POLICY ROUNDTABLE ON EXPANDING NALOXONE ACCESS

OVERVIEW AND STRATEGY IMPACT

On March 31, 2021, the Collaborative for Effective Prescription Opioid Policies (CEPOP) convened stakeholders to discuss policy approaches to expand access to naloxone, a medication designed to rapidly reverse opioid overdose. This virtual roundtable event focused on three key aspects of naloxone access: addressing prescription opportunities, promoting community-based access, and ensuring a pathway from naloxone use to treatment and recovery. Lead discussants and participants shared their views on these topics and identified potential actions that could be taken by CEPOP and others. This summarizes the proceedings of the roundtable and the recommended next steps to be included in CEPOP's policy and advocacy strategy.

Background

As the opioid pandemic continues to rage in the U.S., fueled by new factors stemming from the COVID-19 pandemic, there is a pressing need for those who use prescription and illicit opioids to be able to access this life-saving treatment. There are currently three forms of naloxone approved by U.S. Food and Drug Administration (FDA): nasal spray, injectable, and auto-injector, all of which require a prescription. The U.S. Centers for Disease Control and Prevention (CDC) has issued guidelines related to naloxone prescription and access and many states have passed laws on this topic, but many people are unaware of how to access or use naloxone. As highlighted by multiple roundtable participants, there also is significant stigma around naloxone, which many people assume is intended solely for illegal drug users and those with opioid use disorder rather than anyone who might be at risk of an overdose.

CEPOP (www.CEPOPonline.org) was formed in January 2015 as a national advocacy platform to engage diverse stakeholders in a comprehensive and coordinated strategy against the opioid epidemic. The Roundtable featured one discussant panel on each topic area. Speakers included representatives from federal and state government, healthcare professional associations, treatment centers, and advocacy organizations. The program agenda and list of participants are included as Appendix A and Appendix B, respectively.

Summary

The roundtable began with introductions and a brief overview of the goals of the roundtable by meeting moderators the Honorable Mary Bono and General Barrye Price. The discussants then shared insights during their respective panels, each of which was followed by moderated discussion with other meeting participants. A summary of the points discussed is included below.

I. Addressing Prescription Opportunities

In recent years, federal and state governments have taken steps to reduce prescription-related barriers to naloxone access by expanding prescription authorities for licensed healthcare providers and better ensuring that those who are prescribed high-dose opioids are co-prescribed naloxone. Federal regulators also have sought to spur innovation in the development of naloxone and other opioid reversal medications and to use labels to better communicate the risks of opioid medications. Participants recognized the importance of these developments while noting a need for actions to address several barriers to naloxone access, as well as the stigma challenge for some potential users.

- FDA efforts to broaden access to naloxone include implementing drug safety label changes, publishing drug facts labels, ensuring that sponsor applications for opioid reversal medications receive priority review, supporting new developments in the opioid reversal space (e.g. reformulations, novel treatments), and enabling sponsors to develop Over The Counter (OTC) naloxone.
    - In 2020, FDA released drug safety label changes that include the need for patients who are prescribed opioids to have a discussion with their providers about the risks associated with opioid use. Health care professionals should also consider prescribing naloxone if the patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.
    - For other patients at increased risk of opioid overdose, health care professionals should consider prescribing naloxone, even if the patient is not receiving a prescription for an opioid pain reliever or medicine to treat OUD. This may include people with a current or past diagnosis of OUD or who have experienced a previous opioid overdose.
- A dozen or so states have updated opioid prescribing policies to include requirements for offering certain opioid patients an opioid antagonist, such as naloxone and include education on opioids and the antidote.
- Target groups to consider for requiring the co-prescribing of an opioid antagonist:
    - Opioid-naïve patients;
    - Patients on high-dose opioids (50 milligram morphine equivalents (MME) or higher);
    - Patients concurrently taking benzodiazepines;
    - Parents of young children (who could accidentally access their parents' medications);
    - Elderly patients (who may be more at risk of accidentally taking more than the prescribed dose); and
    - Patients with mental health comorbidities e.g., depression or anxiety.
- Many states have standing orders that allow licensed healthcare providers, including pharmacists, to write prescriptions for naloxone that are available to a large group of people. This allows community pharmacists to serve as a primary access point for naloxone. There needs to be increased awareness that naloxone is available at pharmacies and covered under health insurance, and that it is available at the pharmacy for preparedness and not just emergencies.
- Even when prescription barriers are addressed, the cost of naloxone and the stigma associated with naloxone use may decrease the likelihood that people will obtain it.
    - Consumers may have the opportunity to get naloxone without a prescription, but may still hesitate to accept it if it is not free or low-cost.
    - There is stigma associated with naloxone use because it is often associated with drug use. If an insurance covers naloxone, beneficiaries may not want to use their insurance to cover it because they do not want to tell their insurance that they use opioids.

Additionally, there is concern that youth and young adults could be flagged by their insurance when ambulatory and emergency response services are billed.

- Health insurance plans are invested in keeping people safe and providing access to naloxone. Many health plans currently use data to identify people who are at high risk and should speak with their providers about opioids.
- It would be useful to implement Electronic Health Record prompts that flag if a person has a history of opioid use disorder and prompt the healthcare provider to co-prescribe Naloxone when prescribing Medication-Assisted Treatment (MAT) and/or opioids that meet the criteria for 'at risk'.

II. Promoting Community-Based Access

Many participants in the roundtable noted the need to make naloxone readily accessible throughout the community and reduce the stigma associated with obtaining it. In order to ensure that naloxone is widely accessible it must be made available in places outside of traditional healthcare settings and to both people who might be at risk of an overdose and those who might be likely to see another person overdose. Access to naloxone could be improved if it was as ubiquitous as other emergency rescue interventions, such as epinephrine auto-injectors or automated external defibrillators. Participants offered specific recommendations for places and people that should have access to naloxone including law enforcement, first responders, community centers, and relatives of people with a history of overdosing. Many states and communities are already implementing such initiatives, creating an opportunity to identify best practices and apply them more broadly across the U.S.

- To create buy-in and reduce stigma, education efforts could center on framing naloxone as a positive resource that has benefits for all members of the community, and emphasize that naloxone is not exclusively for drug users.
- Additional education efforts should include educating patients, family members, and the community about how naloxone can be accessed through pharmacies, training more laypeople on how to administer naloxone, and educating all people who have a prescription for opioids (e.g. opiate naïve patients, senior citizens on high-dose opioids, people with a history of anxiety and depression, patients who are on opiates for chronic pain) about the importance of keeping naloxone in their homes.
- At the state and city levels, several efforts are underway to reduce stigma, remove barriers, and improve access to naloxone throughout the community, including:
    - Training law enforcement and laypeople in administering naloxone, with an emphasis that administering naloxone may require more than one dose;
    - Using correctional facilities and Emergency Medical Services as channels to link post-overdose patients to care;
    - Engaging with residential treatment programs and correctional facilities about the need for naloxone, training people throughout the correctional system in administering naloxone, and equipping everyone with a substance use disorder who leaves these facilities with naloxone;
    - Targeting naloxone distribution to all responders, including law enforcement, first responders, and Fish and Wildlife Officers;
    - Removing civil and criminal liability for administering naloxone;

    - Engaging with local Public Health Departments to play a role in educating the community about naloxone and the opioid epidemic to reduce stigma and the assumptions about naloxone users;
    - Utilizing community-led overdose mapping to enhance community engagement; and
    - Framing Good Samaritan Laws as not just an opportunity to remove barriers for people who want to help, but also as a duty to respond if the person is adequately trained to administer naloxone.
- Collaborations between the harm reduction community, treatment providers, community support members, first responders, and other community members across the spectrum are key to removing silos and improving community-based access.

III. Pathway to Treatment and Recovery

In order to offer a more complete picture of how naloxone fits into broader efforts to combat the opioid crisis, this panel focused on creating a linkage between the administration of naloxone with treatment and recovery services. Roundtable participants spoke about the need to act quickly—within a matter of hours or days—to ensure that a person whose overdose was reversed with naloxone has the resources they need to get treatment. Much of the discussion focused on the need to educate those who are likely to administer naloxone about available treatment and recovery services. In addition, participants noted that there may be opportunities to extend new provisions implemented during the COVID-19 pandemic in order to promote access to treatment and recovery services on a more long-term basis.

- The timeframe to get people into treatment and recovery after an overdose reversal is short because people are likely to deny treatment shortly after an overdose reversal. However, there are several recommendations for moving people into treatment and recovery post-overdose reversal that build on the success of direct engagement, including:
    - Training health professionals, law enforcement, and first responders in motivational techniques, engagement, and how to collaborate with peer recovery support to engage directly with people who have experienced an overdose reversal;
    - Developing peer support opportunities that occur in the ambulance, pre-emergency room settings, and correctional facilities;
    - Training Emergency Medical Technicians and other first responders to administer buprenorphine at the site of an overdose so they can administer MAT if the patient consents and is ready to receive treatment;
    - Developing improved messaging about naloxone for addiction and broader drug use, and expanding the messaging to schools as a form a primary prevention.
- The COVID-19 pandemic led to relaxations with telehealth, which has been helpful with expanding reach treatment and recovery services to underserved and rural areas. The Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) have it within their authority to make regulatory relaxations for telehealth permanent (See The Pew Charitable Trusts Report).
- Medicare coverage of all FDA-approved forms of MAT has helped with access. Medicaid requires all states to cover all three forms in their Medicaid program, unless states ask for a waiver. However, the mandate expires in 2025. Medicaid is the largest payer for behavioral health services so this coverage will become increasingly important as Baby Boomers age.

Policy Matrix
The table summarizes specific Naloxone access recommendations identified by Roundtable discussants and participants.

Addressing Prescription Barriers	Promoting Community Access	Pathway to Treatment/Recovery
• Expand standing orders for prescription of naloxone and continue existing orders. • Use insurance data to identify people at risk of an overdose and ensure that they are co-prescribed naloxone. Include this information in electronic health records. • Consider whether milligram morphine equivalents (MME) standards for prescribing could be adjusted based on whether naloxone is co-prescribed. Consider strategies to lower cost.	• Strengthen Good Samaritan laws and better implement and enforce those laws. • Expand access to naloxone and training on use for law enforcement officers and other first responders. • Increase distribution of naloxone by correctional facilities to discharged inmates identified as being at risk of an overdose. • Use overdose detection mapping to identify areas of high need. • Pursue efforts to reduce stigma of naloxone to increase adoption, recognizing that is it not only for people with opioid use disorder. • Increase awareness of how to access naloxone in the community and how to use it (consider sharing information in health and non-health settings: schools, fairs). • Encourage employers to make naloxone and training on how to use it available in the workplace.	• Ensure that community access points for naloxone also have the necessary information to facilitate the transition to treatment and recovery. • Enhance abilities of professionals administering naloxone (physicians, law enforcement, first responders) to motivate and engage patients about treatment and recovery. • Expand use of peer recovery support services in settings where naloxone is commonly administered.

Next Steps and Action Items

Based on the recommendations shared during the Policy Roundtable and the resulting Policy Matrix, CEPOP will incorporate the following steps into its 2021 workplan.

- Promote recommendations from Roundtable when engaging with White House, Federal Agency, and Congressional leaders around CEPOP policy priorities;
- Identify and promote legislation and regulatory policies designed to expand access to naloxone at federal and state levels;
- Consider a congressional briefing on naloxone access strategies; and
- Consider a national best practices webinar to advance access to naloxone.

APPENDIX A

POLICY ROUNDTABLE: EXPANDING NALOXONE ACCESS

Wednesday, March 31, 2021 | 1:00-3:30 p.m. EST

AGENDA

1:00-1:10 Opening Remarks

Hon. Mary Bono, Co-Convenor and Member of Congress (ret.)
Gen. Barrye Price, PhD, Co-Convenor and President & CEO, CADCA

1:10-1:50 Addressing Prescription Opportunities[1]

Discussants
Tim Fensky, RPh, DPh, FACA, National Association of Boards of Pharmacy
Courtney Hunter, MPA, Shatterproof
Marta Sokolowska, PhD, Food & Drug Administration
Moderator: Barrye Price

1:50-2:30 Promoting Community-Based Access

Discussants
Rich Hamburg, MPA, Safe States Alliance
Deb Houry, MD, MPH, Centers for Disease Control & Prevention
Van Ingram, Kentucky Office of Drug Control Policy
Moderator: Mary Bono

2:30-2:40 Break

2:40-3:20 Pathway to Treatment & Recovery

Discussants
Beth Connolly, Pew Charitable Trusts
Stephen Delisi, MD, Hazelden Betty Ford Foundation
Brandee Izquierdo, MPA, SAFEProject
Rob Morrison, National Association of State Alcohol and Drug Abuse Directors
Moderator: Barrye Price

3:10-3:20 Next Steps and Closing Remarks

[1] Each section will have initial exchange among the moderator and discussants, followed by comments from all participants.

APPENDIX B

ROUNDTABLE PARTICIPANTS

- Susan Awad, *American Society of Addiction Medicine*
- Lauren Bloch, *Faegre Drinker Consulting*
- Mary Bono, *Mothers Against Prescription Drug Abuse*
- Jasey Cardenas, *American Association of Colleges of Pharmacy*
- Elizabeth Connolly, *Pew Charitable Trusts*
- Rachael Cooper, *National Safety Council*
- Jonah Cunningham, *Trusts for America's Health*
- Stephen Delisi, *Hazelden Betty Ford Foundation*
- Wade Delk, *American Society for Pain Management Nursing*
- Chris Frech, *Emergent BioSolutions*
- Maeghan Gilmore, *Association for Behavioral Health and Wellness*
- Ian Goldstein, *National Association of County Health Officials*
- Jill Hamaker, *Emergent BioSolutions*
- Rich Hamburg, *Safe States Alliance*
- Jeff Horwitz, *SAFE Project*
- Deb Houry, *Centers for Disease Control and Prevention*
- Courtney Hunter, *Shatterproof*
- Van Ingram, *Kentucky Office of Drug Control Policy*
- Brandee Izquierdo, *SAFE Project*
- Andrew Kessler, *Slingshot Solutions*
- Deepti Loharikar, *Association for Behavioral Health and Wellness*
- Sarah Lowry, *Centers for Disease Control and Prevention*
- Rob Morrison, *National Association of State Alcohol and Drug Abuse Directors*
- Nick Motu, *Hazelden Betty Ford Foundation*
- Steve Passik, *Collegium Pharmaceutical*
- Barrye Price, *Community Anti-Drug Coalitions of America*
- Chris Regal, *America's Health Insurance Plans*
- Shannon Robinson Ahmed, *Centers for Disease Control and Prevention*
- Kevin Roy, *Shatterproof*
- Sanjyot Sangodkar, *Faegre Drinker Consulting*
- Marta Sokolowska, *Food and Drug Administration*
- Elizabeth Solhtalab, *Centers for Disease Control and Prevention*
- Cecilia Spitznas, *Office of National Drug Control Policy*
- Sue Thau, *Community Anti-Drug Coalitions of America*
- Michael Vitali, *Emergent BioSolutions*
- Kevin Webb, *Mallinckrodt Pharmaceuticals*
- Shalini Wickramatilake, *National Association of State Alcohol and Drug Abuse Directors*
- Dave Zook, *Faegre Drinker Consulting*