

CEPOP-MAPDA Webinar Series

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Confluence of a National Epidemic and Global Pandemic

Confronting Pain and Opioid Use Disorders Amid COVID-19

Addressing Access and Utilization of Opioid Overdose Reversal Medications

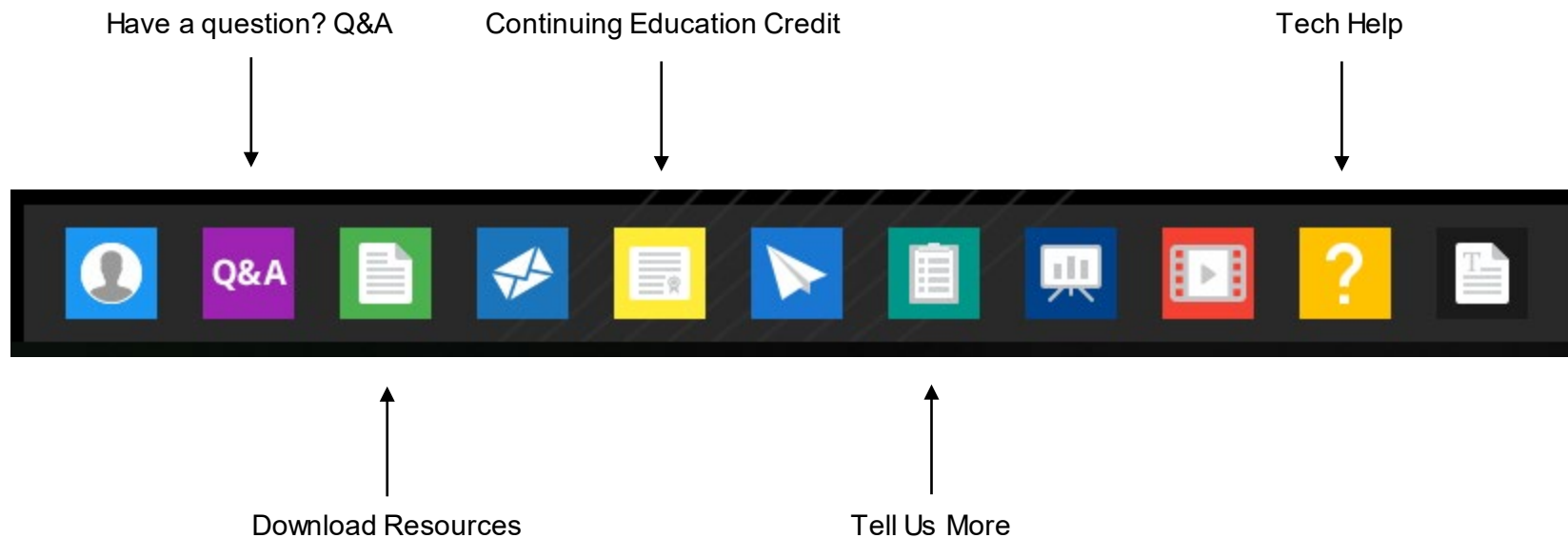
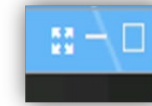
Monday, August 10, 2020

3:00pm – 4:00pm



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Today's Agenda

1. A View from Capitol Hill: Congressional Efforts to Improve Naloxone Access

The Honorable Dave Joyce (OH-14), United States House of Representatives

2. Overdose Prevention and Naloxone National Priorities During COVID-19 and Beyond

Kemp L. Chester, Assistant Director, Office of National Drug Control Policy

3. Adjusting Opioid Labeling to Improve Naloxone Access

Marta Sokolowska, Ph.D., *Assistant Director for Controlled Substances, Center for Drug Evaluation and Research, U.S. FDA*

4. Reducing Overdose Deaths Through Increased Naloxone Access and Utilization: Understanding COVID-19 Implications on Overdose Reversal

a. **State Representative Deborah Conroy (IL-46)**, *Illinois State Assembly*

b. **Tim Fensky, RPh, DPh, FACA**, *President, National Association of Boards of Pharmacy (NABP)*



**The Honorable
Mary Bono**

*Chairman and CEO,
MAPDA*

CEPOP Co-Convener



A View from Capitol Hill: Congressional Efforts to Improve Naloxone Access

The Honorable Dave Joyce

*Ohio's 14th Congressional District
U.S. House of Representatives*





Overdose Prevention and Naloxone National Priorities During COVID-19 and Beyond

CEPOP-MAPDA Webinar

Kemp Chester, Assistant Director for the National Opioids and Synthetics Coordination Group

OFFICE OF NATIONAL DRUG CONTROL POLICY



August 10, 2020

National Drug Control Strategy Priorities

- Safer Prescribing
 - Guidelines involve Naloxone
- Improving the Response to and Monitoring of Overdose
 - Naloxone access varies throughout the country
 - Most states have standing physician's order
 - CDC Guideline and DoD/VA Guideline suggest co-prescribing
 - We must do more to ensure that the reversal of a potentially fatal overdose is not just another event in a long and protracted struggle with an addiction to dangerous drugs, but rather the first important step toward effective treatment and sustained recovery



Special Concerns

- Access during COVID (People who use alone)
- Special Populations –including students, reentry, rural, and tribal
- Non-opioid illicit products - cocaine, methamphetamine, pressed pills, that are contaminated with synthetics
- Growing use of illicit opioids by Hispanic and African Americans, and growing death rate
- Law Enforcement and First Responders



Adjusting Opioid Labeling to Improve Naloxone Access: Understanding FDA's Revised Drug Safety Communication

Marta Sokolowska, Ph.D.

*Associate Director for Controlled Substances
Center for Drug Evaluation and Research
U.S. Food and Drug Administration*



FDA Actions to Increase Naloxone Access

Aug. 10, 2020

FDA's priorities to address the opioid crisis



1

Decreasing Exposure & Prevent New Addiction

2

Supporting the Treatment of Those With Opioid Use Disorder

3

Fostering the Development of Novel Pain Treatment Therapies

4

Improving Enforcement & Assessing Benefit-Risk

Increasing access to naloxone is one specific strategy



1

Decreasing Exposure & Prevent New Addiction

2

Supporting the Treatment of Those With Opioid Use Disorder

3

- Increase access to naloxone

4

Improvi

"Increased access to the opioid reversal medicine, naloxone, may help save lives by preventing opioid overdose deaths."
- FDA Drug Safety Communication, July 2020

Naloxone

Naloxone rapidly reverses the effects of opioid overdose and is the standard treatment for overdose.

*Three FDA-
approved
forms of
naloxone*



Injectable



Auto-Injector



Nasal Spray

***FDA is taking actions to make naloxone more readily
available and more accessible.***

Major FDA actions involving naloxone



Proactively developed and tested a consumer-friendly Drug Facts label (DFL) to support development of an OTC version of naloxone (*January 2019*)

DESCRIPTION	CLINICAL PHARMACOLOGY	INDICATIONS AND USAGE	CONTRAINDICATIONS	WARNINGS	PRECAUTIONS	ADVERSE REACTIONS	Directions	Warnings	Other information	Inactive ingredients
[Dense, illegible text representing a traditional Drug Facts label]										



Drug Facts Label

Drug Facts	
Active ingredient (in each tablet) Chlorpheniramine maleate 2 mg	Purpose Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat	
Warnings Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions adults and children 12 years and over take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours children 6 years to under 12 years take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours children under 6 years ask a doctor	

Drug Facts (continued)	
Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture	
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Drug Facts	
Active ingredient (in each XX) Naloxone hydrochloride 2 mg	Purpose Emergency treatment of opioid overdose
Uses • To "reverse" someone during an overdose from many prescription pain medications or street drugs such as heroin • This medicine can save a life.	
Directions	
1. CHECK 	Step 1: CHECK: • CHECK for a suspected overdose: the person will not wake up or is very sleepy or not breathing well. • yell "Wake up!" • shake the person gently. • If the person is not awake, go to Step 2.
2. GIVE 	Step 2: GIVE 1st dose • GIVE the 1 st dose of this medicine. • Place the injector on the LEG above the knee and press down.
3. CALL 	Step 3: CALL • CALL 911 immediately after giving the 1 st dose.
4. WATCH/GIVE 	Step 4: WATCH & GIVE • WAIT 2-3 minutes after the 1 st dose to give the medicine. • If the person wakes up, Go to Step 5. • If the person does not wake up, CONTINUE TO GIVE doses every 2-3 minutes until the person wakes up. • It is safe to keep giving doses.
5. STAY 	Step 5: STAY • STAY until ambulance arrives, even if the person wakes up. • GIVE another dose if the person becomes very sleepy again. • You may need to give all the doses in the pack.
Warnings When using this product some people may experience symptoms when they wake up, such as: shakiness, nausea, or feeling angry. This is to be expected.	
Other information store at room temperature. (please insert important statement here)	
Inactive ingredients	
Questions? (include number, website)	

Major FDA actions involving naloxone



Two-day advisory committee meeting on strategies to increase availability of naloxone for community use (*December 2018*)



Approval of first generic naloxone nasal spray (Narcan) for use in a community setting by those without medical training (*April 2019*)



Opioid products label update recommending health care professionals consider prescribing naloxone to those at increased risk of opioid overdose (*July 2020*)

Major FDA actions involving naloxone



**FDA recommends health care professionals
discuss naloxone with all patients when
prescribing opioid pain relievers or medicines to
treat opioid use disorder**

Consider prescribing naloxone to those at increased risk of opioid overdose

- Recommends health care professionals discuss availability of naloxone + consider prescribing it for:
 - All patients who are prescribed opioid pain relievers
 - All patients prescribed medicines to treat OUD
 - Other patients at increased risk of opioid overdose (e.g., current or past OUD diagnosis)
- Requires drug manufacturers add new recommendations about naloxone to the prescribing information + Medication Guides

Conclusion

- FDA priorities to focus on addressing the opioid crisis
 - Multiple actions have been implemented to increase access to naloxone
 - FDA continues to monitor impact of COVID-19 on availability of naloxone



Reducing Overdose Deaths Through Increased Naloxone Access and Utilization

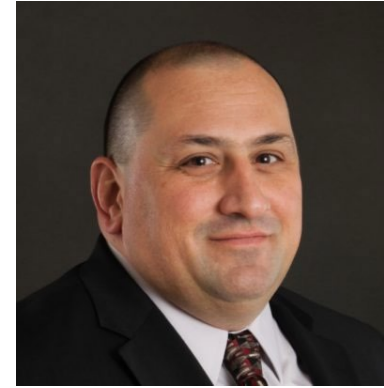
Understanding the Implications of COVID-19 on Overdose Reversal

Meet Your Panelists



Representative Deb Conroy

*Illinois State Assembly
46th District*



Tim Fensky, RPh, DPh, FACA

*President
National Association of
Boards of Pharmacy (NABP)*

A State Approach to Addressing Overdose Reversal

State Representative Deb Conroy

*Illinois State Assembly
46th District*





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Combating the Opioid Crisis During COVID-19 Pandemic

Improving Access to Naloxone through
Pharmacies

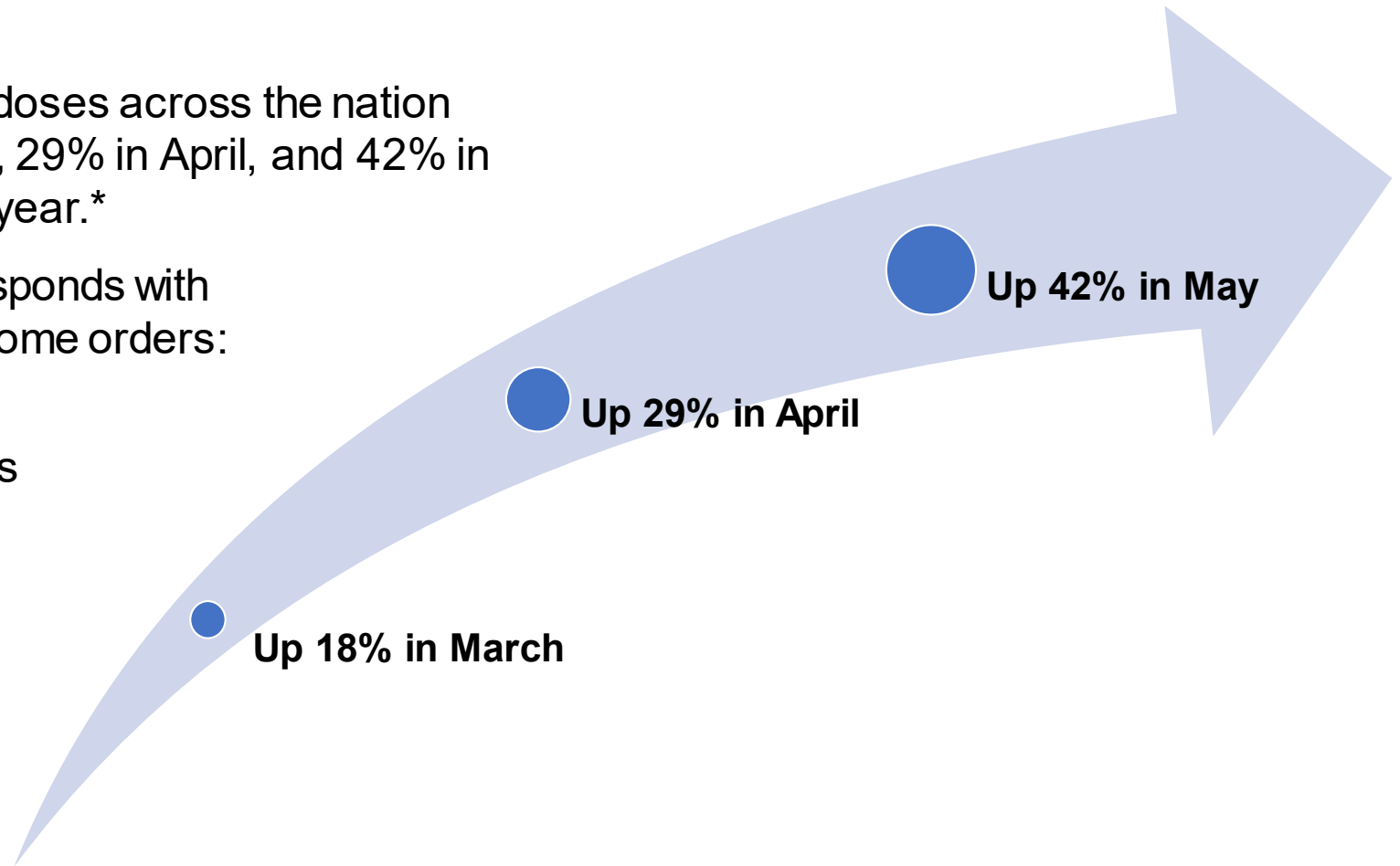


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Opioid Epidemic Exacerbated by COVID-19 Pandemic

- In 2020, suspected overdoses across the nation increased 18% in March, 29% in April, and 42% in May compared with last year.*
- Rise in overdoses corresponds with COVID-related stay-at-home orders:
 - continued isolation
 - economic disruptions
 - disruption in illegal drug supply chain



* *The Washington Post*, July 1, 2020



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Access to Treatment Found Lacking

- Only a fraction of those needing treatment for opioid use disorder (OUD) treatment appear to be receiving it.
- 21.2 million people aged 12 or older needed treatment for substance use in 2018; only 17.5% of them received any treatment that year.*
- In 2017, 1.7 million Americans in need of Medication Assisted Treatment (MAT) were unable to access treatment.

* US Substance Abuse and Mental Health Services Administration

MAT Widely Acknowledged as Effective Against OUD

- MAT combines medication treatment and behavioral counseling.
- Prescription medications, including controlled substances, used for initial detoxification and in long-term follow-up to suppress withdrawal symptoms and reduce cravings.
- Intended to help patients re-establish normal brain function and prevent relapse, complementing and facilitating behavioral therapy.



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Federal Restrictions Create Barriers

- Although the federal government has prioritized expanding access to MAT to reduce OUDs and overdoses, barriers remain:
 - rigid requirements for the provision of MAT
 - exclusion of providers like pharmacists
 - burdens on eligible practitioners
- To prescribe MAT drugs as part of an office-based treatment program, providers must obtain a DATA 2000 waiver (named after the Drug Addiction Treatment Act of 2000 that established it).
- It is estimated that fewer than 3% of eligible providers have the DATA 2000 waiver.

What is a DATA 2000 Waiver?

- The waiver allows providers to treat opioid dependency outside of a formal opioid treatment program with medications approved for the treatment of OUD.
- Carries its own requirements and limitations:
 - completion of additional training
 - cap on the number of patients a provider can treat with MAT



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Allowing Pharmacists to Treat OUD Patients Would Boost Access to MAT

- Currently, pharmacists largely play a dispensing role in the provision of MAT; however, given their accessibility and expertise, pharmacists can easily take on the role of prescribing MAT.
- In almost every state, pharmacists may enter into collaborative practice agreements with physicians to prescribe certain medications and, in at least eight states, expanded scope of practice laws allow pharmacists to prescribe controlled substances used for MAT.
- Pharmacists could facilitate counseling and support services.
- Congress should pass legislation that would remove the DATA 2000 waiver process altogether, allowing states to decide what providers can offer MAT within their communities.



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State Control Would Build on Progress of Boards of Pharmacy

- Allowing pharmacist-provided MAT for patients diagnosed with OUD and allowing control at the state level will build on recent efforts of the state boards of pharmacy to combat the opioid crisis.
- State boards of pharmacy have been instrumental in expanding the use of prescription monitoring programs and **helping limit overdose deaths by advocating and facilitating easier access to naloxone.**



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Opioid Overdose Reversal with Naloxone

- In 2017, more than 70,000 people in the US died from drug overdoses and nearly 68 percent of those deaths involved opioids.
- From 1996 to 2014, at least 26,000 opioid overdoses were reversed with naloxone provided by community-based organizations.
- Naloxone access laws correlate with a 9 – 11 percent reduction in opioid-related deaths.
- State-approved naloxone programs prepare laypersons and emergency responders to administer naloxone to individuals who are experiencing an overdose.

Three FDA-Approved Formulations of Naloxone Are Available:

- Injectable (commonly used by paramedics, emergency room doctors, and other specially trained first responders)
- Autoinjectable (EVZIO® is a prefilled device that makes it easy for families or emergency personnel to inject naloxone quickly into the outer thigh)
- Prepackaged nasal spray (NARCAN® Nasal Spray is a prefilled, needle-free device and is sprayed into one nostril while patients lie on their back.)



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State Laws Increase Access to Naloxone through Pharmacies

- All 50 states allow for naloxone access in community pharmacies. This is generally accomplished through laws or rules that allow pharmacist prescribing or establish a statewide prescribing protocol or standing order.*
- While naloxone dispensing has increased in recent years, not everyone who may need naloxone receives it.**
- Prescribing and dispensing varies widely across the US despite consistent state laws and recommendations.**
- Dispensing naloxone in areas hardest hit by the opioid overdose epidemic can increase the number of overdose reversals and the opportunity to link overdose survivors into treatment.**

*National Alliance of State Pharmacy Associations

**Centers for Disease Control and Prevention



Partnership for
Drug-Free Kids





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Boards Encourage Dispensing Naloxone with High-Dose Opioids

- Many state boards of pharmacy have encouraged pharmacies to dispense naloxone with high-dose opioid prescriptions and advise on how to recognize an overdose and administer naloxone.
- Particularly important with high-dose opioid prescriptions. Patients or caretakers can accidentally take or administer the wrong dose or wrong medication.
- While naloxone dispensing by pharmacies increased from 2012 to 2018, only one naloxone prescription was dispensed for every 69 high-dose opioid prescriptions in 2018.
- The lowest rates of naloxone dispensing were observed in the most rural counties.



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Evolving Illicit Drug Landscape May Change Use of Naloxone

- Fentanyl is often found in counterfeit prescription pills and street drugs.
- Because of fentanyl's high potency, the way naloxone is used may need to change, requiring higher doses administered more quickly.
- Naloxone lasts only 30 to 45 minutes before it wears off, and additional doses may be needed.



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Steps to Prevent Overdoses and Increase Naloxone Access Locally

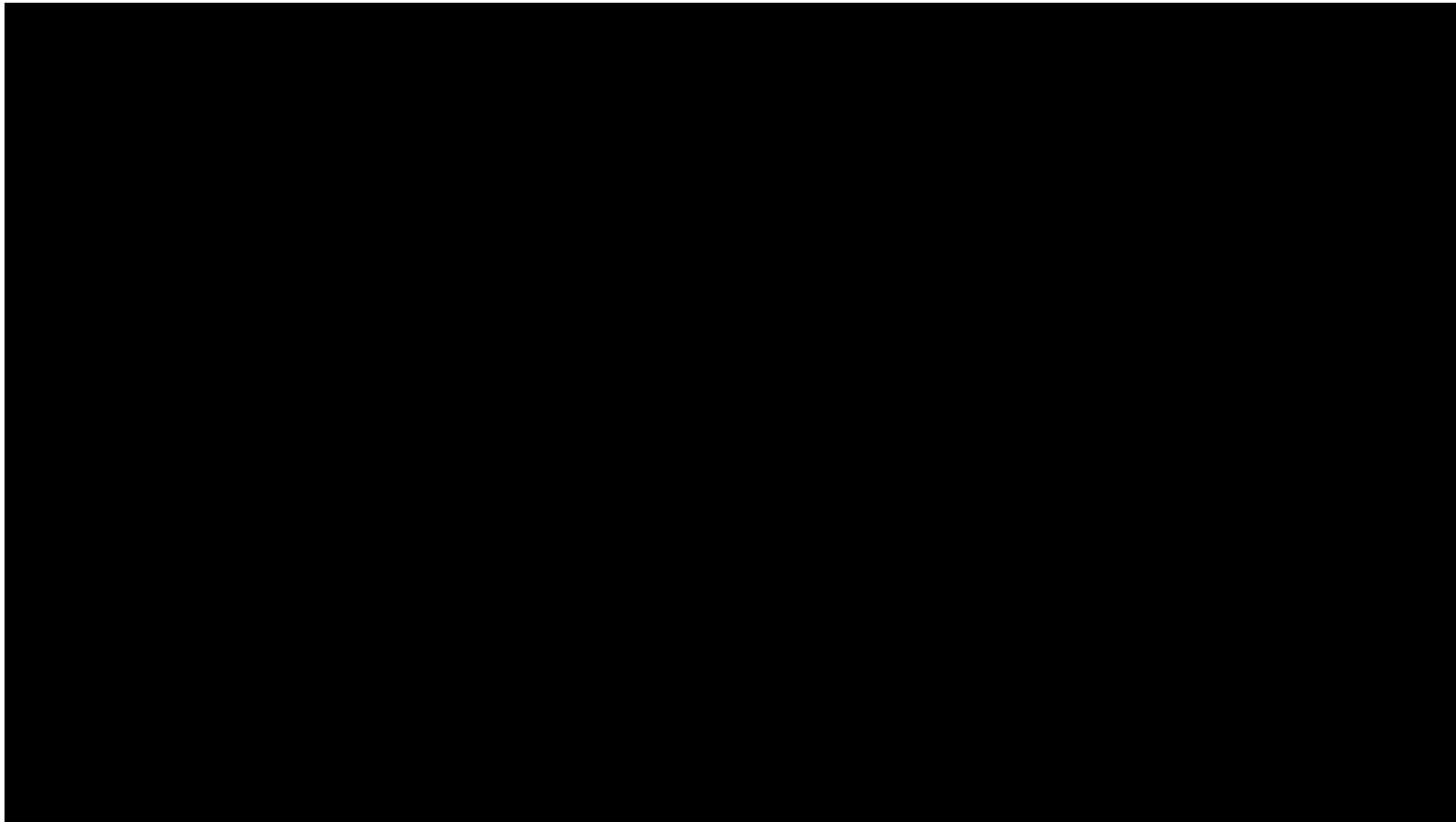
- Dispense naloxone with high-dose opioid prescriptions.
- Counsel patients and caregivers on how to use naloxone.
- Learn the naloxone access laws in your state.
- Spread the word about community groups and harm reduction organizations that provide free naloxone kits and training.
- Encourage legislators or regulators to allow for pharmacist prescribing or collaborative practice agreements.
- Work with the state department of public health to expand naloxone delivery through statewide protocols.
- Advocate for increasing awareness and putting naloxone boxes in public places.
- Recommend that anyone who is using opioids or who knows someone using opioids carry naloxone.



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A Parent's Perspective: Joe Adams



<https://youtu.be/gajiEMHE0Bk>



Thank you!



Roundtable Question & Answer Session

Please submit questions to our panelists using the chat function in the left-hand side of your screen.

If joining via mobile device, email questions to matthew.rubin@faegredrinker.com.

Upcoming CEPOP-MAPDA Webinars

Digital Health and Telemedicine

• Monday, July 27 at 3:00 p.m. ET

Policy Changes to Medication Assisted Treatment

Monday, July 27 at 3:30 p.m. ET

Access and Utilization of Oversedication Reversal Medications

Monday, August 10 at 3:00 p.m. ET

Excess Medications in the Home

Monday, August 17 at 3:00 p.m. ET





Thank you for joining us today!

Please refer any questions to:

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