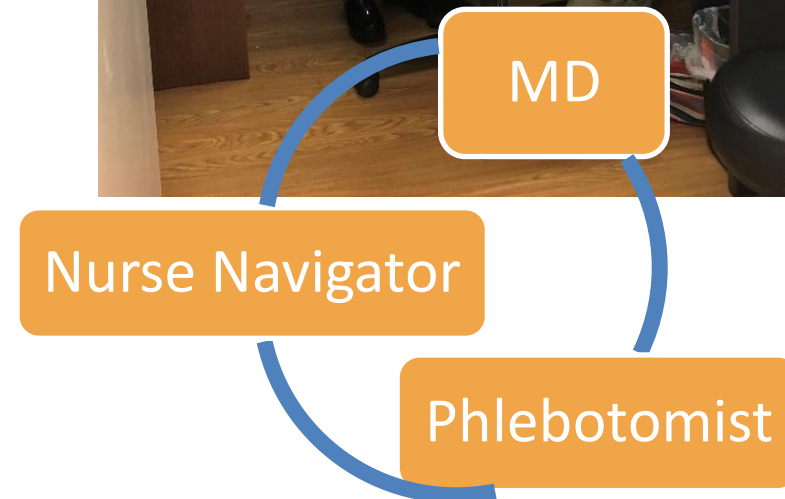
Harm Reduction/Partnership w SSP



Raynald Joseph, Prevention Supervisor

Embedded HCV Medical Team

- Physician
- Nurse/Navigator
- Phlebotomist
- Success based on trust, respect, non-judgment



Sophie Sprecht-Walsh LPN, Elenita Arias, Jackie Habchi PharmD

Streamlined Test to Treat Pathway

Enter care: 1 blood draw. Universal, opt-out. Annual testing for uninfected.

- HCV Ab screening with reflex RNA, genotype
- HAV, HBV, HIV, syphilis serologies [treat HBV, HIV, syphilis]
- Liver panel (ALT, AST, Alb, Tbili)
 - Calculate FIB4/APRI to assess liver disease. Fibrosure if discrepancy.
- CBC, Cr, (PT/INR)

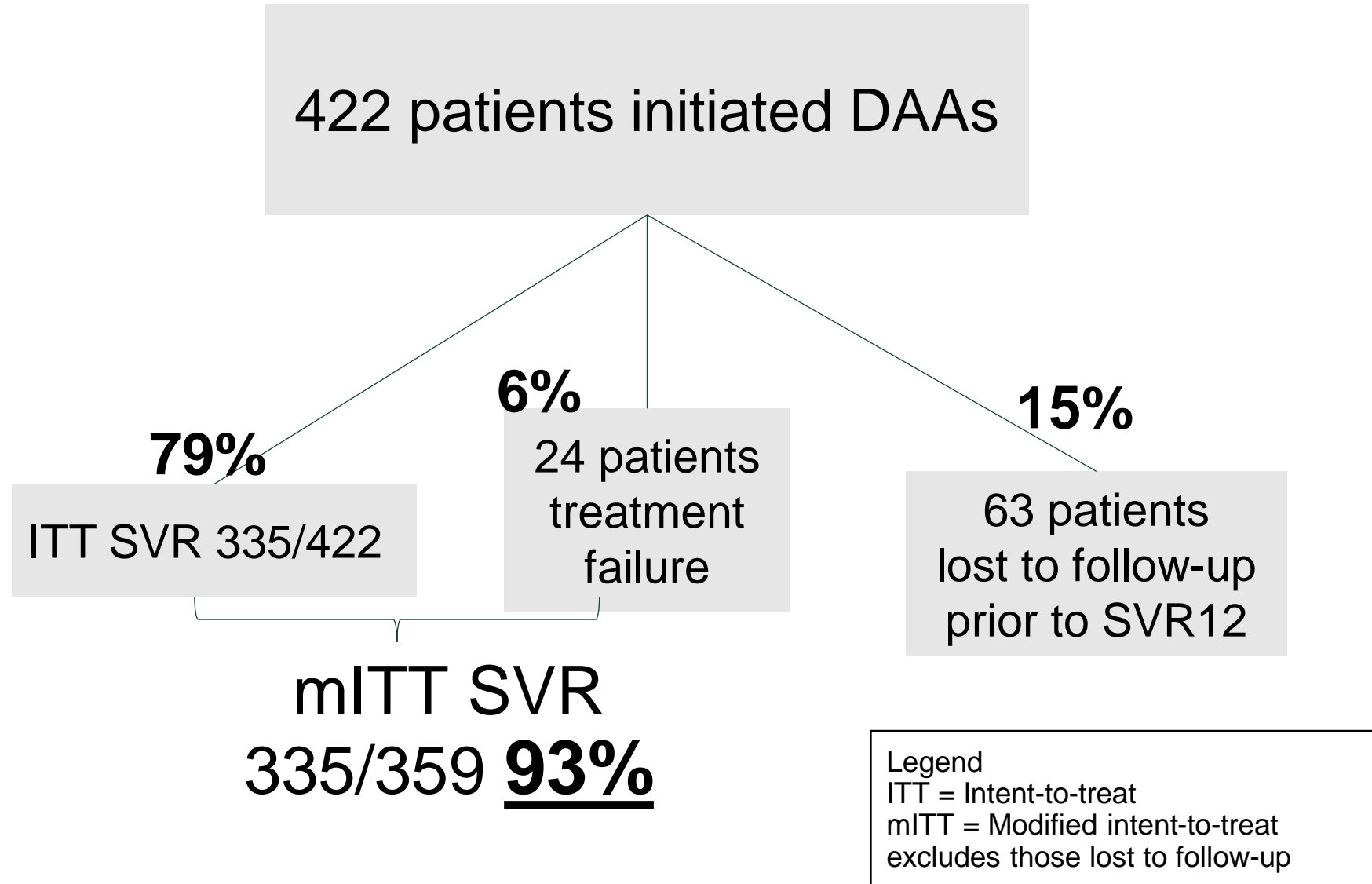
Nurse navigates patients to initial physician visit

1st MD visit: Patient-led. Hx/PE, med list/drug interactions, contraception, assess cirrhosis or not. Substance use discussed; non-probing, patient-led. Education transmission, natural history, HCV vs. HAV/HBV, vaccination. DAAs ordered/Prior Auth submitted if needed. Cirrhosis pathway: CPT score, HCC screening AFP/US, etc.

1st/2nd visit: DAA initiation (in-person/phone as pt prefers). In person: UHCG

 **SVR** → Prevent/test for/treat reinfection. Manage liver disease.

DAA Treatment Outcomes



Building trustworthy HCV services in OTPs

- OTP a place of rationed trust
 - “Ruling peoples’ lives,” “fear of repercussions from transgressions against clinic rules,” can impact trust in HCV services.
- While HCV/OAT co-location = good policy, HCV health care workers may be suspect.
 - For effective HCV care, patients must build trust in HCV service & staff through service boundaries & promotion through peers.
- Examples: Safe place to talk openly
 - HCV records only seen by HCV team
 - HCV physician documents bare minimum



Who has not seen a typical U.S.
OTP?

Standard of Care Must Be:

Would this be acceptable medical care for a patient with cancer?

- If NOT, then it is not acceptable for an individual receiving methadone
- RI: no addiction training or expertise needed to be a doctor providing methadone, just 'interest'
- Pts. fear speaking up because 'behavior' can impact take home doses

Weimer M. et al Patients With OUD
Deserve Trained Providers
Ann Intern Med 2019



U.S. OTPs need to be medicalized

**We cannot build optimal medical care
on a faulty foundation...**

- U.S. OTPs
 - More often for-profit than non-profit
 - Operated by only 3 different organizations as of 2018
 - Can be mills where patients contending with life-threatening medical issues handed methadone in substandard environments without adequate medical care, infection control, evidence-based practices, addiction expertise



“A methadone patient is monitored more closely than a paroled murderer.” Edwin Salsitz MD



Patients describe accessing daily methadone as having to walk through broken glass

- Nearly all states have restrictive OTP rules not evidence-based, beyond federal regulations, limiting care access, worsening patient experience, reducing retention.
 - States with more regulations have poorer opioid-related outcomes, including increased fatalities.

Roadmap for next steps: Methadone Manifesto: Treatment Experiences & Policy Recommendations From Methadone Patient Activists AJPH 2022

- Methadone regulations should be supported by current research.
- Regulations beyond the federal level should not be allowed.
- Policymakers & methadone programs should give patients decision-making roles in policy & program practice.

Lessons Learned - HCV



- DAA treatment is effective in a co-located methadone/HCV/HR program.
 - Scale up integration of HCV care into settings where PWID access OAT with on-site test to treat
- Simplified algorithms are here.
 - Enable population-level treatment delivery
- DAAs are not enough. Need:
 - OAT, HR, DAAs
 - Provide whole-person care for PWID, not just cure virus
 - Do not want SVR then overdose
 - Provide as much medical care as possible on-site – HCV prevention/test to treat, cirrhosis care, surveillance for reinfection, vaccination, screening/care for related infections, wound care, ideally w foundation primary care, psychiatry

Conclusions OAT:

Change Federal Methadone Regulations

- Limiting methadone dispensing to OTPs:
 - Separates methadone from medical system
 - Requires patients to visit OTP daily for months or years before receiving take home medication
 - Because of a “not in my backyard” sentiment, often requires people to make daily visits to areas may be associated w public drug use, increasing risk recurrent use
- Act now to
 - Improve quality of OTP services
 - Remove state rules that go beyond federal law
- Broaden access to evidence-based methadone
 - Expand methadone availability across diverse clinical settings
 - Many nations, physicians prescribe & pharmacies dispense methadone
 - Opportunity – paucity OTPs in U.S.; Let’s build them right way

Acknowledgements

The many individuals I have had privilege to provide medical care to over past 25+ years

Partners: Sophie Sprecht-Walsh LPN,
Elenita Arias



International Network on Health and Hepatitis in Substance Users

Jackie Habchi Pharm D

Erin McManus

Jason Grebely, Tanya Applegate, Carla Treolar, Kirby Institute
UNSW Australia

Kevin Costello, Center for Health Law & Policy Innovation,
Harvard Law School

Jennifer Wood, RI Center for Justice

Raynald Joseph, Oz Lugo, AIDS Care Ocean State

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RI DEFEATS
HEP C



Hepatitis C and SAMHSA

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Centers for Substance Abuse Treatment

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services



SAMHSA
Substance Abuse and Mental Health
Services Administration

Integrated Care is a SAMHSA Priority



Priority Areas for CSAT FY23/FY24 (and beyond)

Equity Assessments

Incorporation of Harm
Reduction and Recovery-
Oriented Care

Contingency
Management
Expansion

Hepatitis C Elimination
Including Intersection with
Alcohol Interventions

MOUD Expansion as a
Tool and a Connector

Methadone
Modernization

SAMHSA's Hepatitis C Approach

- Taking a syndemic approach to healthcare delivery based on populations served through utilization, as appropriate, of:
 - low barrier substance use disorder (SUD) treatment;
 - mental healthcare;
 - HIV and viral hepatitis testing and treatment;
 - HIV prevention including condom, Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) distribution;
 - and harm reduction services.

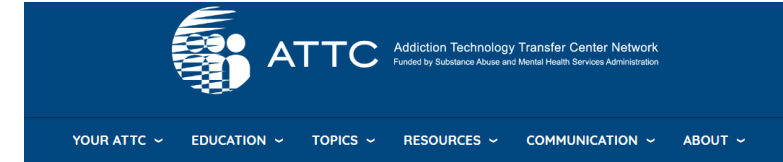


Hepatitis C can be cured.

- Training and TA Resources for HCV

- Enhance OTPs by implementing 42 CFR Part 8

- Incorporate regulatory flexibilities
- Encourage Harm Reduction and Recovery-Oriented Care within OTPs
- Encourage integration of primary care and OTP services



HCV Current is a national initiative of the ATTC Network to increase hepatitis C (HCV) knowledge among medical and behavioral health professionals.

Products



NOW AVAILABLE! 2023 Supplement to Your Guide to Integrating HCV Services into Opioid Treatment Programs

Request for Information

Interested in learning more about the ATTC Network's HCV efforts? Complete the form below:

Sign in to Google to save your progress. [Learn more](#)

<https://attcnetwork.org/centers/global-attc/hcv-current-initiative>



Programs that Support HCV Testing and Linkage to Care

MHAF TI-23-024

- **Minority HIV/AIDS Fund: Integrated Behavioral Health and HIV Care for Unsheltered Populations Pilot Project**
- **Short title:** Portable Clinical Care Pilot Project
- **Anticipated Total Available Funding:** Up to \$2,000,000
- **Anticipated Number of Awards:** 3
- **Anticipated Award Amount:** Up to \$666,666 per year
- **Length of Project:** Up to 3 years

MAI TI-23-008

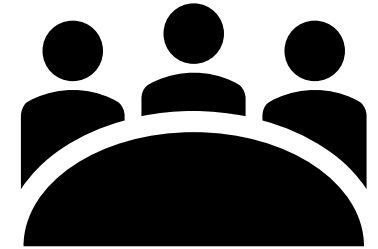
- **Minority AIDS Initiative: Substance Use Disorder Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS**
- **Short title:** MAI: High Risk Populations
- **Anticipated Total Available Funding:** Up to \$20,900,000
- **Anticipated Number of Awards:** Up to 42 (up to 5 for tribes/tribal organizations)
- **Anticipated Award Amount:** Up to \$500,000 per year per award
- **Length of Project:** Up to five years

MAT-PDOA TI-23-001

- **Medication-Assisted Treatment – Prescription Drug and Opioid Addiction**
- **Short title:** MAT-PDOA
- **Anticipated Total Available Funding:** Up to \$18,200,000
- **Anticipated Number of Awards:** 24 (up to 13 for tribes/tribal organizations)
- **Anticipated Award Amount:** Up to \$750,000 per year
- **Length of Project:** Up to 5 years

Looking Ahead

- MAI TI-24-005
 - Anticipated 21 grant recipients in fiscal year 2024
- PACHA (Presidential Advisory Council on HIV/AIDS) :
 - meeting (Sept 20-21) in Charleston, WV
 - Focusing on the HIV epidemic in Appalachia including the syndemic of HIV, viral hepatitis, SUDs and mental illness.
- Certified Community Behavioral Health Clinics (CCBHCs) HCV criteria



Thank You

SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and positive outcomes.

www.samhsa.gov

And we encourage you to visit SAMHSA Store for mental health and substance use resources

<https://store.samhsa.gov/>

And

<https://www.samhsa.gov/find-help/national-helpline>

And

<https://findtreatment.samhsa.gov/>

1-877-SAMHSA-7 (1-877-726-4727) • 1-800-487-4889 (TDD)