Considerations for Buprenorphine Initiation and Maintenance Care

Wednesday, May 10 from 1 – 4:45 pm ET and Thursday, May 11 from 1 – 4:30 pm ET
Virtual Public Meeting

Agenda

Meeting Description:
The Reagan-Udall Foundation for the FDA, in partnership with the U.S. Food and Drug Administration (FDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), is holding a two-part virtual public meeting entitled "Considerations for Buprenorphine Initiation and Maintenance Care." This virtual public meeting will explore real-world experiences and scientific evidence for buprenorphine initiation strategies as well as medication dosing and management during continued treatment across different care settings. To support efforts to develop products and approaches to treat Opioid use disorder (OUD), presentations and discussions will include people who use drugs, their families and community, harm reduction programs, health professionals from inpatient and outpatient settings, academic researchers, and federal partners.

OUD is a major public health issue. Buprenorphine is a safe and effective prescription medication used for treatment of OUD. One challenge in accessing treatment for OUD with buprenorphine is that initiation of buprenorphine takes careful planning: patients must already be experiencing mild to moderate withdrawal symptoms or risk precipitated withdrawal. An increase in fentanyl in the illicit drug supply has further complicated buprenorphine initiation and maintenance. Current evidence underlying the best strategy for initiating and maintaining buprenorphine care is mixed. A better understanding of the landscape of available tools and strategies for best practices in OUD care with buprenorphine is needed to advance the development of and access to evidence-based treatment for OUD, a priority under the FDA Overdose Prevention Framework and the U.S. Department of Health and Human Services (HHS) Overdose Prevention Strategy.

Meeting Goals:

1. Understand real-world experiences and scientific evidence for:
    a. various buprenorphine initiation strategies, including low-dose, cross-tapering, and high-dose methods
    b. buprenorphine medication dosing and management strategies for opioid use disorder during stabilization, maintenance, and discontinuation/tapering to optimize patient engagement, retention, and outcomes
2. Identify gaps and opportunities for product development (e.g., new formulations, packaging concepts, dosing regimens) to optimize buprenorphine initiation in different care settings (e.g., emergency department, telehealth, treatment program) and minimize risk

Day 1

1 pm — Welcome

Speaker: Susan C. Winckler, RPh, Esq, Chief Executive Officer, Reagan-Udall Foundation for the FDA

1:05 pm — Opening Remarks on Current Regulatory Landscape

Speakers:

- Yngvild K. Olsen, MD, MPH, Substance Abuse and Mental Health Services Administration
- Marta Sokolowska, PhD, U.S. Food and Drug Administration

1:25 pm — Session 1: Overview of Clinical Guidelines

Speaker: Melissa Weimer, DO, MCR, Yale University, American Society of Addiction Medicine

1:45 pm — Session 2: Buprenorphine Initiation in the Inpatient Setting

Presenter:

- Amer Raheemullah, MD, Stanford University

Panelists:

- Dionna Berkholder, North Colorado Health Alliance
- Gerard Carroll, MD, FAAEM, EMT-P, Cooper University Health Care
- Gail D'Onofrio, MD, MS, Yale University
- Michael A. Smith, PharmD, BCPS, University of Michigan Health

2:50 pm — Break

3 pm — Session 3: Buprenorphine Initiation and Maintenance in the Community Setting

Presenter:

- Michelle Lofwall, MD, DFAPA, DFASAM, University of Kentucky

Panelists:

- Jeffrey Bratberg, PharmD, FAPhA, University of Rhode Island
- Jeremy Dubin, DO, FASAM, Front Range Clinic
- Eliza Hutchinson, MD, Packard Health
- Jade Waits, Boulder Care

4 pm — Session 4: Buprenorphine Initiation and Maintenance in Special Populations

Panelists:

- Andrea Bonny, MD, Nationwide Children's
- Caitlin Martin, MD, MPH, Virginia Commonwealth University
- Amesika Nyaku, MD, MS, Rutgers University
- Chad Sabora, MS, JD, Faces & Voices of Recovery

4:45 pm — Adjourn

Day 2

1 pm — Opening Remarks and Recap of Day 1

Speaker: Susan Winckler

1:05 pm — Session 5: Promoting Access to Buprenorphine in the Real-World Setting

Presenter:

- Barbara Andraka-Christou, PhD, JD, University of Central Florida

Panelists:

- Dwayne Dean, RCPF, CPRS, RPS, Peer Recovery Training and Support Services
- Tom Menighan, MBA, ScD, FAPhA, Catizone, Luce & Menighan
- Matthew Strait, MS, Drug Enforcement Administration
- Robert Baillieu, MD, MPH, FAAFP, Substance Abuse and Mental Health Services Administration

2:05 pm — Session 6: Opportunities to Address Treatment Needs through Product Development

Presenter:

- Kelly Dunn, PhD, MBA, MS, Johns Hopkins University

Speakers/Panelists:

- Pouya Azar, MD, Vancouver General Hospital
- Bartholt Bloomfield-Clagett, MD, U.S. Food and Drug Administration
- Jody Green, PhD, FAACT, Uprise Health
- Iván Montoya, MD, MPH, National Institute on Drug Abuse
- Michelle Winberg, Harm Reduction Michigan

3:20 pm — Break

3:30 pm — Session 7: Future Directions

Speakers:

- Brian Clear, MD, Bicycle Health
- Michelle Lofwall, MD, DFAPA, DFASAM, University of Kentucky
- Yngvild K. Olsen, MD, MPH, Substance Abuse and Mental Health Services Administration
- Marta Sokolowska, PhD, U.S. Food and Drug Administration
- Nora Volkow, MD, National Institute on Drug Abuse

4:30 pm — Adjourn

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