

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

**Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws
A Workshop**

March 3-4, 2022 | Virtual

Workshop Objectives:

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a two-day public workshop that brings together experts and key stakeholders to examine the current federal regulatory and legal landscape regarding provision of and access to methadone for the treatment of opioid use disorder.

Invited presentations and discussions will be designed to:

- Examine current federal regulations governing methadone treatment services, including the current COVID-19 emergency regulatory relief;
- Discuss the impact of these regulations relative to other factors affecting treatment services;
- Explore potential options for modifying federal regulations and laws to expand access to quality treatment with methadone; and
- Explore state laws that may conflict with federal regulations.

Workshop Planning Committee

Alan Leshner, PhD, (Chair) CEO Emeritus, American Association for the Advancement of Science
Gavin Bart, MD, PhD, Hennepin County Medical Center; University of Minnesota
Richard Bonnie, LLB, University of Virginia
Magdalena Cerdá, DrPH, New York University
Abby Coulter, Urban Survivors Union
Bridget Dooling, JD, George Washington University
Sheri Doyle, MPH, The Pew Charitable Trusts
Tracie Gardner, Legal Action Center
Helena Hansen, MD, PHD, University of California, Los Angeles
Van Ingram, Kentucky Office of Drug Control Policy
Matthew Lawrence, JD, Emory University School of Law
Gail Mattox, MD, DLFAACAP, DLFAPA, Morehouse School of Medicine
Josiah “Jody” Rich, MD, MPH, Brown University
Danielle Russell, MS, Sonoran Prevention Works
Kenneth Stoller, MD, FAPA, Johns Hopkins University
Jonathan H Watanabe, PhD, PharmD, MS, University of California, Irvine School of Pharmacy & Pharmaceutical Sciences

DAY 1: Thursday, March 3, 2022

9:30am ET **Welcome and Opening Remarks**
Alan Leshner, CEO Emeritus, American Association for the Advancement of Science; *Workshop Chair*

9:35am **Opening Talks Highlighting Lived Experiences**
Abby Coulter, Urban Survivor's Union; co-author of the Methadone Manifesto; *Planning Committee Member*
Walter Ginter, Medication Assisted Recovery Support Team
Brenda Davis, National Alliance for Medication Assisted Recovery, Inc.

Session 1: Methadone Treatment and Regulation – Historical Perspective and Overview of Where We Are Today

Session Objective: Examine the history and current status of methadone treatment and regulations in the U.S.

Key Discussion Questions:

- How have methadone regulations evolved to where they are today?
- What are the effects of methadone regulation on health inequities, including social barriers to treatment, and the considerations for special populations?
- What are some of the federal priorities and collaborative efforts aimed at addressing longstanding barriers and improving access to quality treatment?

10:05am **Session Overview**
Helena Hansen, University of California, Los Angeles; *Planning Committee Member*; *Session Moderator*

10:10am **The Politics of Stigma and Racialization in the Early Years of Methadone Maintenance Regulation**
Samuel Kelton Roberts, Jr., Columbia University

10:25am **Racial Disparities in Access, Initiation, and Retention in Methadone Treatment and Implications for Policy Formulation**
Magdalena Cerdá, New York University; *Planning Committee Member*

10:40am **Considerations for Special Populations and Circumstances**

- **Pregnant/Parenting People**
Mishka Terplan, Friends Research Institute
- **People living with HIV & LGBTQIA+ Populations**
Alex Keuroghlian, The Fenway Institute; Harvard Medical School
- **Older Adults**
Ximena Levander, Oregon Health & Science University

- 11:10am **Moderated Discussion with the Speakers and Q&A**
- 11:30am **BREAK**
- 11:40am **ONDCP Presentation – Goals and Priorities of the Administration**
Rahul Gupta, Director, Office of National Drug Control Policy,
Executive Office of the President
- 11:50am **Overview of the Current Regulatory Landscape and Flexible Responses during COVID-19**
- **U.S. Department of Health and Human Services (HHS)**
Rebecca Haffajee, Acting Assistant Secretary for Planning and Evaluation
 - **Substance Abuse and Mental Health Services Administration (SAMHSA)**
Yngvild Olsen, Acting Director for the Center for Substance Abuse Treatment
 - **Drug Enforcement Administration (DEA)**
Kristi O'Malley, Special Advisor to the Administrator
- 12:20am **Lessons Learned from COVID-19 and Regulatory Change in the Wake of Necessity**
Noa Krawczyk, New York University
- 12:35pm **Overview of The Pew Charitable Trusts' 50-State Analysis of Methadone Regulations**
Frances McGaffey, The Pew Charitable Trusts
- 12:45pm **Moderated Discussion with the Speakers and Q&A**
- 1:05pm **LUNCH**

Session 2: Improving Access to Quality Treatment in OTPs through Regulatory Innovation

Session Objective: Explore broad implementation of innovations, supported by evidence, and best practices to ensure access and quality treatment in opioid treatment programs (OTPs): What is allowed now and what requires regulatory change?

Key Discussion Questions:

- What innovations and best practices, including those from the COVID-19 pandemic, could be more broadly implemented within the existing regulatory framework to support (a) access, (b) quality, and (c) safety?
 - What evidence is available regarding the effect of regulatory innovation and flexibility implemented during the COVID-19 pandemic?
 - Other opportunities for regulatory flexibility
- What potentially useful innovations would require formal rulemaking or legislative action?
 - What concretely would that look like?
- What steps would enhance health equity?

- 1:40pm **Session Overview**
Ken Stoller, Johns Hopkins University; *Planning Committee Member; Session Moderator*

- 1:45pm **Legal Analysis**
 Bridget Dooling, George Washington University; *Planning Committee Member*
- 2:00pm **Pharmacy Dispensing as an Extension of OTPs**
 Robert Brooner, Friends Research Institute
- 2:15pm **Mobile Units**
 Valerie Mielke, New Jersey Department of Human Services
- 2:30pm **OTPs as Hub Sites in Systemic Expansion**
 Mark Parrino, American Association for the Treatment of Opioid Dependence, Inc.
- 2:45pm **Moderated Discussion with the Speakers and Q&A**
- 3:10pm **BREAK**

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| <p>Session 3: Improving Access to Quality Treatment in the Criminal Justice System and Other Institutional Settings</p> |
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Session Objective: Explore possible regulatory initiatives at the federal level that would improve access to quality treatment with methadone in federal, state and local correctional settings, and in other institutional settings.

Key Discussion Questions:

- What available discretion in existing regulations could be better leveraged to support (a) access, (b) quality, and (c) safety in institutional settings?
- What evidence is available regarding the effect of the innovations and regulatory flexibility implemented during the COVID-19 pandemic?
- What regulatory [or statutory?] changes at the federal level are needed to improve access and quality in federal, state, and local institutional settings? What concretely would that look like?
- What steps would enhance health equity?

- 3:25pm **Session Overview**
 Tracie Gardner, Legal Action Center, *Planning Committee Member; Session Moderator*
- 3:30pm **Cross-Cutting Regulatory Issues that Impact Corrections Facilities at All Levels and Other Institutions**
 Josiah “Jody” Rich, Brown University; *Planning Committee Member*
- 3:45pm **Transitional Clinic Networks**
 Emily Wang, Yale School of Medicine
- 4:00pm **A State Trial Court Perspective**
 Judge Michael Barrasse, Lackawanna County Court of Common Pleas, Pennsylvania
- 4:15pm **Civil Rights Litigation to Enable Methadone Treatment in Institutions**
 Rachael Rollins and **Greg Dorchak**, U.S. States Attorneys’ Offices – Massachusetts

- 4:30pm **Moderated Discussion with the Speakers and Q&A**
- 4:55pm **Day 1 Closing Remarks**
Alan Leshner, CEO Emeritus, American Association for the Advancement of Science;
Workshop Chair
- 5:00pm **ADJOURN**
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DAY 2: Friday, March 4, 2022

- 9:30am ET **Welcome and Recap of Day 1**
Alan Leshner, CEO Emeritus, American Association for the Advancement of Science;
Workshop Chair

Session 4: Expanding Access to Methadone through Regulatory Innovation

Session Objective: Explore broad implementation of innovations, supported by evidence, and best practices to ensure access and quality treatment using models and settings other than OTPs: What is allowed now and what requires regulatory change?

Key Discussion Questions:

- What innovations and best practices involving models and settings other than OTPs could be more broadly implemented within the existing regulatory framework to support (a) access, (b) quality, and (c) safety?
 - Are there available regulatory opportunities not currently understood or leveraged?
- What innovations require formal rulemaking or legislative action?
 - What concretely would that look like?
- What steps would enhance health equity?

- 9:40am **Session Overview**
Gavin Bart, Hennepin Healthcare; University of Minnesota Medical School; *Planning Committee Member; Session Moderator*
- 9:45am **Office-Based Methadone**
Robert Schwartz, Friends Research Institute
- 10:00am **Pharmacy-Based Dispensing**
Li-Tzy Wu, Duke University School of Medicine
- 10:15am **International Models of Pharmacy-Based Dispensing**
Janie Sheridan, University of Auckland
Suzanne Nielsen, Monash University
- 10:30am **Innovative Models of Initiation under Existing Regulations – Inpatient and Outpatient Settings**
Alexander Walley, Boston University and Massachusetts Department of Public Health

- 10:45am **Potential New Treatment Modalities/Settings that Could be Opened up with Regulatory Changes**
Ayana Jordan, New York University
Kamilla Venner, University of New Mexico
- 11:15am **BREAK**
- 11:30am **Regulatory Opportunities to Remove Current Barriers**
Corey Davis, The Network for Public Health Law
- 11:45am **Regulatory Incentives to Facilitate Access to Quality Treatment**
Matthew Lawrence, Emory University School of Law; *Planning Committee Member*
- 12:00pm **Moderated Discussion with the Speakers and Q&A**
- 12:45pm **LUNCH**

Session 5: Assessing Potential Legal and Regulatory Changes

Session Objective: Explore a framework that might guide the assessment of potential legal and regulatory changes that would yield the most benefit for improving access to quality methadone treatment for all.

Key Discussion Question:

- How can the potential impact of the different regulatory mechanisms discussed throughout the workshop be assessed and prioritized? For example:
 - When considering the evidence, how many more people might have access to treatment?
 - What might the health outcomes be, and at what cost?
 - What inroads can such actions might make on health equity?
 - How can a framework address both public health and diversion concerns?

- 1:30pm **Overview**
Alan Leshner, CEO Emeritus, American Association for the Advancement of Science;
Workshop Chair; Session Moderator
- 1:35pm **A Policy Analysis Framework to Support Health Policy Decisions**
Richard Frank, Harvard Medical School; The Brookings Institution
- 1:55pm **A Cost-Effectiveness Framework to Assess Potential Legal and Regulatory Changes**
Michael French, University of Miami
- 2:15pm **Moderated Discussion with Speakers and Q&A**
- 2:35pm **BREAK**
- 2:50pm **Synthesis and Prioritization of Legal and Regulatory Actions**
Richard Bonnie, University of Virginia, *Planning Committee Member*

- 3:00pm **Panel Discussion on Concrete Actions**
John Brooklyn, BAART St. Albans and Howard Center Burlington Vermont
Chinazo Cunningham, New York State Office of Addiction Services and Supports
David Frank, New York University
Joy Rucker, Former Executive Director, Texas Harm Reduction Alliance
Brendan Saloner, Johns Hopkins University
Shelly Weizman, O'Neill Institute for National and Global Health Law, Georgetown Law
- 3:45pm **Audience Q&A**
- 4:25pm **Acknowledgements and Concluding Remarks**
Alan Leshner, CEO Emeritus, American Association for the Advancement of Science;
Workshop Chair
- 4:30pm **ADJOURN WORKSHOP**