EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

December 1, 2020

Austin Evers
American Oversight
1030 15th Street, NW
Washington, DC 20005

Subject: FOIA Request

Dear Mr. Evers:

This letter responds to your request to the Office of National Drug Control Policy ("ONDCP") under the Freedom of Information Act (FOIA). Your request has been designated as FOIA 2019203.

After a review of ONDCP records, we are providing you with the below link to the responsive documents. Please open the link and save the document to your computer or hard drive. The link will expire in 30 days.

ONDCP has made certain redactions as noted under FOIA exemption 6 (relating to personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy). See 5 U.S.C. §§ 552(b)(6).

If you are not satisfied with the action on this request, you may submit an appeal in writing. To be considered timely, it must be submitted electronically or postmarked (in the case of postal mail) within 90 calendar days from the date of this response via U.S. postal mail addressed to FOIA Appeals Officer, Office of National Drug Control Policy, Executive Office of the President, 1800 G Street NW, Washington, D.C. 20503. ONDCP strongly recommends using electronic means for submitting appeals. Due to COVID-19, appeals submitted through conventional mail delivery services may not be received in a timely manner.

You also have the right to seek assistance from ONDCP's FOIA Public Liaison at (202) 395-6622 or from the Office of Government Information Services (OGIS). OGIS offers mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, Room 2510, 8601 Adelphi Road, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

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Thank you for your interest in learning about your government.

Sincerely,

Dwight J. Lacy

Dwight J. Lacy
Attorney-Advisor
EOP ONDCP OGC

Attachment:

Link: https://drive.max.gov/share/9bb238ef1947f606

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[EXTERNAL] CEPOP All-Participants Teleconference (July 2018) -AGENDA ATTACHED

From: "Rubin, Matthew J." <(b)(6) (b)(6)

To: Keysha Brooks-Coley <(b)(6) (b)(6) Gary Mendell (b)(6) Andrew kessler <(b)(6) Myra Christopher <(b)(6) Becky Salay <(b)(6) Robert Forman <(b)(6) (b)(6) Patricia Farley <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Sue Thau <(b)(6) Aryka Chapman <(b)(6) Eli Briggs <(b)(6) Alice Dembner <(b)(6) Kate McFadyen <(b)(6) Chris Zimmerman <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) Brian Bowden <(b)(6) Rebecca Slater Abbott <(b)(6) "Zook, David R." <(b)(6) (b)(6) Jeffrey Ekoma <(b)(6) Gabrielle de la Gueronniere <(b)(6) "Robin Swift (b)(6) (b)(6) <(b)(6) (b)(6) Teresa Baker <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Amanda Sears <(b)(6) (b)(6) "Rachel Rivera (b)(6) <(b)(6) Lorraine Yarde <(b)(6) Susan Weinstein <(b)(6) "Nadine Gracia (b)(6) <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Ed Kaleta <(b)(6)(b)(6) Caren Kagan Evans <(b)(6) (b)(6) "Gabriella Witte (APHA)" <(b)(6) (b)(6) Shalini Wickramatilake <(b)(6) Dan Buffington <(b)(6) "Dr. Renan Castillo" <(b)(6) Carol Thornton <(b)(6) (b)(6) Elizabeth Solhtalab <(b)(6) "Sue Thau (Gmail)" <(b)(6) "Gen. Arthur Dean" <(b)(6) Julian Hoffman <(b)(6) (b)(6) Judi Lund Person (b)(6) "Dr. John Harrison" <(b)(6) "Stephanie Pellitt (NCBH)"

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<(b)(6) Amy Callendar <(b)(6) "Christian, Jeanine M" <(b)(6) "Sarah Nerad (Alkermes)" <(b)(6) (b)(6) Geoffrey Laredo <(b)(6) "Dr. Anita Gupta" <(b)(6) Karen Tracy <(b)(6) Mike Smith <(b)(6) "Cristi L. Schwarcz" <(b)(6) "Hannah Riffle (b)(6) <(b)(6) Paul Ross <(b)(6) James Appleby <(b)(6) David May <(b)(6) Patricia Bruckenthal <(b)(6) (b)(6) John Donahue <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Chuck Ingoglia <(b)(6) Nick Motu <(b)(6) Patricia D'Antonio <(b)(6) Addie Liles <(b)(6) Kathleen O'Conner <(b)(6) "Clay Alspach (b)(6) (b)(6) <(b)(6) (b)(6) John O'Brien <john.(b)(6) Scott Proescholdbell <(b)(6) (b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) (b)(6) Steve Passik <(b)(6) "Alexander, Tesfa" <(b)(6) "Patel, Beena S." <(b)(6) (b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Erika Long <(b)(6) (b)(6) Brad Tallamy <(b)(6) "Evans, Daniel F." <(b)(6) (b)(6) Sara patterson <(b)(6) "Donald A. Lohman **(MNK)"** <(b)(6) (b)(6) Kimberly Wilkinson <(b)(6) Vince Ventimiglia <(b)(6) Samantha Arsenault <(b)(6) Rebecca Farley <(b)(6) Rita Norton <(b)(6) Jane Terry <(b)(6) (b)(6) Tracie Thomas <(b)(6) Hadi Sedigh <(b)(6) Kate Berry <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) Melissa Ough <(b)(6) "Cara Moon (Egalet)" <(b)(6) "Bono, Mary" <(b)(6) (b)(6) Dennis Brennan <(b)(6) (b)(6) Wade Delk <(b)(6) Mary Winnefeld <(b)(6) "Tim Hermes <(b)(6) <(b)(6) "Dr. Jack Stein" <(b)(6) (b)(6) "Derek Naten (MNK)" <(b)(6) (b)(6) Blair Clark-Schoeb

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<(b)(6) "Deana Haworth (Hirons)" <(b)(6)
Susan Awad <(b)(6) Jeremiah Lindemann <(b)(6)
Jason Sundby <(b)(6) Kevin Walker
<(b)(6) "Jessica Johnston (BD)"
<(b)(6) Sonya Clay <(b)(6) Marcia Lee Taylor
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L Cates-Wessel" <(b)(6) Charlie Cichon <(b)(6) Aiken
Hackett <(b)(6) (b)(6) "Dr. Elizabeth Salisbury-Afshar"
<(b)(6) (b)(6) David Trewolla <(b)(6) (b)(6)
Michael DeGeorge <(b)(6) Van Ingram
<(b)(6)(b)(6) Courtney Hunter <(b)(6) (b)(6) Nicole
Burda <(b)(6) (b)(6) Donald Hoppert <(b)(6) (b)(6) Dani
Peters <(b)(6) "Hanson, Roberta J."
<(b)(6)(b)(6) Alton Kelley <(b)(6) morgan wagner
<(b)(6)

Cc: Anne Marie Polak <(b)(6) (b)(6) "Motu, Nick"
<(b)(6) "Patterson, Sara S. (CDC/ONDIEH/NCIPC)"
<(b)(6) "Smith, Quincey V."<(b)(6) (b)(6) Emily Kibling
<(b)(6)

Date: Wed, 25 Jul 201816:45:29 -0400

Attachments: CEPOP All-Participants Meeting Agenda (July 2018).pdf (32.44 kB); not supported calendar message.ics (18.07 kB)

CEPOP Participants - In advance of our upcoming All-Participants teleconference, please find the agenda attached below. We are pleased to have three focus topic speakers for this month's All-Participant's call, including:

- **Joann Yoon Kang,** *Lead, Policy and Partnerships, CDC National Center for Injury Prevention and Control*
- **Dr. Virginia Caine,** *Director, Marion County {IN} Public Health Department*
- **Brianna Ehley,** *Health Care Reporter, Politico*

We look forward to a productive discussion on Monday afternoon!

CE POP All-Participants Teleconference (July 2018)

- To join WebEx via computer, please **CLICK HERE.**

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- Or, to join via conference call:
    - **Conference Line:** (b)(6)
    - **Participant Code:** (b)(6)

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CEPOP MONTHLY ALL-PARTICIPANTS CALL (JULY 2018)

Date: Monday, July 30, 2018

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Presentations

- **A. CDC National Center for Injury Prevention Control and Epidemic Response Update**
  Joann Yoon Kang, Lead for Policy and Partnerships, Division of Unintentional Injury Prevention, CDC National Center for Injury Prevention and Control
- **B. Creating a Safe Needle Exchange in Marion County, Indiana (link #1 and link #2)**
  Dr. Virginia Caine, Director, Marion County Public Health Department
- **C. Politico-Harvard Poll on American Perspectives on the Opioid Epidemic (link)**
  Brianna Ehley, Health Reporter, Politico

III. Advocacy and Policy Priorities

- **A.** Updates on Congressional Opioid Activity
  - **i.** House and Senate Bills
    1. CEPOP Priorities
       - **a.** MAT in Medicare
       - **b.** Safe Disposal
  - **ii.** House and Senate Timeline
  - **iii.** Next Steps and Related Advocacy
- **B.** NIH RFI on Healing Communities Initiative (LINK)

IV. Working Groups

- **A.** Takeback and Anti-Diversion
  - **i.** Safe Disposal: DEA Clearinghouse Legislation
- **B.** Safe Use and Prevention
  - **i.** Abuse Deterrent Formulation Policy Roundtable – Non-Therapeutic Benefits

V. Organizational Updates

- **A.** No August All-Participants Meeting; September Quarterly In-Person
- **B.** Sharing Intel, Participant News and Updates

Next Quarterly In-Person All-Participants Meeting: Monday, September 17th, 3:00pm – 4:30pm

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[EXTERNAL] CEPOP Quarterly In-Person All-Participants Meeting (Sept. 2018)

From: "Rubin, Matthew J." <(b)(6)

To: Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) Brad Tallamy <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach (b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) David May <(b)(6) David Trewolla <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Dennis Brennan <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Donald Hoppert <(b)(6) "Dr. Anita Gupta" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) "Dr. Jack Stein" <(b)(6) "Dr. John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emmanuel Oga (Battelle)" <(b)(6) Erika Long <(b)(6)

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"Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)"
<(b)(6) Gabrielle de la Gueronniere (b)(6) (b)(6)
Gary Mendell <(b)(6) shatterproof.org>, "Gen. Arthur Dean"
<(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6)
Geoffrey Laredo <(b)(6) Hadi Sedigh <(b)(6)
"Hannah Riffle (<(b)(6) <(b)(6) "Hanson, Roberta J."
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Ekoma <(b)(6) Jeremiah Lindemann <(b)(6)
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<(b)(6) John O'Brien <john.(b)(6) Judi Lund
Person (b)(6) Julian Hoffman <(b)(6) Karen
Tracy <(b)(6) Kate Berry <(b)(6) Kate McFadyen
<(b)(6) Kathleen O'Conner (b)(6)
"Kathryn L. Cates-Wessel" <(b)(6) Kevin Walker
<(b)(6) Keysha Brooks-Coley (b)(6)
Kimberly Wilkinson <(b)(6) Lorraine
Yarde <(b)(6) Marcia Lee Taylor
<(b)(6) Mary Winnefeld <(b)(6)
Melissa Ough <(b)(6) Michael DeGeorge
<(b)(6) Mike Smith <(b)(6) Myra
Christopher <(b)(6) Nick Motu
<(b)(6) Nicole Burda <(b)(6) "Patel, Beena S."
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<(b)(6) Patricia D'Antonio <(b)(6)
Patricia Farley <(b)(6) "Patty McCarthy (FaVoR)"
<(b)(6) Paul Ross
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Farley <(b)(6) Rebecca Slater Abbott
<(b)(6) Rita Norton <(b)(6) Rob
Morrison <(b)(6) Robert Forman
<(b)(6) "Robin Swift (<(b)(6)
<(b)(6) Samantha Arsenault <(b)(6)
Sara patterson <(b)(6) "Sarah Nerad (Alkermes)"

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<(b)(6) Scott Proescholdbell
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<(b)(6) Shelley Starkey
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<(b)(6) Becky Salay <(b)(6) "Bono, Mary"
<(b)(6) "Derek Naten (MNK)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) "Nadine Gracia (b)(6)
<(b)(6) "Zook, David R." <(b)(6) "Everett Crosland (Pear Therapeutics)" <(b)(6)
(b)(6)

Date: Mon, 06 Aug 2018 17:15:05 -0400

Attachments: not supported calendar message.ics (17.06 kB)

Formal agenda and materials forthcoming.

Meeting Location
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

For those unable to attend in-person, a WebEx will be made available to all participants to participate remotely.

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP Quarterly In-Person All-Participants Meeting (Sept. 2018) - AGENDA ATTACHED

Where:	FaegreBD Consulting Offices (1050 K Street NW, Suite 400); WebEx Available
When:	Mon Sep 17 15:00:00 2018 (America/New_York)
Until:	Mon Sep 17 16:30:00 2018 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	"Rubin, Matthew J." <(b)(6) (b)(6) Teresa Baker <(b)(6) Caren Kagan Evans <(b)(6) "Dr. John Harrison" <(b)(6) Robert Forman <(b)(6) Addie Liles <(b)(6) Keysha Brooks-Coley <(b)(6) "Dr. Anita Gupta" <(b)(6) Julian Hoffman <(b)(6) Sue Thau <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) "Alexander, Tesfa" <(b)(6) Andrew kessler <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Hanson, Roberta J." <(b)(6) Aiken Hackett <(b)(6) "Tim Hermes (<(b)(6) Jane Terry <(b)(6) Dan Buffington <(b)(6) Rebecca Farley <(b)(6) "Deana Haworth (Hirons)" <(b)(6) Scott Proescholdbell <(b)(6) "Gen. Arthur Dean" <(b)(6) Patricia D'Antonio <(b)(6)

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Courtney Hunter <(b)(6)
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Michael DeGeorge <(b)(6)
Gabrielle de la Gueronniere <(b)(6)
Sara patterson <(b)(6)
James Appleby <(b)(6)
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Jeremiah Lindemann (b)(6)
Rebecca Slater Abbott <(b)(6)
"Christian, Jeanine M" <(b)(6)
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"Sue Thau (Gmail)" <(b)(6)

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"Dr. Jack Stein" <(b)(6)
Mike Smith <(b)(6)
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Karen Tracy <(b)(6)
Marcia Lee Taylor <(b)(6)
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Donald Hoppert <(b)(6)
Hadi Sedigh <(b)(6)
"Cara Moon (Egalet)" <(b)(6)
"Deb Waugh (Affiliated Monitors)" <(b)(6)
Rob Morrison <(b)(6)
"Nadine Gracia ((b)(6) <(b)(6)
"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)
Kevin Walker <(b)(6)
"Rachel Rivera ((b)(6)
<(b)(6)

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Amy Callendar <(b)(6)
Judi Lund Person <(b)(6)
Amanda Sears <(b)(6) (b)(6)
Chuck Ingoglia <(b)(6)
Patricia Bruckenthal <(b)(6) (b)(6)
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Rita Norton <(b)(6)
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Patricia Farley <(b)(6)
"Robin Swift (b)(6) (b)(6) <(b)(6) (b)(6)

CEPOP Participants - In advance of our upcoming quarterly, in-person All-Participants meeting, please find the agenda attached below. We are pleased to have three fantastic focus topic speakers for this month's All-Participants meeting, including:

- **The Honorable Leslie Rutledge,** Arkansas Attorney General
- **Kourtenaye Sturgeon,** Overdose Lifeline
- **Ali Toal,** United States Senator Corey Gardner (CO)

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We look forward to a productive discussion on Monday afternoon. As always, please do not hesitate to reach out with any questions.

Meeting Location

Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

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  - **Participant Code:** (b)(6)

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TITLE I: Opioid Crisis Response Act	
Sec. 1001. Definitions.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle A: Reauthorization of Cures Funding	
Sec. 1101. Cures Funding Extension.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle B: Research and Innovation	
Sec. 1201. Advancing Cutting-Edge Research.	• Allows the National Institutes of Health (NIH) to use its "other transactions authority" for high impact cutting-edge research projects that respond to public health threats, including the opioid crisis and finding a new, non-addictive painkiller. NIH was given this authority for the Precision Medicine Initiative and fifty percent of the Common Fund in the 21st Century Cures Act.
Sec. 1202. Pain Research	• Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the Food and Drug Administration.
Sec. 1203. Report on Synthetic Drug Use	• Requires the Secretary of HHS to submit to Congress a report on the health effects of new psychoactive substances, including synthetic drugs, by adolescents and young adults.
Subtitle C: Medical Products & Controlled Substances Safety	

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Sec. 1301. Clarifying FDA Regulations for Non-Addictive and Non-Opioids Products.	• Clarifies the development and regulatory pathways of the Food and Drug Administration (FDA) for medical product manufacturers through guidance for new non-addictive medical products intended to treat pain or addiction. • Requires the FDA to hold one or more public meeting on the challenges and barriers to developing non-addictive medical products intended to treat pain, including how the risk of misuse and abuse may be incorporated into FDA's assessments, novel clinical trial designs, and evidentiary standards related to opioid sparing. • Requires the FDA to issue guidance to address: o *Expedited Pathways* – To help medical product manufacturers navigate FDA, this would clarify FDA's interpretation of how the qualification parameters for expedited pathways like Breakthrough Designation and Accelerated Approval apply to novel non-addictive pain or addiction treatments. o *Pain Endpoints* – To help medical product manufacturers design clinical trials for innovative non-addictive pain treatments, this would require FDA to provide guidance on the appropriate use of pain endpoints across review divisions. o *Opioid Sparing* – To help advance the development of products that can reduce, replace, or avoid patients' use of opioids to control pain, this would direct FDA to clarify requirements for opioid sparing data to be used in the label that a medicine is as

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	effective at controlling pain and able to reduce, replace, or avoid the amount of opioids a patient needs to control pain. ○ *Risk Benefit related to Misuse and Abuse* – To clarify FDA's role in protecting public health, this would require FDA to provide clear guidance on how the agency will consider the risks and benefits of drugs that have a potential to be misused or abused.
Sec. 1302. Clarifying FDA Packaging Authorities.	• Clarifies FDA's authority to require drug manufacturers to package certain opioids to allow for a set treatment duration – for example, a blister pack with a 3 or 7-day supply. • Clarifies FDA's authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.
Sec. 1303. Strengthening FDA & CBP Coordination & Capacity.	• Improves detection and seizure of illegal drugs, such as fentanyl, by strengthening coordination activities between FDA and the United States Customs and Border Protection (CBP), which may be carried out through a memorandum of understanding between such agencies. • Provides facility and physical infrastructure improvements, including renovations or upgrades, and laboratory capacity for purposes of detection and testing imports. • Provides that FDA has access to innovative detection technology and testing equipment to facilitate near-real-time information sharing. • Requires a report on implementation and summary of progress made towards near-real-time information sharing and the interoperability of such technologies.
Sec. 1304. Clarifying FDA post-market authorities.	• Clarifies FDA's post-market authorities for drugs, such as opioids, which may have reduced efficacy over time, by modifying the definition of an adverse drug experience to include such situations.
Sec. 1305. Restricting Entrance of Illicit Drugs	• Codifies the current practice of FDA upon discovering or receiving a package containing an illegal opioid or controlled substance, FDA will transfer that package to CBP for destruction under CBP's existing authorities. • Debars a person from importing an FDA-regulated product into the US if they have been convicted of a felony related to importation of illegal drugs or controlled substances. • Gives FDA greater ability to refuse the admission of counterfeit drugs.
Sec. 1306. First Responder Training.	• Expands a grant program authorized by the Comprehensive Addiction and Recovery Act, which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose, and to include training on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.
Sec. 1307. Disposal of Controlled Substances by Hospice Programs.	• Provides certain health professionals in qualified hospice programs the legal authority to dispose of controlled substances in the hospice setting to help reduce the risk of diversion or misuse.

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Sec. 1308. GAO Study and Report on Hospice Safe Disposal Management.	• Requires the Government Accountability Office (GAO) to conduct a study and report on hospice programs' written policies and procedures on the management and disposal of controlled substances in the home of an individual.
Sec. 1309. Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation.	• Permits implantable or injectable controlled substances for the purpose of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner, while maintaining proper controls, such as storage and record keeping.
Subtitle D: Treatment & Recovery	
Sec. 1401. Comprehensive Opioid Recovery Centers.	• Authorizes a grant program through the Substance Abuse and Mental Health Services Administration (SAMHSA) for entities to establish or operate comprehensive opioid recovery centers that serve as a resource for the community. These entities may utilize the ECHO model, which supports care coordination and services delivery through technology.
Sec. 1402. Program to support coordination and continuation of care for drug overdose patients.	• Requires the Secretary of the Department of Health and Human Services (HHS) to issue best practices for emergency treatment of a known or suspected drug overdose, use of recovery coaches after a non-fatal overdose, coordination and continuation of care and treatment after an overdose, and provision of overdose reversal medication, as appropriate. • Authorizes a grant program for education on overdose prevention, the establishment or implementation of policies and procedures to treat and support recovery for individuals who have experienced a non-fatal
Sec. 1403. Alternatives to opioids.	• Requires HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. • Authorizes a grant program to support hospitals and other acute care settings that manage pain with alternatives to opioids.
Sec. 1404. Building communities of recovery.	• Reauthorizes and modifies the Building Communities of Recovery program to include peer support networks. This program provides funding for community organizations providing long-term recovery support services.
Sec. 1405. Peer support technical assistance center.	• Requires HHS to establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, to provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to substance use disorder.
Sec. 1406. Medication-Assisted Treatment for Recovery from Addiction.	• Allows physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements to prescribe medication-assisted treatment (MAT), to obtain a waiver to prescribe MAT.
Sec. 1407. Grant Program.	• Authorizes a grant program to support development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.
Sec. 1408. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.	• Codifies the ability of qualified physicians to prescribe MAT for up to 275 patients, to improve access to MAT.

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Sec. 1409. Recovery Housing Best Practices and Identification of Potentially Fraudulent Recovery Housing Operators.	• Requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid addiction with housing. • Requires HHS to identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.
Sec. 1410. Addressing Economic & Workforce Impacts of the Opioid Crisis.	• Authorizes the Department of Labor to award dislocated worker grants to states through the Workforce Innovation and Opportunity Act to support local workforce boards and local partnerships in tackling shortages in substance use disorder and mental health treatment workforce and provide coordinated job training and treatment services to individuals in affected communities with opioid or substance use disorder.
Sec. 1411. CAREER Act	• Authorizes the Secretary of HHS to establish a grant program to support individuals in recovery from a substance use disorder transition to independent living and the workforce.
Sec. 1412. Pilot Program to Help Individuals in Recovery from a Substance Use Disorder become Stably Housed	• Authorizes a pilot program to provide individuals in recovery from a substance use disorder with stable, temporary housing.
Sec. 1413. Youth Prevention and Recovery.	• Requires the Secretary of HHS in consultation with the Department of Education, to disseminate best practices, establish a resource center to provide technical assistance, and issue grants for prevention of and recovery from substance use disorder in children, adolescents and young adults.
Sec. 1414. Plans of Safe Care.	• Provides support for states to collaborate and improve plans of safe care for substance-exposed infants. States may use funds to coordinate with various agencies responsible for child and family wellbeing, develop policies and procedures, train health care and child welfare professionals, establish partnerships, and develop and update technology and monitoring systems to more effectively implement plans of safe care. Requires the Secretary to extend technical assistance programs and issue guidance on plans of safe care.
Sec. 1415. Regulations Relating to Special Registration for Telemedicine.	• Clarifies the ability of the Drug Enforcement Administration (DEA) to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
Sec. 1416. National Health Service Corps Behavioral and Mental Health Professionals Providing Obligated Services in Schools and other Community-Based Settings.	• Allows an entity to direct National Health Service Corps participants to provide behavioral and mental health services at a school or other community-based setting located in a health professional shortage area, and for these services to be applied towards completion of their obligated service requirements.
Sec. 1417. Loan Repayment for Substance Abuse Treatment Providers.	• Requires the Secretary of HHS to enter into contracts to provide loan repayment to behavioral health providers practicing in substance use disorder treatment facilities in mental health professional shortage areas through National Health Service Corps authorities.

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Sec. 1418. Protecting moms and infants.	• Requires the Secretary of HHS to issue and periodically update a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to the Protecting Our Infants Act of 2015. • Reauthorizes the Residential Treatment for Pregnant and Postpartum Women grant program.
Sec. 1419. Early interventions for pregnant women and infants.	• Requires the Center for Substance Abuse Prevention to develop, in cooperation with the Centers for Disease Control and Prevention (CDC), educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy. • Requires implementation and dissemination, as appropriate, of the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy," issued by HHS in 2017.
Sec. 1420. Report on investigations regarding parity in mental health and substance use disorder benefits.	• Requires the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Secretary of the Treasury, to provide additional information in annual reports to Congress on mental health parity compliance, including information on which agencies are conducting investigations and information about any coordination with State regulators.
Subtitle E: Prevention	
Sec. 1501. Study on Prescribing Limits.	• Requires HHS, in consultation with the Attorney General (AG), to submit to Congress a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions.
Sec. 1502. Programs for health care workforce.	• Increases education and training in pain care by requiring grant recipients to develop a comprehensive education and training plan. Such plan would include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. • Updates pain care programs to include alternatives to opioid pain treatment and by promoting non-addictive and non-opioid pain treatments, and non-pharmacologic treatment. • Updates mental and behavioral health education and training grant program to include trauma-informed care.
Sec. 1503. Education and Awareness Campaigns.	• Advances education and awareness among the public and providers. With regards to providers, advances continuing education to promote improved prescribing practices and improved education on and use of evidence-based prescribing guidelines across health care settings. • Provides education and awareness for providers, patients, and consumers about the prescribing and dispensing options related to partial fills of controlled substances in the Controlled Substances Act.
Sec. 1504. Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.	• Authorizes the CDC's work to combat the opioid crisis through the collection, analysis, and dissemination of data, including through grants for states, localities, and tribes.

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Sec. 1505. Preventing Overdoses of Controlled Substances.	• Provides support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs) and implement other evidence-based prevention strategies, encourages data sharing between states, and supports other prevention and research activities related to controlled substances.
Sec. 1506. CDC Surveillance and Data Collection for Child, Youth, and Adult Trauma	• Authorizes CDC to support states' efforts to collect and report data on adverse childhood experiences through existing public health surveys.
Sec. 1507. Reauthorization of NASPER.	• Reauthorizes this HHS grant program to allow states to develop, maintain, or improve PDMPs and improve the interoperability of PDMPs with other states and with other health information technology.
Sec. 1508. Jessie's Law.	• Requires HHS to develop best practices for prominently displaying substance use treatment information in electronic health records, when requested by the patient.
Sec. 1509. Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records.	• Requires HHS to identify Model Programs and Materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.
Sec. 1510. Communication with Families During Emergencies	• Requires the Secretary to notify providers annually regarding sharing of certain health information with family and caregivers during an emergency such as an overdose.
Sec. 1511. Prenatal and Postnatal Health.	• Authorizes data collection and analysis on neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.
Sec. 1512. Surveillance and Education Regarding Infections Associated with Injection Drug Use and Other Risk Factors.	• Reauthorizes and builds upon CDC's program to prevent and respond to infections commonly associated with injection drug use, including viral hepatitis and HIV, by supporting state and federal efforts to collect data on such infections and identify and assist patients who may be at risk of infection.
Sec. 1513. Task Force To Develop Best Practices For Trauma-Informed Identification, Referral, and Support.	• Creates an interagency task force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants, children, youth, and their families. • Requires the task force to develop a set of best practices and national strategy, and to identify existing federal authorities and grant programs where trauma-informed practices are allowable. • Requires the task force to submit a final report of findings and recommendations to Congress, relevant cabinet Secretaries, and the general public not less than three years after its first meeting.
Sec. 1514. Grants to Improve Trauma Support Services and Mental Health Care for Children and Youth in Educational Settings.	• Authorizes the Secretary of Education, in coordination with the Assistant Secretary of Mental Health and Substance Use, to make grants that link educational agencies with mental health systems in order to increase student access to evidence-based trauma support services to help prevent and mitigate trauma that children and youth experience. • Requires the Secretary to conduct a rigorous, independent analysis and disseminate findings from the demonstration grants.
Sec. 1515. National Child Traumatic Stress Initiative.	• Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to

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	communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.
Sec. 1516. National Milestones to Measure Success in Curtailing the Opioid Crisis	• Requires the Secretary of HHS to develop or identify existing national indicators to measure success in curtailing the opioid crisis and significantly reversing the incidence and prevalence of opioid misuse and abuse and opioid-related morbidity and mortality in the United States within 5 years of enactment.
TITLE II: HEAL Act of 2018	
Sec. 2001. Short title.	• "Helping to End Addiction and Lessen Substance Use Disorders Act of 2018" or the "HEAL Act of 2018"
Subtitle A: Medicare	
Sec. 2101. Medicare opioid safety education.	• Requires that the annual *Medicare & You* handbook for Medicare beneficiaries include: references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.
Sec. 2102. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.	• Eliminates certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders, beginning January 1, 2019. • Allows payment for substance use disorder treatment services furnished via telehealth to Medicare beneficiaries at originating sites, including a beneficiary's home, regardless of geographic location. A separate facility fee would not be provided if the originating site is the beneficiary's home.
Sec. 2103. Comprehensive screenings for seniors.	• Requires that Medicare Initial Preventive Physical Examination (also known as the "Welcome to Medicare" visit) and annual wellness visits include a review of the beneficiary's current opioid prescriptions and screening for potential substance use disorders, including a referral to treatment as appropriate.
Sec. 2104. Every prescription conveyed securely.	• Requires that physicians and other practitioners prescribe Part D-covered controlled substances electronically so as to improve tracking of opioid use and prevent diversion. • Directs the Centers for Medicare and Medicaid Services (CMS) to establish a list of exceptions, as well as the penalty for failure to comply when the e-prescribing requirement applies, in consultation with stakeholders.
Sec. 2105. Standardizing electronic prior authorization for safe prescribing.	• Requires that prior authorizations related to Part D prescriptions that are processed electronically use a standard format, improving the efficiency with which prior authorizations are processed and enabling beneficiaries to more promptly receive needed drugs.
Sec. 2106. Strengthening partnerships to prevent opioid abuse.	• Requires CMS to establish a web-based portal to enhance communication between the agency, Medicare Advantage plans with prescription drug plans (MA-PDs), standalone prescription drug plans, and Medicare Drug Integrity Contractors, enhancing the ability to address fraud, waste, and abuse.

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Sec. 2107. Commit to opioid medical prescriber accountability and safety for seniors.	• Requires CMS to notify Part D prescribers who are identified as a statistical outlier when it comes to prescribing opioids as compared to their peers, with the notification including the peer comparison details and information on evidence-based opioid prescribing guidelines. • Directs CMS to connect the prescribers identified as a persistent statistical outlier with entities that provide educational assistance, and gives CMS authority to require those prescribers to enroll in Medicare.
Sec. 2108. Fighting the opioid epidemic with sunshine.	• Enhances the CMS-run Open Payments, or "sunshine", program by expanding the types of professionals for whom a drug and device manufacturer is required to report when the manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. • Sunsets the prohibition that prevents inclusion of the unique identification number, known as the National Provider Identifier, for all professionals and other entities displayed on the CMS Open Payments website.
Sec. 2109. Demonstration testing coverage of certain services furnished by opioid treatment programs.	• Requires that the HHS Secretary conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder treatment services furnished by an eligible Opioid Treatment Program, to begin no later than January 1, 2021. • An eligible OTP selected to participate in the demonstration would receive a bundled payment made under Part B for opioid use disorder treatment services. Those treatment services would include dispensing and administering FDA-approved opioid agonist and antagonist treatment medication, substance use disorder counseling, individual and group therapy, toxicology testing, and other services determined appropriate by the HHS Secretary. • Directs the HHS Secretary to provide a report to Congress that includes an evaluation of the demonstration no later than two years after its completion.
Sec. 2110. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.	• Requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in its system for monitoring those potentially at-risk for prescription drug abuse, enabling prescription drug plans to take steps that inform prescribers and dispensing pharmacies and facilitate improved care.
Sec. 2111. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.	• Requires that a beneficiary enrolled in Medicare Part D who CMS identifies as potentially at-risk for prescription drug abuse (or is subsequently identified as at-risk) can automatically escalate an appeal of such designation to an entity external to the prescription drug plan if the plan affirms its own decision at the initial appeal level.

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Sec. 2112. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.	• Clarifies that the CMS Center for Medicare and Medicaid Innovation may test payment and delivery models that provide incentive payments to behavioral health providers for the adoption and use of certified electronic health record technology to improve the quality and coordination of care through the electronic documentation and exchange of health information.
Sec. 2113. Medicare Improvement Fund.	• Deposits $65 million into the Medicare Improvement Fund that is available to CMS to make improvements under the original Medicare fee-for-service program.
Subtitle B: Medicaid	
Sec. 2201. Caring recovery for infants and babies.	• Clarifies states' ability under Medicaid to provide care for infants with neonatal abstinence syndrome in residential pediatric recovery centers, as well as those centers' option to provide counseling or other services to mothers or caretakers provided those services are otherwise covered.
Sec. 2202. Peer support enhancement and evaluation review.	• Directs the GAO to study and submit a report on how Medicaid covers peer support services, including: the types of services provided; payment models; states' experiences providing peer support services; and how states measure the extent to which peer support services improve costs and outcomes for beneficiaries.
Sec. 2203. Medicaid substance use disorder treatment via telehealth.	• Directs CMS to issue guidance to states on options for providing services via telehealth that address substance use disorders under Medicaid. Requires guidance to cover state options for federal reimbursement for substance use disorder services and treatment using telehealth including, services addressing high-risk individuals, provider education through a hub-and-spoke model, and options for providing telehealth services to students in school-based health centers. • Directs GAO to evaluate children's access to Medicaid services to treat substance use disorders, including options to improve access through telehealth. • Directs CMS to issue a report to Congress identifying best practices and potential solutions to barriers to furnishing services to children via telehealth to compare services delivered via telehealth to in-person.
Sec. 2204. Enhancing patient access to non-opioid treatment options.	• Directs CMS to issue guidance on states' options for treating and managing beneficiaries' pain through non-opioid pain treatment and management options under Medicaid.
Sec. 2205. Assessing barriers to opioid use disorder treatment.	• Directs GAO to analyze and issue a report to Congress on the barriers to access to substance use disorder treatment medications under various drug distribution models, such as buy-and-bill, as well as addressing options for state Medicaid programs to reduce or remove such barriers. GAO is directed to make recommendations, as appropriate.

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Sec. 2206. Help for moms and babies.	• Modifies the "IMD exclusion" for pregnant and postpartum women to address a subset of the prohibition on Medicaid from paying for otherwise coverable Medicaid services for certain adults while in institutions for mental disease (IMD). Modifies Section 1905(a) of the Social security act to ensure that pregnant and postpartum women receiving care for substance use disorders in an IMD can continue to receive other Medicaid-covered care outside of the IMD, such as prenatal services.
Sec. 2207. Securing flexibility to treat substance use disorders.	• Clarifies flexibilities around Medicaid's IMD exclusion where, in some cases, managed care plans may provide alternative services in lieu of other services that are not permitted under the state plan. Codifies regulations permitting managed care plans to cover treatment in an IMD for a certain number of days in a month in lieu of other types of services.
Sec. 2208. MACPAC study and report on MAT utilization controls under State Medicaid programs.	• Directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on utilization management controls applied to medication-assisted treatment options in both fee-for-service and managed Medicaid programs.
Sec. 2209. Opioid addiction treatment programs enhancement.	• Requires the Secretary to publish a data book detailing, for each state, statistics on the prevalence and treatment of substance abuse disorder among Medicaid beneficiaries, including beneficiaries receiving treatment under fee for service and managed care arrangements. Requires the data book to be issued within one year and use data from the Transformed Medicaid Statistical Information System (T-MSIS). Requires HHS to make T-MSIS data available to researchers in the same manner in which precursor data had been made available in the past, including relevant privacy and security protections.
Sec. 2210. Better data sharing to combat the opioid crisis.	• Clarifies states' ability to access and share data from prescription drug monitoring program databases, consistent with the parameters established in state law, including with providers and managed care entities, and in adherence to applicable security and privacy protections and laws.
Sec. 2211. Mandatory reporting with respect to adult behavioral health measures.	• Requires state Medicaid programs to report on all behavioral health quality measures included in the mandatory core set of adult health quality measures beginning 2024.
Sec. 2212. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.	• Directs HHS to issue a report on innovative state initiatives and covered housing-related services that state Medicaid programs may use to provide supports to Medicaid enrollees with substance use disorders who are experiencing homelessness or are at risk of homelessness.

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Sec. 2213. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.	• Directs HHS to provide technical assistance to states to develop and coordinate housing-related supports and services under Medicaid, either through state plans or waivers, and care coordination services, for Medicaid enrollees with substance use disorders.
Subtitle C: Human Services	
Sec. 2301. Supporting family-focused residential treatment.	• Requires HHS to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment programs by: o Describing existing opportunities under Medicaid to support parents in family-focused residential treatment; o Explaining how states can coordinate Medicaid, foster care, and other HHS funding to support substance abuse treatment and other services provided by treatment facilities; and o Describing how states can coordinate Medicaid and foster care funding—specifically per the new authority granted in the *Family First Prevention Services Act*—to support children placed with their parents in family-based treatment facilities.
Sec. 2302. Improving recovery and reunifying families.	• Provides $15 million to HHS to replicate a "recovery coach" program for parents with children in foster care due to parental substance abuse, which has been shown to reduce the length of time children spend in foster care. This will allow HHS to determine whether the program can be replicated in another state and yield the same results.
Sec. 2303. Building capacity for family-focused residential treatment.	• Beginning in FY 2020, states will be eligible to receive funding to provide evidence-based substance abuse prevention and treatment services to families with children at risk of entering foster care (as a result of the *Family First Prevention Services Act*). This section authorizes $20 million in funding for HHS to award to states to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that will later qualify for funding under *Family First*.
Subtitle D: Synthetics Trafficking and Overdose Prevention	
See separate section by section of S.3057.	
TITLE III: JUDICIARY	
Subtitle A: Access to Increased Drug Disposal	
Sec. 3101. Short title.	• Access to Increased Drug Disposal Act of 2018
Sec. 3102. Definitions.	• Defines terms "Attorney General," "authorized collector," "covered grant," and "eligible collector."
Sec. 3103. Authority to make grants.	• Allows the AG to award grants to States to increase the participation of eligible collectors as authorized collectors for drug-disposal programs.

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Sec. 3104. Application.	• Outlines the requirements that a state must meet if submitting an application for a grant, which includes: ○ Identifying a state agency that oversees pharmaceutical care; ○ Detailing a plan to increase participation rates of authorized collectors; and ○ Describing how the state will select eligible collectors to be served under the grant.
Sec. 3105. Use of grant funds.	• Limits the use of the grant that a state receives to the costs of installation, maintenance, training, purchasing, and disposal of controlled substance associated with the participation of collectors.
Sec. 3106. Eligibility for grant.	• Requires that the AG shall award a grant to five states, not less than three of which are in the lowest 25 percent of states in participation rates for drug take-back programs.
Sec. 3107. Duration of grants.	• Allows the AG to determine the period of years for which the grant is made to the state.
Sec. 3108. Accountability and oversight.	• Requires a state that receives a grant to provide a report to the AG that lists the recipients of grant amounts, describes the activities used by the grant amounts, and contains performance measures as to the effectiveness of the grant, including participation rates.
Sec. 3109. Duration of program.	• Limits the AG to award grants for each of the first 5 fiscal years after enactment.
Sec. 3110. Authorization of appropriations.	• Outlines that there are authorized to be appropriated to the AG such sums as may be necessary to carry out this Act.
Subtitle B: Using Data to Prevent Opioid Diversion	
Sec. 3201. Short title.	• Using Data to Prevent Opioid Diversion Act of 2018
Sec. 3202. Purpose.	• States the purpose of the bill, which is to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids which will in turn reduce diversion rates.
Sec. 3203. Amendments.	• Requires DEA to make anonymized information available to registrants with access to ARCOS, including the total number of distributors serving a single pharmacy or practitioner, and the total number of opioid pills distributed to a single pharmacy or practitioner. • Mandates that DEA share information on amounts, outliers, and trends of distributor and pharmacy registrants. • Increases civil and criminal penalties for drug manufacturers and distributors.
Sec. 3204. Report.	• Requires DEA to report to Congress on how it is using ARCOS data to identify and stop suspicious orders of opioids.
Subtitle C: Substance Abuse Prevention	
Sec. 3301. Short title.	• Substance Abuse Prevention Act of 2018

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Sec. 3302. Reauthorization of the Office of National Drug Control Policy.	• Reauthorizes the Office of National Drug Control Policy (ONDCP) at the White House, which oversees all Executive Branch efforts on narcotics control, including the development of a national drug control strategy.
Sec. 3303. Reauthorization of the Drug-Free Communities Program.	• Reauthorizes the Drug-Free Communities (DFC) Program through 2022. DFC is a grant program administered by ONDCP that works to prevent youth substance abuse and reduce the demand for illicit narcotics at a community level.
Sec. 3304. Reauthorization of the National Community Anti-Drug Coalition Institute.	• Reauthorizes the National Community Anti-Drug Coalition Institute through 2022.
Sec. 3305. Reauthorization of the High-Intensity Drug Trafficking Area Program.	• Reauthorizes the ONDCP High-Intensity Drug Trafficking Area (HIDTA) Program. HIDTA provides funding for federal, state, and local law enforcement task forces operating in our nation's most critical drug trafficking regions.
Sec. 3306. Reauthorization of drug court program.	• Reauthorizes Department of Justice funding for drug courts through 2022.
Sec. 3307. Drug court training and technical assistance.	• Allows non-profit organizations to provide important training and technical assistance to drug courts.
Sec. 3308. Drug overdose response strategy.	• Improves upon the HIDTA by targeting funds for implementing a coordinated drug overdose response strategy, which includes: o Coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdose; o Increasing data sharing among public safety and public health officials on drug-related abuse trends; and o Enabling collaborative resources on substance use addiction and narcotics trafficking.
Sec. 3309. Protecting law enforcement officers from accidental exposure.	• Provides supplemental grants to law enforcement agencies to protect law enforcement from accidental exposure to dangerous narcotics. • Grants may be used for purchasing portable equipment to test for fentanyl and other substances, training law enforcement officers and first responders on best practices, and purchasing protective equipment.
Sec. 3310. COPS Anti-Meth Program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies with high seizures of precursor chemicals, methamphetamine, and laboratories for the purpose of investigating illicit activities, such as diversion, laboratories, or methamphetamine trafficking.
Sec. 3311. COPS anti-heroin task force program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies in states with high rates of treatment admissions, for the purpose of investigating illicit activities. • This task force will function through statewide collaboration with the greater effort to dismantle the distribution of heroin, fentanyl, Carfentanil, or the unlawful distribution of prescription opioids.

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Sec. 3312. Comprehensive Addiction and Recovery Act education and awareness.	• Allows the AG to may grants to entities that focus on addiction and substance use disorders and specialize in family and patient services.
Sec. 3313. Protecting children with addicted parents.	• Requires HHS to disseminate best practices for states on interventions and strategies to keep families affected by substances use disorder together. • Allows the Secretary of HHS to award grants to states, units of local government, and tribal governments to: o Develop programs designed to keep pregnant women who have substance use disorder together with their newborns; and o Support the attendance of children who have a family member with substance use disorder at therapeutic camps or programs aimed at addiction prevention education, coping strategies, and family support initiatives aimed at keeping families together.
Sec. 3314. Reimbursement of substance use disorder treatment professionals.	• Mandates the Comptroller General to submit to Congress a report examining how substance use disorder services are reimbursed. • This is required no later than January 1, 2020.
Sec. 3315. Sobriety Treatment and Recovery Teams (START).	• Authorizes SAMHSA to provide grants to establish Sobriety Treatment and Recovery Teams (START) to determine the effectiveness of pairing social workers and mentors with families that are struggling with substance use disorder and child abuse or neglect.
Sec. 3316. Provider education.	• Requires the AG and Secretary of HHS to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances.
Sec. 3317: Demand Reduction	• Amends the definition of "Demand Reduction" so that it includes responsibilities related to recovery from substance use disorder.
Sec. 3318: Anti-Drug Media Campaign	• Expands the scope of ONDCP's media campaign to focus on anti-drug messages for all age groups and not limiting it to only a "youth" anti-drug media campaign.
Subtitle D: Synthetic Abuse and Labeling of Toxic Substances	
Sec. 3401. Short title.	• Synthetic Abuse and Labeling of Toxic Substances Act of 2017
Sec. 3402. Controlled substance analogues.	• Addresses gap in identifying synthetic analogs to controlled substances that are "not intended for human consumption," which allows bad actors to get around prosecution. • Provides factors to consider when determining whether a controlled substances is intended for human consumption, including marketing and labeling of the substance, difference between advertised vs. sale price, diversion from legitimate channels, and whether the defendant knew the substance intended to be consumed by injection, inhalation, or ingestion.
Subtitle E: Opioid Quota Reform	
Sec. 3501. Short title.	• Opioid Quota Reform Act

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Sec. 3502. Strengthening considerations for DEA opioid quotas.	• Sets mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts. • Requires DEA to explain health benefits if DEA approves any increase in annual opioid quota.
Subtitle F: Preventing Drug Diversion	
Sec. 3601. Short title.	• Preventing Drug Diversion Act of 2018
Sec. 3602. Improvements to prevent drug diversion.	• Requires registrants to design systems to identify and report suspicious orders; also requires DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with States.
Subtitle G: Sense of Congress	
Sec. 3701. Sense of Congress.	• Expresses the Sense of Congress that the Federal Government must work to prevent patient brokers from taking advantage of individuals with substance use disorders, while also ensuring that legitimate entities can continue to assist individuals in need of treatment find reputable providers, sober living, or recovery homes.
TITLE IV: COMMERCE	
Subtitle A: Fighting Opioid Abuse in Transportation	
Sec.4101.Short title.	• Provides that the bill may be cited as the "Fighting Opioid Abuse in Transportation Act."
Sec. 4102. Rail mechanical employee controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate rail mechanical employees as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4103. Rail yardmaster controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate yardmasters as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4104. Department of Transportation public drug and alcohol testing database.	• Requires the Secretary of Transportation to establish and make publicly available on its website a database of drug and alcohol testing data reported by employers for each mode of transportation and to update the database annually, while protecting commercially sensitive data and ensuring individual employers and employees are not identified.
Sec. 4105. GAO report on Department of Transportation's collection and use of drug and alcohol testing data.	• Requires the GAO to review Department of Transportation's Drug and Alcohol Testing Information Management System and to submit a report on the review, including potential recommendations for improvement, to relevant congressional committees.
Sec. 4106. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl.	• Requires the Secretary of HHS to determine, within 6 months, whether the inclusion of fentanyl on the panel of drugs authorized for testing is justified and—if justified— requires the Secretary to issue a revision to HHS mandatory guidelines to include fentanyl on the testing panel. • Requires, if the Secretary of HHS justifies the inclusion of fentanyl and revises the guidelines, the Secretary of Transportation to publish a final rule adding fentanyl to Department of Transportation's testing panel.

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Sec. 4107. Status reports on hair testing guidelines.	• Requires the Secretary of HHS to report to Congress on the status of the final notice for the statutorily-required scientific and technical guidelines for hair testing, within 30 days of enactment of this bill and every 6 months thereafter, until the agency publishes a final notice of guidelines for hair testing. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4108. Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid	• Requires the Secretary of HHS to publish a final notice of mandatory guidelines for oral fluid testing not later than December 31, 2018, based on the notice of proposed mandatory guidelines published in 2015. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4109. Electronic recordkeeping.	• Requires the HHS, not later than 1 year from the date of enactment of this bill, to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval. • Requires the Secretary of Transportation, not later than 30 months from the date of enactment of this bill, to issue a final rule authorizing the use of electronic signatures for all paperless chain of custody forms under part 40 of title 49, Code of Federal Regulations.
Sec. 4110. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.	• Requires the Federal Motor Carrier Safety Administration to submit a report to Congress biannually on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse, until such rule is fully implemented.
Subtitle B: Opioid Addiction Recovery Fraud Prevention	
Sec. 4201. Short title.	• This section would title the subtitle as the "Opioid addiction Recovery Fraud Prevention Act of 2018."
Sec. 4202. Definitions.	• This section would define the term "Opioid Treatment Product" to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term "Opioid Treatment Program" to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term "Opioid Use Disorder" to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.

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Sec. 4203. False or misleading representations with respect to opioid treatment programs and products.	• Section 4203(a) would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. • Section 4203(b) provides that any such violation would be considered a violation of a Federal Trade Commission (FTC) trade regulation rule (TRR), allowing the FTC to seek civil penalties under Section 5 and the remedies set forth in Section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies that it can already obtain under the FTC Act. The maximum civil penalty amount the FTC may seek for violations of TRRs is $41,484 per violation, as currently adjusted for inflation. *See* 15 U.S.C. § 45(m)(1)(A) and 16 C.F.R. § 1.98. The Section 19 remedies for TRR violations include "rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation . . . except that nothing in this subsection is intended to authorize the imposition of any exemplary or punitive damages." *See* 15 U.S.C. § 57b(b).
	• Section 4203(c) would empower states to bring actions in federal court against entities for violations of this section and to obtain appropriate relief. It would also require states to notify the FTC in writing before filing a case if possible, or if not feasible immediately upon filing the action. The FTC would have the authority to intervene in the state action. Once the FTC or the AG on the FTC's behalf files an action, states may not file during the pendency of the FTC action their own actions against a party named in the FTC action alleging the same violation. This section also addresses venue and service of process issues. • Section 4203(d) would preserve the authority of the FTC and the FDA such that nothing in this title shall be construed to limit the authority of the FTC or the FDA.

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CEPOP
COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

1050 K Street NW ▾ Suite 400
Washington ▾ DC 20001-4448
(b)(6)
www.CEPOPonline.org

VIA ELECTRONIC DELIVERY

Tuesday, September 04, 2018

The Honorable [Insert Name]
Committee on [Insert]
[Address]
Washington, DC 20510

RE: Support for S. 2875 and Collaborative Efforts to Improve Access and Coverage to All Food and Drug Administration (FDA)-Approved Treatments for Opioid Use Disorder

Dear Senator [Insert]:

Following the Center for Disease Control and Prevention's recent announcement of preliminary overdose deaths for 2017 and near 10% increase over the previous year, efforts to combat opioid use disorder remain a top priority. In response to activity in both the House and Senate around improving access to all U.S. Food and Drug Administration (FDA)-approved medication-assisted treatment (MAT) products, the Collaborative for Effective Prescription Opioid Policies (CEPOP) and the undersigned organizations encourage you and your colleagues to advance S. 2875, the Comprehensive Opioid Management and Bundled Addiction Treatment (COMBAT) Act of 2018.

CEPOP was formed more than three years ago to develop, disseminate and advocate for balanced solutions to this crisis. With over 80 national participants, CEPOP engages a diverse group of stakeholders to pursue a comprehensive strategy to reduce misuse and promote treatment options. We support effective programs and policies to prevent prescription misuse and overdose, while ensuring patients' access to effective pain and opioid use disorder treatment.

An October 2017 Government Accountability Office (GAO) Report on Medicare oversight of prescription opioid utilization identified 727,000 beneficiaries receiving high doses of opioids and over 300,000 beneficiaries having been diagnosed with an opioid use disorder. Moreover, at this time, Medicare beneficiaries demonstrates one of the fastest growing rates of opioid use disorders, with hospitalizations due to opioid misuse/abuse-related complications continuing to rise. With 6 out of every 1,000 Medicare beneficiaries diagnosed with an opioid use disorder, there are more than 300,000 individuals in need of appropriate, evidence-based treatment and recovery services.[1]

We believe Medicare beneficiaries with an opioid use disorder should have access to all FDA-approved products so that their clinician can identify and provide the most appropriate treatment for any individual. According to a January 2018 report in Health Affairs, only 319 (2.65%) of over 12,000 substance abuse treatment centers offer all three FDA-approved MAT products. Furthermore, eight states at that time did not have a single opioid use disorder treatment center offering all three MAT products.

[1] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238

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As part of the comprehensive treatment protocol for opioid use disorder, it is critical that patients have appropriate access to evidence-based programs, including those offered by opioid treatment programs (OTPs). Healthcare providers operating in OTPs ensure patients receive both evidence-based pharmacologic interventions along with behavioral therapy and related support services. Certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are upwards of 1,500 OTPs operating nationally treating approximately 400,000 patients.

As you and your colleagues continue to advance legislation to address the opioid epidemic, we encourage you to expand access to these life-saving medications for Medicare beneficiaries. Various proposals are currently being discussed within the Senate, some of which create a bundled payment for MAT and wraparound services within the Medicare program while others would first develop a Medicare demonstration around bundled payments and expanded access.

Now is not the time to fund another demonstration as evidence has proven the effectiveness of opioid treatment programs in addressing opioid abuse. Provisions within S. 3120, the Helping to End Addiction and Lessen Substance Use Disorders (HEAL) Act of 2018, simply do not go far enough to ensure access to all FDA-approved MAT products for Medicare beneficiaries. The undersigned organizations support – and we encourage you to do so as well – the COMBAT Act of 2018 (S. 2875) which would create a permanent mechanism for coverage.

Once again, thank you for your leadership to address our nation's opioid epidemic. CEPOP, its participants, and the other organizations included on this letter stand ready to assist in any way possible. Please contact Matt Rubin ((b)(6) or (b)(6) with any questions.

Respectfully,

[INSERT SIGNATORIES]

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CEPOP QUARTERLY IN-PERSON ALL-PARTICIPANTS MEETING

Date: Monday, September 17, 2018

Time: 3:00pm – 4:30pm EST

WebEx: **Faegre Baker Daniels Consulting** (1050 K Street NW, Suite 400)
To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions: 2018 Work Plan Emphasis on Youth Prevention

- **A. Prescription for Life, Youth Education and the State Response to the Opioid Epidemic**
  The Honorable Leslie Rutledge, *Arkansas Attorney General*
- **B. Youth Education and Outreach – "This is (not) About Drugs" Program**
  Kourtnaye Sturgeon, *Board Member and Education Committee Chair, Overdose Lifeline*
- **C. Discussion**: Opportunities to Advance Primary Prevention Strategies
  - **i.** 1Q2019 Briefing or Convening on Prevention
  - **ii.** Potential CEPOP Panel at Rx Summit on Primary Prevention Strategies

III. Advocacy and Policy Priorities

- **A.** Updates on Congressional Opioid Activity
  - **i.** Status on House and Senate Legislation
    1. CEPOP Priorities (MAT Access in Medicare; Safe Disposal)
    2. Anticipated Timeline
- **B.** FY2019 Appropriations Update (ONDCP, HIDTA, Drug Free Communities)
- **C.** White House Announces DFC Program Funding with CADCA (link)
- **D.** EPA Memo on Law Enforcement Drug Disposal (link)

IV. Focus Topic Discussion #2

- **A. Preventing Drug Diversion with Realtime Data-Sharing:** DEA Order Clearinghouse Act of 2018 (S. 3282)
  Ali Toal, *Legislative Assistant, U.S. Senator Cory Gardner (CO)*

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A. Takeback and Anti-Diversion

i. CEPOP-BD Initiative on Acute Care Diversion Prevention

B. Safe Use and Prevention

i. Abuse-Deterrent Formulations Non-Therapeutic Benefits Roundtable

1. FDA Commissioner Gottlieb's Remarks on Advancing ADFs at National Press Club Event (August 17); Alignment with April 2018 CEPOP-FDA Meeting

ii. Engagement with Johns Hopkins University *Stigma Lab*

VI. Organizational Updates; Sharing Intel, Participant News and Updates

Next Monthly CEPOP All-Participants Teleconference: Monday, October 29th, 3:00pm – 4:00pm

AMERICAN OVERSIGHT

[EXTERNAL] CEPOP Quarterly In-Person All-Participants Meeting (Sept. 2018) - AGENDA ATTACHED

Where:	FaegreBD Consulting Offices (1050 K Street NW, Suite 400); WebEx Available
When:	Mon Sep 17 15:00:00 2018 (America/New_York)
Until:	Mon Sep 17 16:30:00 2018 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	(b)(6) Teresa Baker <(b)(6) Caren Kagan Evans <(b)(6) "Dr. John Harrison" <(b)(6) Robert Forman <(b)(6) Addie Liles <(b)(6) Keysha Brooks-Coley <(b)(6) "Dr. Anita Gupta" <(b)(6) Julian Hoffman <(b)(6) Sue Thau <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) "Alexander, Tesfa" <(b)(6) Andrew kessler <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Hanson, Roberta J." <(b)(6) Aiken Hackett <(b)(6) "Tim Hermes (b)(6) <(b)(6) Jane Terry <(b)(6) Dan Buffington <(b)(6) Rebecca Farley <(b)(6) "Deana Haworth (Hirons)" <(b)(6) Scott Proescholdbell <(b)(6) "Gen. Arthur Dean" <(b)(6) Patricia D'Antonio <(b)(6) Courtney Hunter <(b)(6)

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John Donahue <(b)(6)
Michael DeGeorge <(b)(6)
Gabrielle de la Gueronniere <(b)(6)
Sara patterson <(b)(6)
James Appleby <(b)(6)
"Gabriella Witte (APHA)" <(b)(6)
Jeremiah Lindemann (b)(6)
Rebecca Slater Abbott <(b)(6)
"Christian, Jeanine M" <(b)(6)
Alice Dembner <(b)(6)
David May <(b)(6)
Vince Ventimiglia <(b)(6)
"Sarah Nerad (Alkermes)" <(b)(6)
Kate Berry <(b)(6)
"Carrier Latimer (Hirons)" <(b)(6)
Erika Long <(b)(6)
"Patel, Beena S." <(b)(6)
"Dr. Renan Castillo" <(b)(6)
"Kevin Webb (MNK)" <(b)(6)
"Ian Goldstein (NACCHO)" <(b)(6)
Steve Passik <(b)(6)
"Zook, David R." <(b)(6)
Kimberly Wilkinson <(b)(6)
Charlie Cichon <(b)(6)
"Stephanie Pellitt (NCBH)" <(b)(6)
David Trewolla <(b)(6)
Susan Weinstein <(b)(6)
Blair Clark-Schoeb <(b)(6)
"Dr. Stuart Gitlow" <(b)(6)
Carol Thornton <(b)(6)
Becky Salay <(b)(6)
"Danna Droz (NABP)" <(b)(6)
Mary Winnefeld <(b)(6)
Daniel Raymond <(b)(6)
"Sue Thau (Gmail)" <(b)(6)
"Dr. Jack Stein" <(b)(6)

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Mike Smith <(b)(6)
"Dr. Elizabeth Salisbury-Afshar" <(b)(6)
"Bono, Mary" <(b)(6)
Jeffrey Ekoma <(b)(6)
"Jessica Johnston (BD)" <(b)(6)
John O'Brien <john.(b)(6)
Elizabeth Solhtalab <(b)(6)
Nicole Burda <(b)(6)
Brian Bowden <(b)(6)
Karen Tracy <(b)(6)
Marcia Lee Taylor <(b)(6)
"Evans, Daniel F." <(b)(6)
"Kathryn L. Cates-Wessel" <(b)(6)
Paul Ross <(b)(6)
"Emmanuel Oga (Battelle)" <(b)(6)
"Derek Naten (MNK)" <(b)(6)
Chris Zimmerman <(b)(6)
Shalini Wickramatilake <(b)(6)
Susan Awad <(b)(6)
Shelley Starkey <(b)(6)
"Patty McCarthy (FaVoR)" <(b)(6)
"Clay Alspach (b)(6) <(b)(6)
Dennis Brennan <(b)(6)
"Hannah Riffle (b)(6) <(b)(6)
"Celia Hagan (NILA)" <(b)(6)
Donald Hoppert <(b)(6)
Hadi Sedigh <(b)(6)
"Cara Moon (Egalet)" <(b)(6)
"Deb Waugh (Affiliated Monitors)" <(b)(6)
Rob Morrison <(b)(6)
"Nadine Gracia (b)(6) <(b)(6)
"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)
Kevin Walker <(b)(6)
"Rachel Rivera (b)(6)
<(b)(6)
Amy Callendar <(b)(6)

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Judi Lund Person (b)(6)
Amanda Sears <(b)(6)
Chuck Ingoglia <(b)(6)
Patricia Bruckenthal <(b)(6)
Tracie Thomas <(b)(6)
Samantha Arsenault <(b)(6)
Kathleen O'Conner <(b)(6)
Nick Motu <(b)(6)
Kate McFadyen <(b)(6)
Aryka Chapman <(b)(6)
Jason Sundby <(b)(6)
Sonya Clay <(b)(6)
"Everett Crosland (Pear Therapeutics)" <(b)(6)
Eli Briggs <(b)(6)
Lorraine Yarde <(b)(6)
"Brooke Goldberg (SAFE Project US)" <(b)(6)
Wade Delk <(b)(6)
"Cristi L. Schwarcz" <(b)(6)
"Donald A. Lohman (MNK)" <(b)(6)
Melissa Ough <(b)(6)
Gary Mendell (b)(6)
Geoffrey Laredo <(b)(6)
Myra Christopher <(b)(6)
Van Ingram <(b)(6)
Brad Tallamy <(b)(6)
Rita Norton <(b)(6)
Ed Kaleta <(b)(6)
Patricia Farley <(b)(6)
"Robin Swift (b)(6) <(b)(6)

CEPOP Participants – In advance of our upcoming quarterly, in-person All-Participants meeting, please find the agenda attached below. We are pleased to have three fantastic focus topic speakers for this month's All-Participants meeting, including:

- **The Honorable Leslie Rutledge**, Arkansas Attorney General
- **Kourtenaye Sturgeon**, Overdose Lifeline
- **Ali Toal**, United States Senator Corey Gardner (CO)

We look forward to a productive discussion on Monday afternoon. As always, please do not hesitate to reach out with any questions.

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Meeting Location

Faegre Baker Daniels Consulting Offices

1050 K Street NW, Suite 400

Washington, DC 20001

For those unable to attend in-person, a WebEx will be made available to all participants to participate remotely.

- To join WebEx, please **CLICK HERE.**
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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TITLE I: Opioid Crisis Response Act	
Sec. 1001. Definitions.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle A: Reauthorization of Cures Funding	
Sec. 1101. Cures Funding Extension.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle B: Research and Innovation	
Sec. 1201. Advancing Cutting-Edge Research.	• Allows the National Institutes of Health (NIH) to use its "other transactions authority" for high impact cutting-edge research projects that respond to public health threats, including the opioid crisis and finding a new, non-addictive painkiller. NIH was given this authority for the Precision Medicine Initiative and fifty percent of the Common Fund in the 21st Century Cures Act.
Sec. 1202. Pain Research	• Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the Food and Drug Administration.
Sec. 1203. Report on Synthetic Drug Use	• Requires the Secretary of HHS to submit to Congress a report on the health effects of new psychoactive substances, including synthetic drugs, by adolescents and young adults.
Subtitle C: Medical Products & Controlled Substances Safety	

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Sec. 1301. Clarifying FDA Regulations for Non-Addictive and Non-Opioids Products.	• Clarifies the development and regulatory pathways of the Food and Drug Administration (FDA) for medical product manufacturers through guidance for new non-addictive medical products intended to treat pain or addiction. • Requires the FDA to hold one or more public meeting on the challenges and barriers to developing non-addictive medical products intended to treat pain, including how the risk of misuse and abuse may be incorporated into FDA's assessments, novel clinical trial designs, and evidentiary standards related to opioid sparing. • Requires the FDA to issue guidance to address: ○ *Expedited Pathways* – To help medical product manufacturers navigate FDA, this would clarify FDA's interpretation of how the qualification parameters for expedited pathways like Breakthrough Designation and Accelerated Approval apply to novel non-addictive pain or addiction treatments. ○ *Pain Endpoints* – To help medical product manufacturers design clinical trials for innovative non-addictive pain treatments, this would require FDA to provide guidance on the appropriate use of pain endpoints across review divisions. ○ *Opioid Sparing* – To help advance the development of products that can reduce, replace, or avoid patients' use of opioids to control pain, this would direct FDA to clarify requirements for opioid sparing data to be used in the label that a medicine is as

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	effective at controlling pain and able to reduce, replace, or avoid the amount of opioids a patient needs to control pain. ○ *Risk Benefit related to Misuse and Abuse* – To clarify FDA's role in protecting public health, this would require FDA to provide clear guidance on how the agency will consider the risks and benefits of drugs that have a potential to be misused or abused.
Sec. 1302. Clarifying FDA Packaging Authorities.	• Clarifies FDA's authority to require drug manufacturers to package certain opioids to allow for a set treatment duration – for example, a blister pack with a 3 or 7-day supply. • Clarifies FDA's authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.
Sec. 1303. Strengthening FDA & CBP Coordination & Capacity.	• Improves detection and seizure of illegal drugs, such as fentanyl, by strengthening coordination activities between FDA and the United States Customs and Border Protection (CBP), which may be carried out through a memorandum of understanding between such agencies. • Provides facility and physical infrastructure improvements, including renovations or upgrades, and laboratory capacity for purposes of detection and testing imports. • Provides that FDA has access to innovative detection technology and testing equipment to facilitate near-real-time information sharing. • Requires a report on implementation and summary of progress made towards near-real-time information sharing and the interoperability of such technologies.
Sec. 1304. Clarifying FDA post-market authorities.	• Clarifies FDA's post-market authorities for drugs, such as opioids, which may have reduced efficacy over time, by modifying the definition of an adverse drug experience to include such situations.
Sec. 1305. Restricting Entrance of Illicit Drugs	• Codifies the current practice of FDA upon discovering or receiving a package containing an illegal opioid or controlled substance, FDA will transfer that package to CBP for destruction under CBP's existing authorities. • Debars a person from importing an FDA-regulated product into the US if they have been convicted of a felony related to importation of illegal drugs or controlled substances. • Gives FDA greater ability to refuse the admission of counterfeit drugs.
Sec. 1306. First Responder Training.	• Expands a grant program authorized by the Comprehensive Addiction and Recovery Act, which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose, and to include training on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.
Sec. 1307. Disposal of Controlled Substances by Hospice Programs.	• Provides certain health professionals in qualified hospice programs the legal authority to dispose of controlled substances in the hospice setting to help reduce the risk of diversion or misuse.

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Sec. 1308. GAO Study and Report on Hospice Safe Disposal Management.	• Requires the Government Accountability Office (GAO) to conduct a study and report on hospice programs' written policies and procedures on the management and disposal of controlled substances in the home of an individual.
Sec. 1309. Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation.	• Permits implantable or injectable controlled substances for the purpose of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner, while maintaining proper controls, such as storage and record keeping.
Subtitle D: Treatment & Recovery	
Sec. 1401. Comprehensive Opioid Recovery Centers.	• Authorizes a grant program through the Substance Abuse and Mental Health Services Administration (SAMHSA) for entities to establish or operate comprehensive opioid recovery centers that serve as a resource for the community. These entities may utilize the ECHO model, which supports care coordination and services delivery through technology.
Sec. 1402. Program to support coordination and continuation of care for drug overdose patients.	• Requires the Secretary of the Department of Health and Human Services (HHS) to issue best practices for emergency treatment of a known or suspected drug overdose, use of recovery coaches after a non-fatal overdose, coordination and continuation of care and treatment after an overdose, and provision of overdose reversal medication, as appropriate. • Authorizes a grant program for education on overdose prevention, the establishment or implementation of policies and procedures to treat and support recovery for individuals who have experienced a non-fatal
Sec. 1403. Alternatives to opioids.	• Requires HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. • Authorizes a grant program to support hospitals and other acute care settings that manage pain with alternatives to opioids.
Sec. 1404. Building communities of recovery.	• Reauthorizes and modifies the Building Communities of Recovery program to include peer support networks. This program provides funding for community organizations providing long-term recovery support services.
Sec. 1405. Peer support technical assistance center.	• Requires HHS to establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, to provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to substance use disorder.
Sec. 1406. Medication-Assisted Treatment for Recovery from Addiction.	• Allows physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements to prescribe medication-assisted treatment (MAT), to obtain a waiver to prescribe MAT.
Sec. 1407. Grant Program.	• Authorizes a grant program to support development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.
Sec. 1408. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.	• Codifies the ability of qualified physicians to prescribe MAT for up to 275 patients, to improve access to MAT.

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Sec. 1409. Recovery Housing Best Practices and Identification of Potentially Fraudulent Recovery Housing Operators.	• Requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid addiction with housing. • Requires HHS to identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.
Sec. 1410. Addressing Economic & Workforce Impacts of the Opioid Crisis.	• Authorizes the Department of Labor to award dislocated worker grants to states through the Workforce Innovation and Opportunity Act to support local workforce boards and local partnerships in tackling shortages in substance use disorder and mental health treatment workforce and provide coordinated job training and treatment services to individuals in affected communities with opioid or substance use disorder.
Sec. 1411. CAREER Act	• Authorizes the Secretary of HHS to establish a grant program to support individuals in recovery from a substance use disorder transition to independent living and the workforce.
Sec. 1412. Pilot Program to Help Individuals in Recovery from a Substance Use Disorder become Stably Housed	• Authorizes a pilot program to provide individuals in recovery from a substance use disorder with stable, temporary housing.
Sec. 1413. Youth Prevention and Recovery.	• Requires the Secretary of HHS in consultation with the Department of Education, to disseminate best practices, establish a resource center to provide technical assistance, and issue grants for prevention of and recovery from substance use disorder in children, adolescents and young adults.
Sec. 1414. Plans of Safe Care.	• Provides support for states to collaborate and improve plans of safe care for substance-exposed infants. States may use funds to coordinate with various agencies responsible for child and family wellbeing, develop policies and procedures, train health care and child welfare professionals, establish partnerships, and develop and update technology and monitoring systems to more effectively implement plans of safe care. Requires the Secretary to extend technical assistance programs and issue guidance on plans of safe care.
Sec. 1415. Regulations Relating to Special Registration for Telemedicine.	• Clarifies the ability of the Drug Enforcement Administration (DEA) to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
Sec. 1416. National Health Service Corps Behavioral and Mental Health Professionals Providing Obligated Services in Schools and other Community-Based Settings.	• Allows an entity to direct National Health Service Corps participants to provide behavioral and mental health services at a school or other community-based setting located in a health professional shortage area, and for these services to be applied towards completion of their obligated service requirements.
Sec. 1417. Loan Repayment for Substance Abuse Treatment Providers.	• Requires the Secretary of HHS to enter into contracts to provide loan repayment to behavioral health providers practicing in substance use disorder treatment facilities in mental health professional shortage areas through National Health Service Corps authorities.

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Sec. 1418. Protecting moms and infants.	• Requires the Secretary of HHS to issue and periodically update a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to the Protecting Our Infants Act of 2015. • Reauthorizes the Residential Treatment for Pregnant and Postpartum Women grant program.
Sec. 1419. Early interventions for pregnant women and infants.	• Requires the Center for Substance Abuse Prevention to develop, in cooperation with the Centers for Disease Control and Prevention (CDC), educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy. • Requires implementation and dissemination, as appropriate, of the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy," issued by HHS in 2017.
Sec. 1420. Report on investigations regarding parity in mental health and substance use disorder benefits.	• Requires the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Secretary of the Treasury, to provide additional information in annual reports to Congress on mental health parity compliance, including information on which agencies are conducting investigations and information about any coordination with State regulators.
Subtitle E: Prevention	
Sec. 1501. Study on Prescribing Limits.	• Requires HHS, in consultation with the Attorney General (AG), to submit to Congress a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions.
Sec. 1502. Programs for health care workforce.	• Increases education and training in pain care by requiring grant recipients to develop a comprehensive education and training plan. Such plan would include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. • Updates pain care programs to include alternatives to opioid pain treatment and by promoting non-addictive and non-opioid pain treatments, and non-pharmacologic treatment. • Updates mental and behavioral health education and training grant program to include trauma-informed care.
Sec. 1503. Education and Awareness Campaigns.	• Advances education and awareness among the public and providers. With regards to providers, advances continuing education to promote improved prescribing practices and improved education on and use of evidence-based prescribing guidelines across health care settings. • Provides education and awareness for providers, patients, and consumers about the prescribing and dispensing options related to partial fills of controlled substances in the Controlled Substances Act.
Sec. 1504. Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.	• Authorizes the CDC's work to combat the opioid crisis through the collection, analysis, and dissemination of data, including through grants for states, localities, and tribes.

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Sec. 1505. Preventing Overdoses of Controlled Substances.	• Provides support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs) and implement other evidence-based prevention strategies, encourages data sharing between states, and supports other prevention and research activities related to controlled substances.
Sec. 1506. CDC Surveillance and Data Collection for Child, Youth, and Adult Trauma	• Authorizes CDC to support states' efforts to collect and report data on adverse childhood experiences through existing public health surveys.
Sec. 1507. Reauthorization of NASPER.	• Reauthorizes this HHS grant program to allow states to develop, maintain, or improve PDMPs and improve the interoperability of PDMPs with other states and with other health information technology.
Sec. 1508. Jessie's Law.	• Requires HHS to develop best practices for prominently displaying substance use treatment information in electronic health records, when requested by the patient.
Sec. 1509. Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records.	• Requires HHS to identify Model Programs and Materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.
Sec. 1510. Communication with Families During Emergencies	• Requires the Secretary to notify providers annually regarding sharing of certain health information with family and caregivers during an emergency such as an overdose.
Sec. 1511. Prenatal and Postnatal Health.	• Authorizes data collection and analysis on neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.
Sec. 1512. Surveillance and Education Regarding Infections Associated with Injection Drug Use and Other Risk Factors.	• Reauthorizes and builds upon CDC's program to prevent and respond to infections commonly associated with injection drug use, including viral hepatitis and HIV, by supporting state and federal efforts to collect data on such infections and identify and assist patients who may be at risk of infection.
Sec. 1513. Task Force To Develop Best Practices For Trauma-Informed Identification, Referral, and Support.	• Creates an interagency task force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants, children, youth, and their families. • Requires the task force to develop a set of best practices and national strategy, and to identify existing federal authorities and grant programs where trauma-informed practices are allowable. • Requires the task force to submit a final report of findings and recommendations to Congress, relevant cabinet Secretaries, and the general public not less than three years after its first meeting.
Sec. 1514. Grants to Improve Trauma Support Services and Mental Health Care for Children and Youth in Educational Settings.	• Authorizes the Secretary of Education, in coordination with the Assistant Secretary of Mental Health and Substance Use, to make grants that link educational agencies with mental health systems in order to increase student access to evidence-based trauma support services to help prevent and mitigate trauma that children and youth experience. • Requires the Secretary to conduct a rigorous, independent analysis and disseminate findings from the demonstration grants.
Sec. 1515. National Child Traumatic Stress Initiative.	• Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to

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	communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.
Sec. 1516. National Milestones to Measure Success in Curtailing the Opioid Crisis	• Requires the Secretary of HHS to develop or identify existing national indicators to measure success in curtailing the opioid crisis and significantly reversing the incidence and prevalence of opioid misuse and abuse and opioid-related morbidity and mortality in the United States within 5 years of enactment.
TITLE II: HEAL Act of 2018	
Sec. 2001. Short title.	• "Helping to End Addiction and Lessen Substance Use Disorders Act of 2018" or the "HEAL Act of 2018"
Subtitle A: Medicare	
Sec. 2101. Medicare opioid safety education.	• Requires that the annual *Medicare & You* handbook for Medicare beneficiaries include: references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.
Sec. 2102. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.	• Eliminates certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders, beginning January 1, 2019. • Allows payment for substance use disorder treatment services furnished via telehealth to Medicare beneficiaries at originating sites, including a beneficiary's home, regardless of geographic location. A separate facility fee would not be provided if the originating site is the beneficiary's home.
Sec. 2103. Comprehensive screenings for seniors.	• Requires that Medicare Initial Preventive Physical Examination (also known as the "Welcome to Medicare" visit) and annual wellness visits include a review of the beneficiary's current opioid prescriptions and screening for potential substance use disorders, including a referral to treatment as appropriate.
Sec. 2104. Every prescription conveyed securely.	• Requires that physicians and other practitioners prescribe Part D-covered controlled substances electronically so as to improve tracking of opioid use and prevent diversion. • Directs the Centers for Medicare and Medicaid Services (CMS) to establish a list of exceptions, as well as the penalty for failure to comply when the e-prescribing requirement applies, in consultation with stakeholders.
Sec. 2105. Standardizing electronic prior authorization for safe prescribing.	• Requires that prior authorizations related to Part D prescriptions that are processed electronically use a standard format, improving the efficiency with which prior authorizations are processed and enabling beneficiaries to more promptly receive needed drugs.
Sec. 2106. Strengthening partnerships to prevent opioid abuse.	• Requires CMS to establish a web-based portal to enhance communication between the agency, Medicare Advantage plans with prescription drug plans (MA-PDs), standalone prescription drug plans, and Medicare Drug Integrity Contractors, enhancing the ability to address fraud, waste, and abuse.

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Sec. 2107. Commit to opioid medical prescriber accountability and safety for seniors.	• Requires CMS to notify Part D prescribers who are identified as a statistical outlier when it comes to prescribing opioids as compared to their peers, with the notification including the peer comparison details and information on evidence-based opioid prescribing guidelines. • Directs CMS to connect the prescribers identified as a persistent statistical outlier with entities that provide educational assistance, and gives CMS authority to require those prescribers to enroll in Medicare.
Sec. 2108. Fighting the opioid epidemic with sunshine.	• Enhances the CMS-run Open Payments, or "sunshine", program by expanding the types of professionals for whom a drug and device manufacturer is required to report when the manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. • Sunsets the prohibition that prevents inclusion of the unique identification number, known as the National Provider Identifier, for all professionals and other entities displayed on the CMS Open Payments website.
Sec. 2109. Demonstration testing coverage of certain services furnished by opioid treatment programs.	• Requires that the HHS Secretary conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder treatment services furnished by an eligible Opioid Treatment Program, to begin no later than January 1, 2021. • An eligible OTP selected to participate in the demonstration would receive a bundled payment made under Part B for opioid use disorder treatment services. Those treatment services would include dispensing and administering FDA-approved opioid agonist and antagonist treatment medication, substance use disorder counseling, individual and group therapy, toxicology testing, and other services determined appropriate by the HHS Secretary. • Directs the HHS Secretary to provide a report to Congress that includes an evaluation of the demonstration no later than two years after its completion.
Sec. 2110. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.	• Requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in its system for monitoring those potentially at-risk for prescription drug abuse, enabling prescription drug plans to take steps that inform prescribers and dispensing pharmacies and facilitate improved care.
Sec. 2111. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.	• Requires that a beneficiary enrolled in Medicare Part D who CMS identifies as potentially at-risk for prescription drug abuse (or is subsequently identified as at-risk) can automatically escalate an appeal of such designation to an entity external to the prescription drug plan if the plan affirms its own decision at the initial appeal level.

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Sec. 2112. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.	• Clarifies that the CMS Center for Medicare and Medicaid Innovation may test payment and delivery models that provide incentive payments to behavioral health providers for the adoption and use of certified electronic health record technology to improve the quality and coordination of care through the electronic documentation and exchange of health information.
Sec. 2113. Medicare Improvement Fund.	• Deposits $65 million into the Medicare Improvement Fund that is available to CMS to make improvements under the original Medicare fee-for-service program.
Subtitle B: Medicaid	
Sec. 2201. Caring recovery for infants and babies.	• Clarifies states' ability under Medicaid to provide care for infants with neonatal abstinence syndrome in residential pediatric recovery centers, as well as those centers' option to provide counseling or other services to mothers or caretakers provided those services are otherwise covered.
Sec. 2202. Peer support enhancement and evaluation review.	• Directs the GAO to study and submit a report on how Medicaid covers peer support services, including: the types of services provided; payment models; states' experiences providing peer support services; and how states measure the extent to which peer support services improve costs and outcomes for beneficiaries.
Sec. 2203. Medicaid substance use disorder treatment via telehealth.	• Directs CMS to issue guidance to states on options for providing services via telehealth that address substance use disorders under Medicaid. Requires guidance to cover state options for federal reimbursement for substance use disorder services and treatment using telehealth including, services addressing high-risk individuals, provider education through a hub-and-spoke model, and options for providing telehealth services to students in school-based health centers. • Directs GAO to evaluate children's access to Medicaid services to treat substance use disorders, including options to improve access through telehealth. • Directs CMS to issue a report to Congress identifying best practices and potential solutions to barriers to furnishing services to children via telehealth to compare services delivered via telehealth to in-person.
Sec. 2204. Enhancing patient access to non-opioid treatment options.	• Directs CMS to issue guidance on states' options for treating and managing beneficiaries' pain through non-opioid pain treatment and management options under Medicaid.
Sec. 2205. Assessing barriers to opioid use disorder treatment.	• Directs GAO to analyze and issue a report to Congress on the barriers to access to substance use disorder treatment medications under various drug distribution models, such as buy-and-bill, as well as addressing options for state Medicaid programs to reduce or remove such barriers. GAO is directed to make recommendations, as appropriate.

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Sec. 2206. Help for moms and babies.	• Modifies the "IMD exclusion" for pregnant and postpartum women to address a subset of the prohibition on Medicaid from paying for otherwise coverable Medicaid services for certain adults while in institutions for mental disease (IMD). Modifies Section 1905(a) of the Social security act to ensure that pregnant and postpartum women receiving care for substance use disorders in an IMD can continue to receive other Medicaid-covered care outside of the IMD, such as prenatal services.
Sec. 2207. Securing flexibility to treat substance use disorders.	• Clarifies flexibilities around Medicaid's IMD exclusion where, in some cases, managed care plans may provide alternative services in lieu of other services that are not permitted under the state plan. Codifies regulations permitting managed care plans to cover treatment in an IMD for a certain number of days in a month in lieu of other types of services.
Sec. 2208. MACPAC study and report on MAT utilization controls under State Medicaid programs.	• Directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on utilization management controls applied to medication-assisted treatment options in both fee-for-service and managed Medicaid programs.
Sec. 2209. Opioid addiction treatment programs enhancement.	• Requires the Secretary to publish a data book detailing, for each state, statistics on the prevalence and treatment of substance abuse disorder among Medicaid beneficiaries, including beneficiaries receiving treatment under fee for service and managed care arrangements. Requires the data book to be issued within one year and use data from the Transformed Medicaid Statistical Information System (T-MSIS). Requires HHS to make T-MSIS data available to researchers in the same manner in which precursor data had been made available in the past, including relevant privacy and security protections.
Sec. 2210. Better data sharing to combat the opioid crisis.	• Clarifies states' ability to access and share data from prescription drug monitoring program databases, consistent with the parameters established in state law, including with providers and managed care entities, and in adherence to applicable security and privacy protections and laws.
Sec. 2211. Mandatory reporting with respect to adult behavioral health measures.	• Requires state Medicaid programs to report on all behavioral health quality measures included in the mandatory core set of adult health quality measures beginning 2024.
Sec. 2212. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.	• Directs HHS to issue a report on innovative state initiatives and covered housing-related services that state Medicaid programs may use to provide supports to Medicaid enrollees with substance use disorders who are experiencing homelessness or are at risk of homelessness.

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Sec. 2213. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.	• Directs HHS to provide technical assistance to states to develop and coordinate housing-related supports and services under Medicaid, either through state plans or waivers, and care coordination services, for Medicaid enrollees with substance use disorders.
Subtitle C: Human Services	
Sec. 2301. Supporting family-focused residential treatment.	• Requires HHS to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment programs by: o Describing existing opportunities under Medicaid to support parents in family-focused residential treatment; o Explaining how states can coordinate Medicaid, foster care, and other HHS funding to support substance abuse treatment and other services provided by treatment facilities; and o Describing how states can coordinate Medicaid and foster care funding—specifically per the new authority granted in the *Family First Prevention Services Act*—to support children placed with their parents in family-based treatment facilities.
Sec. 2302. Improving recovery and reunifying families.	• Provides $15 million to HHS to replicate a "recovery coach" program for parents with children in foster care due to parental substance abuse, which has been shown to reduce the length of time children spend in foster care. This will allow HHS to determine whether the program can be replicated in another state and yield the same results.
Sec. 2303. Building capacity for family-focused residential treatment.	• Beginning in FY 2020, states will be eligible to receive funding to provide evidence-based substance abuse prevention and treatment services to families with children at risk of entering foster care (as a result of the *Family First Prevention Services Act*). This section authorizes $20 million in funding for HHS to award to states to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that will later qualify for funding under *Family First*.
Subtitle D: Synthetics Trafficking and Overdose Prevention	
See separate section by section of S.3057.	
TITLE III: JUDICIARY	
Subtitle A: Access to Increased Drug Disposal	
Sec. 3101. Short title.	• Access to Increased Drug Disposal Act of 2018
Sec. 3102. Definitions.	• Defines terms "Attorney General," "authorized collector," "covered grant," and "eligible collector."
Sec. 3103. Authority to make grants.	• Allows the AG to award grants to States to increase the participation of eligible collectors as authorized collectors for drug-disposal programs.

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Sec. 3104. Application.	• Outlines the requirements that a state must meet if submitting an application for a grant, which includes: ○ Identifying a state agency that oversees pharmaceutical care; ○ Detailing a plan to increase participation rates of authorized collectors; and ○ Describing how the state will select eligible collectors to be served under the grant.
Sec. 3105. Use of grant funds.	• Limits the use of the grant that a state receives to the costs of installation, maintenance, training, purchasing, and disposal of controlled substance associated with the participation of collectors.
Sec. 3106. Eligibility for grant.	• Requires that the AG shall award a grant to five states, not less than three of which are in the lowest 25 percent of states in participation rates for drug take-back programs.
Sec. 3107. Duration of grants.	• Allows the AG to determine the period of years for which the grant is made to the state.
Sec. 3108. Accountability and oversight.	• Requires a state that receives a grant to provide a report to the AG that lists the recipients of grant amounts, describes the activities used by the grant amounts, and contains performance measures as to the effectiveness of the grant, including participation rates.
Sec. 3109. Duration of program.	• Limits the AG to award grants for each of the first 5 fiscal years after enactment.
Sec. 3110. Authorization of appropriations.	• Outlines that there are authorized to be appropriated to the AG such sums as may be necessary to carry out this Act.
Subtitle B: Using Data to Prevent Opioid Diversion	
Sec. 3201. Short title.	• Using Data to Prevent Opioid Diversion Act of 2018
Sec. 3202. Purpose.	• States the purpose of the bill, which is to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids which will in turn reduce diversion rates.
Sec. 3203. Amendments.	• Requires DEA to make anonymized information available to registrants with access to ARCOS, including the total number of distributors serving a single pharmacy or practitioner, and the total number of opioid pills distributed to a single pharmacy or practitioner. • Mandates that DEA share information on amounts, outliers, and trends of distributor and pharmacy registrants. • Increases civil and criminal penalties for drug manufacturers and distributors.
Sec. 3204. Report.	• Requires DEA to report to Congress on how it is using ARCOS data to identify and stop suspicious orders of opioids.
Subtitle C: Substance Abuse Prevention	
Sec. 3301. Short title.	• Substance Abuse Prevention Act of 2018

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Sec. 3302. Reauthorization of the Office of National Drug Control Policy.	• Reauthorizes the Office of National Drug Control Policy (ONDCP) at the White House, which oversees all Executive Branch efforts on narcotics control, including the development of a national drug control strategy.
Sec. 3303. Reauthorization of the Drug-Free Communities Program.	• Reauthorizes the Drug-Free Communities (DFC) Program through 2022. DFC is a grant program administered by ONDCP that works to prevent youth substance abuse and reduce the demand for illicit narcotics at a community level.
Sec. 3304. Reauthorization of the National Community Anti-Drug Coalition Institute.	• Reauthorizes the National Community Anti-Drug Coalition Institute through 2022.
Sec. 3305. Reauthorization of the High-Intensity Drug Trafficking Area Program.	• Reauthorizes the ONDCP High-Intensity Drug Trafficking Area (HIDTA) Program. HIDTA provides funding for federal, state, and local law enforcement task forces operating in our nation's most critical drug trafficking regions.
Sec. 3306. Reauthorization of drug court program.	• Reauthorizes Department of Justice funding for drug courts through 2022.
Sec. 3307. Drug court training and technical assistance.	• Allows non-profit organizations to provide important training and technical assistance to drug courts.
Sec. 3308. Drug overdose response strategy.	• Improves upon the HIDTA by targeting funds for implementing a coordinated drug overdose response strategy, which includes: o Coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdose; o Increasing data sharing among public safety and public health officials on drug-related abuse trends; and o Enabling collaborative resources on substance use addiction and narcotics trafficking.
Sec. 3309. Protecting law enforcement officers from accidental exposure.	• Provides supplemental grants to law enforcement agencies to protect law enforcement from accidental exposure to dangerous narcotics. • Grants may be used for purchasing portable equipment to test for fentanyl and other substances, training law enforcement officers and first responders on best practices, and purchasing protective equipment.
Sec. 3310. COPS Anti-Meth Program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies with high seizures of precursor chemicals, methamphetamine, and laboratories for the purpose of investigating illicit activities, such as diversion, laboratories, or methamphetamine trafficking.
Sec. 3311. COPS anti-heroin task force program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies in states with high rates of treatment admissions, for the purpose of investigating illicit activities. • This task force will function through statewide collaboration with the greater effort to dismantle the distribution of heroin, fentanyl, Carfentanil, or the unlawful distribution of prescription opioids.

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Sec. 3312. Comprehensive Addiction and Recovery Act education and awareness.	• Allows the AG to may grants to entities that focus on addiction and substance use disorders and specialize in family and patient services.
Sec. 3313. Protecting children with addicted parents.	• Requires HHS to disseminate best practices for states on interventions and strategies to keep families affected by substances use disorder together. • Allows the Secretary of HHS to award grants to states, units of local government, and tribal governments to: o Develop programs designed to keep pregnant women who have substance use disorder together with their newborns; and o Support the attendance of children who have a family member with substance use disorder at therapeutic camps or programs aimed at addiction prevention education, coping strategies, and family support initiatives aimed at keeping families together.
Sec. 3314. Reimbursement of substance use disorder treatment professionals.	• Mandates the Comptroller General to submit to Congress a report examining how substance use disorder services are reimbursed. • This is required no later than January 1, 2020.
Sec. 3315. Sobriety Treatment and Recovery Teams (START).	• Authorizes SAMHSA to provide grants to establish Sobriety Treatment and Recovery Teams (START) to determine the effectiveness of pairing social workers and mentors with families that are struggling with substance use disorder and child abuse or neglect.
Sec. 3316. Provider education.	• Requires the AG and Secretary of HHS to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances.
Sec. 3317: Demand Reduction	• Amends the definition of "Demand Reduction" so that it includes responsibilities related to recovery from substance use disorder.
Sec. 3318: Anti-Drug Media Campaign	• Expands the scope of ONDCP's media campaign to focus on anti-drug messages for all age groups and not limiting it to only a "youth" anti-drug media campaign.
Subtitle D: Synthetic Abuse and Labeling of Toxic Substances	
Sec. 3401. Short title.	• Synthetic Abuse and Labeling of Toxic Substances Act of 2017
Sec. 3402. Controlled substance analogues.	• Addresses gap in identifying synthetic analogs to controlled substances that are "not intended for human consumption," which allows bad actors to get around prosecution. • Provides factors to consider when determining whether a controlled substances is intended for human consumption, including marketing and labeling of the substance, difference between advertised vs. sale price, diversion from legitimate channels, and whether the defendant knew the substance intended to be consumed by injection, inhalation, or ingestion.
Subtitle E: Opioid Quota Reform	
Sec. 3501. Short title.	• Opioid Quota Reform Act

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Sec. 3502. Strengthening considerations for DEA opioid quotas.	• Sets mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts. • Requires DEA to explain health benefits if DEA approves any increase in annual opioid quota.
Subtitle F: Preventing Drug Diversion	
Sec. 3601. Short title.	• Preventing Drug Diversion Act of 2018
Sec. 3602. Improvements to prevent drug diversion.	• Requires registrants to design systems to identify and report suspicious orders; also requires DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with States.
Subtitle G: Sense of Congress	
Sec. 3701. Sense of Congress.	• Expresses the Sense of Congress that the Federal Government must work to prevent patient brokers from taking advantage of individuals with substance use disorders, while also ensuring that legitimate entities can continue to assist individuals in need of treatment find reputable providers, sober living, or recovery homes.
TITLE IV: COMMERCE	
Subtitle A: Fighting Opioid Abuse in Transportation	
Sec.4101.Short title.	• Provides that the bill may be cited as the "Fighting Opioid Abuse in Transportation Act."
Sec. 4102. Rail mechanical employee controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate rail mechanical employees as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4103. Rail yardmaster controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate yardmasters as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4104. Department of Transportation public drug and alcohol testing database.	• Requires the Secretary of Transportation to establish and make publicly available on its website a database of drug and alcohol testing data reported by employers for each mode of transportation and to update the database annually, while protecting commercially sensitive data and ensuring individual employers and employees are not identified.
Sec. 4105. GAO report on Department of Transportation's collection and use of drug and alcohol testing data.	• Requires the GAO to review Department of Transportation's Drug and Alcohol Testing Information Management System and to submit a report on the review, including potential recommendations for improvement, to relevant congressional committees.
Sec. 4106. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl.	• Requires the Secretary of HHS to determine, within 6 months, whether the inclusion of fentanyl on the panel of drugs authorized for testing is justified and—if justified— requires the Secretary to issue a revision to HHS mandatory guidelines to include fentanyl on the testing panel. • Requires, if the Secretary of HHS justifies the inclusion of fentanyl and revises the guidelines, the Secretary of Transportation to publish a final rule adding fentanyl to Department of Transportation's testing panel.

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Sec. 4107. Status reports on hair testing guidelines.	• Requires the Secretary of HHS to report to Congress on the status of the final notice for the statutorily-required scientific and technical guidelines for hair testing, within 30 days of enactment of this bill and every 6 months thereafter, until the agency publishes a final notice of guidelines for hair testing. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4108. Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid	• Requires the Secretary of HHS to publish a final notice of mandatory guidelines for oral fluid testing not later than December 31, 2018, based on the notice of proposed mandatory guidelines published in 2015. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4109. Electronic recordkeeping.	• Requires the HHS, not later than 1 year from the date of enactment of this bill, to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval. • Requires the Secretary of Transportation, not later than 30 months from the date of enactment of this bill, to issue a final rule authorizing the use of electronic signatures for all paperless chain of custody forms under part 40 of title 49, Code of Federal Regulations.
Sec. 4110. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.	• Requires the Federal Motor Carrier Safety Administration to submit a report to Congress biannually on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse, until such rule is fully implemented.
Subtitle B: Opioid Addiction Recovery Fraud Prevention	
Sec. 4201. Short title.	• This section would title the subtitle as the "Opioid addiction Recovery Fraud Prevention Act of 2018."
Sec. 4202. Definitions.	• This section would define the term "Opioid Treatment Product" to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term "Opioid Treatment Program" to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term "Opioid Use Disorder" to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.

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Sec. 4203. False or misleading representations with respect to opioid treatment programs and products.	• Section 4203(a) would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. • Section 4203(b) provides that any such violation would be considered a violation of a Federal Trade Commission (FTC) trade regulation rule (TRR), allowing the FTC to seek civil penalties under Section 5 and the remedies set forth in Section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies that it can already obtain under the FTC Act. The maximum civil penalty amount the FTC may seek for violations of TRRs is $41,484 per violation, as currently adjusted for inflation. *See* 15 U.S.C. § 45(m)(1)(A) and 16 C.F.R. § 1.98. The Section 19 remedies for TRR violations include "rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation . . . except that nothing in this subsection is intended to authorize the imposition of any exemplary or punitive damages." *See* 15 U.S.C. § 57b(b).
	• Section 4203(c) would empower states to bring actions in federal court against entities for violations of this section and to obtain appropriate relief. It would also require states to notify the FTC in writing before filing a case if possible, or if not feasible immediately upon filing the action. The FTC would have the authority to intervene in the state action. Once the FTC or the AG on the FTC's behalf files an action, states may not file during the pendency of the FTC action their own actions against a party named in the FTC action alleging the same violation. This section also addresses venue and service of process issues. • Section 4203(d) would preserve the authority of the FTC and the FDA such that nothing in this title shall be construed to limit the authority of the FTC or the FDA.

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1050 K Street NW ▾ Suite 400
Washington ▾ DC 20001-4448
(b)(6)
www.CEPOPonline.org

VIA ELECTRONIC DELIVERY

Tuesday, September 04, 2018

The Honorable [Insert Name]
Committee on [Insert]
[Address]
Washington, DC 20510

RE: Support for S. 2875 and Collaborative Efforts to Improve Access and Coverage to All Food and Drug Administration (FDA)-Approved Treatments for Opioid Use Disorder

Dear Senator [Insert]:

Following the Center for Disease Control and Prevention's recent announcement of preliminary overdose deaths for 2017 and near 10% increase over the previous year, efforts to combat opioid use disorder remain a top priority. In response to activity in both the House and Senate around improving access to all U.S. Food and Drug Administration (FDA)-approved medication-assisted treatment (MAT) products, the Collaborative for Effective Prescription Opioid Policies (CEPOP) and the undersigned organizations encourage you and your colleagues to advance S. 2875, the Comprehensive Opioid Management and Bundled Addiction Treatment (COMBAT) Act of 2018.

CEPOP was formed more than three years ago to develop, disseminate and advocate for balanced solutions to this crisis. With over 80 national participants, CEPOP engages a diverse group of stakeholders to pursue a comprehensive strategy to reduce misuse and promote treatment options. We support effective programs and policies to prevent prescription misuse and overdose, while ensuring patients' access to effective pain and opioid use disorder treatment.

An October 2017 Government Accountability Office (GAO) Report on Medicare oversight of prescription opioid utilization identified 727,000 beneficiaries receiving high doses of opioids and over 300,000 beneficiaries having been diagnosed with an opioid use disorder. Moreover, at this time, Medicare beneficiaries demonstrates one of the fastest growing rates of opioid use disorders, with hospitalizations due to opioid misuse/abuse-related complications continuing to rise. With 6 out of every 1,000 Medicare beneficiaries diagnosed with an opioid use disorder, there are more than 300,000 individuals in need of appropriate, evidence-based treatment and recovery services.[1]

We believe Medicare beneficiaries with an opioid use disorder should have access to all FDA-approved products so that their clinician can identify and provide the most appropriate treatment for any individual. According to a January 2018 report in Health Affairs, only 319 (2.65%) of over 12,000 substance abuse treatment centers offer all three FDA-approved MAT products. Furthermore, eight states at that time did not have a single opioid use disorder treatment center offering all three MAT products.

[1] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238

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As part of the comprehensive treatment protocol for opioid use disorder, it is critical that patients have appropriate access to evidence-based programs, including those offered by opioid treatment programs (OTPs). Healthcare providers operating in OTPs ensure patients receive both evidence-based pharmacologic interventions along with behavioral therapy and related support services. Certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are upwards of 1,500 OTPs operating nationally treating approximately 400,000 patients.

As you and your colleagues continue to advance legislation to address the opioid epidemic, we encourage you to expand access to these life-saving medications for Medicare beneficiaries. Various proposals are currently being discussed within the Senate, some of which create a bundled payment for MAT and wraparound services within the Medicare program while others would first develop a Medicare demonstration around bundled payments and expanded access.

Now is not the time to fund another demonstration as evidence has proven the effectiveness of opioid treatment programs in addressing opioid abuse. Provisions within S. 3120, the Helping to End Addiction and Lessen Substance Use Disorders (HEAL) Act of 2018, simply do not go far enough to ensure access to all FDA-approved MAT products for Medicare beneficiaries. The undersigned organizations support – and we encourage you to do so as well – the COMBAT Act of 2018 (S. 2875) which would create a permanent mechanism for coverage.

Once again, thank you for your leadership to address our nation's opioid epidemic. CEPOP, its participants, and the other organizations included on this letter stand ready to assist in any way possible. Please contact Matt Rubin ((b)(6) or (b)(6) with any questions.

Respectfully,

[INSERT SIGNATORIES]

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[EXTERNAL] CEPOP Quarterly In-Person All-Participants Meeting (Sept. 2018) - AGENDA ATTACHED

From: "Rubin, Matthew J." <(b)(6)

To: "Terry McGeeney, MD, MBA" <(b)(6) "Hanson, Roberta J." <(b)(6) Jeremiah Lindemann <(b)(6) "Tim Hermes (<(b)(6) <(b)(6) Jane Terry <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) Carol Thornton <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) "Gen. Arthur Dean" <(b)(6) Patricia D'Antonio <(b)(6) Melissa Ough <(b)(6) Keysha Brooks-Coley (b)(6) John Donahue <(b)(6) Gabrielle de la Gueronniere <(b)(6) "Rachel Rivera (<(b)(6) <(b)(6) Myra Christopher <(b)(6) David May <(b)(6) James Appleby <(b)(6) "Gabriella Witte (APHA)" <(b)(6) Brad Tallamy <(b)(6) "Christian, Jeanine M" <(b)(6) Alice Dembner <(b)(6) Caren Kagan Evans <(b)(6) Vince Ventimiglia <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Patel, Beena S." <(b)(6) "Dr. Anita Gupta" <(b)(6) Kevin Walker <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Erika Long <(b)(6) "Kathryn L. Cates-Wessel" <(b)(6) "Cristi L. Schwarcz" <(b)(6) Brian Bowden <(b)(6) Gary Mendell <(b)(6) "Zook, David R." <(b)(6) Charlie Cichon <(b)(6) Van Ingram <(b)(6) Rebecca Farley <(b)(6) Scott Proescholdbell <(b)(6) Courtney Hunter <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Becky Salay <(b)(6) Michael DeGeorge <(b)(6)

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Susan Weinstein <(b)(6) Sonya Clay <(b)(6) Mike Smith <(b)(6) Daniel Raymond <(b)(6) Sara patterson <(b)(6) "Dr. Renan Castillo" <(b)(6) "Dr. Jack Stein" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) Robert Forman <(b)(6) "Robin Swift (b)(6) <(b)(6) "Sue Thau (Gmail)" <(b)(6) Steve Passik <(b)(6) "Jessica Johnston (BD)" <jessica(b)(6) Marcia Lee Taylor <(b)(6) Rebecca Slater Abbott <(b)(6) Elizabeth Solhtalab <(b)(6) Nicole Burda <(b)(6) "Sarah Nerad (Alkermes)" <(b)(6) Nick Motu <(b)(6) Kate Berry <(b)(6) "Evans, Daniel F." <(b)(6) Paul Ross <(b)(6) "Clay Alspach (b)(6) <(b)(6) Chris Zimmerman <(b)(6) Shalini Wickramatilake <(b)(6) Samantha Arsenault (b)(6), Susan Awad <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Dennis Brennan <(b)(6) "Hannah Riffle (b)(6) <(b)(6) David Trewolla <(b)(6) Donald Hoppert <(b)(6) Hadi Sedigh <(b)(6) Mary Winnefeld <(b)(6) Dan Buffington <(b)(6) Rob Morrison <(b)(6) "Derek Naten (MNK)" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Jeffrey Ekoma <(b)(6) "Alexander, Tesfa" <(b)(6) Chuck Ingoglia <(b)(6) Patricia Bruckenthal <(b)(6) John O'Brien <john.(b)(6) Kate McFadyen <(b)(6) Amanda Sears <(b)(6) Aiken Hackett <(b)(6) Aryka Chapman <(b)(6) Jason Sundby <(b)(6) Shelley Starkey <(b)(6) Lorraine Yarde <(b)(6) Amy

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Callendar <(b)(6) Wade Delk <(b)(6) Eli Briggs <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) "Bono, Mary" <(b)(6) Karen Tracy <(b)(6) "Cara Moon (Egalet)" <(b)(6) Geoffrey Laredo <(b)(6) "Celia Hagan (NILA)" <(b)(6) Rita Norton <(b)(6) Ed Kaleta <(b)(6) Patricia Farley <(b)(6) Blair Clark-Schoeb <(b)(6) "Nadine Gracia (b)(6) <(b)(6) "Danna Droz (NABP)" <(b)(6) "Everett Crosland (Pear Therapeutics)" <(b)(6) Teresa Baker <(b)(6) "Dr. John Harrison" <(b)(6) "Emmanuel Oga (Battelle)" <(b)(6) (b)(6) Judi Lund Person (b)(6) Kathleen O'Conner <(b)(6) Julian Hoffman <(b)(6) Andrew kessler <(b)(6) Addie Liles <(b)(6) Sue Thau <(b)(6) Tracie Thomas <(b)(6) Kimberly Wilkinson <(b)(6)

Cc: "Patterson, Sara S. (CDC/CDC OD/PPEO)" <(b)(6)

Date: Mon, 17 Sep 2018 13:24:13 -0400

Attachments: CEPOP Quarterly All-Participants Meeting Agenda (Sept. 2018).pdf (34.74 kB); Opioid Crisis Response Act Section-by-Section.pdf (540.57 kB); CEPOP Senate Letter on MAT Access (Aug. 2018).pdf (108.51 kB); Overdose-Lifeline-Youth-Program-2-Up.pdf (1.93 MB); Overdose-Lifeline-Youth-Program.pdf (229.33 kB); not supported calendar message.ics (18.12 kB)

CEPOP Participants – In advance of our upcoming quarterly, in-person All-Participants meeting, please find the agenda attached below. We are pleased to have three fantastic focus topic speakers for this month's All-Participants meeting, including:

- **The Honorable Leslie Rutledge**, Arkansas Attorney General
- **Kourtnaye Sturgeon**, Overdose Lifeline
- **Ali Toal**, United States Senator Corey Gardner (CO)

We look forward to a productive discussion on Monday afternoon. As always, please do not hesitate to reach out with any questions.

Meeting Location

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Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

For those unable to attend in-person, a WebEx will be made available to all participants to participate remotely.

- To join WebEx, please **CLICK HERE.**
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP QUARTERLY IN-PERSON ALL-PARTICIPANTS MEETING

Date: Monday, September 17, 2018

Time: 3:00pm – 4:30pm EST

WebEx: **Faegre Baker Daniels Consulting** (1050 K Street NW, Suite 400)
To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions: 2018 Work Plan Emphasis on Youth Prevention

- **A. Prescription for Life, Youth Education and the State Response to the Opioid Epidemic**
  The Honorable Leslie Rutledge, *Arkansas Attorney General*
- **B. Youth Education and Outreach – "This is (not) About Drugs" Program**
  Kourtnaye Sturgeon, *Board Member and Education Committee Chair, Overdose Lifeline*
- **C. Discussion**: Opportunities to Advance Primary Prevention Strategies
  - **i.** 1Q2019 Briefing or Convening on Prevention
  - **ii.** Potential CEPOP Panel at Rx Summit on Primary Prevention Strategies

III. Advocacy and Policy Priorities

- **A.** Updates on Congressional Opioid Activity
  - **i.** Status on House and Senate Legislation
    1. CEPOP Priorities (MAT Access in Medicare; Safe Disposal)
    2. Anticipated Timeline
- **B.** FY2019 Appropriations Update (ONDCP, HIDTA, Drug Free Communities)
- **C.** White House Announces DFC Program Funding with CADCA (link)
- **D.** EPA Memo on Law Enforcement Drug Disposal (link)

IV. Focus Topic Discussion #2

- **A. Preventing Drug Diversion with Realtime Data-Sharing:** DEA Order Clearinghouse Act of 2018 (S. 3282)
  Ali Toal, *Legislative Assistant, U.S. Senator Cory Gardner (CO)*

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V. Working Groups

A. Takeback and Anti-Diversion

i. CEPOP-BD Initiative on Acute Care Diversion Prevention

B. Safe Use and Prevention

i. Abuse-Deterrent Formulations Non-Therapeutic Benefits Roundtable

1. FDA Commissioner Gottlieb's Remarks on Advancing ADFs at National Press Club Event (August 17); Alignment with April 2018 CEPOP-FDA Meeting

ii. Engagement with Johns Hopkins University *Stigma Lab*

VI. Organizational Updates; Sharing Intel, Participant News and Updates

Next Monthly CEPOP All-Participants Teleconference: Monday, October 29th, 3:00pm – 4:00pm

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TITLE I: Opioid Crisis Response Act	
Sec. 1001. Definitions.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle A: Reauthorization of Cures Funding	
Sec. 1101. Cures Funding Extension.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
Subtitle B: Research and Innovation	
Sec. 1201. Advancing Cutting-Edge Research.	• Allows the National Institutes of Health (NIH) to use its "other transactions authority" for high impact cutting-edge research projects that respond to public health threats, including the opioid crisis and finding a new, non-addictive painkiller. NIH was given this authority for the Precision Medicine Initiative and fifty percent of the Common Fund in the 21st Century Cures Act.
Sec. 1202. Pain Research	• Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the Food and Drug Administration.
Sec. 1203. Report on Synthetic Drug Use	• Requires the Secretary of HHS to submit to Congress a report on the health effects of new psychoactive substances, including synthetic drugs, by adolescents and young adults.
Subtitle C: Medical Products & Controlled Substances Safety	

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Sec. 1301. Clarifying FDA Regulations for Non-Addictive and Non-Opioids Products.	• Clarifies the development and regulatory pathways of the Food and Drug Administration (FDA) for medical product manufacturers through guidance for new non-addictive medical products intended to treat pain or addiction. • Requires the FDA to hold one or more public meeting on the challenges and barriers to developing non-addictive medical products intended to treat pain, including how the risk of misuse and abuse may be incorporated into FDA's assessments, novel clinical trial designs, and evidentiary standards related to opioid sparing. • Requires the FDA to issue guidance to address: ○ *Expedited Pathways* – To help medical product manufacturers navigate FDA, this would clarify FDA's interpretation of how the qualification parameters for expedited pathways like Breakthrough Designation and Accelerated Approval apply to novel non-addictive pain or addiction treatments. ○ *Pain Endpoints* – To help medical product manufacturers design clinical trials for innovative non-addictive pain treatments, this would require FDA to provide guidance on the appropriate use of pain endpoints across review divisions. ○ *Opioid Sparing* – To help advance the development of products that can reduce, replace, or avoid patients' use of opioids to control pain, this would direct FDA to clarify requirements for opioid sparing data to be used in the label that a medicine is as

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	effective at controlling pain and able to reduce, replace, or avoid the amount of opioids a patient needs to control pain. ○ *Risk Benefit related to Misuse and Abuse* – To clarify FDA's role in protecting public health, this would require FDA to provide clear guidance on how the agency will consider the risks and benefits of drugs that have a potential to be misused or abused.
Sec. 1302. Clarifying FDA Packaging Authorities.	• Clarifies FDA's authority to require drug manufacturers to package certain opioids to allow for a set treatment duration – for example, a blister pack with a 3 or 7-day supply. • Clarifies FDA's authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.
Sec. 1303. Strengthening FDA & CBP Coordination & Capacity.	• Improves detection and seizure of illegal drugs, such as fentanyl, by strengthening coordination activities between FDA and the United States Customs and Border Protection (CBP), which may be carried out through a memorandum of understanding between such agencies. • Provides facility and physical infrastructure improvements, including renovations or upgrades, and laboratory capacity for purposes of detection and testing imports. • Provides that FDA has access to innovative detection technology and testing equipment to facilitate near-real-time information sharing. • Requires a report on implementation and summary of progress made towards near-real-time information sharing and the interoperability of such technologies.
Sec. 1304. Clarifying FDA post-market authorities.	• Clarifies FDA's post-market authorities for drugs, such as opioids, which may have reduced efficacy over time, by modifying the definition of an adverse drug experience to include such situations.
Sec. 1305. Restricting Entrance of Illicit Drugs	• Codifies the current practice of FDA upon discovering or receiving a package containing an illegal opioid or controlled substance, FDA will transfer that package to CBP for destruction under CBP's existing authorities. • Debars a person from importing an FDA-regulated product into the US if they have been convicted of a felony related to importation of illegal drugs or controlled substances. • Gives FDA greater ability to refuse the admission of counterfeit drugs.
Sec. 1306. First Responder Training.	• Expands a grant program authorized by the Comprehensive Addiction and Recovery Act, which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose, and to include training on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.
Sec. 1307. Disposal of Controlled Substances by Hospice Programs.	• Provides certain health professionals in qualified hospice programs the legal authority to dispose of controlled substances in the hospice setting to help reduce the risk of diversion or misuse.

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Sec. 1308. GAO Study and Report on Hospice Safe Disposal Management.	• Requires the Government Accountability Office (GAO) to conduct a study and report on hospice programs' written policies and procedures on the management and disposal of controlled substances in the home of an individual.
Sec. 1309. Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation.	• Permits implantable or injectable controlled substances for the purpose of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner, while maintaining proper controls, such as storage and record keeping.
Subtitle D: Treatment & Recovery	
Sec. 1401. Comprehensive Opioid Recovery Centers.	• Authorizes a grant program through the Substance Abuse and Mental Health Services Administration (SAMHSA) for entities to establish or operate comprehensive opioid recovery centers that serve as a resource for the community. These entities may utilize the ECHO model, which supports care coordination and services delivery through technology.
Sec. 1402. Program to support coordination and continuation of care for drug overdose patients.	• Requires the Secretary of the Department of Health and Human Services (HHS) to issue best practices for emergency treatment of a known or suspected drug overdose, use of recovery coaches after a non-fatal overdose, coordination and continuation of care and treatment after an overdose, and provision of overdose reversal medication, as appropriate. • Authorizes a grant program for education on overdose prevention, the establishment or implementation of policies and procedures to treat and support recovery for individuals who have experienced a non-fatal
Sec. 1403. Alternatives to opioids.	• Requires HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. • Authorizes a grant program to support hospitals and other acute care settings that manage pain with alternatives to opioids.
Sec. 1404. Building communities of recovery.	• Reauthorizes and modifies the Building Communities of Recovery program to include peer support networks. This program provides funding for community organizations providing long-term recovery support services.
Sec. 1405. Peer support technical assistance center.	• Requires HHS to establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, to provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to substance use disorder.
Sec. 1406. Medication-Assisted Treatment for Recovery from Addiction.	• Allows physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements to prescribe medication-assisted treatment (MAT), to obtain a waiver to prescribe MAT.
Sec. 1407. Grant Program.	• Authorizes a grant program to support development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.
Sec. 1408. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.	• Codifies the ability of qualified physicians to prescribe MAT for up to 275 patients, to improve access to MAT.

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Sec. 1409. Recovery Housing Best Practices and Identification of Potentially Fraudulent Recovery Housing Operators.	• Requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid addiction with housing. • Requires HHS to identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.
Sec. 1410. Addressing Economic & Workforce Impacts of the Opioid Crisis.	• Authorizes the Department of Labor to award dislocated worker grants to states through the Workforce Innovation and Opportunity Act to support local workforce boards and local partnerships in tackling shortages in substance use disorder and mental health treatment workforce and provide coordinated job training and treatment services to individuals in affected communities with opioid or substance use disorder.
Sec. 1411. CAREER Act	• Authorizes the Secretary of HHS to establish a grant program to support individuals in recovery from a substance use disorder transition to independent living and the workforce.
Sec. 1412. Pilot Program to Help Individuals in Recovery from a Substance Use Disorder become Stably Housed	• Authorizes a pilot program to provide individuals in recovery from a substance use disorder with stable, temporary housing.
Sec. 1413. Youth Prevention and Recovery.	• Requires the Secretary of HHS in consultation with the Department of Education, to disseminate best practices, establish a resource center to provide technical assistance, and issue grants for prevention of and recovery from substance use disorder in children, adolescents and young adults.
Sec. 1414. Plans of Safe Care.	• Provides support for states to collaborate and improve plans of safe care for substance-exposed infants. States may use funds to coordinate with various agencies responsible for child and family wellbeing, develop policies and procedures, train health care and child welfare professionals, establish partnerships, and develop and update technology and monitoring systems to more effectively implement plans of safe care. Requires the Secretary to extend technical assistance programs and issue guidance on plans of safe care.
Sec. 1415. Regulations Relating to Special Registration for Telemedicine.	• Clarifies the ability of the Drug Enforcement Administration (DEA) to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
Sec. 1416. National Health Service Corps Behavioral and Mental Health Professionals Providing Obligated Services in Schools and other Community-Based Settings.	• Allows an entity to direct National Health Service Corps participants to provide behavioral and mental health services at a school or other community-based setting located in a health professional shortage area, and for these services to be applied towards completion of their obligated service requirements.
Sec. 1417. Loan Repayment for Substance Abuse Treatment Providers.	• Requires the Secretary of HHS to enter into contracts to provide loan repayment to behavioral health providers practicing in substance use disorder treatment facilities in mental health professional shortage areas through National Health Service Corps authorities.

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Sec. 1418. Protecting moms and infants.	• Requires the Secretary of HHS to issue and periodically update a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to the Protecting Our Infants Act of 2015. • Reauthorizes the Residential Treatment for Pregnant and Postpartum Women grant program.
Sec. 1419. Early interventions for pregnant women and infants.	• Requires the Center for Substance Abuse Prevention to develop, in cooperation with the Centers for Disease Control and Prevention (CDC), educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy. • Requires implementation and dissemination, as appropriate, of the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy," issued by HHS in 2017.
Sec. 1420. Report on investigations regarding parity in mental health and substance use disorder benefits.	• Requires the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Secretary of the Treasury, to provide additional information in annual reports to Congress on mental health parity compliance, including information on which agencies are conducting investigations and information about any coordination with State regulators.
Subtitle E: Prevention	
Sec. 1501. Study on Prescribing Limits.	• Requires HHS, in consultation with the Attorney General (AG), to submit to Congress a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions.
Sec. 1502. Programs for health care workforce.	• Increases education and training in pain care by requiring grant recipients to develop a comprehensive education and training plan. Such plan would include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. • Updates pain care programs to include alternatives to opioid pain treatment and by promoting non-addictive and non-opioid pain treatments, and non-pharmacologic treatment. • Updates mental and behavioral health education and training grant program to include trauma-informed care.
Sec. 1503. Education and Awareness Campaigns.	• Advances education and awareness among the public and providers. With regards to providers, advances continuing education to promote improved prescribing practices and improved education on and use of evidence-based prescribing guidelines across health care settings. • Provides education and awareness for providers, patients, and consumers about the prescribing and dispensing options related to partial fills of controlled substances in the Controlled Substances Act.
Sec. 1504. Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.	• Authorizes the CDC's work to combat the opioid crisis through the collection, analysis, and dissemination of data, including through grants for states, localities, and tribes.

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Sec. 1505. Preventing Overdoses of Controlled Substances.	• Provides support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs) and implement other evidence-based prevention strategies, encourages data sharing between states, and supports other prevention and research activities related to controlled substances.
Sec. 1506. CDC Surveillance and Data Collection for Child, Youth, and Adult Trauma	• Authorizes CDC to support states' efforts to collect and report data on adverse childhood experiences through existing public health surveys.
Sec. 1507. Reauthorization of NASPER.	• Reauthorizes this HHS grant program to allow states to develop, maintain, or improve PDMPs and improve the interoperability of PDMPs with other states and with other health information technology.
Sec. 1508. Jessie's Law.	• Requires HHS to develop best practices for prominently displaying substance use treatment information in electronic health records, when requested by the patient.
Sec. 1509. Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records.	• Requires HHS to identify Model Programs and Materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.
Sec. 1510. Communication with Families During Emergencies	• Requires the Secretary to notify providers annually regarding sharing of certain health information with family and caregivers during an emergency such as an overdose.
Sec. 1511. Prenatal and Postnatal Health.	• Authorizes data collection and analysis on neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.
Sec. 1512. Surveillance and Education Regarding Infections Associated with Injection Drug Use and Other Risk Factors.	• Reauthorizes and builds upon CDC's program to prevent and respond to infections commonly associated with injection drug use, including viral hepatitis and HIV, by supporting state and federal efforts to collect data on such infections and identify and assist patients who may be at risk of infection.
Sec. 1513. Task Force To Develop Best Practices For Trauma-Informed Identification, Referral, and Support.	• Creates an interagency task force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants, children, youth, and their families. • Requires the task force to develop a set of best practices and national strategy, and to identify existing federal authorities and grant programs where trauma-informed practices are allowable. • Requires the task force to submit a final report of findings and recommendations to Congress, relevant cabinet Secretaries, and the general public not less than three years after its first meeting.
Sec. 1514. Grants to Improve Trauma Support Services and Mental Health Care for Children and Youth in Educational Settings.	• Authorizes the Secretary of Education, in coordination with the Assistant Secretary of Mental Health and Substance Use, to make grants that link educational agencies with mental health systems in order to increase student access to evidence-based trauma support services to help prevent and mitigate trauma that children and youth experience. • Requires the Secretary to conduct a rigorous, independent analysis and disseminate findings from the demonstration grants.
Sec. 1515. National Child Traumatic Stress Initiative.	• Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to

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	communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.
Sec. 1516. National Milestones to Measure Success in Curtailing the Opioid Crisis	• Requires the Secretary of HHS to develop or identify existing national indicators to measure success in curtailing the opioid crisis and significantly reversing the incidence and prevalence of opioid misuse and abuse and opioid-related morbidity and mortality in the United States within 5 years of enactment.
TITLE II: HEAL Act of 2018	
Sec. 2001. Short title.	• "Helping to End Addiction and Lessen Substance Use Disorders Act of 2018" or the "HEAL Act of 2018"
Subtitle A: Medicare	
Sec. 2101. Medicare opioid safety education.	• Requires that the annual *Medicare & You* handbook for Medicare beneficiaries include: references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.
Sec. 2102. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.	• Eliminates certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders, beginning January 1, 2019. • Allows payment for substance use disorder treatment services furnished via telehealth to Medicare beneficiaries at originating sites, including a beneficiary's home, regardless of geographic location. A separate facility fee would not be provided if the originating site is the beneficiary's home.
Sec. 2103. Comprehensive screenings for seniors.	• Requires that Medicare Initial Preventive Physical Examination (also known as the "Welcome to Medicare" visit) and annual wellness visits include a review of the beneficiary's current opioid prescriptions and screening for potential substance use disorders, including a referral to treatment as appropriate.
Sec. 2104. Every prescription conveyed securely.	• Requires that physicians and other practitioners prescribe Part D-covered controlled substances electronically so as to improve tracking of opioid use and prevent diversion. • Directs the Centers for Medicare and Medicaid Services (CMS) to establish a list of exceptions, as well as the penalty for failure to comply when the e-prescribing requirement applies, in consultation with stakeholders.
Sec. 2105. Standardizing electronic prior authorization for safe prescribing.	• Requires that prior authorizations related to Part D prescriptions that are processed electronically use a standard format, improving the efficiency with which prior authorizations are processed and enabling beneficiaries to more promptly receive needed drugs.
Sec. 2106. Strengthening partnerships to prevent opioid abuse.	• Requires CMS to establish a web-based portal to enhance communication between the agency, Medicare Advantage plans with prescription drug plans (MA-PDs), standalone prescription drug plans, and Medicare Drug Integrity Contractors, enhancing the ability to address fraud, waste, and abuse.

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Sec. 2107. Commit to opioid medical prescriber accountability and safety for seniors.	• Requires CMS to notify Part D prescribers who are identified as a statistical outlier when it comes to prescribing opioids as compared to their peers, with the notification including the peer comparison details and information on evidence-based opioid prescribing guidelines. • Directs CMS to connect the prescribers identified as a persistent statistical outlier with entities that provide educational assistance, and gives CMS authority to require those prescribers to enroll in Medicare.
Sec. 2108. Fighting the opioid epidemic with sunshine.	• Enhances the CMS-run Open Payments, or "sunshine", program by expanding the types of professionals for whom a drug and device manufacturer is required to report when the manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. • Sunsets the prohibition that prevents inclusion of the unique identification number, known as the National Provider Identifier, for all professionals and other entities displayed on the CMS Open Payments website.
Sec. 2109. Demonstration testing coverage of certain services furnished by opioid treatment programs.	• Requires that the HHS Secretary conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder treatment services furnished by an eligible Opioid Treatment Program, to begin no later than January 1, 2021. • An eligible OTP selected to participate in the demonstration would receive a bundled payment made under Part B for opioid use disorder treatment services. Those treatment services would include dispensing and administering FDA-approved opioid agonist and antagonist treatment medication, substance use disorder counseling, individual and group therapy, toxicology testing, and other services determined appropriate by the HHS Secretary. • Directs the HHS Secretary to provide a report to Congress that includes an evaluation of the demonstration no later than two years after its completion.
Sec. 2110. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.	• Requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in its system for monitoring those potentially at-risk for prescription drug abuse, enabling prescription drug plans to take steps that inform prescribers and dispensing pharmacies and facilitate improved care.
Sec. 2111. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.	• Requires that a beneficiary enrolled in Medicare Part D who CMS identifies as potentially at-risk for prescription drug abuse (or is subsequently identified as at-risk) can automatically escalate an appeal of such designation to an entity external to the prescription drug plan if the plan affirms its own decision at the initial appeal level.

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Sec. 2112. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.	• Clarifies that the CMS Center for Medicare and Medicaid Innovation may test payment and delivery models that provide incentive payments to behavioral health providers for the adoption and use of certified electronic health record technology to improve the quality and coordination of care through the electronic documentation and exchange of health information.
Sec. 2113. Medicare Improvement Fund.	• Deposits $65 million into the Medicare Improvement Fund that is available to CMS to make improvements under the original Medicare fee-for-service program.
Subtitle B: Medicaid	
Sec. 2201. Caring recovery for infants and babies.	• Clarifies states' ability under Medicaid to provide care for infants with neonatal abstinence syndrome in residential pediatric recovery centers, as well as those centers' option to provide counseling or other services to mothers or caretakers provided those services are otherwise covered.
Sec. 2202. Peer support enhancement and evaluation review.	• Directs the GAO to study and submit a report on how Medicaid covers peer support services, including: the types of services provided; payment models; states' experiences providing peer support services; and how states measure the extent to which peer support services improve costs and outcomes for beneficiaries.
Sec. 2203. Medicaid substance use disorder treatment via telehealth.	• Directs CMS to issue guidance to states on options for providing services via telehealth that address substance use disorders under Medicaid. Requires guidance to cover state options for federal reimbursement for substance use disorder services and treatment using telehealth including, services addressing high-risk individuals, provider education through a hub-and-spoke model, and options for providing telehealth services to students in school-based health centers. • Directs GAO to evaluate children's access to Medicaid services to treat substance use disorders, including options to improve access through telehealth. • Directs CMS to issue a report to Congress identifying best practices and potential solutions to barriers to furnishing services to children via telehealth to compare services delivered via telehealth to in-person.
Sec. 2204. Enhancing patient access to non-opioid treatment options.	• Directs CMS to issue guidance on states' options for treating and managing beneficiaries' pain through non-opioid pain treatment and management options under Medicaid.
Sec. 2205. Assessing barriers to opioid use disorder treatment.	• Directs GAO to analyze and issue a report to Congress on the barriers to access to substance use disorder treatment medications under various drug distribution models, such as buy-and-bill, as well as addressing options for state Medicaid programs to reduce or remove such barriers. GAO is directed to make recommendations, as appropriate.

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Sec. 2206. Help for moms and babies.	• Modifies the "IMD exclusion" for pregnant and postpartum women to address a subset of the prohibition on Medicaid from paying for otherwise coverable Medicaid services for certain adults while in institutions for mental disease (IMD). Modifies Section 1905(a) of the Social security act to ensure that pregnant and postpartum women receiving care for substance use disorders in an IMD can continue to receive other Medicaid-covered care outside of the IMD, such as prenatal services.
Sec. 2207. Securing flexibility to treat substance use disorders.	• Clarifies flexibilities around Medicaid's IMD exclusion where, in some cases, managed care plans may provide alternative services in lieu of other services that are not permitted under the state plan. Codifies regulations permitting managed care plans to cover treatment in an IMD for a certain number of days in a month in lieu of other types of services.
Sec. 2208. MACPAC study and report on MAT utilization controls under State Medicaid programs.	• Directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on utilization management controls applied to medication-assisted treatment options in both fee-for-service and managed Medicaid programs.
Sec. 2209. Opioid addiction treatment programs enhancement.	• Requires the Secretary to publish a data book detailing, for each state, statistics on the prevalence and treatment of substance abuse disorder among Medicaid beneficiaries, including beneficiaries receiving treatment under fee for service and managed care arrangements. Requires the data book to be issued within one year and use data from the Transformed Medicaid Statistical Information System (T-MSIS). Requires HHS to make T-MSIS data available to researchers in the same manner in which precursor data had been made available in the past, including relevant privacy and security protections.
Sec. 2210. Better data sharing to combat the opioid crisis.	• Clarifies states' ability to access and share data from prescription drug monitoring program databases, consistent with the parameters established in state law, including with providers and managed care entities, and in adherence to applicable security and privacy protections and laws.
Sec. 2211. Mandatory reporting with respect to adult behavioral health measures.	• Requires state Medicaid programs to report on all behavioral health quality measures included in the mandatory core set of adult health quality measures beginning 2024.
Sec. 2212. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.	• Directs HHS to issue a report on innovative state initiatives and covered housing-related services that state Medicaid programs may use to provide supports to Medicaid enrollees with substance use disorders who are experiencing homelessness or are at risk of homelessness.

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Sec. 2213. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.	• Directs HHS to provide technical assistance to states to develop and coordinate housing-related supports and services under Medicaid, either through state plans or waivers, and care coordination services, for Medicaid enrollees with substance use disorders.
Subtitle C: Human Services	
Sec. 2301. Supporting family-focused residential treatment.	• Requires HHS to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment programs by: o Describing existing opportunities under Medicaid to support parents in family-focused residential treatment; o Explaining how states can coordinate Medicaid, foster care, and other HHS funding to support substance abuse treatment and other services provided by treatment facilities; and o Describing how states can coordinate Medicaid and foster care funding—specifically per the new authority granted in the *Family First Prevention Services Act*—to support children placed with their parents in family-based treatment facilities.
Sec. 2302. Improving recovery and reunifying families.	• Provides $15 million to HHS to replicate a "recovery coach" program for parents with children in foster care due to parental substance abuse, which has been shown to reduce the length of time children spend in foster care. This will allow HHS to determine whether the program can be replicated in another state and yield the same results.
Sec. 2303. Building capacity for family-focused residential treatment.	• Beginning in FY 2020, states will be eligible to receive funding to provide evidence-based substance abuse prevention and treatment services to families with children at risk of entering foster care (as a result of the *Family First Prevention Services Act*). This section authorizes $20 million in funding for HHS to award to states to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that will later qualify for funding under *Family First*.
Subtitle D: Synthetics Trafficking and Overdose Prevention	
See separate section by section of S.3057.	
TITLE III: JUDICIARY	
Subtitle A: Access to Increased Drug Disposal	
Sec. 3101. Short title.	• Access to Increased Drug Disposal Act of 2018
Sec. 3102. Definitions.	• Defines terms "Attorney General," "authorized collector," "covered grant," and "eligible collector."
Sec. 3103. Authority to make grants.	• Allows the AG to award grants to States to increase the participation of eligible collectors as authorized collectors for drug-disposal programs.

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Sec. 3104. Application.	• Outlines the requirements that a state must meet if submitting an application for a grant, which includes: ○ Identifying a state agency that oversees pharmaceutical care; ○ Detailing a plan to increase participation rates of authorized collectors; and ○ Describing how the state will select eligible collectors to be served under the grant.
Sec. 3105. Use of grant funds.	• Limits the use of the grant that a state receives to the costs of installation, maintenance, training, purchasing, and disposal of controlled substance associated with the participation of collectors.
Sec. 3106. Eligibility for grant.	• Requires that the AG shall award a grant to five states, not less than three of which are in the lowest 25 percent of states in participation rates for drug take-back programs.
Sec. 3107. Duration of grants.	• Allows the AG to determine the period of years for which the grant is made to the state.
Sec. 3108. Accountability and oversight.	• Requires a state that receives a grant to provide a report to the AG that lists the recipients of grant amounts, describes the activities used by the grant amounts, and contains performance measures as to the effectiveness of the grant, including participation rates.
Sec. 3109. Duration of program.	• Limits the AG to award grants for each of the first 5 fiscal years after enactment.
Sec. 3110. Authorization of appropriations.	• Outlines that there are authorized to be appropriated to the AG such sums as may be necessary to carry out this Act.
Subtitle B: Using Data to Prevent Opioid Diversion	
Sec. 3201. Short title.	• Using Data to Prevent Opioid Diversion Act of 2018
Sec. 3202. Purpose.	• States the purpose of the bill, which is to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids which will in turn reduce diversion rates.
Sec. 3203. Amendments.	• Requires DEA to make anonymized information available to registrants with access to ARCOS, including the total number of distributors serving a single pharmacy or practitioner, and the total number of opioid pills distributed to a single pharmacy or practitioner. • Mandates that DEA share information on amounts, outliers, and trends of distributor and pharmacy registrants. • Increases civil and criminal penalties for drug manufacturers and distributors.
Sec. 3204. Report.	• Requires DEA to report to Congress on how it is using ARCOS data to identify and stop suspicious orders of opioids.
Subtitle C: Substance Abuse Prevention	
Sec. 3301. Short title.	• Substance Abuse Prevention Act of 2018

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Sec. 3302. Reauthorization of the Office of National Drug Control Policy.	• Reauthorizes the Office of National Drug Control Policy (ONDCP) at the White House, which oversees all Executive Branch efforts on narcotics control, including the development of a national drug control strategy.
Sec. 3303. Reauthorization of the Drug-Free Communities Program.	• Reauthorizes the Drug-Free Communities (DFC) Program through 2022. DFC is a grant program administered by ONDCP that works to prevent youth substance abuse and reduce the demand for illicit narcotics at a community level.
Sec. 3304. Reauthorization of the National Community Anti-Drug Coalition Institute.	• Reauthorizes the National Community Anti-Drug Coalition Institute through 2022.
Sec. 3305. Reauthorization of the High-Intensity Drug Trafficking Area Program.	• Reauthorizes the ONDCP High-Intensity Drug Trafficking Area (HIDTA) Program. HIDTA provides funding for federal, state, and local law enforcement task forces operating in our nation's most critical drug trafficking regions.
Sec. 3306. Reauthorization of drug court program.	• Reauthorizes Department of Justice funding for drug courts through 2022.
Sec. 3307. Drug court training and technical assistance.	• Allows non-profit organizations to provide important training and technical assistance to drug courts.
Sec. 3308. Drug overdose response strategy.	• Improves upon the HIDTA by targeting funds for implementing a coordinated drug overdose response strategy, which includes: o Coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdose; o Increasing data sharing among public safety and public health officials on drug-related abuse trends; and o Enabling collaborative resources on substance use addiction and narcotics trafficking.
Sec. 3309. Protecting law enforcement officers from accidental exposure.	• Provides supplemental grants to law enforcement agencies to protect law enforcement from accidental exposure to dangerous narcotics. • Grants may be used for purchasing portable equipment to test for fentanyl and other substances, training law enforcement officers and first responders on best practices, and purchasing protective equipment.
Sec. 3310. COPS Anti-Meth Program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies with high seizures of precursor chemicals, methamphetamine, and laboratories for the purpose of investigating illicit activities, such as diversion, laboratories, or methamphetamine trafficking.
Sec. 3311. COPS anti-heroin task force program.	• Authorizes the AG to make competitive grants available to state law enforcement agencies in states with high rates of treatment admissions, for the purpose of investigating illicit activities. • This task force will function through statewide collaboration with the greater effort to dismantle the distribution of heroin, fentanyl, Carfentanil, or the unlawful distribution of prescription opioids.

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Sec. 3312. Comprehensive Addiction and Recovery Act education and awareness.	• Allows the AG to may grants to entities that focus on addiction and substance use disorders and specialize in family and patient services.
Sec. 3313. Protecting children with addicted parents.	• Requires HHS to disseminate best practices for states on interventions and strategies to keep families affected by substances use disorder together. • Allows the Secretary of HHS to award grants to states, units of local government, and tribal governments to: o Develop programs designed to keep pregnant women who have substance use disorder together with their newborns; and o Support the attendance of children who have a family member with substance use disorder at therapeutic camps or programs aimed at addiction prevention education, coping strategies, and family support initiatives aimed at keeping families together.
Sec. 3314. Reimbursement of substance use disorder treatment professionals.	• Mandates the Comptroller General to submit to Congress a report examining how substance use disorder services are reimbursed. • This is required no later than January 1, 2020.
Sec. 3315. Sobriety Treatment and Recovery Teams (START).	• Authorizes SAMHSA to provide grants to establish Sobriety Treatment and Recovery Teams (START) to determine the effectiveness of pairing social workers and mentors with families that are struggling with substance use disorder and child abuse or neglect.
Sec. 3316. Provider education.	• Requires the AG and Secretary of HHS to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances.
Sec. 3317: Demand Reduction	• Amends the definition of "Demand Reduction" so that it includes responsibilities related to recovery from substance use disorder.
Sec. 3318: Anti-Drug Media Campaign	• Expands the scope of ONDCP's media campaign to focus on anti-drug messages for all age groups and not limiting it to only a "youth" anti-drug media campaign.
Subtitle D: Synthetic Abuse and Labeling of Toxic Substances	
Sec. 3401. Short title.	• Synthetic Abuse and Labeling of Toxic Substances Act of 2017
Sec. 3402. Controlled substance analogues.	• Addresses gap in identifying synthetic analogs to controlled substances that are "not intended for human consumption," which allows bad actors to get around prosecution. • Provides factors to consider when determining whether a controlled substances is intended for human consumption, including marketing and labeling of the substance, difference between advertised vs. sale price, diversion from legitimate channels, and whether the defendant knew the substance intended to be consumed by injection, inhalation, or ingestion.
Subtitle E: Opioid Quota Reform	
Sec. 3501. Short title.	• Opioid Quota Reform Act

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Sec. 3502. Strengthening considerations for DEA opioid quotas.	• Sets mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts. • Requires DEA to explain health benefits if DEA approves any increase in annual opioid quota.
Subtitle F: Preventing Drug Diversion	
Sec. 3601. Short title.	• Preventing Drug Diversion Act of 2018
Sec. 3602. Improvements to prevent drug diversion.	• Requires registrants to design systems to identify and report suspicious orders; also requires DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with States.
Subtitle G: Sense of Congress	
Sec. 3701. Sense of Congress.	• Expresses the Sense of Congress that the Federal Government must work to prevent patient brokers from taking advantage of individuals with substance use disorders, while also ensuring that legitimate entities can continue to assist individuals in need of treatment find reputable providers, sober living, or recovery homes.
TITLE IV: COMMERCE	
Subtitle A: Fighting Opioid Abuse in Transportation	
Sec.4101.Short title.	• Provides that the bill may be cited as the "Fighting Opioid Abuse in Transportation Act."
Sec. 4102. Rail mechanical employee controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate rail mechanical employees as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4103. Rail yardmaster controlled substances and alcohol testing.	• Requires the Secretary of Transportation to publish a final rule to designate yardmasters as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
Sec. 4104. Department of Transportation public drug and alcohol testing database.	• Requires the Secretary of Transportation to establish and make publicly available on its website a database of drug and alcohol testing data reported by employers for each mode of transportation and to update the database annually, while protecting commercially sensitive data and ensuring individual employers and employees are not identified.
Sec. 4105. GAO report on Department of Transportation's collection and use of drug and alcohol testing data.	• Requires the GAO to review Department of Transportation's Drug and Alcohol Testing Information Management System and to submit a report on the review, including potential recommendations for improvement, to relevant congressional committees.
Sec. 4106. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl.	• Requires the Secretary of HHS to determine, within 6 months, whether the inclusion of fentanyl on the panel of drugs authorized for testing is justified and—if justified— requires the Secretary to issue a revision to HHS mandatory guidelines to include fentanyl on the testing panel. • Requires, if the Secretary of HHS justifies the inclusion of fentanyl and revises the guidelines, the Secretary of Transportation to publish a final rule adding fentanyl to Department of Transportation's testing panel.

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Sec. 4107. Status reports on hair testing guidelines.	• Requires the Secretary of HHS to report to Congress on the status of the final notice for the statutorily-required scientific and technical guidelines for hair testing, within 30 days of enactment of this bill and every 6 months thereafter, until the agency publishes a final notice of guidelines for hair testing. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4108. Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid	• Requires the Secretary of HHS to publish a final notice of mandatory guidelines for oral fluid testing not later than December 31, 2018, based on the notice of proposed mandatory guidelines published in 2015. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4109. Electronic recordkeeping.	• Requires the HHS, not later than 1 year from the date of enactment of this bill, to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval. • Requires the Secretary of Transportation, not later than 30 months from the date of enactment of this bill, to issue a final rule authorizing the use of electronic signatures for all paperless chain of custody forms under part 40 of title 49, Code of Federal Regulations.
Sec. 4110. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.	• Requires the Federal Motor Carrier Safety Administration to submit a report to Congress biannually on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse, until such rule is fully implemented.
Subtitle B: Opioid Addiction Recovery Fraud Prevention	
Sec. 4201. Short title.	• This section would title the subtitle as the "Opioid addiction Recovery Fraud Prevention Act of 2018."
Sec. 4202. Definitions.	• This section would define the term "Opioid Treatment Product" to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term "Opioid Treatment Program" to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term "Opioid Use Disorder" to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.

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Sec. 4203. False or misleading representations with respect to opioid treatment programs and products.	• Section 4203(a) would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. • Section 4203(b) provides that any such violation would be considered a violation of a Federal Trade Commission (FTC) trade regulation rule (TRR), allowing the FTC to seek civil penalties under Section 5 and the remedies set forth in Section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies that it can already obtain under the FTC Act. The maximum civil penalty amount the FTC may seek for violations of TRRs is $41,484 per violation, as currently adjusted for inflation. *See* 15 U.S.C. § 45(m)(1)(A) and 16 C.F.R. § 1.98. The Section 19 remedies for TRR violations include "rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation . . . except that nothing in this subsection is intended to authorize the imposition of any exemplary or punitive damages." *See* 15 U.S.C. § 57b(b).
	• Section 4203(c) would empower states to bring actions in federal court against entities for violations of this section and to obtain appropriate relief. It would also require states to notify the FTC in writing before filing a case if possible, or if not feasible immediately upon filing the action. The FTC would have the authority to intervene in the state action. Once the FTC or the AG on the FTC's behalf files an action, states may not file during the pendency of the FTC action their own actions against a party named in the FTC action alleging the same violation. This section also addresses venue and service of process issues. • Section 4203(d) would preserve the authority of the FTC and the FDA such that nothing in this title shall be construed to limit the authority of the FTC or the FDA.

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Overdose Lifeline, Inc.



Indiana nonprofit on the front-lines of the Opioid Health Crisis since 2014

- ADVOCACY
- HARM REDUCTION
- TRAINING + EDUCATION
- YOUTH PREVENTION + EDUCATION
- SUPPORT

Information > OverdoseLifeline.org

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The Center of Disease Control recognizes young adults, ages 18-25, as **the most at-risk group**, reporting heroin use has more than doubled among this age group in the past decade. Since 2009, more than 31,000 youth have lost their lives to a drug overdose.

Ages 18-24 the Most At-Risk Group

Source: "Vital Signs." Centers for Disease Control and Prevention. 7 July 2015, www.cdc.gov/vitalsigns/heroin/index.html.

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With a reported 80% of heroin users beginning with the nonmedical (not prescribed) use of opioids, there is a significant need to enhance our youth's knowledge of substance use and misuse.

Early intervention strategies are imperative in turning the tide of this epidemic.



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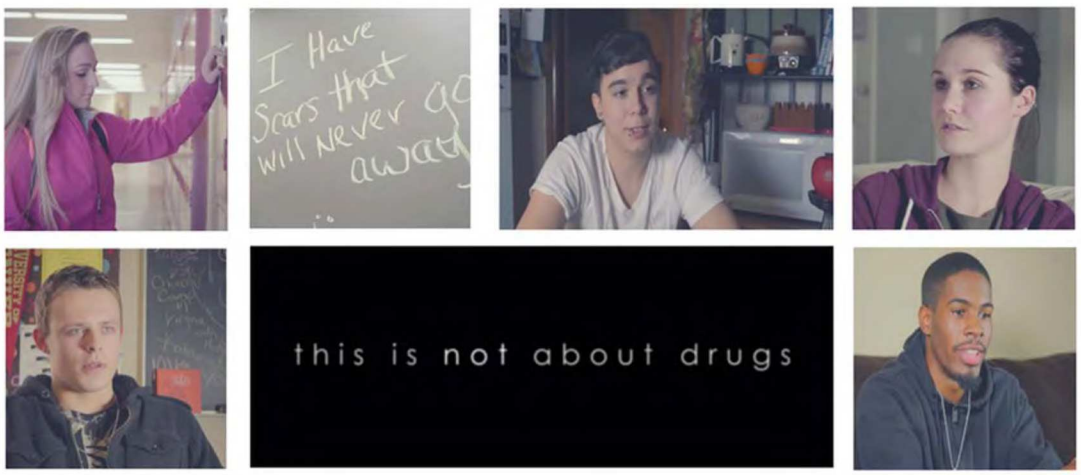

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This is (Not) About Drugs

An outcome-driven, science-based program designed to raise awareness to substance misuse, with a special emphasis on prescription opioids. The program incorporates NIDA principles, risk and protective factors and is designed to fit within school time constraints and aligns with the most common health curriculums.

The program follows an efficacy-based model of design with continuous measurement and improvement.

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This is (Not) About Drugs

Takes a peer-to-peer approach and makes use of personal stories to educate and influence the decisions – or choices – someone makes about their own body and health.

Choices are the theme of the program and behind the program title – This is (Not) About Drugs.



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Learning Objectives

After completing the lesson, youth will

- Understand the risks of prescription pain drug misuse
- How misuse can lead to addiction, heroin use, overdose, and death
- Recognize opioid overdose symptoms, availability of naloxone, and necessity to call 911
- Understand the disease of addiction and the impact on the individual and the family and friends
- Self-efficacy and alternatives when confronted with stressors
- Where to find applicable resources and the many ways to ask for help

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Specifically Addresses the National Opioid Health Crisis

Fits 45 Minutes Classroom Schedule | Ability to Expand

Accessible Trainer Program Built for Rapid Deployment

300+ Delivery Partners, Across 20 U.S. States

Pre-Post Student Survey } 3rd Party Study

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The program recently completed an quasi-experimental evaluation by researchers from the Indiana University Public Policy Institute.

Preliminary results indicate a significant increase in understanding the risks associated with the use of non-prescribed pain pills, the dangers of using/misusing opioids one time, and the relationship between prescription pain medication and heroin.

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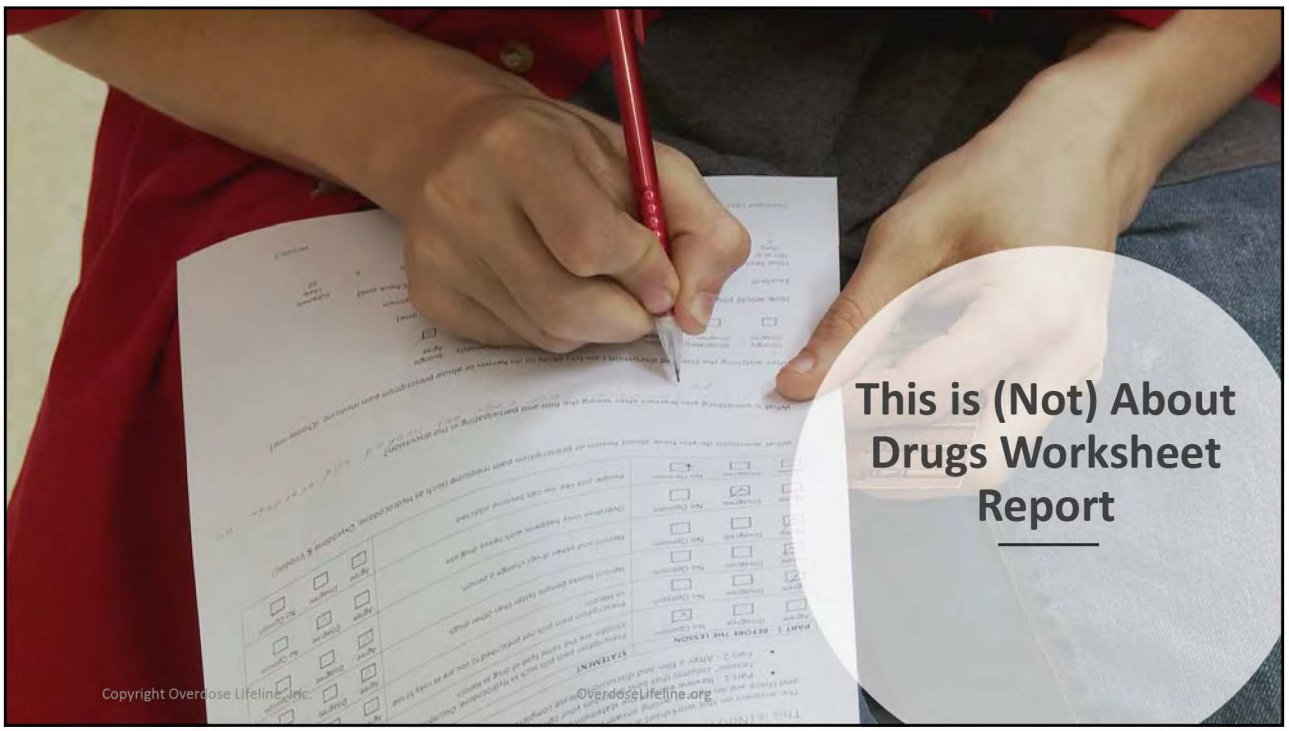
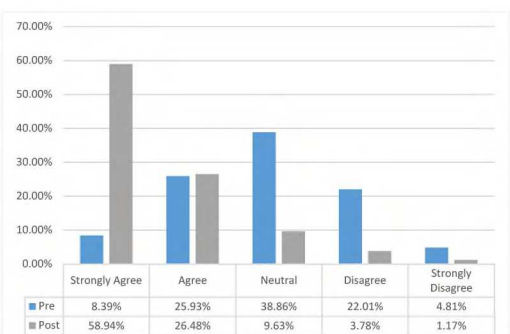
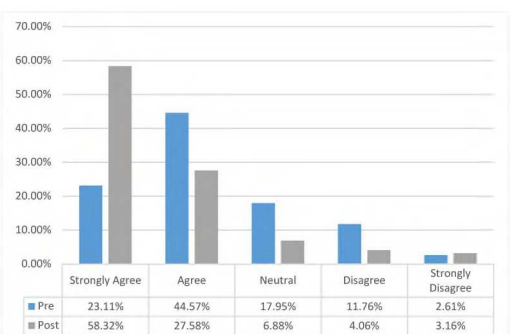


This is (Not) About Drugs Student Worksheet Report

Pain Pills and Heroin Relationship and Misuse Risks



Prescription pain pills such as Hydrocodone, Oxycodone, and Vicodin are the SAME TYPE of drug as heroin.
Before, ONLY 8% Strongly Agree that Pain Pills and Heroin are the Same Type of Drug. After, 59% Strongly Agree – a 51% INCREASE.



Prescription pain pills not prescribed to you are AS RISKY as using heroin.
Before, ONLY 23% Strongly Agree that misusing pain pills was as risky as heroin. After, 58% Strongly Agree – a 35% INCREASE

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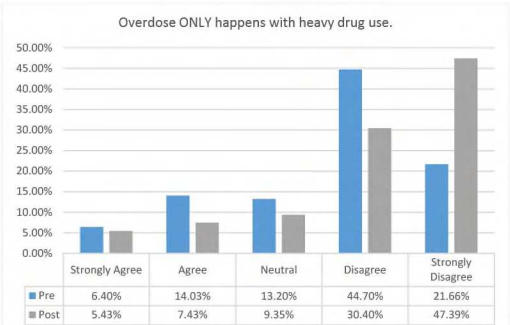
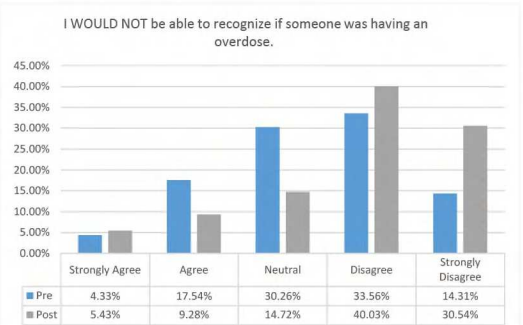
This is (Not) About Drugs Student Worksheet Report

Misuse and Overdose Risk and Ability to Recognize the Signs of an Overdose



	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Pre	6.40%	14.03%	13.20%	44.70%	21.66%
Post	5.43%	7.43%	9.35%	30.40%	47.39%



	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Pre	4.33%	17.54%	30.26%	33.56%	14.31%
Post	5.43%	9.28%	14.72%	40.03%	30.54%

Overdose ONLY happens with heavy drug use.
Before, ONLY 22% understood (strongly) that overdose can happen the 1st, 2nd, 3rd, etc. time someone misuses. After, 47% agree (strongly) – a 25% INCREASE.

I WOULD NOT be able to recognize if someone was having an opioid overdose.
Before, ONLY 14% stated that they could recognize signs of an overdose. After, 31% stated (strongly) that they could a 17% INCREASE.

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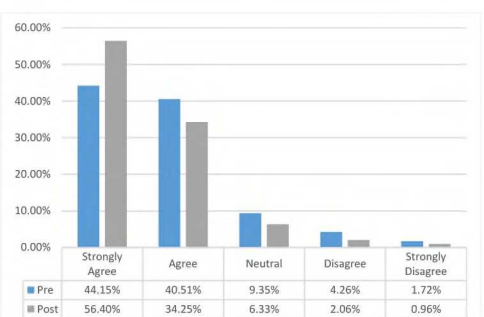
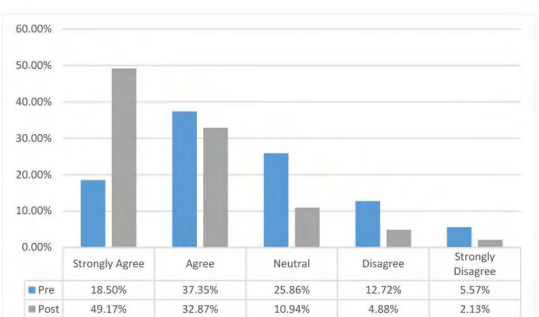
This is (Not) About Drugs Student Worksheet Report

When Substance Use Starts (Age) and Use of Other Drugs Increase Risks



	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Pre	44.15%	40.51%	9.35%	4.26%	1.72%
Post	56.40%	34.25%	6.33%	2.06%	0.96%



	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Pre	18.50%	37.35%	25.86%	12.72%	5.57%
Post	49.17%	32.87%	10.94%	4.88%	2.13%

The younger someone starts drinking alcohol or using drugs INCREASES the risk of addiction or alcoholism.
Before, 44% Strongly Agree that the age that someone starts drinking/using substances increases the risks of addiction. After, 56% Strongly Agree – a 12% INCREASE.

Drinking alcohol, using marijuana or other drugs INCREASES the likelihood that someone would use heroin.
Before, ONLY 18% Strongly Agree that using other substances can progress to heroin. After, 49% Strongly Agree – a 31% INCREASE.

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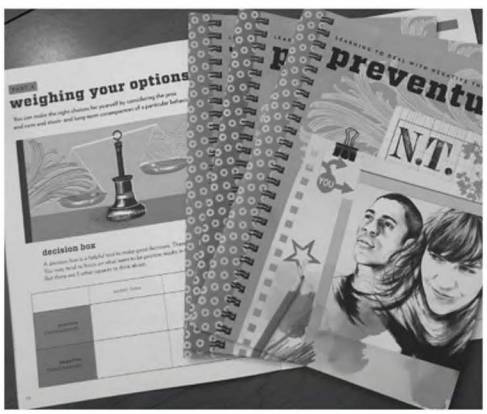
Preventure Personality Targeted - Selective EBP

Developed by Patricia Conrod, PhD, University of Montreal

An evidence-based program which takes a personality-targeted approach to adolescent substance use prevention.

The program content was developed to target personality types found to be at highest risk for substance misuse.

Preventure includes a Substance Use Risk Profile Scale (SURPS) assessment and two, 90-minutes workshops for students with high SURPS indicators across four (4) personality types.



Information: overdose-lifeline.org/preventure

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Beyond Youth – Taking a Socio-Ecological Model



A Socio-Ecological Model (SEM) allows us to approach prevention education using a lens that looks at the complex interplay between individuals and their environment.

This model highlights the importance of working with parents, communities, and beyond to confront the opioid epidemic.

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Overdose Lifeline Training Courses & Programs

Overdose Lifeline has worked with subject matter experts to develop effective, evidence-informed adult training courses and programs addressing the opioid health crisis and addiction / substance use disorder.

Available for **individual learning and continuing education** or as **trainer programs** that allow a trainer to deliver within their local community(ies).

Visit: OverdoseLifeline.org/Training

Continuing Education	OPTIONS	Trainer Programs

DEVELOPING: CE and Certificate Program in Partnership with Purdue University

Overdose Lifeline, Inc. Outlook

Due to the time sensitive and critical nature of the health crisis, ODL aims to **rapidly increase its delivery partners to provide prevention programs to youth across the nation and continue the expansion of the adult programming**.

In response to the reported success of our opioid prevention program, ODL also intends to **expand the TINAD intervention** to youth segments (ie: youth athletes, college) and to inform students on a broader range of substance use.

Our organization acknowledges that a public health crisis is multifaceted, and therefore **requires a shift in practices and beliefs across various sectors of society.** It is of great importance for our organization to recognize and deploy the foremost intervention strategies that will abate the many lives being lost to overdose every day – and the many lives affected by opioid use disorder.

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Contact Us

Kourtnaye Sturgeon, Director of Education

(b)(6)

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(b)(6) | OverdoseLifeline.org

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Our work …



Narcan (naloxone) is now available over the counter **as a result of our work**

Increased awareness and knowledge via **evidence-informed adult training** and **programming** for local delivery

Our Youth Awareness Prevention Program is now used in **more than 20 U.S. states** by over **300 delivery partners**

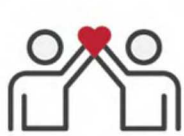


Engaged **264 First Responder Departments**. Trained over **15,000** First Responders and over **3,000 layperson** on Narcan.





First in the U.S. to deliver an **evidence-based personality-targeted approach** to adolescent substance use prevention



Saved **thousands of Indiana residents' lives**

Overdose Lifeline, Inc.

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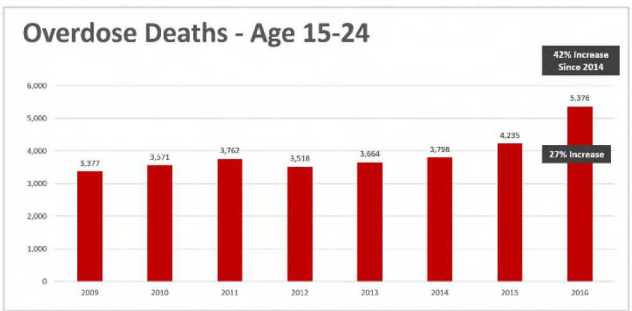
Overdose Lifeline, Inc.

The Opioid Epidemic & Youth

The Centers for Disease Control recognizes young adults, ages 18-25, as the most at-risk group, reporting heroin use has more than doubled among this age group in the past decade.[i] Since 2009, more than 31,000 youth have lost their lives to a drug overdose. In 2016, overdose deaths of ages 15-24 increased by 27% from the year prior, and there was a 42% increase over rates in 2014.[ii] With a reported 80% of heroin users beginning with the nonmedical (not prescribed) use of opioids,[iii] there is a significant need to enhance our youth's knowledge of substance use and misuse. Early intervention strategies are imperative in turning the tide of this epidemic.



Who We Are

Overdose Lifeline, Inc. (ODL) is a nonprofit dedicated to addressing the opioid epidemic and helping those affected by the disease of addiction and substance use disorder. ODL has been on the front-lines of the opioid epidemic since 2014, focusing its initiatives on advocacy, education, prevention, harm reduction, resources and support.

Our Prevention Program *"This is (Not) About Drugs"*

Overdose Lifeline, Inc has created the first universal youth education prevention program addressing the opioid health crisis.

"This is (Not) About Drugs" (TINAD) is an outcome driven, science-based program designed to raise awareness to substance misuse, with a special emphasis on prescription opioids. The program is designed to fit within the school time constraints and aligns with the most common health curriculums.

After completing the lesson, students will know and understand:

- The risks of prescription pain drug misuse
- How misuse can lead to addiction, heroin use, overdose and death
- Recognize opioid overdose symptoms, availability of naloxone, and necessity to call 911
- Understand the disease of addiction and its impact on the individual, family and friends
- Self-efficacy and alternatives to using substances when confronted with stressors
- Where to find applicable resources and the many ways to ask for help

ODL's approach seeks to change attitudes, beliefs, and remove stigmas associated with substance use disorder. The program follows an efficacy-based model of design with continuous measurement and improvement. The program recently completed a quasi-experimental evaluation by researchers from the Indiana University Public Policy Institute. Preliminary results indicate a significant increase in understanding the risks associated with the use of non-prescribed pain pills, the dangers of using/misusing opioids one time, and the relationship between prescription pain medication and heroin.

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"Preventure"

A selective intervention (targeted to select youth) has been added to ODL's youth programming implementation plan.

Preventure, developed by Patricia Conrod, PhD, at the University of Montreal, is an evidence-based program which takes a personality-targeted approach to adolescent substance use prevention. The program content was developed to target personality types found to be at highest risk for substance misuse. Preventure includes a Substance Use Risk Profile Scale (SURPS) assessment and two, 90-minutes workshops for students with high SURPS indicators across four (4) personality types.

Beyond Our Youth Programs

Overdose Lifeline's objective is not merely to bring evidenced based *programs* to individuals, but intentionally and consistently demonstrate the *practices* that achieve greater knowledge and attitude changes across the board. This requires we broaden our focus and efforts.

ODL applies the Socio-Ecological Model (SEM) to our work, which allows us to approach prevention education using a lens that looks at the complex interplay between individuals and their environment. This model highlights the importance of working with parents, communities, and beyond to confront the opioid epidemic. True prevention education through the SEM addresses the entire community, educating them on addiction as a disease, treatment options and harm reduction practices.



Overdose Lifeline, Inc. Outlook

As of May 2018, Overdose Lifeline has 330 delivery partners across 20+ states. Due to the time sensitive and critical nature of the health crisis, ODL aims to rapidly increase its delivery partners to provide prevention programs to youth across the nation and continue the expansion of the ODL adult programming.

In response to the reported success of our opioid prevention program, ODL also intends to expand the TINAD intervention to youth segments (i.e.: athletes, college) and inform students on a broader range of substance use in the future. Our organization acknowledges that a public health crisis is multifaceted, and therefore requires a shift in practices and beliefs across various sectors of society. It is of great importance for our organization to recognize and deploy the foremost intervention strategies that will abate the many lives being lost to overdose every day.

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[i] "Vital Signs." *Centers for Disease Control and Prevention*. 7 July 2015, www.cdc.gov/vitalsigns/heroin/index.html.
[ii] "National Center for Health Statistics." *Centers for Disease Control and Prevention*. 11 Jan. 2018, www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/.
[iii] "Opioid Overdose Crisis." *NIDA*, 6 Mar. 2018, www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#seven.

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CEPOP
COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

1050 K Street NW ▾ Suite 400
Washington ▾ DC 20001-4448
(b)(6)
www.CEPOPonline.org

VIA ELECTRONIC DELIVERY

Tuesday, September 04, 2018

The Honorable [Insert Name]
Committee on [Insert]
[Address]
Washington, DC 20510

RE: Support for S. 2875 and Collaborative Efforts to Improve Access and Coverage to All Food and Drug Administration (FDA)-Approved Treatments for Opioid Use Disorder

Dear Senator [Insert]:

Following the Center for Disease Control and Prevention's recent announcement of preliminary overdose deaths for 2017 and near 10% increase over the previous year, efforts to combat opioid use disorder remain a top priority. In response to activity in both the House and Senate around improving access to all U.S. Food and Drug Administration (FDA)-approved medication-assisted treatment (MAT) products, the Collaborative for Effective Prescription Opioid Policies (CEPOP) and the undersigned organizations encourage you and your colleagues to advance S. 2875, the Comprehensive Opioid Management and Bundled Addiction Treatment (COMBAT) Act of 2018.

CEPOP was formed more than three years ago to develop, disseminate and advocate for balanced solutions to this crisis. With over 80 national participants, CEPOP engages a diverse group of stakeholders to pursue a comprehensive strategy to reduce misuse and promote treatment options. We support effective programs and policies to prevent prescription misuse and overdose, while ensuring patients' access to effective pain and opioid use disorder treatment.

An October 2017 Government Accountability Office (GAO) Report on Medicare oversight of prescription opioid utilization identified 727,000 beneficiaries receiving high doses of opioids and over 300,000 beneficiaries having been diagnosed with an opioid use disorder. Moreover, at this time, Medicare beneficiaries demonstrates one of the fastest growing rates of opioid use disorders, with hospitalizations due to opioid misuse/abuse-related complications continuing to rise. With 6 out of every 1,000 Medicare beneficiaries diagnosed with an opioid use disorder, there are more than 300,000 individuals in need of appropriate, evidence-based treatment and recovery services.[1]

We believe Medicare beneficiaries with an opioid use disorder should have access to all FDA-approved products so that their clinician can identify and provide the most appropriate treatment for any individual. According to a January 2018 report in Health Affairs, only 319 (2.65%) of over 12,000 substance abuse treatment centers offer all three FDA-approved MAT products. Furthermore, eight states at that time did not have a single opioid use disorder treatment center offering all three MAT products.

[1] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238

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As part of the comprehensive treatment protocol for opioid use disorder, it is critical that patients have appropriate access to evidence-based programs, including those offered by opioid treatment programs (OTPs). Healthcare providers operating in OTPs ensure patients receive both evidence-based pharmacologic interventions along with behavioral therapy and related support services. Certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are upwards of 1,500 OTPs operating nationally treating approximately 400,000 patients.

As you and your colleagues continue to advance legislation to address the opioid epidemic, we encourage you to expand access to these life-saving medications for Medicare beneficiaries. Various proposals are currently being discussed within the Senate, some of which create a bundled payment for MAT and wraparound services within the Medicare program while others would first develop a Medicare demonstration around bundled payments and expanded access.

Now is not the time to fund another demonstration as evidence has proven the effectiveness of opioid treatment programs in addressing opioid abuse. Provisions within S. 3120, the Helping to End Addiction and Lessen Substance Use Disorders (HEAL) Act of 2018, simply do not go far enough to ensure access to all FDA-approved MAT products for Medicare beneficiaries. The undersigned organizations support – and we encourage you to do so as well – the COMBAT Act of 2018 (S. 2875) which would create a permanent mechanism for coverage.

Once again, thank you for your leadership to address our nation's opioid epidemic. CEPOP, its participants, and the other organizations included on this letter stand ready to assist in any way possible. Please contact Matt Rubin ((b)(6) or (b)(6) with any questions.

Respectfully,

[INSERT SIGNATORIES]

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[EXTERNAL] CEPOP All-Participants Teleconference (October 2018)

From: "Rubin, Matthew J." <(b)(6)

To: Addie Liles <(b)(6) Becky Salay <(b)(6) "Bono, Mary" <(b)(6) "Derek Naten (MNK)" <(b)(6) "Gen. Arthur Dean" <(b)(6) "Kevin Webb (MNK)" <(b)(6) "Nadine Gracia (<(b)(6) <(b)(6) Rob Morrison <(b)(6) "Sue Thau (Gmail)" <(b)(6) Van Ingram <(b)(6) "Zook, David R." <(b)(6) Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) Brad Tallamy <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach (<(b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) David May <(b)(6) David Trewolla <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Dennis Brennan <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Donald Hoppert <(b)(6) "Dr.

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Anita Gupta" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) "Dr. Jack Stein" <(b)(6) "Dr. John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emmanuel Oga (Battelle)" <(b)(6) Erika Long <(b)(6) "Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)" <(b)(6) Gabrielle de la Gueronniere (b)(6) (b)(6) Gary Mendell (b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Geoffrey Laredo <(b)(6) Hadi Sedigh <(b)(6) "Hannah Riffle (b)(6) <(b)(6) "Hanson, Roberta J." <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) James Appleby <(b)(6) Jane Terry <(b)(6) Jason Sundby <(b)(6) Jeffrey Ekoma <(b)(6) Jeremiah Lindemann <(b)(6) "Jessica Johnston (BD)" (b)(6) John Donahue <(b)(6) John O'Brien <john.(b)(6) Judi Lund Person (b)(6) Julian Hoffman <(b)(6) Karen Tracy <(b)(6) Kate Berry <(b)(6) Kate McFadyen <(b)(6) Kathleen O'Conner (b)(6) "Kathryn L. Cates-Wessel" <(b)(6) Kevin Walker <(b)(6) Keysha Brooks-Coley <(b)(6) Kimberly Wilkinson <(b)(6) Lorraine Yarde <(b)(6) Marcia Lee Taylor <(b)(6) Mary Winnefeld <(b)(6) Melissa Ough <(b)(6) Michael DeGeorge <(b)(6) Mike Smith <(b)(6) Myra Christopher <(b)(6) Nick Motu <(b)(6) Nicole Burda <(b)(6) "Patel, Beena S." <(b)(6) Patricia Bruckenthal <(b)(6) Patricia D'Antonio <(b)(6) Patricia Farley <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Paul Ross <(b)(6) "Rachel Rivera (b)(6) <(b)(6) Rebecca

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Farley <(b)(6) Rebecca Slater Abbott
<(b)(6) Richard Hamburg <(b)(6)
Rita Norton <(b)(6) Robert Forman
<(b)(6) "Robin Swift (<(b)(6)
<(b)(6) Samantha Arsenault (b)(6)
"Sarah Nerad (Alkermes)" <(b)(6) Scott Proescholdbell
<(b)(6) Shalini Wickramatilake
<(b)(6) Shelley Starkey
<(b)(6) Sonya Clay <(b)(6) "Stephanie Pellitt
(NCBH)" <(b)(6) Steve Passik
<(b)(6) Sue Thau <(b)(6) Susan Awad
<(b)(6) Susan Weinstein <(b)(6) Teresa Baker
<(b)(6) "Terry McGeeney, MD, MBA"
<(b)(6) "Tim Hermes (<(b)(6)
<(b)(6) Tracie Thomas <(b)(6) Vince
Ventimiglia <(b)(6) Wade Delk <(b)(6)

Date: Thu, 20 Sep 2018 14:01:45 -0400

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Formal agenda and materials forthcoming.

CEPOP All-Participants Teleconference (July 2018)

- To join WebEx via computer, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP All-Participants Teleconference (October 2018)

From: "Rubin, Matthew J." <(b)(6)

To: Daniel Raymond <(b)(6) John O'Brien <john.(b)(6) Brian Bowden <(b)(6) Mary Bono <(b)(6) David Trewolla <(b)(6) "Dr. Anita Gupta" <(b)(6) Jeffrey Ekoma <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Keysha Brooks-Coley <(b)(6) Dan Buffington <(b)(6) Teresa Baker <(b)(6) "Zook, David R." <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Celia Hagan (NILA)" <(b)(6) (b)(6) Dennis Brennan <(b)(6) "Christian, Jeanine M" <(b)(6) Jeremiah Lindemann <(b)(6) James Appleby <(b)(6) Shelley Starkey <(b)(6) "Dr. Jack Stein" <(b)(6) Donald Hoppert <(b)(6) "Emmanuel Oga (Battelle)" <(b)(6) "Robin Swift (b)(6) <(b)(6) Rita Norton <(b)(6) "Gabriella Witte (APHA)" <(b)(6) Gabrielle de la Gueronniere <(b)(6) "Kevin Webb (MNK)" <(b)(6) Jane Terry <(b)(6) Patricia Farley <(b)(6) Patricia D'Antonio <(b)(6) Vince Ventimiglia <(b)(6) Patricia Bruckenthal <(b)(6) Carol Thornton <(b)(6) Rebecca Farley <(b)(6) Sonya Clay <(b)(6) Andrew kessler <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Mary Winnefeld <(b)(6) "Rachel Rivera (b)(6) <(b)(6) Kevin Walker <(b)(6) Samantha Arsenault (b)(6) Caren Kagan Evans <(b)(6) "Hanson, Roberta J." <(b)(6) Kimberly Wilkinson

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Cc:	<(b)(6) Becky Salay <(b)(6) Gary Mendell <(b)(6) Hadi Sedigh <(b)(6) Chris Zimmerman <(b)(6) Chuck Ingoglia <(b)(6) Marcia Lee Taylor <(b)(6) Myra Christopher <(b)(6) Aryka Chapman <(b)(6) Robert Forman <(b)(6) Judi Lund Person (b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) John Donahue <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Lorraine Yarde <(b)(6) Geoffrey Laredo <(b)(6) "Cristi L. Schwarcz" <(b)(6) Aiken Hackett <(b)(6) "Patel, Beena S." <(b)(6) Susan Weinstein <(b)(6) "Dr. Renan Castillo" <(b)(6) Elizabeth Solhtalab <(b)(6) Tracie Thomas <(b)(6) "Danna Droz (NABP)" <(b)(6) Alice Dembner <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) "Long, Erika" <(b)(6) "Abbott, Rebecca" <(b)(6) "Motu, Nick" <(b)(6) William Hibbs <(b)(6) "Waters, Tinsley (CDC/DDNID/NCIPC)" <(b)(6)
Date:	Mon, 29 Oct 2018 10:57:58 -0400
Attachments:	CEPOP All-Participants Meeting Agenda (Oct. 2018).pdf (31.07 kB); StigmaLab One-Pager.pdf (748.6 kB); not supported calendar message.ics (18.36 kB)

CEPOP Participants – In advance of this afternoon's CEPOP All-Participants teleconference, please find the agenda and relevant documents attached below. We are pleased to have two fantastic focus topic speakers for this month's meeting, including:

- **Dr. Sanzanna Dean**, *Deputy Associate Administrator, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, Department of Justice*
- **Dr. Beth McGinty**, *Associate Professor, Department of Health Policy and Management and Co-Deputy Director, Center for Mental Health and Addiction Policy Research, Johns Hopkins Bloomberg School of Public Health*

We look forward to a productive discussion. As always, please do not hesitate to reach out with any questions.

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CEPOP All-Participants Teleconference (October 2018)

- To join WebEx via computer, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (OCTOBER 2018)

Date: Monday, October 29, 2018

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Justice Department Awards $320 Million to Reduce Opioid Misuse and Abuse (link)**
  Dr. Sanzanna Dean, *Deputy Associate Administrator, Office of Juvenile Justice and Deliquency Prevention, Office of Justice Programs, Department of Justice*
- **B. Reducing Stigma Through Impactful Communication**
  Beth McGinty, PhD, MS, *Associate Professor, Department of Health Policy and Management and Co-Deputy Director, Center for Mental Health and Addiction Policy Research, Johns Hopkins Bloomberg School of Public Health*

III. Advocacy and Policy Priorities

- **A.** SUPPORT for Patients and Communities Act (H.R. 6) Signed into Law
- **B.** FY2019 Budget Priorities

IV. Working Groups

- **A.** Takeback and Anti-Diversion
- **B.** Safe Use and Prevention

V. Organizational Updates; Sharing Intel, Participant News and Updates

- **A.** Timeline for Upcoming Meetings

Next In-Person CEPOP All-Participants 2019 Planning Session:
Mid-December 2018 (Doodle Poll forthcoming)

US.120518424.01

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JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Center for Mental Health and Addiction Policy Research

The aim of the Center for Mental Health and Addiction Policy Research at the Bloomberg School is to improve the lives of persons with mental illness and addiction through engaging in policy research, translating research evidence into policy and practice, and training a next generation of mental health and addiction policy researchers



Economics and Services Research –

- Projects studying effects of accountable care and global payment on individuals with addiction and mental illness

Statistics and Methodology Research -

- Use of propensity scores to assess the generalizability of clinical trial results

Implementation Science Research –

- Project on implementation of health homes for persons with addiction and mental illness in Maryland

Communication Research - (b) JHSPHStigmaLab

- Projects using strategic communications methods to lower stigma & increase support for evidence-based policies



THE JHSPH STIGMA LAB

A home for research to develop evidence-based communication strategies to reduce stigma toward people with mental illness and substance use disorders. @JHSPHStigmaLab

LEARN MORE

Public Opinion & Message Framing Research on the Opioid Epidemic - Center faculty are conducting multiple studies of policy communication around the issue of opioid addiction

- Rethinking the Language of Harm Reduction to Combat the Opioid Epidemic. Under Review. 2018
- Understanding Public Support for Safe Consumption Sites and Syringe Services Programs to Combat the Opioid Epidemic. Under Review. 2018
- Communication strategies to counter stigma and improve mental health and substance use disorder policy. *Psychiatric Services*. 2017
- Stigma toward individuals with opioid analgesic addiction & public support for punitive and public health-oriented policies. *Psychiatric Services*. 2017
- Primary care physicians' perspectives on the prescription opioid epidemic. *Drug and Alcohol Dependence.* 2016
- Effects of Competing Narratives on Public Perceptions of Prescription Opioid Addiction during Pregnancy. *Journal of Health Politics, Policy & Law*. 2016
- Messaging to Increase Public Support for Naloxone Distribution Policies: Results from a Randomized Survey Experiment. *PLOS One*. 2015
- Stigma, Discrimination, Treatment Effectiveness and Public Policy Support: Americans' Attitudes toward Persons with Drug Addiction & Mental Illness. *Psychiatric Services*. 2014

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[EXTERNAL] CEPOP 2019 Annual All-Participants Strategy Session

From: "Rubin, Matthew J." <(b)(6)

To: Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach (b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) David May <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Dennis Brennan <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Donald Hoppert <(b)(6) "Dr. Anita Gupta" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) "Dr. Jack Stein" <(b)(6) "Dr. John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emmanuel

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Oga (Battelle)" <(b)(6) Erika Long <(b)(6)
"Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)"
<(b)(6) Gabrielle de la Gueronniere (b)(6)-
dc.org>, Gary Mendell (b)(6) "Gen. Arthur Dean"
<(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6)
Geoffrey Laredo <(b)(6) Hadi Sedigh <(b)(6)
"Hannah Riffle (b)(6) <(b)(6) "Hanson, Roberta J."
<(b)(6) "Ian Goldstein (NACCHO)"
<(b)(6) James Appleby <(b)(6) Jane Terry
<(b)(6) Jason Sundby <(b)(6) Jeffrey
Ekoma <(b)(6) Jeremiah Lindemann <(b)(6)
"Jessica Johnston (BD)" (b)(6) John Donahue
<(b)(6) John O'Brien <john.(b)(6) Judi Lund
Person (b)(6) Julian Hoffman <(b)(6) Karen
Tracy <(b)(6) Kate Berry <(b)(6) Kate McFadyen
<(b)(6) Kathleen O'Conner (b)(6)
"Kathryn L. Cates-Wessel" <(b)(6) Kevin Walker
<(b)(6) Keysha Brooks-Coley (b)(6) (b)(6)
Kimberly Wilkinson <(b)(6) Kristi
Thompson <(b)(6) Lorraine Yarde
<(b)(6) Marcia Lee Taylor <(b)(6)
Mary Winnefeld <(b)(6) Melissa Ough
<(b)(6) Michael DeGeorge
<(b)(6) Mike Smith <(b)(6) Myra
Christopher <(b)(6) Nick Motu
<(b)(6) Nicole Burda <(b)(6) "Patel, Beena S."
<(b)(6) Patricia Bruckenthal
<(b)(6) Patricia D'Antonio <(b)(6)
Patricia Farley <(b)(6) "Patty McCarthy (FaVoR)"
<(b)(6) Paul Ross
<(b)(6) "Rachel Rivera
(b)(6) <(b)(6) Rebecca
Farley <(b)(6) Rebecca Slater Abbott
<(b)(6) Richard Hamburg <(b)(6)
Rita Norton <(b)(6) Rob Morrison
<(b)(6) Robert Forman <(b)(6) "Robin

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Swift ((b)(6) <(b)(6) Samantha Arsenault (b)(6), "Sarah Nerad (Alkermes)" <(b)(6) Scott Proescholdbell <(b)(6) Shalini Wickramatilake <(b)(6) Shelley Starkey <(b)(6) Sonya Clay <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Steve Passik <(b)(6) Sue Thau <(b)(6) "Sue Thau (Gmail)" <(b)(6) Susan Awad <(b)(6) Teresa Baker <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Tim Hermes ((b)(6) <(b)(6) Tracie Thomas <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) Van Ingram <(b)(6) Vince Ventimiglia <(b)(6) Wade Delk <(b)(6) Addie Liles <(b)(6) Becky Salay <(b)(6) "Derek Naten (MNK)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Mary Bono <(b)(6) "Nadine Gracia ((b)(6) <(b)(6) "Zook, David R." <(b)(6)

Date: Thu, 08 Nov 2018 17:09:11 -0500

Attachments: not supported calendar message.ics (17.05 kB)

Formal agenda and materials forthcoming.

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Meeting Location
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

For those unable to attend in-person, a WebEx will be made available to all participants to participate remotely.

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP All-Participants Teleconference (December 2018)

From: "Rubin, Matthew J." <(b)(6)

To: "Hannah Riffle ((b)(6) <(b)(6) Chris Zimmerman <(b)(6) Keysha Brooks-Coley (b)(6) Marcia Lee Taylor <(b)(6) Tracie Thomas <(b)(6) "Dr. John Harrison" <(b)(6) Alice Dembner <(b)(6) "Cara Moon (Egalet)" <(b)(6) "Sarah Nerad (Alkermes)" <(b)(6) Sonya Clay <(b)(6) Becky Salay <(b)(6) Hadi Sedigh <(b)(6) John O'Brien <john.(b)(6) Charlie Cichon <(b)(6) Caren Kagan Evans <(b)(6) Eli Briggs <(b)(6) "Tim Hermes ((b)(6) <(b)(6) "Gen. Arthur Dean" <(b)(6) Kate Berry <(b)(6) "Evans, Daniel F." <(b)(6) Nick Motu <(b)(6) Patricia Bruckenthal <(b)(6) "Dr. Renan Castillo" <(b)(6) "Jessica Johnston (BD)" <jessica(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) Shelley Starkey <(b)(6) Ed Kaleta <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) "Hanson, Roberta J." <(b)(6) Lorraine Yarde <(b)(6) Van Ingram <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) Erika Long <(b)(6) "Kathryn L. Cates-Wessel" <(b)(6) "Dr. Anita Gupta" <(b)(6) Daniel Raymond <(b)(6) "Celia Hagan (NILA)" <(b)(6) "Nadine Gracia ((b)(6) <(b)(6) Aryka Chapman <(b)(6) "Dr. Jack Stein" <(b)(6) "Rachel Rivera ((b)(6) <(b)(6) Patricia D'Antonio <(b)(6) Kathleen O'Conner <(b)(6) Teresa Baker <(b)(6) "Christian, Jeanine M" <(b)(6) "Cristi L. Schwarcz" <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) Jeremiah Lindemann

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<(b)(6) Nicole Burda <(b)(6) John Donahue <(b)(6) Sue Thau <(b)(6) Mike Smith <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) Mary Winnefeld <(b)(6) Carol Thornton <(b)(6) "Gabriella Witte (APHA)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Jason Sundby <(b)(6) Elizabeth Solhtalab <(b)(6) Amy Callendar <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) "Robin Swift (b)(6) <(b)(6) "Sue Thau (Gmail)" <(b)(6) "Danna Droz (NABP)" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) "Derek Naten (MNK)" <(b)(6) Addie Liles <(b)(6) Amanda Sears <(b)(6) Chuck Ingoglia <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Judi Lund Person (b)(6) Dennis Brennan <(b)(6) Donald Hoppert <(b)(6) Vince Ventimiglia <(b)(6) Gabrielle de la Gueronniere <(b)(6) Samantha Arsenault (b)(6) , Aiken Hackett <(b)(6) Shalini Wickramatilake <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Steve Passik <(b)(6) Michael DeGeorge <(b)(6) Dan Buffington <(b)(6) "Blaire Bryant (NACo)" <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) Richard Hamburg <(b)(6) Susan Awad <(b)(6) David May <(b)(6) Jane Terry <(b)(6) Wade Delk <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Rebecca Slater Abbott <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Robert Forman <(b)(6) "Patel, Beena S." <(b)(6) "Clay Alspach (b)(6) <(b)(6) Andrew kessler <(b)(6) Kimberly Wilkinson <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Myra Christopher <(b)(6) "Zook, David R."

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<(b)(6) Julian Hoffman <(b)(6) "Alexander, Tesfa" <(b)(6) James Appleby <(b)(6) Rob Morrison <(b)(6) Gary Mendell (b)(6), Rebecca Farley <(b)(6) Paul Ross <(b)(6) Mary Bono <(b)(6) Karen Tracy <(b)(6) "Emmanuel Oga (Battelle)" <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Brian Bowden <(b)(6) Kevin Walker <(b)(6) Courtney Hunter <(b)(6) Blair Clark-Schoeb <(b)(6) Kristi Thompson <(b)(6) Kate McFadyen <(b)(6) Scott Proescholdbell <(b)(6) Jeffrey Ekoma <(b)(6) Patricia Farley <(b)(6) "Deana Haworth (Hirons)" <(b)(6) Geoffrey Laredo <(b)(6) Melissa Ough <(b)(6) Brad Tallamy <(b)(6) Rita Norton <(b)(6)

Cc: "Motu, Nick" <(b)(6)

Date: Fri, 16 Nov 2018 17:09:05 -0500

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At the request of the Steering Committee this meeting has been changed – given the recent midterm elections and lack of November meeting – to a one-hour All-Participants Teleconference. CEPOP will subsequently hold its Annual All-Participants Strategy Session in January 2019. Doodle Poll forthcoming with potential dates for that in-person meeting. Thanks!

CEPOP All-Participants Teleconference (December 2018)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
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  - **Participant Code:** (b)(6)

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[EXTERNAL] Mallinckrodt Announces Planned Spin-Off of Specialty Generics Business

From: "Lohman, Donald A" <(b)(6)

To: "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)

Date: Thu, 06 Dec 2018 12:50:20 -0500

Attachments: MNK Announces Planned Specialty Generics Spin-Off 12-6-18.pdf (335.16 kB)

Dear Cece –

I hope this finds you doing well. This morning, Mallinckrodt announced its plan to spin off our Specialty Generics/Active Pharmaceutical Ingredients (API) business into a standalone public company, separate from our Specialty Pharmaceutical Brands business. We are excited that, subject to final approval by our Board of Directors, this step will give both businesses the flexibility, freedom and additional resources to focus on and pursue their respective growth strategies, while allowing each independent company to more closely focus on the patients they serve. Attached is the press release describing the planned spin-off.

I wanted to highlight a few aspects of the plan, which may be of interest:

- For more than a century, the Mallinckrodt name has been associated with the specialty generics and API business, and the newly independent company will adopt the Mallinckrodt name. As a result, the remaining Specialty Pharmaceutical Brands company will have a new name (announced next year) and will continue to trade on the NYSE under a new stock ticker symbol.

- Mark Trudeau will continue to serve as the President and Chief Executive Officer of the Specialty Pharmaceutical Brands company. Matt Harbaugh, who most recently was our Executive Vice President and Chief Financial Officer, is expected to become President and Chief Executive Officer of the newly independent Specialty Generics Company.

- Mallinckrodt currently expects that the spin-off process will be completed by the second half of 2019 or sooner, and it will be business as usual for the time being.

I would be happy to further discuss this announcement, and as always, please let me know if you have any questions.

Kind regards,

Don

Donald A. Lohman | Vice President, General Counsel of Specialty Generics
Mallinckrodt Pharmaceuticals

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Mallinckrodt Plans Spin-Off of Specialty Generics Business to Shareholders

-- Transaction expected to create two differentiated pharmaceutical companies with scale –
One focused on innovative specialty pharmaceutical brands;
One with a portfolio of niche specialty generic products, active pharmaceutical ingredients (APIs), and non-promoted brands including the AMITIZA® product --

-- Transaction expected to be completed in the second half of 2019 --

-- Spun-off company will assume the Mallinckrodt name;
Specialty Pharmaceutical Brands company will be renamed --

STAINES-UPON-THAMES, United Kingdom – Dec. 6, 2018 - Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced plans to spin off a new company consisting of Mallinckrodt's Specialty Generics/Active Pharmaceutical Ingredients (Specialty Generics) business and AMITIZA® (lubiprostone) to Mallinckrodt shareholders, subject to final Board approval. The separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies.

The planned separation is expected to be executed through a pro-rata distribution of common stock to Mallinckrodt's shareholders that is generally tax-free for U.S. federal income tax purposes. The spin-off is projected to be completed in the second half of 2019 or sooner. It is anticipated that the spun-off company will be listed on the New York Stock Exchange (NYSE) and will assume the Mallinckrodt name and ticker symbol (MNK).

The 'remaining' independent Specialty Pharmaceutical Brands company, whose goal is to improve outcomes for underserved patients with severe and critical conditions, will continue to focus on its portfolio of innovative marketed and development products. **Mark Trudeau,** current **President and Chief Executive Officer**, will lead the business. The remaining company will be renamed at a later date.

Angus Russell, Mallinckrodt's Chairman of the Board, said, "Over the past five years, Mallinckrodt has transformed its business through a series of strategic transactions – acquiring a portfolio of marketed and development stage pharmaceutical brands that can drive growth, and divesting non-core assets that could be better maximized by others. In 2016 the Board began to explore a range of strategic alternatives for the company's Specialty Generics business, and believes there is a strong rationale and opportunity to create two new, appropriately capitalized, independent companies that have the potential to unlock and increase value over the long term. We expect this separation will result in greater strategic focus, allowing each business to more effectively enhance returns by commercializing new and current product offerings; drive innovation by allocating resources to the areas of highest opportunity; and pursue growth and investment strategies more directly aligned with each company's respective goals."

Mark Trudeau said, "Today's announcement is another important step forward in our journey to become an innovation-driven, pure-play, specialty pharmaceutical brands growth company. We believe this separation will further enhance our strategic focus and strengthen our balance sheet. It should also provide us with additional liquidity to support investments in our in-line brands and development portfolio and strategically allocate capital."

Trudeau added, "The spin-off of the Specialty Generics business creates an exciting new company which we believe will be well positioned to grow. Operating independently will allow this new company to more rapidly capitalize on its growth opportunities to enhance value."

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PROFILE OF THE NEW SPECIALTY GENERICS COMPANY

For the twelve months ended September 28, 2018, the collective net sales from the new Specialty Generics company exceeded $850 million on an as reported basis inclusive of the AMITIZA product since February 14, 2018.

With approximately 1,600 employees, the newly spun company will include a leading acetaminophen business, a portfolio of both API and generic finished dose forms of controlled substances and other drugs, a niche specialty generics development portfolio, and a strong U.S. manufacturing footprint. The inclusion of the AMITIZA product in the non-promoted assets to be spun off brings added manufacturing facilities and employees in Japan, and diversifies revenues further. Marketed in the U.S. and Japan by alliance partners, Mallinckrodt recognizes net sales from commercial partnership arrangements in the form of AMITIZA product sales, royalties and milestones. The new Specialty Generics company will be positioned financially to grow its ANDA[1] pipeline and expects to launch as many as five new products in 2019. The company will be headquartered in the St. Louis, Missouri area.

Matthew Harbaugh, currently Mallinckrodt's Executive Vice President and Chief Financial Officer (CFO) and President of the Specialty Generics business, is expected to become President and Chief Executive Officer of the new company upon completion of the spin off.

Harbaugh will step down as Mallinckrodt's CFO, effective immediately, to focus exclusively on preparing for separation, but will continue to serve as President of the Specialty Generics business and report to Trudeau. A search for Harbaugh's successor is underway. During this process, **George Kegler**, Mallinckrodt's Vice President of Finance, will serve as interim CFO. Announcements of the Board of Directors for the Specialty Generics business are expected at a later date.

Harbaugh said, "Mallinckrodt has a more than 150-year legacy of operations in St. Louis and a proud history of supplying the highest quality products to customers. As an independent, U.S.-based company, I am confident that we will be well positioned to advance our R&D[2] capabilities and continue to maintain our category leadership in controlled substances."

"Matt has been involved in the Specialty Generics business for over a decade," said Trudeau. "We're very pleased to have someone with his leadership experience take the helm."

PROFILE OF THE SPECIALTY PHARMACEUTICAL BRANDS COMPANY

With net sales in excess of $2.3 billion[3] (inclusive of a $1 billion hospital portfolio and a robust innovative pipeline), the Specialty Pharmaceutical Brands company is expected to gain additional liquidity and financial flexibility from the transaction to enable continued strategic transformation and growth.

As reported on Nov. 6, Mallinckrodt's third quarter 2018 results showed strong customer demand for its branded hospital products – including **INOmax®** (nitric oxide) gas, for inhalation, **OFIRMEV®** (acetaminophen) injection and the **Therakos®** immunotherapy platform – and improved performance for **H.P. Acthar® Gel** (repository corticotropin injection). Solid execution combined with tight expense control helped support increased R&D investments in the company's innovative pipeline. Operational excellence and continued strong commercial execution throughout 2018 have also been the catalysts for Mallinckrodt to raise its guidance for adjusted diluted earnings per share in each of the last two quarters.

The company expects to achieve a number of key milestones for its pharmaceutical brands in coming quarters. It anticipates top-line results from both the completed rheumatoid arthritis clinical trial and multiple sclerosis registry for H.P. Acthar Gel as early as the first half of 2019. Additionally, in the second half of 2019, the company is targeting completion of enrollment in Phase 4 trials in uveitis and lupus for the drug, and anticipates completing enrollment in the H.P. Acthar Gel Phase 2 trial in amyotrophic lateral

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[1] Abbreviated New Drug Application
[2] Research and Development
[3] Reflects last twelve months ended September 28, 2018 on an as reported basis

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sclerosis as well. Top-line results from the company's development program for **CPP-1X/sulindac** are anticipated in the first quarter of 2019, and the pivotal trial results for both **StrataGraft®** viable engineered skin tissue and **terlipressin** are expected to be available in the second half of the year.

Following the spin-off, ordinary shares of the renamed Specialty Pharmaceutical Brands company will continue to trade on the NYSE. The company will maintain its global headquarters in Staines-upon-Thames, United Kingdom, and its principal U.S. office in Bedminster, N.J. The company also plans to maintain other facilities throughout the United States and in Australia, Canada, Ireland, Japan, Luxembourg and Switzerland.

NEXT STEPS IN THE SEPARATION PROCESS

With the pursuit of strategic alternatives for the Specialty Generics business actively underway for more than two years, important progress has already been made in key areas that the company believes will simplify and support a relatively short separation process. Completion of the separation transaction will be subject to certain conditions, including final Board approval, an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Mallinckrodt shareholders, and the U.S. Securities and Exchange Commission (SEC) declaring the Form 10 registration statement effective. There can be no assurance regarding the final allocation of assets between the two companies, the ultimate timing of the proposed separation, or that the spin-off will be completed.

CONFERENCE CALL AND WEBCAST

Mallinckrodt will hold a conference call on Thursday, Dec. 6, 2018, beginning at 8:00 a.m. U.S. Eastern Time. This call can be accessed in three ways:

- At the Mallinckrodt website: http://www.mallinckrodt.com/investors.
- By telephone: For both listen-only participants and those who wish to take part in the question-and-answer portion of the call, the telephone dial-in number in the U.S. is (b)(6) participants outside the U.S., the dial-in number is (b)(6) Callers will need to provide the Conference ID of (b)(6)
- Through an audio replay: A replay of the call will be available beginning at 11:00 a.m. Eastern Time on Thursday, Dec. 6, 2018, and ending at 11:59 p.m. Eastern Time on Thursday, Dec. 20, 2018. Dial-in numbers for U.S.-based participants are (b)(6) or (b)(6) Participants outside the U.S. should use the replay dial-in number of (b)(6) . All callers will be required to provide the Conference ID of (b)(6)

ADVISORS

Goldman, Sachs & Co. is acting as financial advisor on the spin-off and Wachtell, Lipton, Rosen & Katz is acting as legal advisor.

ABOUT THE SPECIALTY GENERICS DISPOSAL GROUP

In light of this announcement, and in accordance with the accounting literature pertaining to discontinued operations, it is expected that the Specialty Generics Disposal Group, which is currently reflected in discontinued operations, will be brought back into Mallinckrodt's continuing operations in conjunction with its next quarterly earnings announcement and within its 2018 Form 10-K to be filed in February 2019.

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ABOUT AMITIZA
AMITIZA (lubiprostone), a leading global product in the branded constipation market, is approved by the U.S. Food and Drug Administration for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. The AMITIZA product is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool.

ABOUT MALLINCKRODT
Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the SEC disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS
Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses and any other statements regarding events or developments the company believes or anticipates will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties.

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: the proposed spin-off of the Specialty Generics business inclusive of Mallinckrodt's AMITIZA product, including the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction; general economic conditions and conditions affecting the industries in which Mallinckrodt operates; the commercial success of Mallinckrodt's products; Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions; conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment; changes in laws and regulations; Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings; Mallinckrodt's and Mallinckrodt's licensers' ability to successfully develop or commercialize new products; Mallinckrodt's and Mallinckrodt's licensers' ability to protect intellectual property rights; Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; customer concentration; Mallinckrodt's reliance on certain individual products that are material to its financial performance; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; the reimbursement practices of a small number of public or private insurers; pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; limited clinical trial data for H.P. Acthar Gel; complex reporting and payment obligations under healthcare rebate programs; Mallinckrodt's ability to navigate price fluctuations; future changes to U.S. and foreign tax laws; Mallinckrodt's ability to achieve expected benefits from

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restructuring activities; complex manufacturing processes; competition; product liability losses and other litigation liability; ongoing governmental investigations; material health, safety and environmental liabilities; retention of key personnel; conducting business internationally; the effectiveness of information technology infrastructure; and cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 29, 2017. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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Government Affairs, Policy, Advocacy
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[EXTERNAL] CEPOP All-Participants Teleconference (December 2018) - AGENDA ATTACHED

Where:	WebEx; (b)(6) // 294 338 760
When:	Tue Dec 18 11:00:00 2018 (America/New_York)
Until:	Tue Dec 18 12:00:00 2018 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	Addie Liles <(b)(6) Rebecca Slater Abbott <(b)(6) "Patel, Beena S." <(b)(6) Nicole Burda <(b)(6) Julian Hoffman <(b)(6) "Evans, Daniel F." <(b)(6) Dan Buffington <(b)(6) Tracie Thomas <(b)(6) "Cristi L. Schwarcz" <(b)(6) Mary Winnefeld <(b)(6) "Celia Hagan (NILA)" <(b)(6) Aiken Hackett <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) Kathleen O'Conner <(b)(6) "Dr. Jack Stein" <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Kristi Thompson <(b)(6) "Zook, David R." <(b)(6) Kevin Walker <(b)(6) "Deana Haworth (Hirons)" <(b)(6) John Donahue <(b)(6) Michael DeGeorge <(b)(6) Kate Berry <(b)(6) Becky Salay <(b)(6) "Clay Alspach (b)(6) <(b)(6)

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Jeffrey Ekoma <(b)(6)

Optional Attendees:

"Motu, Nick" <(b)(6)
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CEPOP Participants – In advance of our December 2018 CEPOP All-Participants teleconference, please find the agenda attached below. We are pleased to have two fantastic focus topic speakers for this month's meeting, including:

- **Rachael Cooper**, *Senior Program Manager, Opioid Use Harm Prevention, National Safety Council*
- **Kelly Kennai Grunig**, *Senior Director, Communications and Advocacy Engagement, Government Relations and Policy, YMCA of the USA*

We look forward to a productive discussion tomorrow morning. As always, please do not hesitate to reach out with any questions.

CEPOP All-Participants Teleconference (December 2018)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (DECEMBER 2018)

Date: Tuesday, December 18, 2018

Time: 11:00am – 12:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Prescription Drug Employer Toolkits – Addressing Rx Drug Abuse Within Organizations**
  Rachael Cooper, *Senior Program Manager, Opioid Use Harm Prevention, National Safety Council*
- **B. Initiative to Improve Public Access to Opioid Reversal Medications (link)**
  Kelly Kennai Grunnig, *Senior Director, Communications and Advocacy Engagement, Government Relations and Policy, YMCA of the USA*

III. Advocacy and Policy Priorities

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    1. Both Prescription and Illicit Opioids
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- **B.** Lame Duck Session Updates
  - **i.** Remaining FY2019 Budget Priorities

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- **A.** Takeback and Anti-Diversion
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- **A.** Timeline for Upcoming Meetings
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Next In-Person CEPOP All-Participants 2019 Planning Session:

January 2019 (calendar appointment forthcoming)

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Where:	WebEx; (b)(6) // 294 338 760
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CEPOP All-Participants Teleconference (December 2018)

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (DECEMBER 2018)

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Next In-Person CEPOP All-Participants 2019 Planning Session:

January 2019 (calendar appointment forthcoming)

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[EXTERNAL] CEPOP 2019 Annual All-Participants Strategy Session (In-Person)

From: "Rubin, Matthew J." <(b)(6)

To: Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach (b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) David May <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Dennis Brennan <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Donald Hoppert <(b)(6) "Dr. Anita Gupta" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) "Dr. Jack Stein" <(b)(6) "Dr. John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) Erika Long

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(MNK)" [redacted] Mary Bono [redacted] "Nadine
Gracia [redacted] "Zook, David R."
[redacted]

Date: Thu, 10 Jan 2019 11:07:09 -0500

Attachments: not supported calendar message.ics (17.06 kB)

Formal agenda and materials forthcoming.

Meeting Location
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

For those unable to attend in-person, a WebEx has been made available for individuals to participate remotely.

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** [redacted]
  - **Participant Code:** [redacted]

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[EXTERNAL] CEPOP 2019 Annual All-Participants Strategy Session (In-Person) -- AGENDA ATTACHED

From: "Rubin, Matthew J." <(b)(6)

To: "Kathryn L. Cates-Wessel" <(b)(6) Charlie Cichon <(b)(6) "Gabriella Witte (APHA)" <(b)(6) Carol Thornton <(b)(6) Wade Delk <(b)(6) "Patel, Beena S." <(b)(6) "Rachel Rivera (b)(6) <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) "Evans, Daniel F." <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) "Kevin Roy (Shatterproof)" <(b)(6) Robert Forman <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Eli Briggs <(b)(6) Mary Winnefeld <(b)(6) Shelley Starkey <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) Amanda Sears <(b)(6) Jeremiah Lindemann <(b)(6) "Gen. Arthur Dean" <(b)(6) Vince Ventimiglia <(b)(6) Alice Dembner <(b)(6) Michael DeGeorge <(b)(6) James Appleby <(b)(6) Patricia D'Antonio <(b)(6) Geoffrey Laredo <(b)(6) "Zook, David R." <(b)(6) Sonya Clay <(b)(6) Karen Tracy <(b)(6) Van Ingram <(b)(6) Rob Morrison <(b)(6) Donald Hoppert <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Dr. Anita Gupta" <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Samantha Arsenault <(b)(6) shatterproof.org>, "Celia Hagan (NILA)" <(b)(6) "Dr. John Harrison" <(b)(6) Sue Thau <(b)(6) Caren Kagan Evans <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Lorraine Yarde <(b)(6) Amy Callendar <(b)(6) Steve Passik <(b)(6) Chris Zimmerman <(b)(6) Rebecca Farley <(b)(6) "Sue Thau (Gmail)" <(b)(6)

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Kate Berry <(b)(6) David May <(b)(6)
"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) Hadi
Sedigh <(b)(6) Kimberly Wilkinson <(b)(6)
"Danna Droz (NABP)" <(b)(6) Gary Mendell
<(b)(6) "Dr. Renan Castillo" <(b)(6) Patricia
Bruckenthal <(b)(6) Kate McFadyen
<(b)(6) Tracie Thomas <(b)(6) "Dr. Jack
Stein" <(b)(6) Elizabeth Solhtalab <(b)(6) Patricia
Farley <(b)(6) Andrew kessler
<(b)(6) "Jessica Johnston (BD)"
<jessica(b)(6) "Robin Swift (b)(6)
<(b)(6) "Nadine Gracia (b)(6) <(b)(6)
Kathleen O'Conner <(b)(6) Jane Terry
<(b)(6) Jeffrey Ekoma <(b)(6) Marcia Lee Taylor
<(b)(6) "Hanson, Roberta J."
<(b)(6) John Donahue <(b)(6) "Cara
Moon (Egalet)" <(b)(6) Nicole Burda <(b)(6)
Jason Sundby <(b)(6) "Sarah Nerad (Alkermes)"
<(b)(6) Kristi Thompson <(b)(6)
"Alexander, Tesfa" <(b)(6) Scott Proescholdbell
<(b)(6) "Brooke Goldberg (SAFE Project US)"
<(b)(6) Shalini Wickramatilake <(b)(6)
Paul Ross <(b)(6) Addie Liles <(b)(6) Blair
Clark-Schoeb <(b)(6) Courtney Hunter
<(b)(6) Teresa Baker <(b)(6) Rita Norton
<(b)(6) Keysha Brooks-Coley <keysha.(b)(6)
cancer.org>, Erika Long <(b)(6) "William Hibbs
(Alkermes)" <(b)(6) Judi Lund Person
(b)(6) Rebecca Slater Abbott <(b)(6)
Chuck Ingoglia <(b)(6) Aryka Chapman
<(b)(6) Susan Awad <(b)(6) "Dr.
Elizabeth Salisbury-Afshar" <(b)(6) "Blaire Bryant
(NACo)" <(b)(6) Mary Bono <(b)(6) Ed Kaleta
<(b)(6) "Cristi L. Schwarcz" <(b)(6) Becky Salay
<(b)(6) Mike Smith <(b)(6) "Ian Goldstein (NACCHO)"
<(b)(6) Daniel Raymond <(b)(6) Julian

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Cc:	Hoffman <(b)(6) Melissa Ough <(b)(6) "Derek Naten (MNK)" <(b)(6) Richard Hamburg <(b)(6) Gabrielle de la Gueronniere <(b)(6) Nick Motu <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Myra Christopher <(b)(6) Dennis Brennan <(b)(6) "Kevin Webb (MNK)" <(b)(6) Kevin Walker <(b)(6) Aiken Hackett <(b)(6) Dan Buffington <(b)(6) "KJ Hertz (March of Dimes)" <(b)(6) John O'Brien <john.(b)(6) Brian Bowden <(b)(6) "Clay Alspach <(b)(6) <(b)(6) "Christian, Jeanine M" <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Brad Tallamy <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) (b)(6) "Brandt Hansberger, Patricia (NIH/OD) [E]" <(b)(6) "Baney, Libby" <(b)(6) "Barbur, Vicki A" <(b)(6) Jonah Cunningham <(b)(6) "Letwat, Julie K." <(b)(6) "Motu, Nick" <(b)(6) Erica Webb-Belzer <(b)(6) Nancy Devine <(b)(6) (b)(6)
Date:	Mon, 28 Jan 2019 15:30:25 -0500
Attachments:	CEPOP Annual Strategy Session Agenda (Jan. 2019).pdf (37.31 kB); not supported calendar message.ics (18.96 kB)

CEPOP Participants – In advance of our forthcoming CEPOP Annual Strategy Session, please find the agenda attached below. We are pleased to have Ms. Michelle Putnam, MPH, join us from the CDC's National Center for Injury Prevention and Control to discuss the recent *Morbidity and Mortality Weekly Reports* and other data sets released focused on the opioid epidemic.

We look forward to a productive discussion and development of CEPOP's 2019 agenda! As always, please do not hesitate to reach out with any questions.

Meeting Location
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400

AMERICAN OVERSIGHT

Washington, DC 20001

For those unable to attend in-person, a WebEx has been made available for individuals to participate remotely.

- To join WebEx, please **CLICK HERE.**
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP 2019 ANNUAL STRATEGY SESSION AGENDA

Date: Wednesday, January 30, 2019

Time: 2:00pm – 4:00pm EST

Location: Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome & Meeting Goals – *Facilitated by Mary Bono* ..... **2:00pm – 2:10pm**

II. Focus Topic Discussions: Framing the Epidemic – *Facilitated by Van Ingram* ..... **2:10pm – 2:30pm**

- **A. Understanding the Data – The Scope and Evolution of the Opioid Epidemic**
  Michelle Putnam, MPH, *Acting Lead for Policy and Partnerships, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC*

III. CEPOP Successes, Growth in 2018 – *Facilitated by Nadine Gracia & Rob Morrison* .... **2:30pm – 3:00pm**

What did CEPOP accomplish in 2018?

- **A.** Advocacy
- **B.** Policy Initiatives
- **C.** Briefing & External Awareness

IV. Developing a 2019 Agenda – *Facilitated by General Dean* ..... **3:00pm – 3:45pm**

- **A. Open Discussion:** Organizational Priorities
- **B.** Building Consensus for a 2019 Workplan
  - **i.** Policy – *With a shifting epidemic and evolving federal policy landscape, what areas should CEPOP focus on in 2019 that would have the most significant impact?*
    1. Moving Upstream – Rising Emphasis on Prevention Strategies
    2. Illicit Opioids – A Shifting Epidemic Calls for a Shift in Focus

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3. Implementation of the 21st Century Cures, CARA, and the SUPPORT for Patients and Communities Acts

4. Safe Disposal of Unused and Unwanted Prescription Drugs

5. Continued Budget and Appropriations Advocacy

6. *Other policy items for consideration?*

ii. Working Groups – *How do we continue to demonstrate our expertise and knowledge with respect to key components of the local and national response?*

1. Safe Use & Prevention – *Should focus remain on accessing safer, abuse-deterrent products or non-opioid alternatives? Is there an education component around stigma?*

2. Takeback & Anti-Diversion – *Closing the loop on the pharmaceutical life cycle. Building upon SUPPORT Act provisions on safe disposal. Continued work on real-time data systems to help reduce*

3. *Are there other potential areas of focus for CEPOP in 2019? Who else should CEPOP and its Working Groups engage?*

C. External Awareness and Visibility – *What events and efforts should CEPOP undertake in 2019 to continue raising organizational awareness? Are there additional opportunities to bring together key partners to discuss research, policy, best practices, etc.?*

i. Events and Convenings

1. 2019 National Rx Drug Abuse and Heroin Summit

ii. Resources

1. Website (www.CEPOPonline.org)

2. Weekly Opioid Policy Report

V. Moving Forward: Setting an Agenda into Action – *Facilitated by Mary Bono* ..... **3:45pm – 4:00pm**

A. Next Steps – *Operationalizing Today's Discussion.*

B. Organizational Update

C. Conclusion

Next Monthly CEPOP All-Participants Teleconference: Monday, February 25, 3:00pm – 4:00pm

Calendar Appointment Forthcoming.

Should you have any questions, please contact Matt Rubin at (b)(6)

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[EXTERNAL] CEPOP 2019 Annual All-Participants Strategy Session (In-Person) -- UPDATED MATERIALS ATTACHED

From: "Rubin, Matthew J." <(b)(6)

To: Marcia Lee Taylor <(b)(6) Andrew kessler <(b)(6) Becky Salay <(b)(6) "Dr. Anita Gupta" <(b)(6) "Dr. John Harrison" <(b)(6) Mary Winnefeld <(b)(6) Rebecca Farley <(b)(6) Donald Hoppert <(b)(6) Rebecca Slater Abbott <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Alice Dembner <(b)(6) "Robin Swift (<(b)(6) <(b)(6) Kristi Thompson <(b)(6) Scott Proescholdbell <(b)(6) Ed Kaleta <(b)(6) Gabrielle de la Gueronniere <(b)(6) Amy Callendar <(b)(6) "Dr. Jack Stein" <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Amanda Sears <(b)(6) Geoffrey Laredo <(b)(6) (b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Teresa Baker <(b)(6) Rita Norton <(b)(6) Vince Ventimiglia <(b)(6) "Kevin Roy (Shatterproof)" <(b)(6) Jane Terry <(b)(6) Sonya Clay <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) Elizabeth Solhtalab <(b)(6) Caren Kagan Evans <(b)(6) "Derek Naten (MNK)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Brian Bowden <(b)(6) Charlie Cichon <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) "Danna Droz (NABP)" <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) Mary Bono <(b)(6) Chris Zimmerman <(b)(6) "Alexander, Tesfa" <(b)(6) Addie Liles <(b)(6) "Gen. Arthur Dean" <(b)(6) Rob Morrison <(b)(6) Patricia D'Antonio <(b)(6) Hadi Sedigh <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) Patricia Bruckenthal

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<(b)(6) "Dr. Renan Castillo" <(b)(6)
Samantha Arsenault (b)(6) , Aryka Chapman
<(b)(6) "Sue Thau (Gmail)" <(b)(6)
"Jessica Johnston (BD)" <jessica(b)(6) "Kathryn L. Cates-Wessel"
<(b)(6) Nick Motu <(b)(6) "KJ Hertz (March of Dimes)"
<(b)(6) Mike Smith <(b)(6) Susan Awad
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Ingram <(b)(6) Jason Sundby <(b)(6)
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<(b)(6) "Tom Supinka (NSC)" <(b)(6)
Kimberly Wilkinson <(b)(6) Courtney Hunter
<(b)(6) Blair Clark-Schoeb <(b)(6)
"Rachel Rivera (b)(6)
<(b)(6) Myra Christopher
<(b)(6) "Zook, David R."
<(b)(6) "Deana Haworth (Hirons)" <(b)(6)
Erika Long <(b)(6) Michael DeGeorge
<(b)(6) "Clay Alspach
(b)(6) <(b)(6) "Deb
Waugh (Affiliated Monitors)" <(b)(6) "Terry McGeeney,
MD, MBA" <(b)(6) "Kevin Webb (MNK)"
<(b)(6) Daniel Raymond <(b)(6) "Nadine
Gracia (b)(6) <(b)(6) Richard Hamburg
<(b)(6) James Appleby <(b)(6)

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Cc:	Jeremiah Lindemann <(b)(6) Eli Briggs <(b)(6) Wade Delk <(b)(6) Brad Tallamy <(b)(6) Aiken Hackett <(b)(6) (b)(6) Lorraine Yarde <(b)(6) Shelley Starkey <(b)(6) Julian Hoffman <(b)(6) Dan Buffington <(b)(6) David May <(b)(6) Robert Forman <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) Carol Thornton <(b)(6) Kathleen O'Conner <(b)(6) John Donahue <(b)(6) Dennis Brennan <(b)(6) Kevin Walker <(b)(6) "Gabriella Witte (APHA)" <(b)(6) "Christian, Jeanine M" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) Steve Passik <(b)(6) "Cara Moon (Egalet)" <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Nicole Burda <(b)(6) "William Hibbs (Alkermes)" <(b)(6) "Motu, Nick" <(b)(6) Jonah Cunningham <(b)(6) "Letwat, Julie K." <(b)(6) "Barbur, Vicki A" <(b)(6) "Brandt Hansberger, Patricia (NIH/OD) [E]" <(b)(6) Nancy Devine <(b)(6) Erica Webb-Belzer <(b)(6) "Baney, Libby" <(b)(6) (b)(6)
Date:	Wed, 30 Jan 2019 09:36:41 -0500
Attachments:	CEPOP Annual Strategy Session Agenda (Jan. 2019).pdf (341.14 kB); CEPOP Annual Strategy Session Deck (Jan. 2019).pdf (2.91 MB); not supported calendar message.ics (19.46 kB)

CEPOP Participants – In advance of our forthcoming CEPOP Annual Strategy Session, please find the agenda attached below. We are pleased to have ***two focus topic speakers*** for this afternoon's meeting.

- **Ms. Michelle Putnam, MPH**, CDC's National Center for Injury Prevention and Control, will discuss the recent *Morbidity and Mortality Weekly Reports* and other data sets released focused on the opioid epidemic.
- **Douglas Throckmorton, MD,** FDA Center for Drug Evaluation and Research, will speak to FDA's ongoing efforts to respond to the public health challenges posed by the opioid epidemic.

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As a reminder, for those unable to attend today's meeting due to travel logistics, we encourage you to join via WebEx. The meeting coordinates are included below.

We look forward to a productive discussion and development of CEPOP's 2019 agenda! As always, please do not hesitate to reach out with any questions.

Meeting Location
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

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AMERICAN OVERSIGHT

CEPOP 2019 ANNUAL STRATEGY SESSION AGENDA

Date: Wednesday, January 30, 2019

Time: 2:00pm – 4:00pm EST

Location: Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

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I. Welcome & Meeting Goals – *Facilitated by Mary Bono*

II. Focus Topic Discussions: Framing the Epidemic – *Facilitated by Mary Bono*

- **A. Understanding the Data – The Scope and Evolution of the Opioid Epidemic**
  Michelle Putnam, MPH, *Acting Lead for Policy and Partnerships, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC*
- **B. Addressing Opioids: The FDA Response to Challenges in Public Health**
  Douglas Throckmorton, MD, *Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

III. CEPOP Successes, Growth in 2018 – *Facilitated by Nadine Gracia & Rob Morrison*

What did CEPOP accomplish in 2018?

- **A.** Advocacy
- **B.** Policy Initiatives
- **C.** Briefing & External Awareness

IV. Developing a 2019 Agenda – *Facilitated by General Dean*

- **A.** Building Consensus for a 2019 Workplan
  - **i.** Policy – *With a shifting epidemic and evolving federal policy landscape, what areas should CEPOP focus on in 2019 that would have the most significant impact?*
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3. Implementation of the 21st Century Cures, CARA, and the SUPPORT for Patients and Communities Acts

4. Safe Disposal of Unused and Unwanted Prescription Drugs

5. Continued Budget and Appropriations Advocacy

6. *Other policy items for consideration? Open discussion.*

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1. 2019 National Rx Drug Abuse and Heroin Summit

ii. Resources

1. Website (www.CEPOPonline.org)

2. Weekly Opioid Policy Report

V. Moving Forward: Setting an Agenda into Action – *Facilitated by Mary Bono*

A. Next Steps – *Operationalizing Today's Discussion.*

B. Organizational Update

C. Conclusion

Next Monthly CEPOP All-Participants Teleconference: Monday, February 25, 3:00pm – 4:00pm

Calendar Appointment Forthcoming.

Should you have any questions, please contact Matt Rubin at (b)(6)

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CEPOP
COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

2019 Annual All-Particip
Strategy Session

WEDNESDAY, JANUARY 30, 2019

2:00PM – 4:00PM

WASHINGTON, DC

WiFi: [redacted] (b)(6) [redacted]

ONDCP-19-0922-A-000158
ONDCP042FY18043_000000031

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CE

Today's Agenda

- Welcome, Introduction and Meeting Goals
- **Focus Topic Presentations:**
  - **CDC:** *Understanding the Data – The Scope and Evolution of the Opioid Ep*
  - **FDA:** *Developing and Improving Therapies to Combat Opioid Misuse, Abu Addiction and Diversion*
- CEPOP Successes and Growth in 2018
- Developing a 2019 CEPOP Agenda
- Moving Forward – Setting an Agenda into Action

ONDCP-19-0922-A-000159
ONDCP042FY18043_000000031

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WELCOME AND OPENING REMARKS



CEPOP
COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

ONDCP-19-0922-A-000160
ONDCP042FY18043_000000031

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CE

Goals of Today's Meeting

What do we want to accomplish today?

- Review CEPOP activities and impact throughout 2018.
- Understand participant priorities and policy goals.
- Identify a robust agenda and workplan for 2019.

Our work against the prescription opioid epidem
must remain coordinated and comprehensive.

ONDCP-19-0922-A-00016 ONDCP042FY18043_000000031

FOCUS TOPIC DISCUSSION:

Michelle Putnam, MPH

Acting Lead for Policy and Partnerships, Division of Unintentional Injury Prevention, National Center for Inj Prevention and Control, CDC



CEPOP
COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

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ONDCP042FY18043_000000031

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National Center for Injury Prevention and Control

Opioid Overdose Epidemic: CDC Update

Michelle Putnam, MPH

Policy and Partnerships Acting Team Lead

Division of Unintentional Injury Prevention

Collaborative for Effective Prescription Opioid Policies
January 30, 2018

ONDCP-19-00243_000000031

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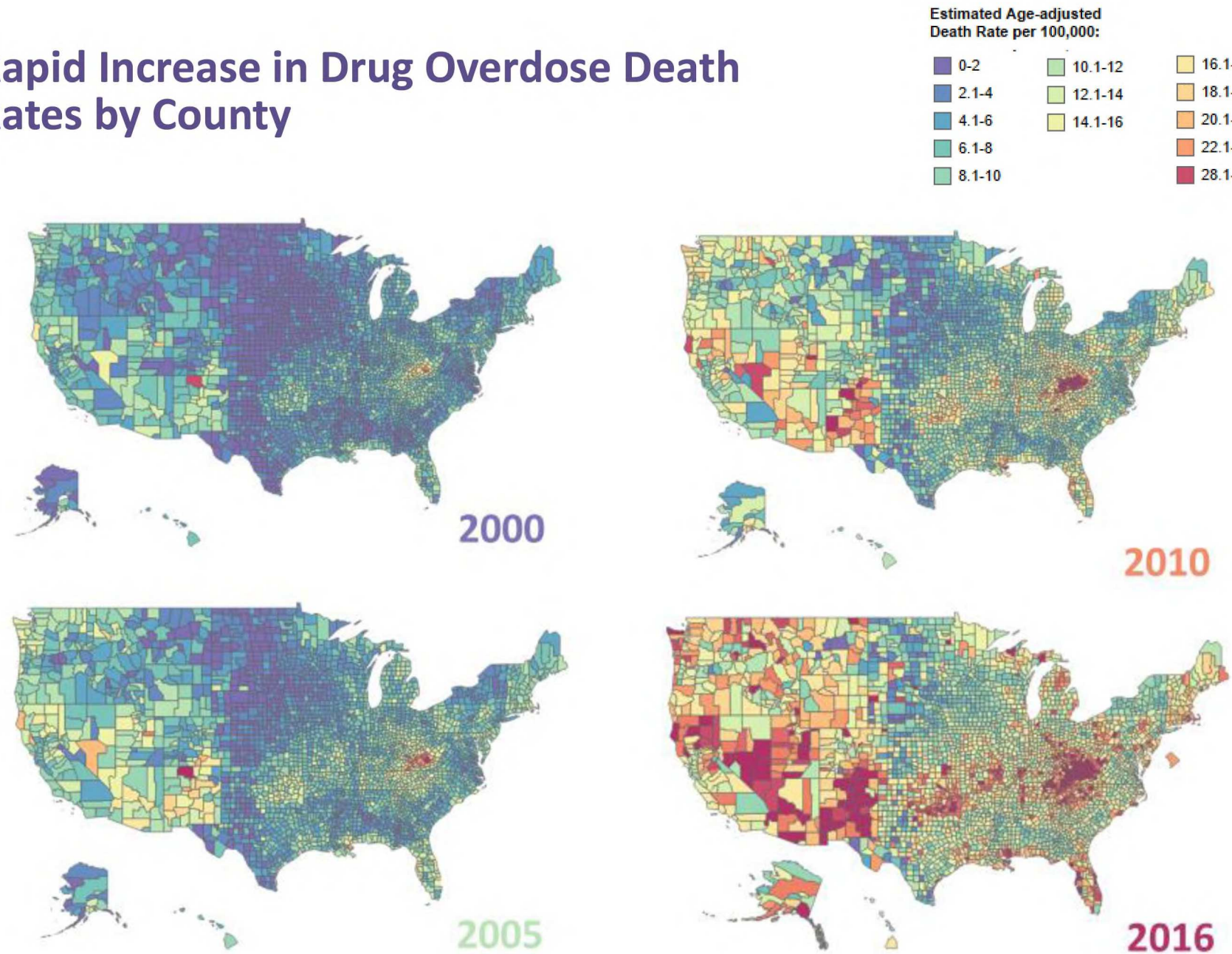
Rapid Increase in Drug Overdose Death Rates by County



SOURCE: NCHS Data Visualization Gallery

ONDCP-19-00243_000000031

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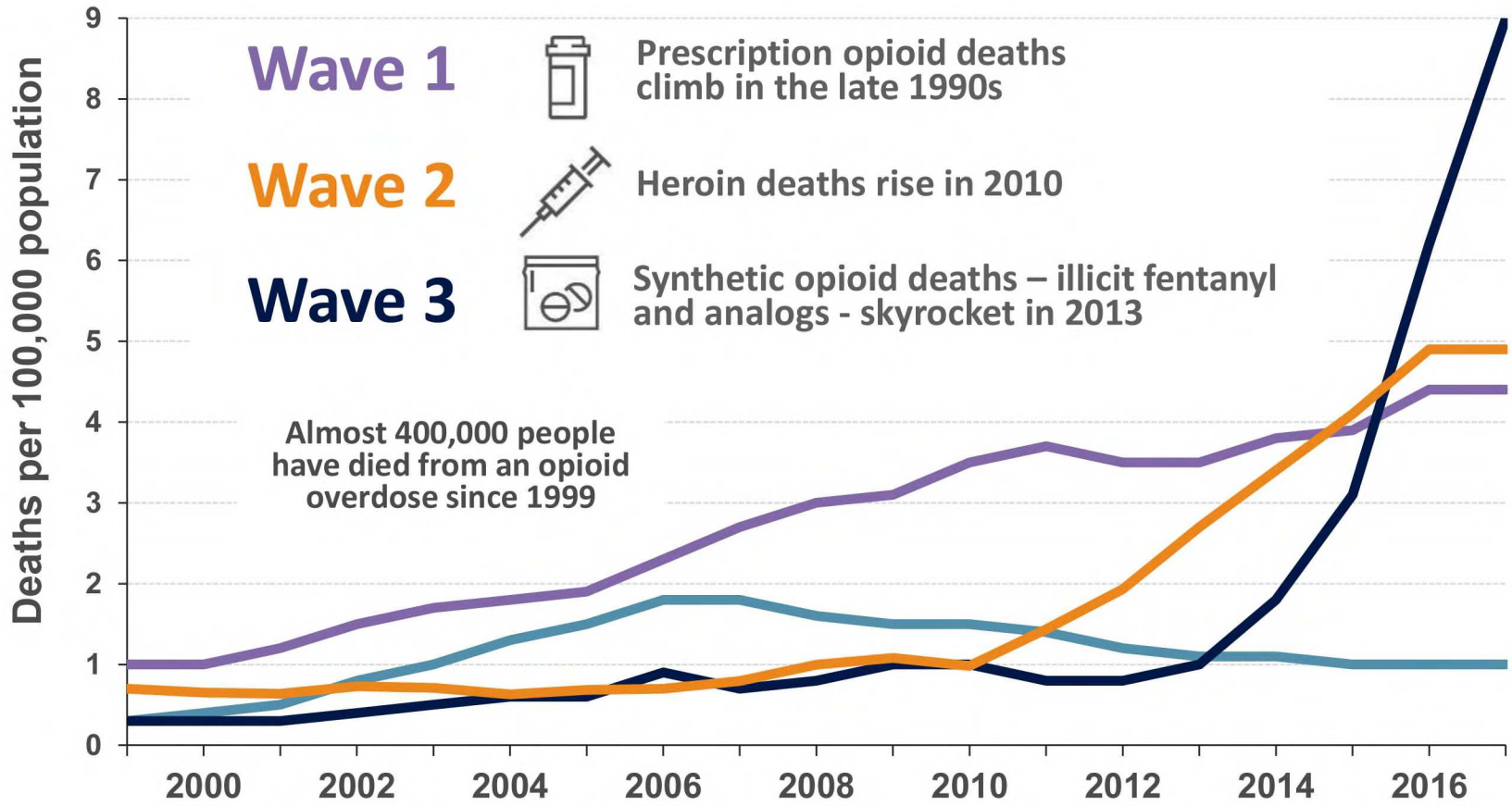
Three Waves of the Opioid Epidemic in the United States



SOURCE: National Vital Statistics System Mortality File

ONDCP-19-00243_000000031

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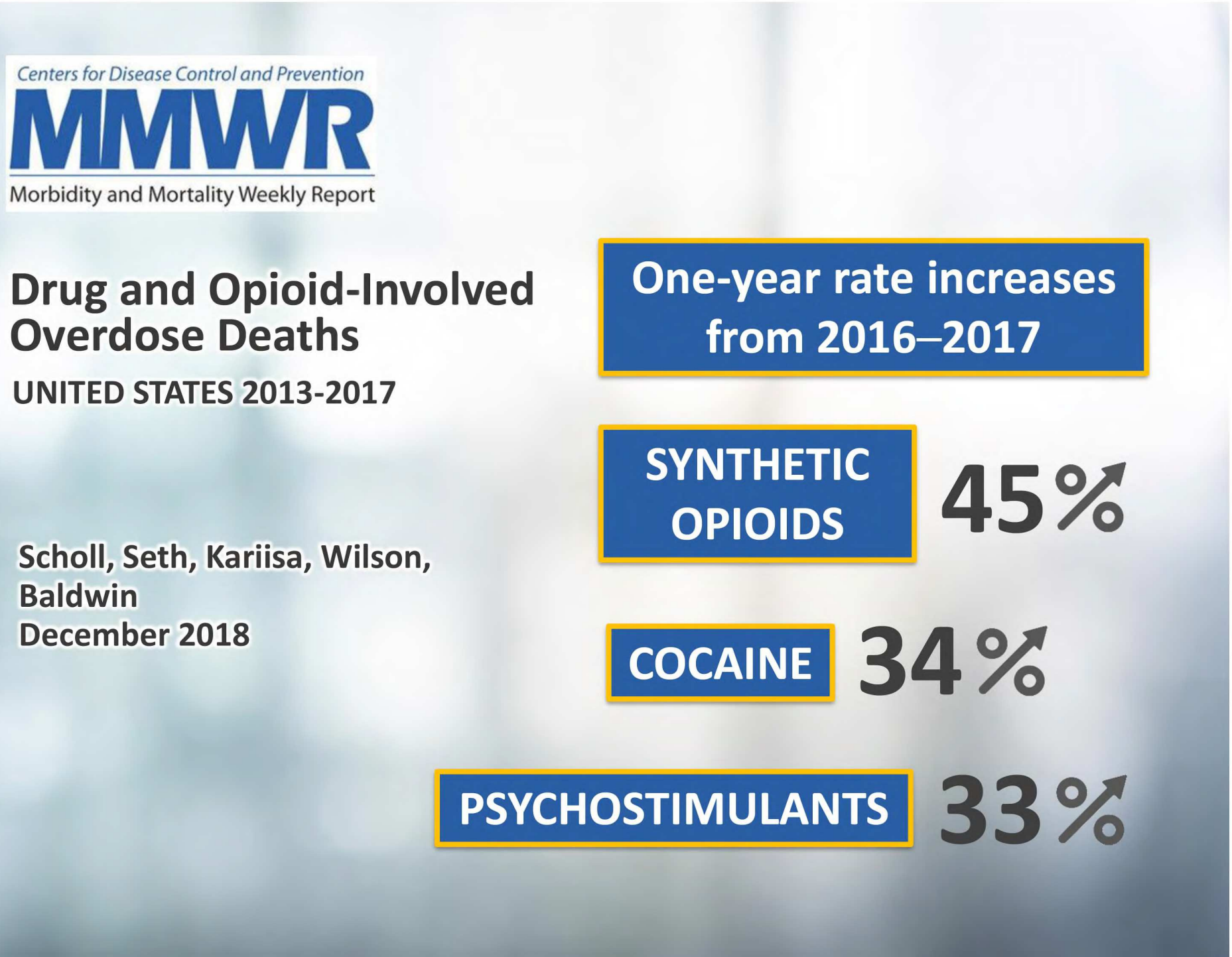

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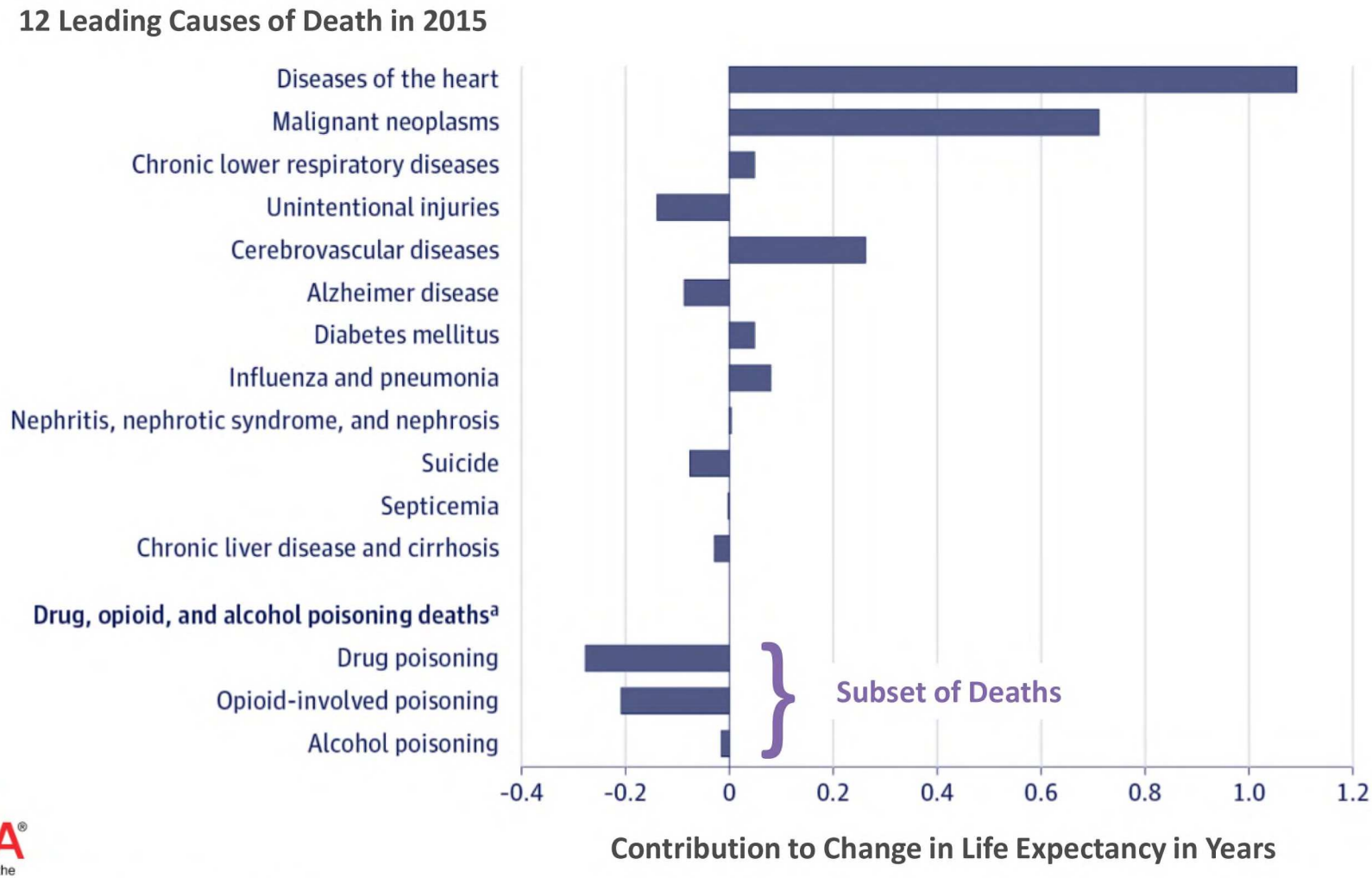
Opioid-involved poisoning has decreased U.S. life expectancy by over 2 months from 2000-2015



JAMA® The Journal of the American Medical Association

SOURCE: Dowell et al., 2017

ONDCP-19-0922-A-001087_000000031

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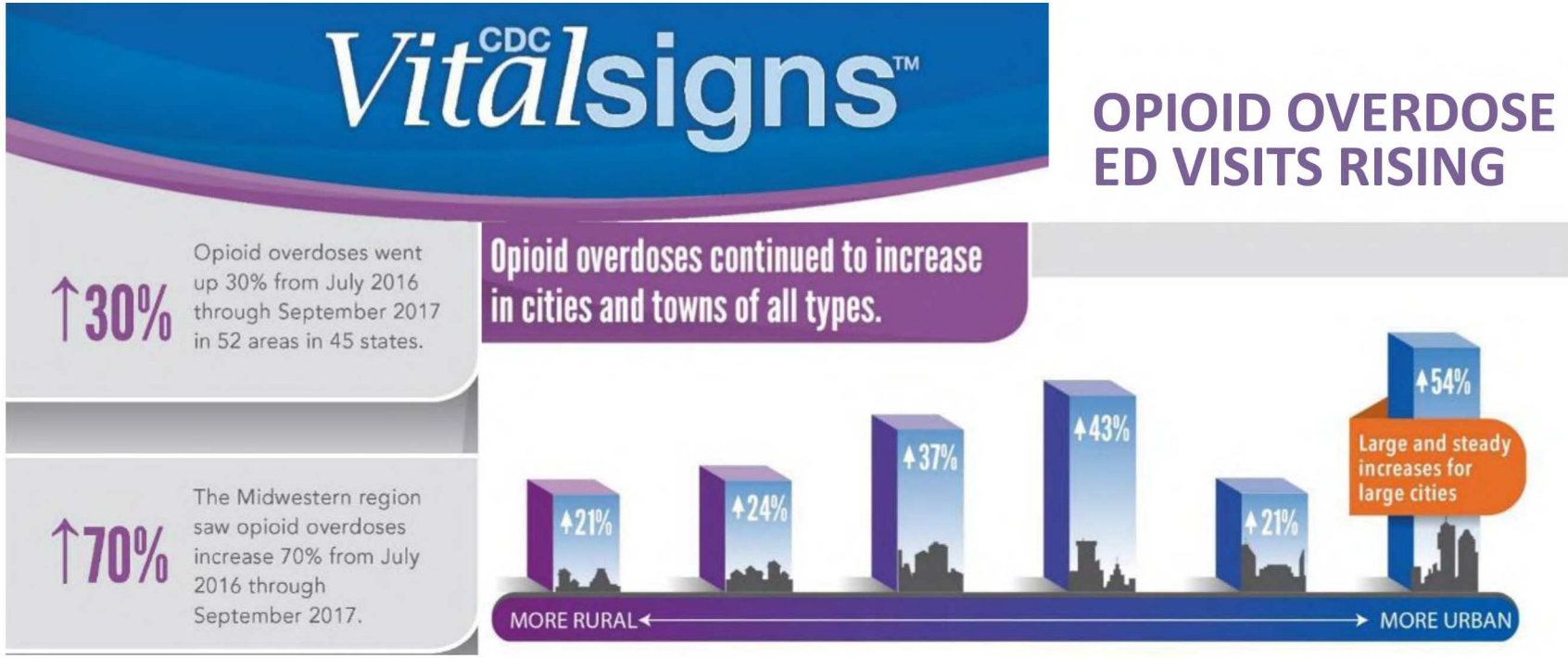
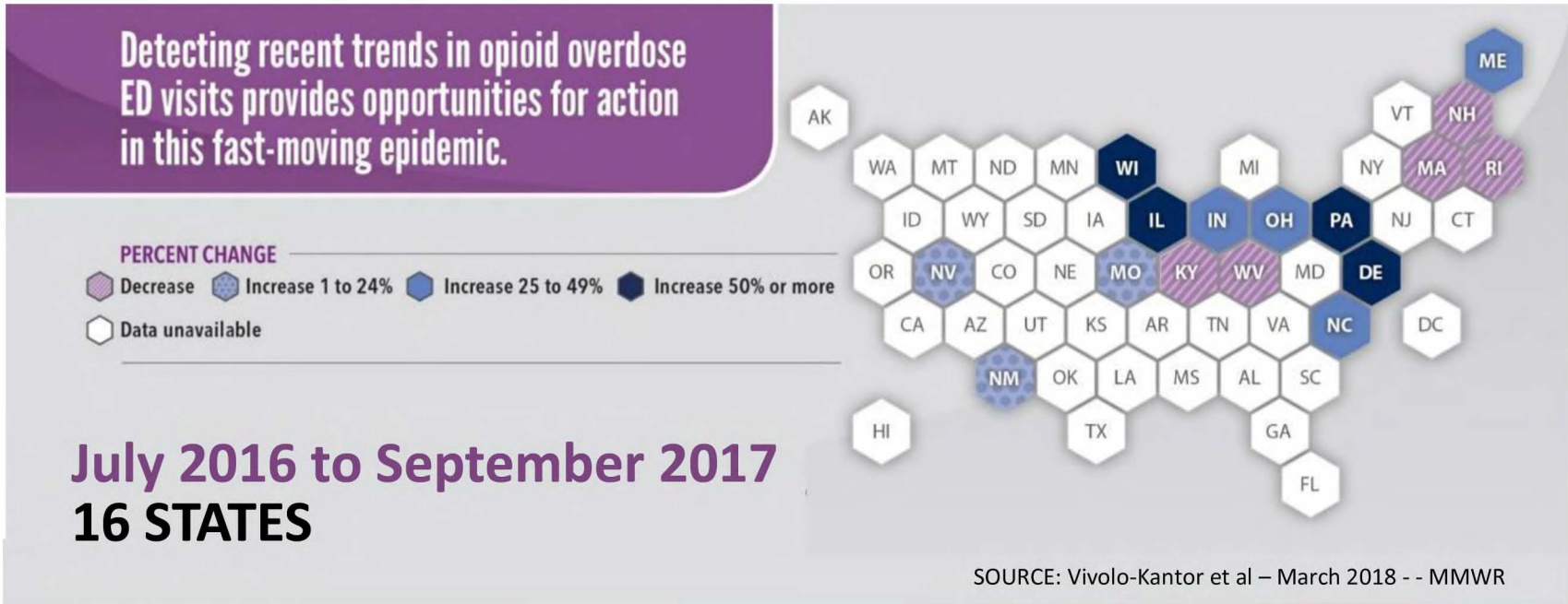
OPIOID OVERDOSE ED VISITS RISING





July 2016 to September 2017
16 STATES

SOURCE: Vivolo-Kantor et al – March 2018 - - MMWR

ONDCP-19-0224-000108_000000031

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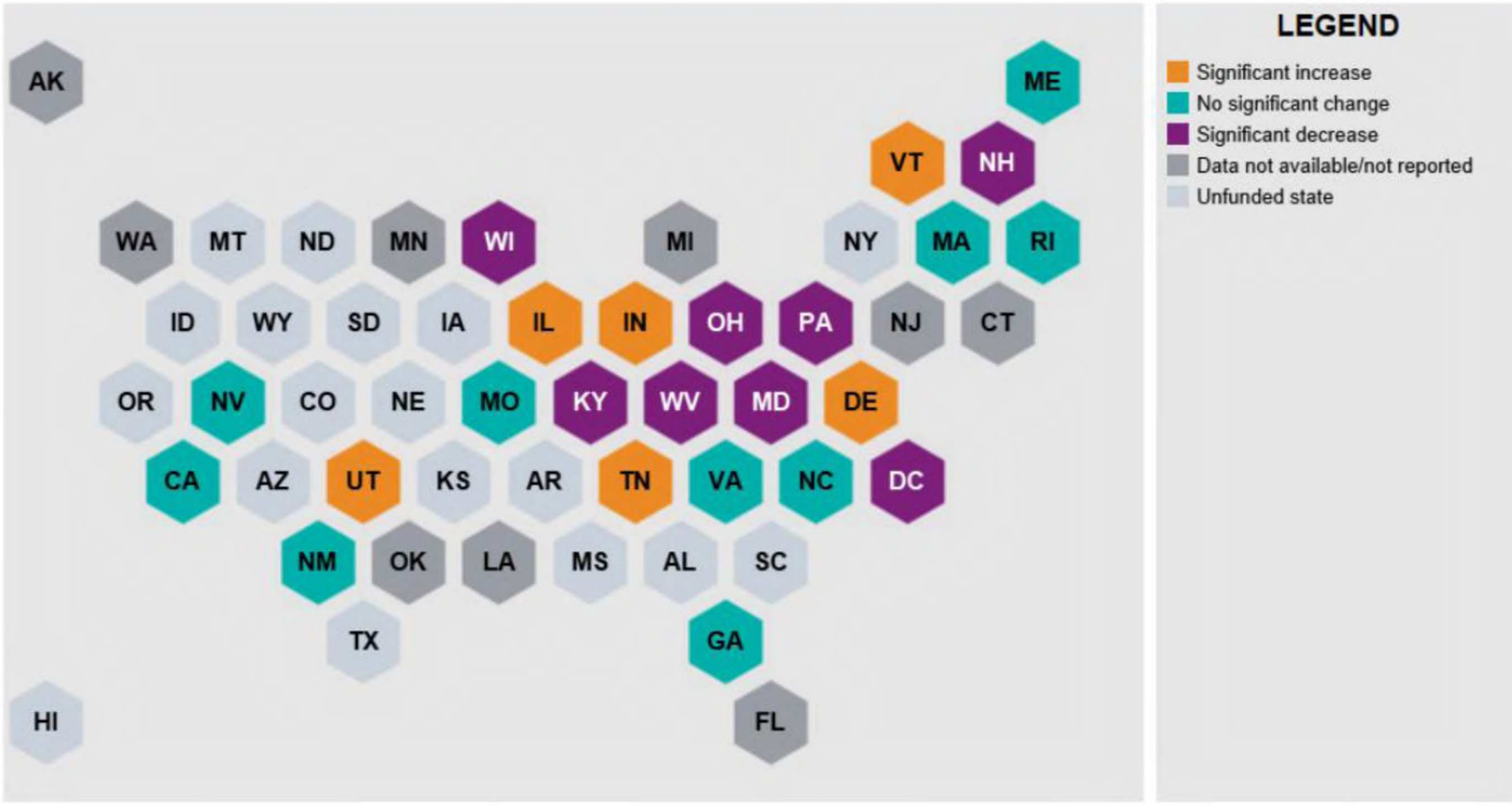
Trends in Emergency Department Visits for Suspected Opioid Overdose, Q2 2017 to Q2 2018

CDC's Enhanced State Opioid Overdose Surveillance Program, Data Current as of October 15, 2018



ONDCP-19-00243_000000031

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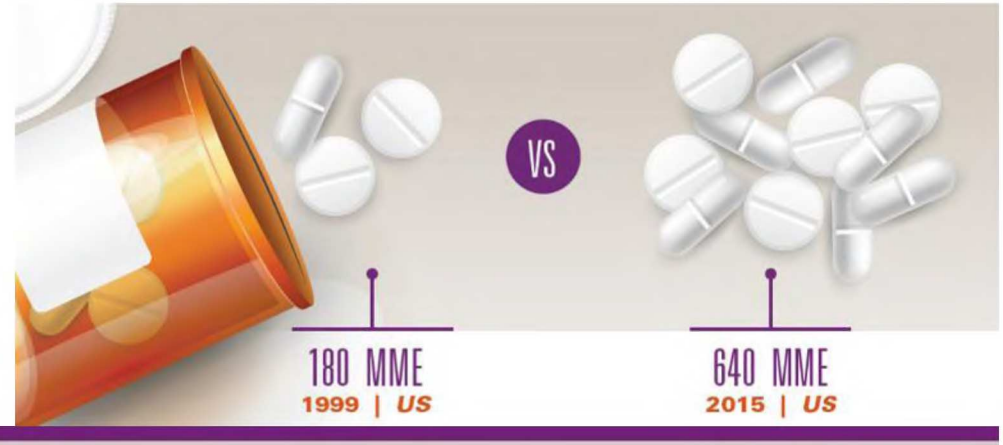
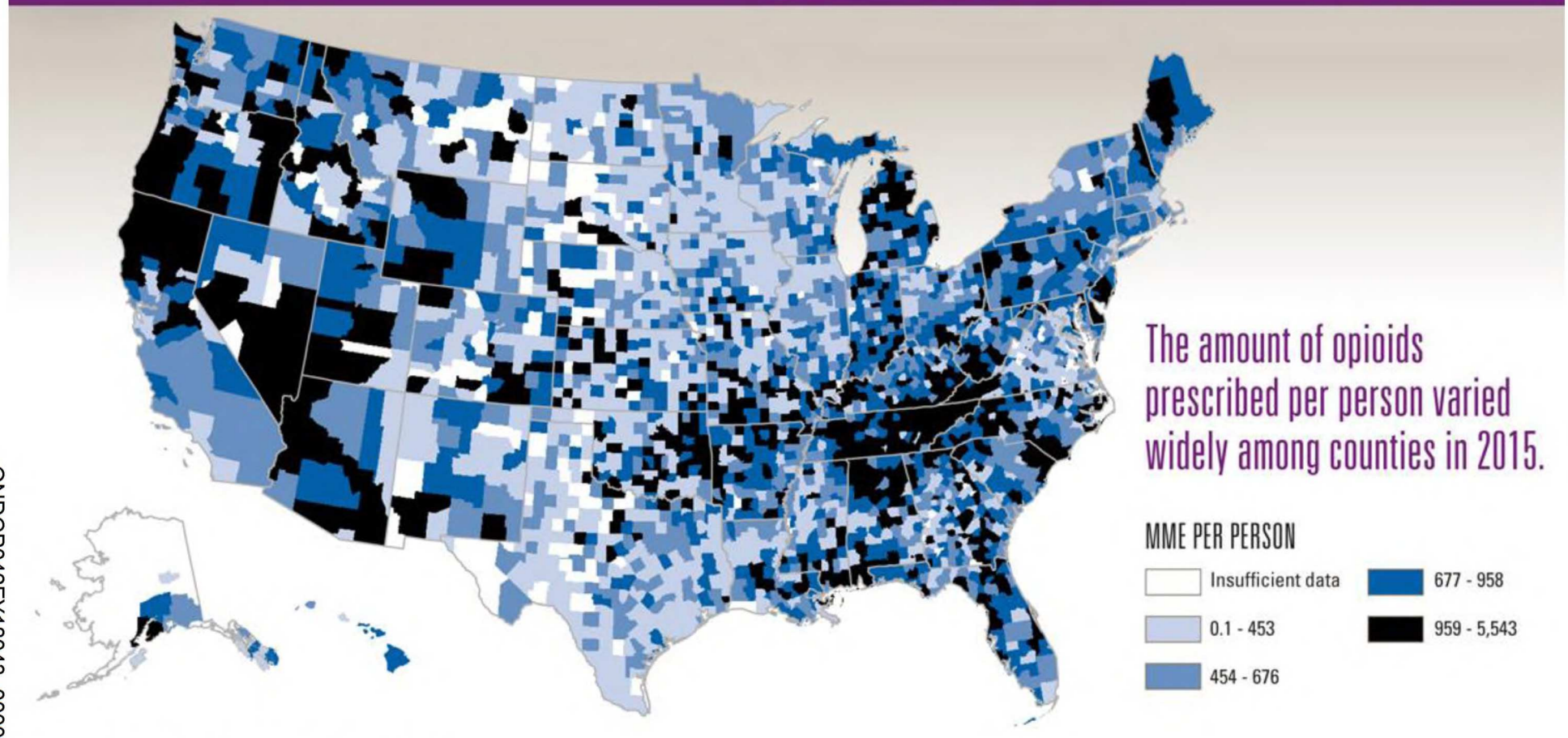
Amount of opioids prescribed increased 3 fold between 1999-2015 and varies 6 fold across counties in 2015





Guy et al. (2017) MMWR 63(26), 563-8.

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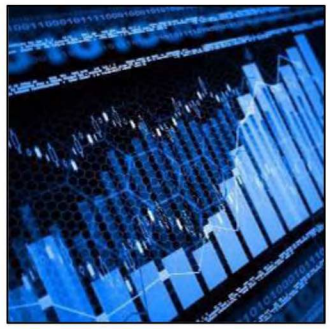
Pillars of CDC Activity

- **Improve data** quality and track trends
- **Strengthen state efforts** by scaling up effective public health interventions
- **Supply healthcare providers with resources** to improve patient safety
- **Collaborate with public safety** to respond more quickly and effectively
- **Empower consumers** to make safe choices





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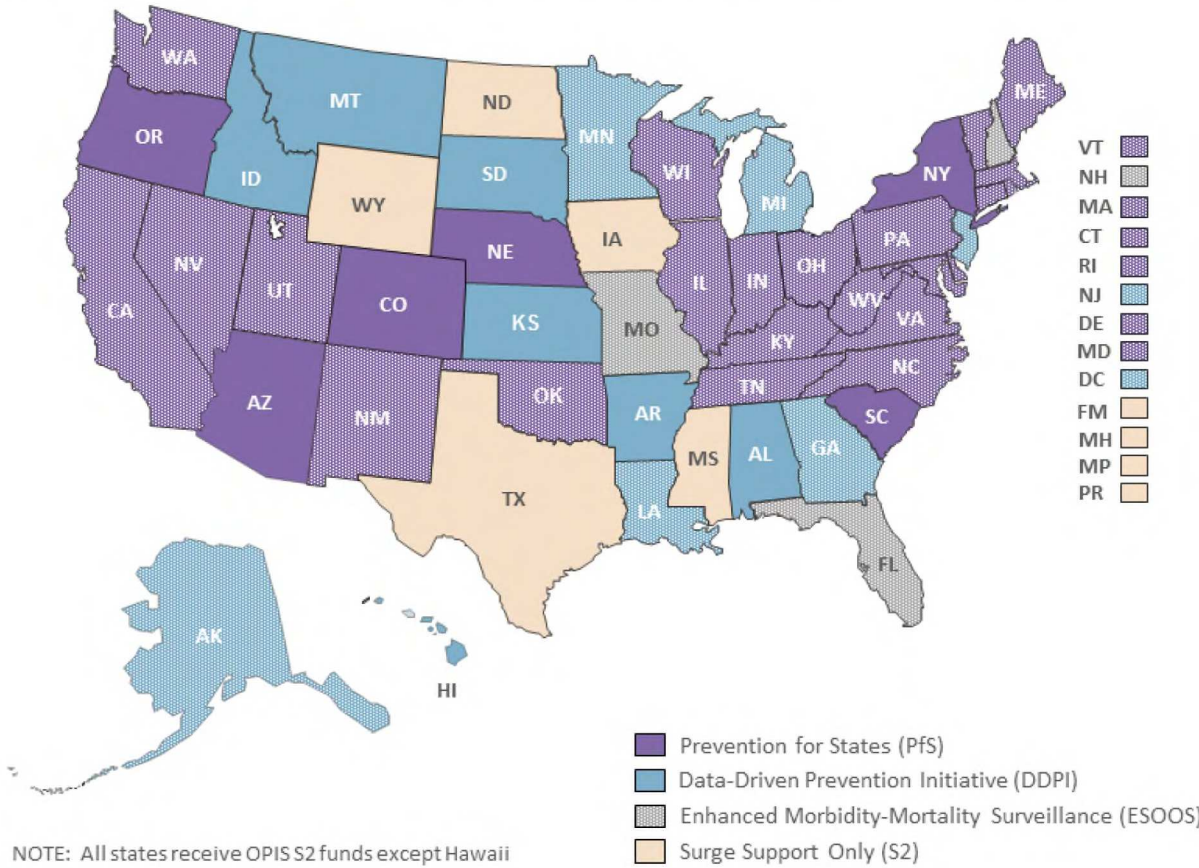
CDC Overdose Prevention in States Initiative



NOTE: All states receive OPIS S2 funds except Hawaii

Five Components



PDMPs



System-Level



Evaluate Policy



Surveillance



Rapid Response

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Eight Key Investments in 2018



OPIS S2 and Partner Support



Tribal Opioid Overdose Prevention



Health System Quality Improvement



Health Care Provider Training



RX Communications Campaign



Adverse Childhood Experiences



RxStat and OD Map



Research on Opioid Overdose Prevention

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Further Reading and References

- Drug and Opioid-Involved Overdose Deaths–United States, 2013-2017
- Opioid Prescribing Rates in Nonmetropolitan and Metropolitan Counties Among Primary Care Providers Using an Electronic Health Record System—United States, 2014–2017
- Drug Overdose Deaths Among Women Aged 30–64 Years—United States, 1999–2017
- Opioid Prescribing by Specialty and Volume in the U.S.
- Evaluation of State-Mandated Reporting of Neonatal Abstinence Syndrome—Six States, 2013–2017
- Gastroschisis Trends and Ecologic Link to Opioid Prescription Rates—United States, 2006–2015
- CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016

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Special thanks to Kristen Sanderson, MPH for her assistance with this presentation.

Please note that the findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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FOCUS TOPIC DISCUSSION:

Douglas Throckmorton, M

Deputy Center Director for Regulatory Programs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



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Addressing Opioids: The FDA Response to Challenges in Public Health

Douglas C. Throckmorton, MD
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
FDA

CEPOP January 30, 2019

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Misuse and Abuse of Prescription Opioid Analgesics Remains an Important Public Health Problem

- In 2017, prescription opioids were the largest category of pharmaceutical products misused and abused in US
  - 11.1 million people estimated to have past-year misuse/abuse
  - 1.7 million people estimated with DSM IV criteria for substance use disorder involving prescription opioid analgesics
- In comparison, 886,000 estimated to have past-year hero use

Source: *Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the U States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rock MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www. samhsa.gov/data/.*

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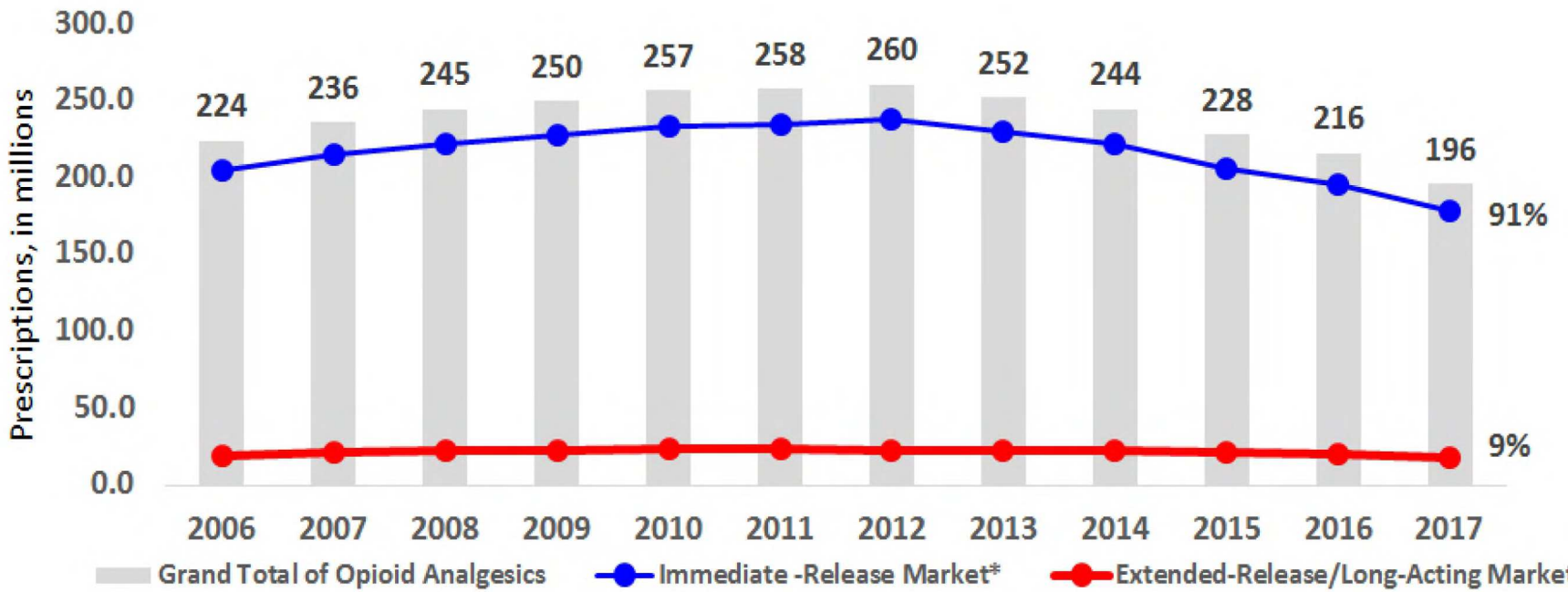
Crisis Ongoing Despite Falling # of Prescriptions for Opioid Analgesics



Source: IQVIA, National Prescription Audit (NPA) and static data 2006-2011. January 2006-December 2017.
Static data extracted March 2017 and 2012-2017 data extracted February 2018.
*Immediate-Release formulations include oral solids, oral liquids, rectal, nasal, and transmucosal
**Extended-Release/Long-Acting formulations include oral solids and transdermal patches
Note: Include opioid analgesics only, excluding injectable formulations as well as opioid-containing cough-cold products and opioid-containing medication-assisted treatment (MAT) products

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Consequences: Prescription Opioids and Overdose Death in the US

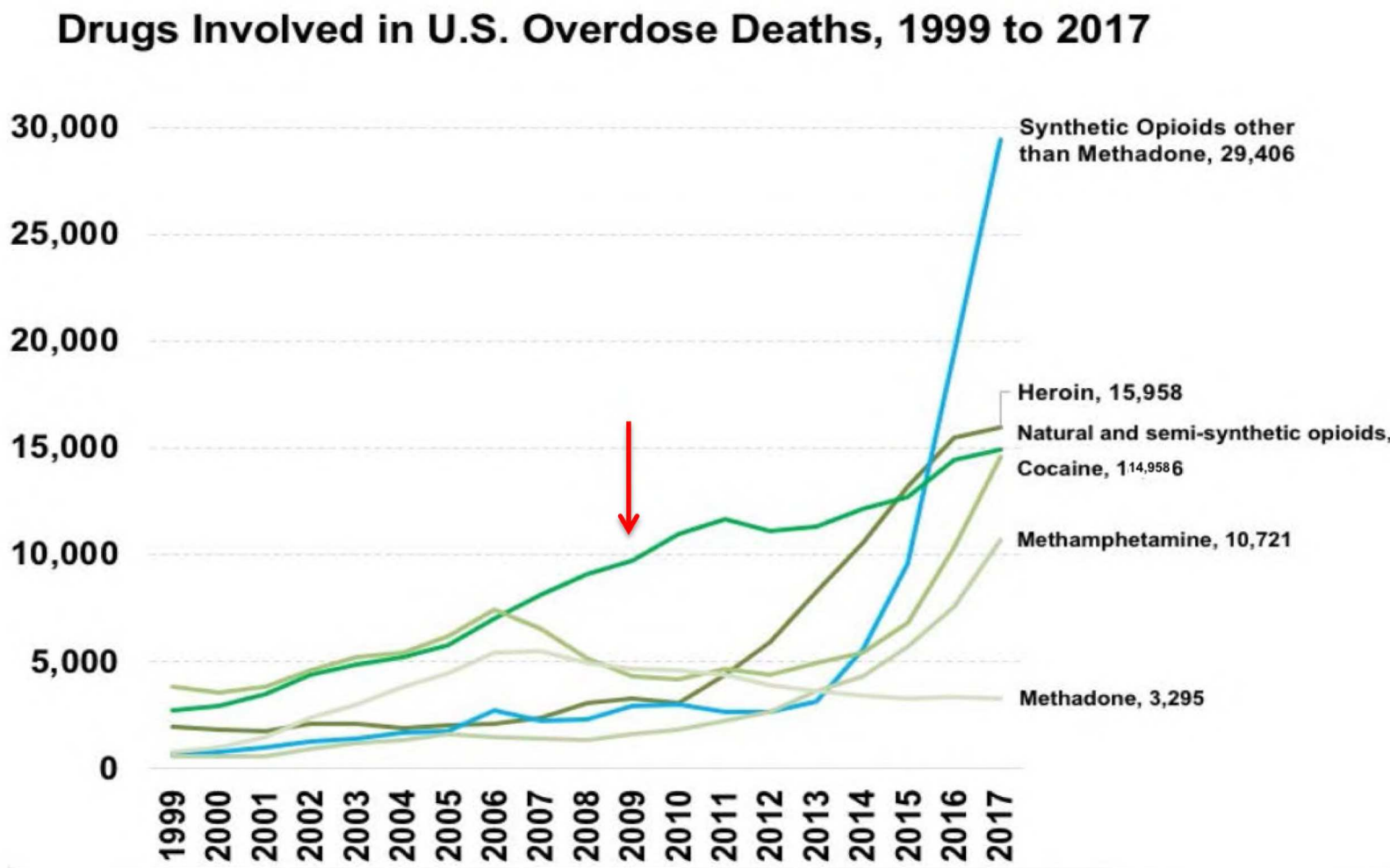

Figure Source: National Institute on Drug Abuse **Data Source:** CDC Wonder
Available from: https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

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The FDA and Opioid Abuse/Misuse

"Unquestionably, our greatest immediate challenge is the problem of opioid abuse. This is a public health crisis of staggering human and economic proportion … we have an important role to play in reducing the rate of new abuse and in giving healthcare providers the tools to reduce exposure to opioids to only clearly appropriate patients, so we can also help reduce the new cases of addiction."

- Scott Gottlieb, FDA Commissioner

Address to FDA staff, May 15, 2017

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The Opioid Crisis: FDA's Priorities

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

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The Opioid Crisis: FDA's Priorities & Strategies

1. Decreasing Exposure & Prevent New Addiction

- Appropriate Dose/Duration Labeling
- Appropriate Packaging, Storage, and Disposal
- Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder

- Naloxone
- Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies

- Partnerships & Meetings
- Abuse Deterrent Formulations (ADFs)
- Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk

- Improving Enforcement
- Assessing Benefit-Risk

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FDA Priorities Align with Recently Passed SUPPORT Act

- Substance Use-Disorder Prevention that Promotes Opioi Recovery and Treatment (SUPPORT)
- Many new provisions affecting FDA including tools to:
  - more efficiently stop illegal, illicit, unapproved, counterfeit and potentially dangerous drugs from entering the U.S. through the IMFs
  - reduce exposure to opioids as a way to lower the rate of nev addiction
  - require certain packaging, such as unit dose blister packs, fo opioids and other drugs that pose a risk of abuse or overdos
  - require that opioids be dispensed with a mail-back pouch or other safe disposal option
- Implementation ongoing

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.ht

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Example: Decreasing Exposure & Preventing New Addiction

	HOW?	WHAT?
Appropriate Packaging, Storage, and Disposal	• Explore how opioid analgesic drug products are **packaged, stored, and discarded**. • Examine use of packaging strategies, such as **unit-of-use packaging** to improve opioid analgesic safety.	• **Jun 1, 2017:** FDA/Duke Margo **workshop and white paper** o packaging, storage, and dispo solutions. • **Dec 11-12, 2017: Public workshop** to gain input on **packaging strategies**. Public docket closed March 2018 wi comments. • **Jan 2018:** Requested **packagi limited amounts** of over-the- counter anti-diarrheal medici **loperamide** to **curb intention misuse and abuse**.

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Opioid Analgesic Needs Vary by Condition/Procedure

Procedure	Mean/ (range) tablets filled	Mean/Median tablets consumed	~Days Used	~Leftove tablets
Outpatient Shoulder Surgery	60 (n.d.)*	37 (n.d.)*	9-10	23
Cesarean Delivery	40 (5-80)*	20*	4-5	20
Tooth Extraction	28 (n.d.)	13	2-3	15
Upper Extremity Surgery	30 (n.d.)	14 (Bone); 9 (Soft Tissue)	2-3	15
Laparoscopic Cholecystectomy	30 (0-100)	10-12	2-3	20
Laparoscopic Appendectomy	30 (n.d.)*	12*	2-3	18
Partial Mastectomy with Node Biopsy	23 (0-60)	6	1-2	17
Laparoscopic Inguinal Hernia Repair	33 (15-70)	9	1-2	24
Open Inguinal Hernia Repair	30 (15-120)	9	1-2	21
Partial Mastectomy	21 (0-50)	3	1	18
Dermatologic Surgery	9 (3-20)	4	1	5

1. Hill, et al., *Ann Surg*, 2017
2. Bateman, et al., *Obstet Gyn*, 2017
3. Maughan, et al., *Drug Alc Dep*, 2016
4. *Harris, et al., JAMA Dermatol. 2013*
5. *Bockman, et al. J Pain, 2017 (Abstract)*
6. *Kumar, et al. AJSM, 2017*

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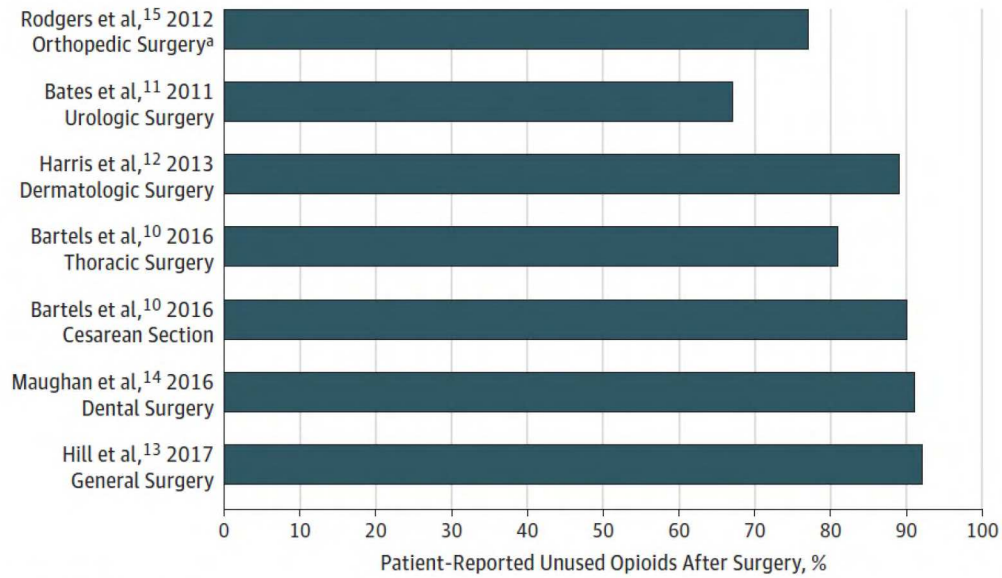
Target: Leftover Opioid Analgesics Reported in Post-surgical Populations

Figure. Prevalence of Unused Opioids Prescribed After Surgery



[a]percentage of patients reporting use of 15 tablets or fewer

- Across many surgica procedures,
  - ➢ >50% of patients reported excess sup of opioid analgesics after treatment of acute pain
  - ➢ Most patients kept excess supply and stored supply in unsecured locations

Figure Source: Bicket MC, Long JJ, Pronovost PJ, Alexander GC, Wu CL. Prescription Opioid Analgesics Commonl, After Surgery: A Systematic Review. JAMA Surg. 2017 Nov 1;152(11):1066-1071.

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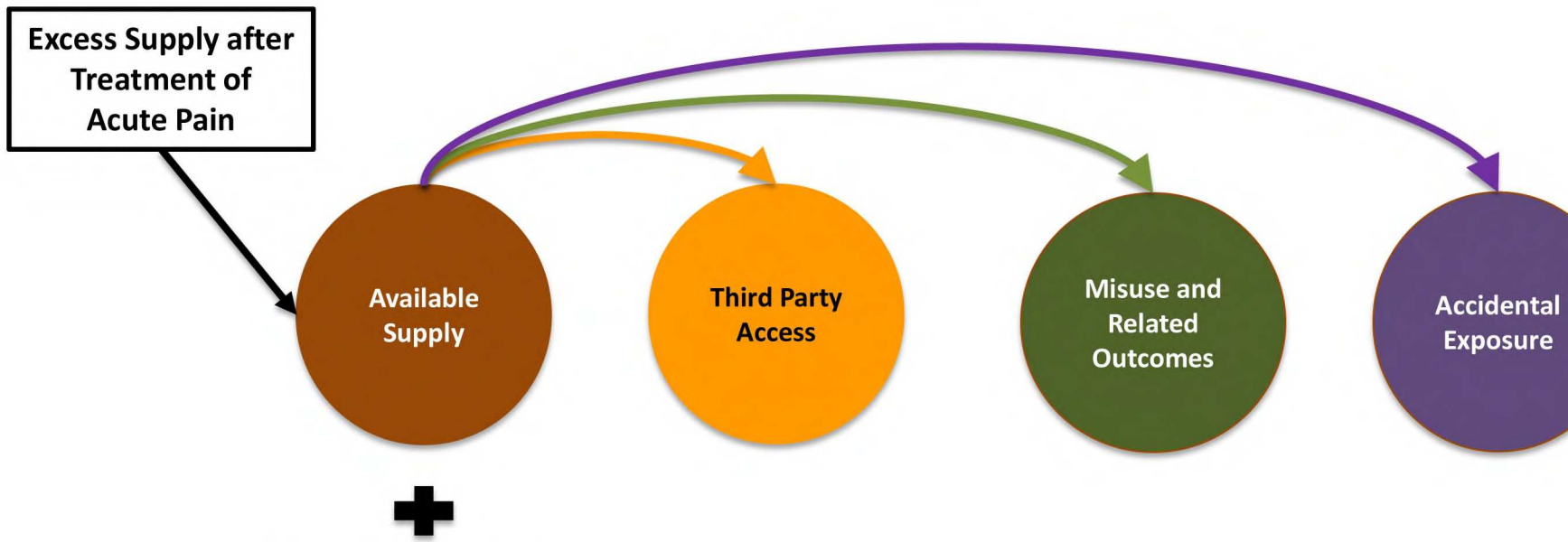
Issue: Opioid Analgesic in the Home Can Feed Other Problems if Misused



- Non-Secure Storage
- Lack of Disposal

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FDA Response: Potential Work on Packaging

- Exploring whether a defined, short-term supply of medication could be packaged in a manner that limits the number of pills dispensed (e.g., blister packs)
- Exploring packaging that could make it easier to track the number of doses that have been taken or reduce the risk for third-party access, such as teen ingesting pills they found in a medicine cabinet
- Work to improve storage and encourage prompt disposal to reduce the available supply of unused opioids

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FDA Response: Improved Data on Opioid Use

- Contract with National Academies of Science, Engineering and Medicine (NASEM)
- Work:
  - Provide best available evidence for prescribers
    - Develop framework for evaluating the evidence base or opioid use in specific therapeutic conditions
    - Inventory available evidence
    - Develop research agenda
  - Support development of new evidence where needed

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Conclusions

- FDA's response to issues raised by opioids reflect unique challenges of how they are used, misused and abused
- FDA has many activities underway, including ways to use packaging tools and to develop improved data on the best uses of opioids

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Thank You



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CEPOP 2018 Successes

Advocacy

- FY2019 Appropriations priorities
- ONDCP programs
- 2018 SUPPORT Act provisions
  - Safe drug disposal
  - Medicare Access to all FDA-approved Medication-Assisted Treatments
- Focus on SUD Treatment and Recovery Quality and Fraud Prevention

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CEPOP 2018 Successes – Policy

Policy Initiatives

- In-person sessions with FDA Commissioner Scott Gottlieb and CMS Pr
  Deputy Administrator Kim Brandt
- CEPOP Roundtable on Quality SUD Treatment and Fraud Prevention
- Collaboration with several federal agencies, Congress, and state polic
  on CEPOP agenda items

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CEPOP 2018 Successes

Briefings and External Awareness

- Monthly Focus Topic Speakers spanning public and private-sector init
- Circulation of a Weekly Opioid Policy Report
- National Rx Drug Abuse Summit Participation and Reception
- Growth in CEPOP Membership (80+ participants)

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Development of a 2019 Agen

Identification of organizational priorities and adva consensus around a 2019 workplan.



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CE

Developing a 2019 CEPOP Agenda

Policy, Advocacy, and Awareness – Where can CEPOP have the most imp
2019 and beyond?

- Moving Upstream – Rising Emphasis on Prevention Strategies
- The Rising Impact of Illicit Opioids
- Implementation of Recent Opioid-Related Legislation
- Safe Drug Disposal
- Continued Budget and Appropriations Advocacy

Are there other items policy-related items for consideration?

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CE

Developing a 2019 CEPOP Agenda

CEPOP Working Groups – Building out CEPOP expertise around prevention, trea
and recovery efforts at the local and national levels.

- Safe Use & Prevention
  - Existing focus on accessing safer, abuse-deterrent opioid products or non-opioid alternatives for the treatment of acute and chronic pain.
  - Should we expand focus to primary prevention needs?
- Takeback & Anti-Diversion
  - Ensuring closure of the pharmaceutical lifecycle with safe disposal.
  - Consider support for the DEA clearinghouse legislation?

Are there others that should be included in Working Group discussions or ou

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Developing a 2019 CEPOP Agenda

External Awareness and Visibility

- How do we continue to raise visibility of both CEPOP and the need fo continued, comprehensive and collaborative efforts to combat the op epidemic?
- Conferences or events where CEPOP should be visible?
- Promotion of the CEPOP website and Weekly Opioid Policy Report

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Development of 2019 CEPOP Agenda

Where do we go from here?

Moving Forward: *Next Steps and Action Items*

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Developing a 2019 CEPOP Agenda

Operationalizing Today's Discussion

- Organizational Update
- Concluding Remarks

Next All-Participants Teleconference

Monday, February 25, 2018
3:00pm – 4:00pm

Calendar Appointment Forthcoming

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THANK YOU!

We look forward to continuing our effort
combat the epidemic in 2019 and beyo

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COLLABORATIVE FOR EFFECTIVE PRESCRIPTION OPIOID POLICIES

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[EXTERNAL] CEPOP All-Participants Teleconference (February 2019)

From: "Rubin, Matthew J." <(b)(6)

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Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emily Diehl (NASADAD)" <(b)(6) Erika Long <(b)(6) "Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)" <(b)(6) Gabrielle de la Gueronniere (b)(6) dc.org>, Gary Mendell (b)(6) , "Gen. Arthur Dean" <(b)(6) "Gena Fitzgerald (SAFE Project)" <(b)(6) Hadi Sedigh <(b)(6) "Hanson, Roberta J." <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) James Appleby <(b)(6) Jane Terry <(b)(6) Jason Sundby <(b)(6) Jeffrey Ekoma <(b)(6) Jeremiah Lindemann <(b)(6) "Jessica Johnston (BD)" (b)(6) John Donahue <(b)(6) Judi Lund Person (b)(6) Julian Hoffman <(b)(6) Karen Tracy <(b)(6) Kate Berry <(b)(6) Kate McFadyen <(b)(6) Kathleen O'Conner <(b)(6) "Kathryn L. Cates-Wessel" <(b)(6) "Kevin Roy (Shatterproof)" <(b)(6) , Kevin Walker <(b)(6) Keysha Brooks-Coley <keysha.(b)(6) cancer.org>, "KJ Hertz (March of Dimes)" <(b)(6) Kristi Thompson <(b)(6) Lorraine Yarde <(b)(6) Marcia Lee Taylor <(b)(6) Mary Winnefeld <(b)(6) Melissa Ough <(b)(6) Michael DeGeorge <(b)(6) Mike Smith <(b)(6) Nick Motu <(b)(6) Nicole Burda <(b)(6) "Patel, Beena S." <(b)(6) Patricia Bruckenthal <(b)(6) Patricia D'Antonio <(b)(6) Patricia Farley <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Paul Ross <(b)(6) "Rachel Rivera (b)(6) <(b)(6) Rebecca Farley <(b)(6) Rebecca Slater Abbott <(b)(6) Richard Hamburg <(b)(6) Rita Norton <(b)(6) Rob Morrison <(b)(6) Robert Forman <(b)(6) "Robin Swift (b)(6) <(b)(6) Samantha Arsenault

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(b)(6), "Sarah Nerad (Alkermes)" <(b)(6) Scott Proescholdbell <(b)(6) Shalini Wickramatilake <(b)(6) Shelley Starkey <(b)(6) Sonya Clay <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) Steve Passik <(b)(6) Sue Thau <(b)(6) "Sue Thau (Gmail)" <(b)(6) Susan Awad <(b)(6) Teresa Baker <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Tom Supinka (NSC)" <(b)(6) Tracie Thomas <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) Van Ingram <(b)(6) Vince Ventimiglia <(b)(6) Wade Delk <(b)(6) "William Hibbs (Alkermes)" <(b)(6)

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Agenda and relevant materials forthcoming.

CEPOP All-Participants Teleconference (February 2019)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP All-Participants Teleconference (February 2019) - MATERIALS ATTACHED

From: "Rubin, Matthew J." <(b)(6)

To: Aryka Chapman <(b)(6) "Cara Moon (Egalet)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Amanda Sears <(b)(6) Wade Delk <(b)(6) "Jessica Johnston (BD)" (b)(6) Carol Thornton <(b)(6) Brad Tallamy <(b)(6) Gary Mendell (b)(6) >, "Blaire Bryant (NACo)" <(b)(6) Judi Lund Person (b)(6) Daniel Raymond <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Mike Smith <(b)(6) Addie Liles <(b)(6) "Dr. John Harrison" <(b)(6) Shelley Starkey <(b)(6) Chris Zimmerman <(b)(6) Charlie Cichon <(b)(6) "Gen. Arthur Dean" <(b)(6) "Patel, Beena S." <(b)(6) "KJ Hertz (March of Dimes)" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP" <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) "Cristi L. Schwarcz" <(b)(6) Patricia Bruckenthal <(b)(6) "Hanson, Roberta J." <(b)(6) Paul Ross <(b)(6) David May <(b)(6) "Rachel Rivera (b)(6) <(b)(6) "Clay Alspach (b)(6) <(b)(6) "Dr. Jack Stein" <(b)(6) Steve Passik <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Jason Sundby <(b)(6) Mary Bono <(b)(6) Jeffrey Ekoma <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) "Jonah Cunningham (TFAH)" <(b)(6) "Kevin Roy (Shatterproof)" (b)(6) , "Kathryn L. Cates-Wessel" <(b)(6) Amy Callendar <(b)(6) Karen Tracy <(b)(6) Chuck Ingoglia <(b)(6) Rob Morrison <(b)(6) Andrew

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kessler <(b)(6) "Ian Goldstein (NACCHO)"
<(b)(6) "Deana Haworth (Hirons)" <(b)(6)
Sonya Clay <(b)(6) Kevin Walker <(b)(6)
James Appleby <(b)(6) Courtney Hunter
<(b)(6) Hadi Sedigh <(b)(6) "Robin Swift
(b)(6) <(b)(6) "Celia Hagan (NILA)"
<(b)(6) "Dr. Stuart Gitlow" <(b)(6) "Valerie Brankovic
(NACo)" <(b)(6) "Zook, David R." <(b)(6)
Richard Hamburg <(b)(6) "Gena Fitzgerald (SAFE
Project)" <(b)(6) Rebecca Farley
<(b)(6) "Sarah Nerad (Alkermes)"
<(b)(6) Donald Hoppert <(b)(6) Nick
Motu <(b)(6) "Carrier Latimer (Hirons)" <(b)(6)
Gabrielle de la Gueronniere <(b)(6) "Christian, Jeanine M"
<(b)(6) Brian Bowden <(b)(6) Caren Kagan Evans
<(b)(6) Scott Proescholdbell
<(b)(6) Dennis Brennan
<(b)(6) "Danna Droz (NABP)"
<(b)(6) Nicole Burda <(b)(6) "William Hibbs
(Alkermes)" <(b)(6) "Whitney Taylor (Integritas)"
<(b)(6) Melissa Ough <(b)(6)
"Gabriella Witte (APHA)" <(b)(6) Sue Thau
<(b)(6) Jane Terry <(b)(6) Rebecca Slater Abbott
<(b)(6) Jeremiah Lindemann (b)(6) Kate
McFadyen <(b)(6) "Evans, Daniel F."
<(b)(6) Susan Awad <(b)(6) "David
Bilardello (Spectrum Health)" <(b)(6) Vince
Ventimiglia <(b)(6) Marcia Lee Taylor
<(b)(6) Aiken Hackett <(b)(6)
"Terry McGeeney, MD, MBA" <(b)(6) "Nadine Gracia
(b)(6) <(b)(6) Michael DeGeorge
<(b)(6) Robert Forman
<(b)(6) "Brooke Goldberg (SAFE Project US)"
<(b)(6) Ed Kaleta <(b)(6) Dan Buffington
<(b)(6) Erika Long <(b)(6) Julian
Hoffman <(b)(6) "Tom Supinka (NSC)" <(b)(6)

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	"Donald A. Lohman (MNK)" <(b)(6) Van Ingram <(b)(6) Samantha Arsenault <(b)(6) "Alexander, Tesfa" <(b)(6) Kathleen O'Conner <(b)(6) "Derek Naten (MNK)" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) Tracie Thomas <(b)(6) Kate Berry <(b)(6) "Dr. Anita Gupta" <(b)(6) "Sue Thau (Gmail)" <(b)(6) Blair Clark-Schoeb <(b)(6) Lorraine Yarde <(b)(6) Teresa Baker <(b)(6) Alice Dembner <(b)(6) Patricia D'Antonio <(b)(6) Patricia Farley <(b)(6) Rita Norton <(b)(6) Mary Winnefeld <(b)(6) Kristi Thompson <(b)(6) John Donahue <(b)(6) Eli Briggs <(b)(6) "Dr. Renan Castillo" <(b)(6) "Emily Diehl (NASADAD)" <(b)(6) Elizabeth Solhtalab <(b)(6) Shalini Wickramatilake <(b)(6) Keysha Brooks-Coley (b)(6) (b)(6)
Cc:	"Harrison, Marcy T." <(b)(6) "Motu, Nick" <(b)(6) Richard Cesar-Meyers <(b)(6)
Date:	Mon, 25 Feb 2019 07:05:52 -0500
Attachments:	CEPOP 2019 Agenda and Workplan.pdf (43.55 kB); CEPOP All-Participants Meeting Agenda (Feb. 2019).pdf (30.62 kB); not supported calendar message.ics (18.14 kB)

CEPOP Participants – In advance of our upcoming CEPOP All-Participant Teleconference, please find the agenda and proposed CEPOP 2019 Workplan attached to this email. We are pleased to have ***two focus topic speakers*** for today's discussion.

- **Kevin Gallagher**, Chief, Achushet (MA) Fire and Rescue Department, and a leader of a state-wide initiative to equip first responders with non-opioid pain medications; and
- **Tim Robinson, JD,** CEO of Addiction Recovery Centers , an Eastern Kentucky SUD treatment provider with strong results serving Medicaid population.

We look forward to a productive discussion this afternoon. Please do not hesitate to reach out with any questions.

CEPOP All-Participants Teleconference (February 2019)

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- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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2019 Agenda and Workplan

Introduction

The CEPOP Steering Committee would like to thank all participants for joining our January 2019 Annual Strategy Session. Heading into our fifth year of operation, we seek to build on a solid record of action and partnership to confront the evolving nature of the opioid epidemic. As participants heard from our CDC speaker, the most recent data indicates a continued increase in opioid-related overdose deaths, attributed to the four "waves" of the epidemic to date. Our FDA speaker confirmed the depth and breadth of these challenges. In short, we have much more work to do and our diverse collaborative is recognized widely as a useful vehicle for best practice sharing, policy and relationship development, and focused advocacy. The balance of this document captures a consensus agenda and workplan for CEPOP in 2019.

Priority Topics

Through our planning process, the CEPOP Steering Committee identifies five areas of strategic emphasis for the coming year. These topics were confirmed in the January 2019 meeting to serve as our operational framework.

- **Moving Upstream – Rising Emphasis on Prevention Strategies.** To supplement the historical CEPOP emphasis on treatment and recovery needs, efforts must be enhanced around strategies to help stem the initial misuse, abuse or diversion and prevent the development of a substance use disorder. While not all of our prevention-related work may be fairly characterized as "primary" in nature, we do need to move more squarely into this arena.
- **Broadened Focus to Include Illicit Opioids – Responding to an Evolving Epidemic.** The exponential rise in overdose deaths related to illicit fentanyl and other synthetic analogues requires different responses to impact the broader opioid epidemic. CEPOP will remain deeply engaged with the prescription opioid dimension of this crisis, but also consider needs within this broadening threat.
- **Implementation of Opioid-Related Legislation, Support Development of Future Policy.** CEPOP should be active in the promotion of existing legislation, such as 21st Century Cures Act, CARA, and the SUPPORT for Patients and Communities Act. There will likely be new legislative opportunities at the federal and state level, but we need to help support full and timely implementation of what is already on the books.
- **Safe Disposal.** Our takeback and anti-diversion working group has been highly productive and positioned CEPOP as a clear leader in advancing an array of policy and program initiatives. The January meeting participants concluded that this should continue and accelerate, with a renaming of the working group to safe disposal and anti-diversion to reflect the full scope.
- **Federal Budget and Appropriations Advocacy.** CEPOP is unique in its breadth of participation and perspectives. This has made our annual budget and appropriations advocacy possible the most comprehensive, balanced effort. CEPOP will remain engaged in this work to help ensure that resources are adequate for current and emerging dimensions of the epidemic.

Strategic Objectives and Timing

I. Advocacy

- **a.** Engage White House, Agency and Congressional leaders around relevant priorities, including those identified by Working Groups (Q1-4).
- **b.** Continued advocacy related to federal budget priorities; engagement with Appropriations Subcommittees of relevant jurisdiction (Q1-3).
- **c.** Identify opportunities to leverage existing opioid-related legislation (e.g. 21st Century Cures, CARA, SUPPORT Act) and implementation; participate in the development of and support forthcoming opioid-related legislation (Q1-4).
- **d.** Consider state-based needs where CEPOP's breadth can have an impact (Q1-4).

II. Policy

- **a.** Development of primary prevention efforts, including on stigma reduction (Q1-4).

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b. Continue to address core policy issues, as identified above; this may include access to medication-assisted treatment, safe storage/disposal, and real-time tracking of opioid prescription and dispensation (Q1-4).

c. Approval and access to abuse-deterrent formulations and non-opioid alternatives (Q1-3).

d. Additional policy priorities, as identified by Working Groups or CEPOP participants (Q1-4).

III. Briefings & External Awareness

a. Continued "Focus Topic" briefings for CEPOP participants on best practices and innovation as part of All-Participants meetings; participant suggestions welcomed (Q1-4).

b. Host *Partner Reception* during 2019 Rx Drug Abuse Summit (April 23, 5:30-7:30pm).

c. Ongoing publication of *Weekly CEPOP Opioid Policy Report* (Q1-4).

d. Continual update of CEPOP website and collateral materials (Q1-4).

e. Identification and outreach to potential partners and CEPOP members for engagement in focus areas.

2019 Schedule

CEPOP will execute a robust array of interactions, information-sharing and advocacy among participants and key policymakers throughout 2019 to include:

- All-Participants Meetings via teleconference on the last Monday of each month, with the exception of quarterly in-person meetings (see below; schedule subject to change);
- Three targeted quarterly in-person meetings (Q1–Q3) and an Annual All-Participants Strategy Session in December 2019;
- Continue to operate CEPOP Steering Committee (oversight and priority-setting) and Safe Disposal & Anti-Diversion and Safe Use & Prevention Working Groups (policy and program incubators); and
- Expand CEPOP membership and external visibility.

Operating Budget

CEPOP continues to operate principally through the financial and in-kind support of its co-convenors. A number of CEPOP participants have also generously provided general and/or project-specific support in 2017 and 2018. The Steering Committee appreciates the investment from its participants and invites others to assist in meeting resource needs based on the following "two-prong" budget approach.

I. **Workplan Support** – All CEPOP participants are invited to make a suggested, annual contribution to support the 2019 agenda according to the following recommended schedule:

a. **$15,000** level for large organizations (greater than $50 million annual revenue);

b. **$10,000** level for mid-sized organizations ($10 million to $50 million annual revenue);

c. **$5,000** level (less than $10 million annual revenue); and

d. **Other** level (discretionary commitments).

II. **Initiative-Specific Support** – CEPOP will continue to develop larger-scale initiatives alongside the core agenda with direct support, subject to Steering Committee approval. CEPOP members are invited to voluntarily underwrite this work and the related budget on a focused basis. Potential 2019 opportunities/activities include:

a. Policy roundtables and Capitol Hill briefings on priority topics;

b. Audience-specific outreach and education campaigns;

c. State-level engagement; and

d. Stakeholder convenings on relevant policy issues.

Thank you for your continuing interest and support for our critical work together!

The CEPOP Steering Committee

Draft (February 2019)

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (FEBRUARY 2019)

Date: Monday, February 25, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. The Local Level of the Opioid Crisis: Where the Rubber Meets the Road**
  Kevin Gallagher, *Chief, Acushnet (MA) Fire and Rescue Department*
- **B. Progress Against the Opioid Epidemic in Eastern Kentucky: Addiction Recovery Care**
  Tim Robinson, *Chief Executive Officer, Addiction Recovery Care*
- **C.** Review and Approval of the Proposed 2019 CEPOP Workplan and Agenda (see attached)

III. Advocacy and Policy Priorities

- **A.** FY2020 Budget and Appropriations

IV. Working Groups (*Proposed*)

- **A.** Prevention
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Seen and Heard
- **B.** Participant News

Next CEPOP All-Participants Teleconference:

Monday, March 25, 2019 (calendar appointment forthcoming)

www.CEPOPonline.org

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[EXTERNAL] Canceled: CEPOP Reception at the National Rx Drug Abuse and Heroin Summit

Where:	Sway Restaurant (Hyatt Regency Atlanta, 265 Peachtree Street NW)
When:	Tue Apr 23 17:30:00 2019 (America/New_York)
Until:	Tue Apr 23 19:30:00 2019 (America/New_York)
Organiser:	Whitney Taylor <(b)(6)
	Whitney Taylor <(b)(6)
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Required Attendees:	"Nadine Gracia ((b)(6) <(b)(6)
	Keysha Brooks-Coley <(b)(6)
	(b)(6)
	(b)(6)
	(b)(6)
	(b)(6)
	Addie Liles <(b)(6)
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	Brian Bowden <(b)(6)
	Van Ingram <(b)(6)
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	Judi Lund Person (b)(6)

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"Alexander, Tesfa" <(b)(6)
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Patty McCarthy Metcalf <(b)(6)

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"Jonah Cunningham (TFAH)" <(b)(6)

"Dr. John Harrison" <(b)(6)

Mary Bono <(b)(6)

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Susan Awad <(b)(6)

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Rob Morrison <(b)(6)

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Sarah Nerad <(b)(6)

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"Gen. Arthur Dean" <(b)(6)

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"Tallamy, Brad" <(b)(6)

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Ekoma Jeffrey <(b)(6)

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"Swift, Robin, DOH" <(b)(6)

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"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)

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Amy Callender <(b)(6)

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Optional Attendees:

Frederick Ryan <(b)(6)

"Webb, Kevin J" <(b)(6)

Patrick Fogarty <(b)(6)

"Grove, Sean" <(b)(6)

"Lohman, Donald A" <(b)(6)

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Jason Sundby <(b)(6)



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PLEASE JOIN US

Collaborative for Effective Prescription Opioid Policies

National Rx Drug Abuse and Heroin Summit Reception

Tuesday, April 23, 2019

5:30PM – 7:30PM

Sway Restaurant
Lobby Level, Hyatt Regency Atlanta

www.CEPOPonline.org

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RE: CEPOP All-Participants Teleconference (February 2019) - MATERIALS ATTACHED

To:

"Rubin, Matthew J." <(b)(6) Aryka Chapman <(b)(6) "Cara Moon (Egalet)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Amanda Sears <(b)(6) Wade Delk <(b)(6) "Jessica Johnston (BD)" <(b)(6) Carol Thornton <(b)(6) Brad Tallamy <(b)(6) Gary Mendell <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Judi Lund Person (b)(6) Daniel Raymond <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Mike Smith <(b)(6) Addie Liles <(b)(6) "Dr. John Harrison" <(b)(6) Shelley Starkey <(b)(6) Chris Zimmerman <(b)(6) Charlie Cichon <(b)(6) "Gen. Arthur Dean" <(b)(6) "Patel, Beena S." <(b)(6) "KJ Hertz (March of Dimes)" <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) "Cristi L. Schwarcz" <(b)(6) Patricia Bruckenthal <(b)(6) "Hanson, Roberta J." <(b)(6) Paul Ross <(b)(6) David May <(b)(6) "Rachel Rivera (b)(6) <(b)(6) "Clay Alspach (b)(6) <(b)(6) "Dr. Jack Stein" <(b)(6) Steve Passik <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Jason Sundby <(b)(6) Mary Bono <(b)(6) Jeffrey Ekoma <(b)(6) "Stephanie Pellitt (NCBH)" <(b)(6) "Jonah Cunningham (TFAH)" <(b)(6) "Kevin Roy (Shatterproof)" <(b)(6) shatterproof.org>, "Kathryn L. Cates-Wessel" <(b)(6) Amy Callendar <(b)(6) Karen Tracy <(b)(6) Chuck Ingoglia <(b)(6) Rob Morrison <(b)(6) Andrew kessler <(b)(6) "Ian Goldstein (NACCHO)" <(b)(6) "Deana Haworth (Hirons)" <(b)(6) Sonya Clay <(b)(6) Kevin Walker <(b)(6) James Appleby <(b)(6) Courtney Hunter <(b)(6) Hadi Sedigh <(b)(6)

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"Robin Swift ([redacted] <[redacted] "Celia Hagan (NILA)"
<[redacted] "Dr. Stuart Gitlow" <[redacted] "Valerie Brankovic (NACo)"
<[redacted] "Zook, David R." <[redacted] Richard Hamburg
<[redacted] "Gena Fitzgerald (SAFE Project)"
<[redacted] Rebecca Farley <[redacted] "Sarah Nerad
(Alkermes)" <[redacted] Donald Hoppert <[redacted]
Nick Motu <[redacted] "Carrier Latimer (Hirons)" <[redacted]
Gabrielle de la Gueronniere <[redacted] "Christian, Jeanine M"
<[redacted] Brian Bowden <[redacted] Caren Kagan Evans
<[redacted] Scott Proescholdbell
<[redacted] Dennis Brennan
<[redacted] "Danna Droz (NABP)" <[redacted]
Nicole Burda <[redacted] "William Hibbs (Alkermes)"
<[redacted] "Whitney Taylor (Integritas)"
<[redacted] Melissa Ough <[redacted]
"Gabriella Witte (APHA)" <[redacted] Sue Thau <[redacted] Jane
Terry <[redacted] Rebecca Slater Abbott <[redacted] Jeremiah
Lindemann [redacted] Kate McFadyen <[redacted] "Evans,
Daniel F." <[redacted] Susan Awad <[redacted] "David
Bilardello (Spectrum Health)" <[redacted] Vince Ventimiglia
<[redacted] Marcia Lee Taylor <[redacted] Aiken
Hackett <[redacted] "Terry McGeeney, MD, MBA"
<[redacted] "Nadine Gracia ([redacted]
<[redacted] Michael DeGeorge <[redacted] Robert
Forman <[redacted] "Brooke Goldberg (SAFE Project US)"
<[redacted] Ed Kaleta <[redacted] Dan Buffington
<[redacted] Erika Long <[redacted] Julian
Hoffman <[redacted] "Tom Supinka (NSC)" <[redacted] "Donald
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<[redacted] Teresa Baker <[redacted] Alice Dembner

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<(b)(6) Patricia D'Antonio <(b)(6) Patricia Farley <(b)(6) Rita Norton <(b)(6) Mary Winnefeld <(b)(6) Kristi Thompson <(b)(6) John Donahue <(b)(6) Eli Briggs <(b)(6) "Dr. Renan Castillo" (b)(6) , "Emily Diehl (NASADAD)" <(b)(6) Elizabeth Solhtalab <(b)(6) Shalini Wickramatilake <(b)(6) Keysha Brooks-Coley <(b)(6)

"Harrison, Marcy T." <(b)(6) "Motu, Nick"

Cc: <(b)(6) Richard Cesar-Meyers <(b)(6)

Date: Wed, 20 Mar 2019 13:31:44 -0400

From: Rubin, Matthew J. <(b)(6)
Sent: Monday, February 25, 2019 7:06 AM
To: Aryka Chapman <(b)(6) Cara Moon (Egalet) <(b)(6) Kevin Webb (MNK) <(b)(6) Amanda Sears <(b)(6) Wade Delk <(b)(6) Jessica Johnston (BD) <jessica(b)(6) Carol Thornton <(b)(6) Brad Tallamy <(b)(6) Gary Mendell <(b)(6) Blaire Bryant (NACo) <(b)(6) Judi Lund Person (b)(6) Daniel Raymond <(b)(6) Brandee Izquierdo (SAFE Project) <(b)(6) Mike Smith <(b)(6) Addie Liles <(b)(6) Dr. John Harrison <(b)(6) Shelley Starkey <(b)(6) Chris Zimmerman <(b)(6) Charlie Cichon <(b)(6) Gen. Arthur Dean <(b)(6) Patel, Beena S. <(b)(6) KJ Hertz (March of Dimes) <(b)(6) Spitznas, Cecelia M. EOP/ONDCP <(b)(6) Patty McCarthy (FaVoR) <(b)(6) Cristi L. Schwarcz <(b)(6) Patricia Bruckenthal <(b)(6) Hanson, Roberta J. <(b)(6) Paul Ross <(b)(6) David May <(b)(6) Rachel Rivera ((b)(6) <(b)(6) Clay Alspach ((b)(6) <(b)(6) Dr. Jack Stein <(b)(6) Steve Passik <(b)(6) Deb Waugh (Affiliated Monitors) <(b)(6) Jason Sundby <(b)(6) Mary Bono <(b)(6) Jeffrey Ekoma <(b)(6) Stephanie Pellitt (NCBH) <(b)(6) Jonah Cunningham (TFAH) <(b)(6) Kevin Roy (Shatterproof) (b)(6) Kathryn L. Cates-Wessel <(b)(6) Amy Callendar <(b)(6) Karen Tracy <(b)(6) Chuck Ingoglia <(b)(6) Rob Morrison <(b)(6) Andrew kessler <(b)(6) Ian Goldstein (NACCHO) <(b)(6) Deana Haworth (Hirons) <(b)(6) Sonya Clay <(b)(6) Kevin Walker <(b)(6) James Appleby

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(Hirons) <(b)(6) Gabrielle de la Gueronniere <(b)(6)
Christian, Jeanine M <(b)(6) Brian Bowden <(b)(6) Caren Kagan
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<(b)(6) Dennis Brennan <(b)(6) Danna
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(Alkermes) <(b)(6) Whitney Taylor (Integritas)
<(b)(6) Melissa Ough <(b)(6) Gabriella Witte
(APHA) <(b)(6) Sue Thau <(b)(6) Jane Terry <(b)(6)
Rebecca Slater Abbott <(b)(6) Jeremiah Lindemann <(b)(6)
Kate McFadyen <(b)(6) Evans, Daniel F. <(b)(6) Susan
Awad <(b)(6) David Bilardello (Spectrum Health) <(b)(6)
Vince Ventimiglia <(b)(6) Marcia Lee Taylor <(b)(6)
Aiken Hackett <(b)(6) Terry McGeeney, MD, MBA
<(b)(6) Nadine Gracia (<(b)(6) <(b)(6) Michael
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Emily Diehl (NASADAD) <(b)(6) Elizabeth Solhtalab <(b)(6) Shalini
Wickramatilake <(b)(6) Keysha Brooks-Coley (b)(6)

Cc: Harrison, Marcy T. <(b)(6) 'Motu, Nick'
<(b)(6) 'Richard Cesar-Meyers' <(b)(6)
Subject: [EXTERNAL] CEPOP All-Participants Teleconference (February 2019) - MATERIALS ATTACHED

CEPOP Participants – In advance of our upcoming CEPOP All-Participant Teleconference, please find the agenda and proposed CEPOP 2019 Workplan attached to this email. We are pleased to have ***two focus topic speakers*** for today's discussion.

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- **Kevin Gallagher**, Chief, Achushet (MA) Fire and Rescue Department, and a leader of a state-wide initiative to equip first responders with non-opioid pain medications; and
- **Tim Robinson, JD,** CEO of Addiction Recovery Centers , an Eastern Kentucky SUD treatment provider with strong results serving Medicaid population.

We look forward to a productive discussion this afternoon. Please do not hesitate to reach out with any questions.

CEPOP All-Participants Teleconference (February 2019)

Ÿ To join WebEx, please **CLICK HERE**.

Ÿ Or, to join via conference call:

- **Conference Line:** (b)(6)
- **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP All-Participants Teleconference (March 2019) – MATERIALS ATTACHED

From: Whitney Taylor <(b)(6)

To: Addie Liles <(b)(6) (b)(6) "Gen. Arthur Dean" <(b)(6) "Jonah Cunningham (TFAH)" <(b)(6) (b)(6) (b)(6) "Nadine Gracia (b)(6) <(b)(6) Rob Morrison <(b)(6) (b)(6) Sue Thau <(b)(6) Van Ingram <(b)(6) "Zook, David R." <(b)(6) (b)(6) (b)(6) (

	jessica(b)(6) (b)(6) Judi Lund Person (b)(6) (b)(6) (b)(6)

- Or, to join via conference call:
    - **Conference Line:** (b)(6)
    - **Participant Code:** (b)(6)

1. **CEPOP Participants –** In advance of our upcoming CEPOP All-Participant Teleconference, please find the agenda and related materials attached to this calendar appointment. We are pleased to have ***two focus topic speakers*** for today's discussion.
    - **The Honorable James Carroll,** *Director, Office of National Drug Control Policy, Executive Office of the President,* to discuss the Administration's comprehensive response to the opioid epidemic and recently released National Drug Control Strategy (attached); and
    - **Kimberley Timpf, M.Ed.,** *Senior Director of Partner Education at EverFI*, to discuss their programmatic efforts to educate youth on the risks of prescription drug abuse through their Prescription Drug Safety Network.

We look forward to a productive discussion! Please do not hesitate to reach out to **Whitney Taylor** or **Matthew Rubin** with any questions.

AMERICAN OVERSIGHT

[EXTERNAL] CEPOP All-Participants Teleconference (March 2019)

From: Whitney Taylor <(b)(6)

To: Addie Liles <(b)(6) (b)(6) "Gen. Arthur Dean" <(b)(6) "Jonah Cunningham (TFAH)" <(b)(6) (b)(6) (b)(6) "Nadine Gracia (b)(6) <(b)(6) Rob Morrison <(b)(6) (b)(6) Sue Thau <(b)(6) Van Ingram <(b)(6) "Zook, David R." <(b)(6) (b)(6) (b)(6) (

	jessica(b)(6) (b)(6) Judi Lund Person (b)(6) "Sue Thau (Gmail)" <(b)(6) (b)(6) (b)(6) (b)(6) (b)(6) (b)(6) (b)(6) (b)(6) (b)(6) (b)(6)
Cc:	Jason Sundby <(b)(6) "Abbott, Rebecca" <(b)(6) "Naten, Derek" <(b)(6) "Webb, Kevin J" <(b)(6) "Motu, Nick" <(b)(6) "Lohman, Donald A" <(b)(6)
Date:	Fri, 22 Mar 2019 11:59:42 -0400
Attachments:	ONDCP National Drug Control Strategy 2019.pdf (592.87 kB); CEPOP Presentation_3.25.pdf (5.85 MB); CEPOP All-Participants Meeting Agenda (Mar. 2019).pdf (31.23 kB); not supported calendar message.ics (20.1 kB)

CEPOP All-Participants Teleconference (March 2019)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:

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- **Conference Line:** (b)(6)
- **Participant Code:** (b)(6)

1. **CEPOP Participants –** In advance of our upcoming CEPOP All-Participant Teleconference, please find the agenda and related materials attached to this calendar appointment. We are pleased to have ***two focus topic speakers*** for today's discussion.
    - **The Honorable James Carroll,** *Director, Office of National Drug Control Policy, Executive Office of the President,* to discuss the Administration's comprehensive response to the opioid epidemic and recently released National Drug Control Strategy (attached); and
    - **Kimberley Timpf, M.Ed.,** *Senior Director of Partner Education at EverFI*, to discuss their programmatic efforts to educate youth on the risks of prescription drug abuse through their Prescription Drug Safety Network.

We look forward to a productive discussion! Please do not hesitate to reach out to **Whitney Taylor** or **Matthew Rubin** with any questions.

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EVERFI AND THE PRESCRIPTION DRUG SAFETY NETWORK

Introduction for the Collaborative for Effective Prescription Opioid Policies

Monday, March 25, 2019

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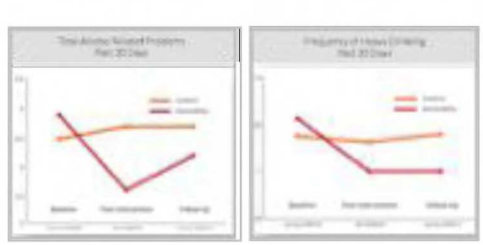
EVERFI By the Numbers

10+ Years of Prevention Education



2015 Recommendation from NIH
AlcoholEdu received the highest possible effectiveness rating from NIAAA

2011 Multisite Randomized Control-Trial
AlcoholEdu Reduces Binge Drinking and Alcohol-Related Harms for Students

20+ Million Learners

25,000+ K-12 Schools

1,500+ Higher Education Institutions

4,300 Partners

500 Team Members

50,000 Teachers Trained

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EVERFI'S Prescription Drug Safety Course

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Prescription Drug Safety Key Components

1. **Population-Wide Approach** - Leverage the healthy majority of students who do NOT misuse Rx drugs to create safe, healthy communities.
2. **Positive Framing** - Avoid scare tactics and focus on the facts. Engage students as parts of the solution vs parts of the problem.
3. **Empower Students** - Encourage students to care about their future and recognize their power to make their own choices. Provide concrete refusal and intervention skills.
4. **Evidence-based** - Rely on behavior change theories and strategies, including social norming and bystander intervention.

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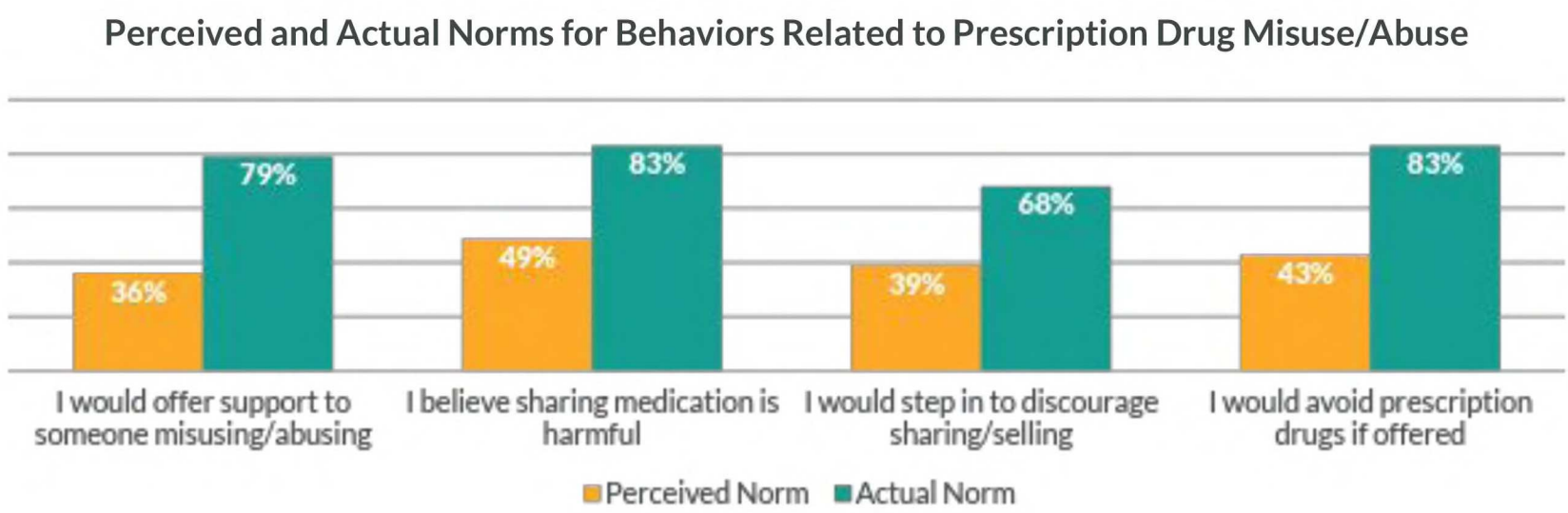
Perceived Versus Actual Behavioral Norms

Closing the gap can encourage prosocial intervention and create healthier communities and schools.



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Impact

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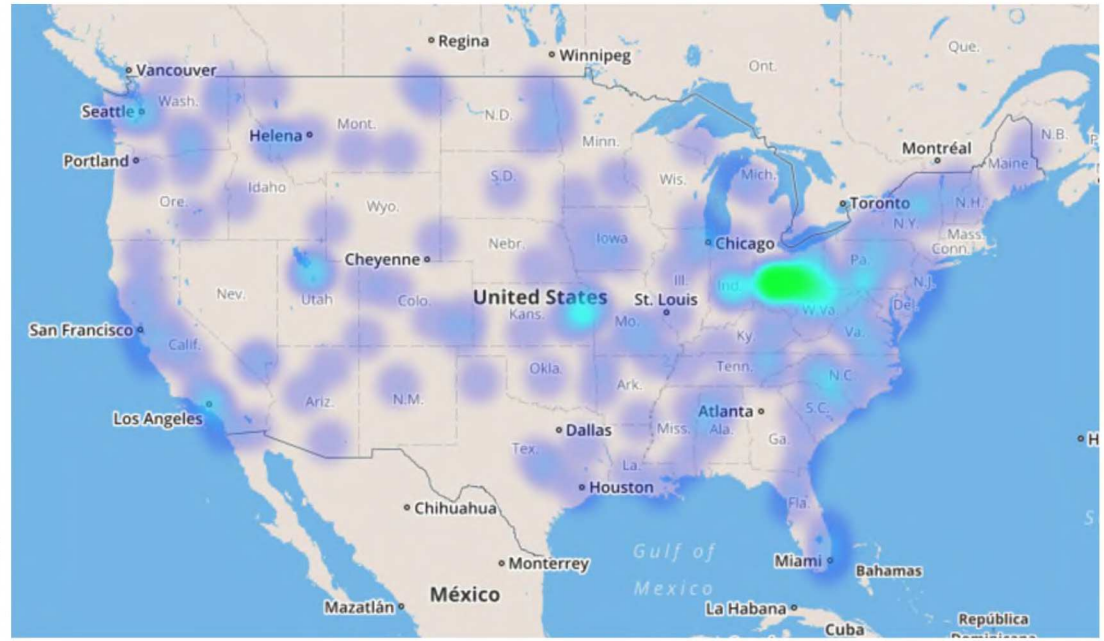
National K-12 Impact to Date

Since Fall 2017

1,800+ schools activated

155,000+ students reached

48% average increase in assessment scores



PRESCRIPTION DRUG SAFETY NETWORK
powered by EVERFI

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Student Feedback

The majority of students felt that the course positively impacted their knowledge in three main areas:

73% The course helped me identify the signs of prescription drug abuse and misuse

72% The course helped me understand the various ways to refuse to participate in the misuse of prescription drugs

71% The course made me more confident in my ability to intervene when I feel a friend may be misusing prescription drugs

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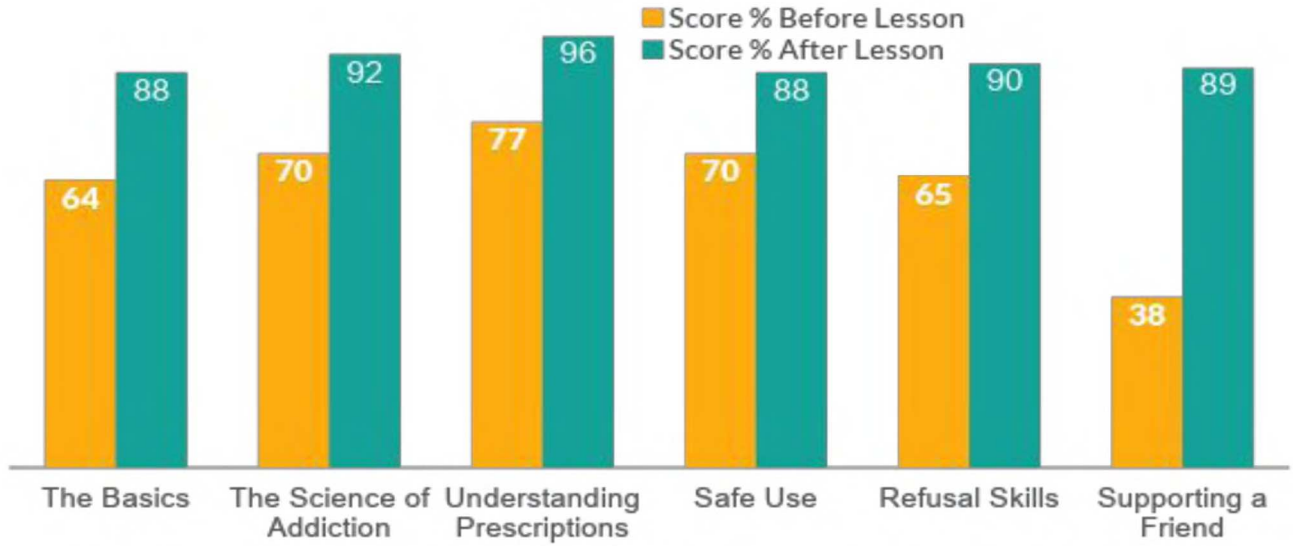
Measurable Outcomes

After taking *Prescription Drug Safety*, students increased their knowledge in key areas that align with course behavioral outcomes..



Pre-post assessment data from 56,000+ learners in 800+ schools nationwide

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Prescription Drug Safety Network

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Implementation Support



Your Local Schools Manager

- Support Specific to your District
- Deep Understanding of State Standards Alignment and Regional Usage
- Dedicated Training and Professional Development

EVERFI

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The Prescription Drug Safety Network

PRESCRIPTION DRUG SAFETY NETWORK

Convening leaders around prevention education as a critical component of efforts to address an urgent public health crisis.



Kroger
The AmerisourceBergen FOUNDATION
Attorney General's Office Arkansas
NCHS
PURDUE
Attorney General State of Indiana
Pittsburgh Penguins Foundation Established 2010
Northwell Health
Walmart
Office of Attorney General Commonwealth of Pennsylvania
ShopRite
The Rite Aid Foundation
UnityPoint Health
aam Association for Accessible Medicines
Florida Coalition Alliance
Prevention Action Alliance Lifetime Prevention | Lifetime Wellness
DACCO Behavioral Health Inc.
The David & June Trone Family Foundation
U.S. Chamber of Commerce Foundation
RALI Maryland
Louisiana

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Learn More. Contact Us!

- **Kimberley Timpf**, Senior Director, Impact & Education: (b)(6) (b)(6)
- **Henry Kegan**, Manager, PDSN: (b)(6) (b)(6)

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Resources: Prescription Drug Safety Network

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White Paper: Leveraging Evidence-Based Strategies

While most efforts to curb prescription drug misuse have focused on response and expanding access to treatment, biotech industry leaders can take.

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Webinar | Prioritizing Impact: Crafting a Community Engagement Strategy

Join us on Thursday, April 11, 2019, at 2 pm ET / 11 am PT for our free webinar to learn how your organization create compelling and actionable community engagement strategies around prevention education to build value and impact communities while standing out in a competitive industry landscape.

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Course Example:
Prescription Drug Safety for High School

Prescription Drug Safety provides students with critical information to make smart, healthy choices about their prescription drugs. Through interactive scenarios and activities, students learn the facts about medications, how to use and dispose of them properly, and how to step in when faced with a situation involving non-medical use or diversion. Learn more here.



LEARNING TIME:
~45 mins

STANDARDS:
National Health Education Standards (NHES)

COURSE TOPICS:
- The Basics
- Science of Addiction
- Reading a Prescription Label
- Safe Use
- Refusal Skills
- Supporting a Friend

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Case Study: UnityPoint Health

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UnityPoint Health is sponsoring schools across their Iowa service area to incorporate prevention in their broader strategic response to an identified community health need.

- Iowa, Illinois, and Wisconsin recently passed legislation aimed at developing new strategies to combat opioid addiction.
- UnityPoint Health regions have identified substance abuse disorders and behavioral health as high priority in Health Needs Assessments.
- UnityPoint executive team wanted a scalable and measurable partnership, with support in communicating their efforts on this issue to key stakeholders at the state and national level.
- Join the Network







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Case Study: Rite Aid Foundation

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The Rite Aid Foundation is sponsoring diverse regions across the country to deliver *Prescription Drug Safety* and further their commitment to health and wellness in the communities they serve.

Partnership at a Glance

- Targeting large urban and suburban markets across 6 states
  - e.g. Detroit, Los Angeles, Portland, Seattle, Pittsburgh, Harrisburg, Akron, Toledo
- 400+ school activation goal nationwide
- Engaging local launch events that feature Rite Aid executives, local pharmacists, and state/local elected leaders
- Join the Network





Western Pennsylvania Coalition

- Unique activation in partnership with Pennsylvania Attorney General Josh Shapiro and the Pittsburgh Penguins to bring *Prescription Drug Safety* to the high-need areas of Pittsburgh and Western PA

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National Drug Control Strategy

A Report by the
Office of National Drug Control Policy

JANUARY 2019

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The negative consequences of the trafficking and use of illicit drugs, along with the toll that drug misuse and abuse is taking across America, have endangered too many communities, ruined too many families, and taken the lives of too many of our fellow Americans.

The Trump Administration's *National Drug Control Strategy* is focused on reversing these developments, saving American lives, and setting our Nation on a path to being stronger, healthier, and drug-free. This *Strategy* is intended to guide and focus Federal government efforts along three complementary lines of effort. First, we must reduce the size of the drug-using population by preventing initiates to illicit drug use through education and evidence-based prevention programs. Second, we must reduce barriers to treatment services so that access to long-term recovery is available for those suffering from substance use disorder. And finally, we must drastically reduce the availability of these drugs in the United States through law enforcement and cooperation with international partners to lessen the negative effects of drug trafficking that impact the safety of our communities and the well-being of our citizens.

While this *Strategy* reflects the President's top priority to address the current opioid crisis and reduce the number of Americans dying from these dangerous drugs, it also sets us on the path to develop further the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century.

This is a *Strategy* of action. It reflects our understanding of the complex interplay between the availability of drugs in the U.S. market and their use, anticipates changes in the drug environment in both the public health and law enforcement domains, and allows us to adapt our actions and make lasting progress against this historic national security, law enforcement, and public health challenge. Most importantly, it demands our full effort and a relentless focus on delivering results. The American People should expect nothing less.

James W. Carroll
Director of National Drug Control Policy

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"We will work to strengthen vulnerable families and communities, and we will help to build and grow a stronger, healthier, and drug-free society."

—PRESIDENT DONALD J. TRUMP

INTRODUCTION

The drug crisis our country faces today is unprecedented. It has evolved over the past several decades and has steadily worsened with time. Every state and county, and every socioeconomic group in our country, is directly affected by the negative consequences of illicit drug use. However, today we can see American ingenuity across the Nation, sparked by the commitment to save lives, at work to establish lasting solutions to this monumental problem. Law enforcement and public health innovators working side-by-side at the local level, assisted and inspired by families who have lost loved ones to the scourge of drug use, resourced by government agencies at every level working with private sector partners, are already making a difference. This *National Drug Control Strategy*, the Trump Administration's first, establishes the President's priorities for addressing the challenge of drug trafficking and use, now and in coming years. It also provides the strategic direction necessary for the Federal government to prevent initiates to drug use through education and evidence-based prevention, provide treatment for those suffering from the disease of addiction so they can reach long-term recovery, and reduce the availability of these dangerous drugs in every American community.

The President's top priority is to address, head on, the current opioid crisis and reduce the number of Americans dying from these dangerous drugs. This crisis alone has resulted in more American deaths in just two years than in the course of the entire Vietnam War. In 2017, there were more than 70,200 drug overdose deaths in the United States according to the Centers for Disease Control and Prevention (CDC). More than 47,500 of these deaths involved an opioid, and more than half of these deaths involved a synthetic opioid such as illicit fentanyl or one of its analogues. From 2014 to 2017, the number of deaths attributed to synthetic opioids like fentanyl and its analogues increased 413 percent, and these synthetic opioids are now involved in more deaths than any other drug such as prescription opioids, heroin, or cocaine. Along with the current opioid crisis, overdose deaths involving heroin, cocaine, methamphetamine, and prescribed opioid painkillers have all increased since 2014 as well, and many of these deaths involved more than one drug.

The Trump Administration is matching the magnitude of today's historic crisis with a historic level of focus and resources. In addition to providing an array of Federal grants across the spectrum of drug issues the President increased resources in his Fiscal Year (FY) 2019 Budget dedicated to the opioid crisis, held two opioid summits at the White House, established *The President's Commission on Combating Drug Addiction and the Opioid Crisis* (herein referred to as the Commission) via Executive Order in March 2017, and announced his *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* in March 2018.

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While confronting today's drug crisis to arrest its growth and reduce its effects, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century. Drug traffickers will continue to attempt to secure ever-greater profits by expanding their customer base, reducing overhead, and mitigating risks to their supply chains. The exponential growth in the availability and use of synthetic drugs in the United States, especially synthetic opioids like fentanyl and its analogues, provides a window into the likely future of drug use and trafficking. Drug trafficking organizations can avoid the costly process of harvesting illicit crops and producing plant-based drugs by the much cheaper and faster process of chemical synthesis. Potent synthetic drugs can be smuggled across our borders in small quantities that can be more easily concealed than bulkier plant-based drugs. They can also be purchased cheaply on the dark web using cryptocurrencies that provide anonymity, and shipped into the United States through international mail or as express consignment shipments. The combination of low production cost, the anonymity of the darkweb and cryptocurrencies, and drugs with higher potency than plant-based drugs, creates a favorable risk-reward structure that drug traffickers will embrace to an even greater degree in the years to come.

Along with the emergence of the greater availability and trafficking of synthetic drugs, we must also confront an emerging crisis of cocaine availability and use in the United States. The increased cultivation of coca and production of cocaine in Colombia, the source of more than 90 percent of the cocaine in the U.S. market, has once again reached record levels. Moreover, the suspension of aerial eradication programs in Colombia during its peace process, from 2015 until today, has led to even greater yield from coca plants, resulting in increased production and purity levels. Cocaine use in the United States started rising again after many years of decline. From 2016 to 2017, overdose deaths in which cocaine was the primary contributing drug increased 34 percent according to the CDC, and the National Survey of Drug Use and Health (NSDUH) shows that in 2017 past-month users of cocaine aged 12 and above increased from 1.9 million Americans to 2.1 million and new initiates to cocaine use increased to 1 million, averaging approximately 2,800 per day.

Given the current drug crisis facing America, and the President's priorities, this *Strategy* adopts a strong bias toward *action*. It focuses on leveraging our understanding of the complex interplay between the availability of drugs in the U.S. market and their use, anticipating changes in the drug environment in both the public health and law enforcement domains, and adapting our actions to seize the initiative to make lasting progress against this historic challenge. The global drug trafficking enterprise is vast, dynamic, and adaptable, but it is not without vulnerabilities. It is only through a unified effort in which the Federal government works with, and in support of, creative and resourceful individuals and organizations across the country, that can we address this complex national security, law enforcement, and public health problem.

STRATEGIC OBJECTIVE AND ASSUMPTIONS

This *Strategy* is focused on achieving one overarching strategic objective:

> *Building a stronger, healthier, drug free society today and in the years to come by drastically reducing the number of Americans losing their lives to drug addiction in today's crisis, and preparing now to dominate the drug environment of the*

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> *future. This will be done by preventing initiates to drug use, providing treatment services leading to long-term recovery for those suffering from addiction, and aggressively reducing the availability of illicit drugs in America's communities.*

This *Strategy* consists of three interrelated elements designed to achieve the President's goal of building and fostering a stronger, healthier, and drug free society: prevention, treatment and recovery, and reducing the availability of drugs in America. The single and most important criterion of success is saving American lives, and achieving that objective requires the Federal government to work with partners at the state, local, and tribal levels; the healthcare sector; industry; foreign partners; and every concerned American citizen to advance our Nation's efforts to promote and maintain healthy lifestyles, and help build and grow safe communities free from the scourge of drug use and addiction.

This *Strategy* makes several key assumptions:

- Deliberate, sustained, and well-coordinated education and prevention efforts will, over time, reduce the number of Americans who initiate illicit drug use.
- Better prescribing practices and the expansion of alternatives to prescription drugs that hold a high potential for addiction and abuse will have a positive effect on reducing the number of initiates to illicit drug use.
- Increasing the availability of treatment services for substance use disorder will lead to a greater number of Americans achieving sustained recovery and reduce the size of the illicit drug market and demand in the United States.
- Reducing the availability of illicit drugs in the United States will enable public health efforts to take hold, increasing the potential for successful prevention and treatment efforts.
- Aggressive and versatile drug trafficking organizations will respond to sustained pressure placed upon them by disruption, dismantlement , interdiction efforts and judicial/prosecutorial efforts, and will adapt their production and trafficking methods to minimize risk and maximize profit.

STRATEGY IMPLEMENTATION

The three fundamental elements that form the heart of this *Strategy*—prevention, treatment and recovery, and reducing availability—are complementary and mutually supporting. Reducing the size of the illicit drug using population involves ***preventing*** initiates to illicit drug use through education and evidence-based prevention programs. Providing ***treatment services leading to long-term recovery*** for those suffering from substance use disorder, often using medication-assisted treatment (MAT) combined with therapy, moves people out of the active user population and on the path to recovery. By reducing the number of individuals who use illicit drugs through prevention and treatment, we can diminish the market forces pulling illicit drugs across our borders and into our communities. Simultaneously, we must drastically reduce the ***availability*** of these drugs in the United States. Increased availability increases the opportunity for individuals to initiate drug use, and the path from first use to chronic use can be brutally short, particularly for potent and highly addictive drugs like opioids. By reducing availability we not only lessen the negative ancillary effects of drug trafficking that impact the safety of

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our communities and the well-being of our citizens, we also relieve the pressure on the public health domain in its prevention and treatment efforts. Reducing the size of the illicit drug-using population through prevention and treatment, together with reducing the availability of drugs in the United States through law enforcement and cooperation with international partners, are complementary efforts that inform and support one other, and will set the Nation on the path to being strong, healthy, and drug-free.

This *Strategy* is not intended to enumerate every activity the Federal government and key stakeholders must execute in order to achieve the President's strategic objective. Rather, it articulates the President's drug control priorities and sets the strategic direction for the Administration to take measures to prevent Americans, especially our future generations, from falling into the cycle of drug use and addiction; to provide Americans who suffer from substance use disorders with world class treatment and recovery services; and to protect America's citizens from the negative effects of drug trafficking and use. It also provides Federal drug control departments and agencies the strategic guidance they need for developing their own drug control plans and strategies, and it ensures programming and resource decisions about Federal drug control budget dollars are allocated in a manner consistent with the Administration's priorities.

PREVENTION

Preventing drug use before it starts is a fundamental tenet of a comprehensive approach to drug control. The science of prevention has evolved and significantly improved, and decades of research show that prevention works when implemented through evidence-based programs focused on specific audiences. Early intervention through informational media campaigns and community support mechanisms can alter the trajectory of young people in a positive direction and increase protective factors while reducing risk factors. Studies show that addiction is a disease that can be prevented and treated through sound public health interventions. Evidence-based prevention is most effective when it is carried out over the long-term with repeated interventions to reinforce original prevention goals.

Combining two or more evidence-based elements in a comprehensive prevention program is more effective than a single activity alone. Moreover, these early investments pay large dividends in substantially reduced treatment and criminal justice costs, saving taxpayer dollars while reducing the number of young people whose lives are tragically affected by early substance abuse.

As the Commission noted, "substance abuse prevention is a process which requires a shift in the behavior, culture, and community norms." The Commission emphasized the three categories of prevention intervention that target risk factors and increase protective measures: universal interventions that attempt to reduce specific health problems across all people in a particular population by reducing a variety of risk factors and promoting a broad range of protective measures; selective interventions delivered to particular communities, families, and children who, due to their exposure to certain environmental considerations, are at increased risk of substance misuse; and appropriate interventions directed to those already involved in a risky behavior such as substance misuse, or are beginning to demonstrate problems but have not yet developed a substance use disorder.

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Implementing a Nationwide Media Campaign

Mass media campaigns are most effective when developed with coherent, credible, evidence-based messages grounded in behavioral science research. The Administration is already addressing the unmet need of a compelling and universal information campaign to educate our Nation on the drug-related vulnerabilities of our youth and other at-risk populations. The Administration implemented the *RxAwareness* campaign as a first step to address this problem, and augmented that initiative by launching a national substance abuse prevention media campaign, *The Truth About Opioids*. This major effort will reach audiences not targeted by *RxAwareness* by addressing topics This major effort will reach audiences not targeted by *RxAwareness* by addressing topics related to the speed at which chronic substance use can develop, the drastic measures those suffering from substance use disorder will take to feed their addiction, and the need to reduce the stigma associated with addiction and treatment for substance abuse.

The media campaign is principally focused on opioids that are killing so many of our citizens. Prevention messages targeting youth are being disseminated through social media and other popular platforms utilized by young people. As the campaign moves forward, its messaging will use data analytics to determine appropriate messaging based on target population and substance, and will employ communication and marketing methods such as market segmentation, demographic data on users, and multiple formats and languages for individuals with disabilities and individuals with limited English proficiency. The campaign will be augmented by science-based primary prevention across multiple sectors using approaches that effectively engage students, parents, schools, health care systems, faith communities, social service organizations, and other sectors, in the development and implementation of community and school-based prevention initiatives.

Addressing Safe Prescribing Practices

There is a compelling need for additional research on, and the implementation of, evidence-based guidelines for the dosages and duration of prescription opioid treatment for injuries and post-surgical pain management. This is particularly important for patients with a history of substance abuse or at elevated risk for drug misuse. Additionally, information on viable alternatives for particular surgeries and pain-related conditions, along with an examination of health care coverage for alternative treatment, will advance efforts to reduce overall opioid prescribing in the United States. Government experts, the healthcare sector, the research community, and stakeholder organizations all play key roles in addressing these needs to build evidence on effective treatment and periodically updating prescriber guidelines. Moreover, clinical guidelines and best practices should be standardized in provider training programs and continuing medical education programs for those who prescribe and administer opioids such as surgeons, emergency medicine providers, and emergency medical technicians.

In 2016, CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* for using opioids to treat chronic pain intended to improve communication between the primary care provider and the patient regarding the risk and benefits of these treatments and to improve the effectiveness of pain management treatment in general. The *Guideline* focus on three areas: determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinua-

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tion; and assessing the risk and harms of opioid use. The Administration will build on the CDC *Guideline* and safe prescribing practices by: working with key stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain; coordinating the development of a national curriculum and standard of care for opioid prescribers that supplements the CDC's *Guideline* and focuses on primary care physicians; and developing a model training program to be disseminated to all levels of medical education on the screening for substance use and health status to identify at-risk patients. Mental illness often occurs together with substance use disorders. Underpinning these initiatives is the awareness that patients with chronic pain must receive the best medical care available to ameliorate their suffering and enable them to enjoy the best possible quality of life, while simultaneously reducing the likelihood that patients will become addicted to these treatment regimens.

Expanding the Use of Prescription Drug Monitoring Programs

A Prescription Drug Monitoring Program (PDMP) is a proven means to increase accountability in opioid prescribing practices and prevent patients from receiving opioids and other controlled medications that may have adverse interactions with opioids from multiple providers. In some states where PDMP checking is optional, providers report difficulty using their PDMP due to lack of integration with electronic health records (EHR) which interrupts workflow and can result in decreased use. Providers also cite lack of interstate data-sharing and concerns about patient confidentiality as reasons not to use the PDMP. In those cases where states' integration services are made available, the service can be costly. Currently, at least two PDMP data sharing hubs exist and many states share data. However, two distinct but related issues make data sharing challenging. First, a patchwork of different state laws governing data sharing has thus far prevented the development and execution of a nationwide PDMP capability. The problem of being unable to share data includes Federal healthcare providers attempting to access PDMP data who encounter similar difficulties dealing with various state laws. Second, even in those cases where there are not legal impediments to sharing data, interoperability challenges to sharing these data exist resulting from the two different data sharing platforms. Improving interoperability within the clinical data workflow, and making PDMP data from neighboring states more accessible, can improve the likelihood that providers will consult the PDMPs. In the coming years, we will build on existing research regarding barriers to nation-wide PDMP implementation, and employ various strategies to support PDMP integration and data sharing, including efforts that address the legal and interoperability challenges, as well as measures to incentivize states to make checking of PDMPs mandatory for all providers.

Strengthening the Capacity of State, Local, and Tribal Communities to Identify and Prevent Substance Abuse

Family, friends, and local communities are the first line of defense in preventing substance abuse, and positive adult involvement in children's lives reduces the likelihood of drug use. As the Commission concludes, "With tools for teachers and parents to enhance youth knowledge of the dangers of drug use, early intervention strategies can be implemented for children with environmental and individual risk factors." Parents and primary caregivers must understand that they can make the most significant difference in the child's attitudes and values regarding the use of drugs. Religious organizations are also an

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integral part of the community response to substance abuse, and clergy and faith-based organizations have been successful at keeping youth away from drugs, as well as providing successful support when they have turned to drug use. This strategy will support and reinforce the positive resources that family, friends, and the community can bring to bear on this crisis at both the prevention as well as the treatment and recovery levels. Parents are historically under-represented in prevention programs despite the fact that parent-based programs play a vital role in delaying the onset and use of alcohol and other drugs. This is true for school outreach programs as well.

Enhancing Research and the Development of Evidence-Based Prevention Programs

The National Academies of Sciences, Engineering, and Medicine outline three categories of prevention intervention: universal, selective, and indicated. These interventions have been studied based on targeted populations and risk factors, and, as the Commission observes, "When evidence-based programs are selected for specific populations and implemented with fidelity, they can be effective. Prevention programs need to be tested for scalability, fidelity, and sustainability after research champions are no longer present to drive the programs."

Advancing our capability to prevent drug use before it starts will require, among other things, the more widespread adoption and use of evidence-based methods to identify at risk individuals using strategies that allow for screening, brief intervention, and referral to treatment. This is especially important for adolescents and young adults from middle school through college. In addition, we must increase opportunities to educate and inform child welfare professionals and healthcare providers about the early signs of substance abuse and identify resources to support pregnant and parenting women, children of parents with substance abuse disorders or addiction, and children born with neonatal abstinence syndrome (NAS). Where evidence about prevention interventions for a population or substance is lacking, we must work to build evidence on effective approaches.

Continuing to Strengthen ONDCP's Drug Free Communities (DFC) Program

ONDCP's Drug-Free Communities (DFC) Support Program, created by the Drug-Free Communities Act of 1997, undergirds the Administration's focus on preventing and reducing youth substance use at the community level. The DFC Program provides grants to community coalitions to strengthen the infrastructure among local partners to create and sustain a reduction in local youth substance use. Since the DFC Program's inception, findings from evaluations of the DFC program found that DFC-funded community coalitions have reduced youth substance use. According to the DFC's 2018 National Cross-Site Evaluation Report, on average DFC-funded community participants cut alcohol use by 19 percent and prescription drug abuse by 18 percent among high school students in their communities. The DFC Program will conduct semiannual training to ensure coalitions have the resources and skillset they need to strengthen the prevention infrastructure within their communities and among their local partners to effectively prevent and reduce youth alcohol, tobacco, marijuana and (illicit) prescription drug use. This training will provide DFC-funded community coalitions with the resources and tools they need to develop local and sustainable prevention initiatives.

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Expanding Drug Take-Back Across the Country

The Drug Enforcement Administration's (DEA's) twice-yearly Take-Back Day serves as an opportunity for citizens to dispose of unused and unneeded prescription drugs and a chance to support community drug prevention efforts. Although year-round take-back programs are expanding, including some by retail drug stores, the DEA program remains an important element of public awareness aimed at reducing the amount of unused medications available for potential diversion and misuse. Expanding the number of registered collectors, including hospitals and law enforcement centers, would allow states and municipalities to reduce their reliance on the Federal government for collection, disposal, and transportation. The DEA and other Federal partners should work to engage state, local, and tribal governments to raise awareness of the importance of disposing unused medications, expand the number of permanent disposal sites across the country, and increase the opportunity for their citizens to do so safely and easily.

Conclusion

Decades of research and data demonstrate addiction is a preventable disease. Today, we face a compelling need to invest in a comprehensive approach to preventing drug abuse, one which emphasizes concrete and lasting policy change at the Federal, state, tribal, and community levels. The Administration will focus its efforts and work across the government to empower communities, youth, parents, caregivers, and families to come together to create sustainable programs, policies, and practices to combat drug abuse. We know that every dollar we invest in research-based substance abuse prevention programs has the potential to save much more in treatment and criminal justice system costs and enhance the overall quality of life for communities and their citizens.

TREATMENT AND RECOVERY

Addiction is a chronic medical condition that affects the brain by causing distinct cognitive, behavioral, and physiological changes. There is a need to improve the availability of treatment while concurrently enhancing the quality of that treatment. Research shows that treatment is most effective when it addresses addiction as a chronic condition requiring continuing services and support structures over an extended period of time. This can be accomplished with ongoing outpatient services provided through opioid treatment, or more intensive initial services such as detoxification and residential treatment, followed by continued care and recovery support in the community. Every individual needs an assessment and individualized treatment plan to address their needs as they relate to opioid and other substances use disorders.

Unfortunately, most people who need treatment do not seek it. According to the NSDUH, in 2017 an estimated 20.7 million Americans aged 12 or older needed treatment for a substance use disorder, but only 4 million received any kind of treatment and only 2.5 million received that treatment at a specialty facility—a disparity known as the "treatment gap." In some cases treatment capacity is simply not available, and in others people do not fully acknowledge their need for treatment. Therefore, in addition to expanding treatment capacity, there is a need to engage with those people who need treatment but, for whatever reason, are not seeking it. As a Nation, we must encourage people who need treatment to seek it, create greater access to treatment, and ensure there is adequate capacity to accommodate the need.

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The Administration prioritizes several distinct initiatives to achieve these goals. First, a proactive response to overdoses to ensure that the patient can enter into a treatment program designed to meet his or her individual needs. Second, consistently using evidence-based approaches to treatment and making Medication-Assisted Treatment (MAT) a standard of care for opioid addiction. This includes increasing the number of physicians providing high-quality, evidence-based treatment for opioid use disorders with MAT, and increasing the availability of MAT for incarcerated individuals. Expanding treatment infrastructure will enable us to increase the initial treatment for the vast majority of people who require treatment but are unable or unwilling to obtain it. Third, examining ways to expand and encouraging the expansion of treatment insurance while reducing reimbursement barriers to encourage those on the margins of accepting treatment to make the positive decision to begin a treatment regimen. Finally, the expanded use of Drug Courts and diversion programs will foster entrance into treatment programs and away from the cycle of destructive and self-defeating behaviors that is the hallmark of the disease of addiction. Addressing these and other challenges will require a comprehensive multi-year strategy to educate the public and policymakers, reduce stigma and misunderstanding of addiction, better integrate substance abuse screening and treatment into mainstream health care, build and stabilize the addiction treatment workforce, increase access to treatment, and foster more effective approaches to care for substance use disorders.

Improving the Response to Overdose

Naloxone is an opioid antagonist medication that can rapidly reverse an opioid overdose. However, there are varying levels of access to naloxone throughout the country. Most states have protocols to expand access to naloxone, such as by allowing dispensing of naloxone under a standing physician's order. The Food and Drug Administration is working to facilitate the development of nonprescription naloxone, by creation and testing of appropriate consumer-friendly Drug Facts labeling. The Commission recommended that all law enforcement personnel in the United States be equipped with naloxone, model legislation be provided to states to allow naloxone dispensing via standing orders, and Good Samaritan laws be enacted to empower the public to provide help. However, even simple rescue breathing can keep a person alive until help arrives, and devices like pocket masks can protect a rescuer while saving someone's life using rescue breathing until naloxone can be administered. We will begin to increase public awareness of the importance of rescue breathing in the event of an opioid overdose in those cases when naloxone is not available as a critical live-saving measure. Moreover, 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 the path to sustained recovery.

Enhancing Evidence-Based Addiction Treatment

We must ensure that health care providers screen for substance use disorders and know how to appropriately counsel or refer patients they encounter with such a disorder. Treatment models that demonstrate the best outcomes incorporate behavioral, psychosocial, and pharmacological elements, and are tailored to the specific circumstance of the individual. The ability to provide a pathway to evidence-based treatment for those who need it depends on skilled and well-trained providers who are appropriately

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credentialed and licensed. This must include a complete evaluation for opioid use disorder and other substance use disorders by a qualified medical professional; access to MAT as a deliberate choice made by a qualified professional in consultation with the patient; simultaneous access to relevant psychosocial treatments such as therapy and relapse prevention; the treatment of co-occurring mental disorders that many patients with substance use disorder suffer from such as Post-Traumatic Stress Disorder (PTSD), depression, and anxiety disorders; and the treatment of co-occurring medical conditions such as cardiac, infectious, and dermatologic issues often associated with prolonged drug use. Additionally, identifying and treating pediatric patients with early substance use disorder can prevent their transition to longer and more severe drug use, potentially saving their lives. Therefore, we must scale up adolescent addiction screening and treatment in pediatrician and family medicine settings.

Eliminating Barriers to Treatment Availability

Individuals with substance use disorders, including opioid addiction, should have access to evidence-based treatment. Fewer than half of the privately funded substance use disorder treatment facilities offer MAT, and only a third of patients with opioid use disorders have access to those treatments. This is especially true in rural areas where the compelling need for access to treatment far exceeds its availability. The Administration will work across the Federal government to remove barriers to substance use disorder treatments, including those that limit access to any forms of FDA-approved MAT, counseling, certain inpatient/residential treatment, and other treatment modalities. All primary care providers employed or funded by the Federal government should screen for alcohol and drug use disorders and, if the patient requests it, provide substance use treatment or a referral for such treatment within 24-48 hours.

Increasing the Size of the Addiction Service Workforce, and Treatment and Recovery Infrastructure

Critical shortages in trained and professional addiction service providers is one of the many factors contributing to the treatment gap. The addiction service workforce currently employs varying styles of service delivery. Promoting training, professional incentives for entering the workforce, and establishing a greater level of standardization for care will equip the addiction service workforce to provide support services across all settings, from prevention through treatment and recovery. Opioid and other addictions require intensive interventions through a team-based approach that includes recovery coaches and medical professionals in hospitals and primary care offices, and includes the full range of health professionals such as drug counselors, behavioral health technicians, health educators, physician assistants, and community health workers. Growing our addiction service workforce requires apprenticeship opportunities for a range of addiction treatment professions. This will enable the more rapid increase of available care professionals than reliance on standard training regimens alone, and enable them to provide addiction treatment services for screening, intervention, and recovery support across the continuum of care, to enhance team treatment for individuals with substance use disorders. Furthermore, increased standardization of care and its associated training will help professionalize the field through credentialing, and provide mentoring opportunities for those patients who successfully complete their treatment and want to assist in the recovery of others.

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Leveraging Drug Courts and Diversion Programs

Providing individuals arrested for non-violent drug-related offenses the opportunity to participate in a Drug Court program or outpatient treatment while under supervision is increasingly becoming the practice throughout the country. From 2009 to 2014 the number of Drug Courts in the United States increased by 24 percent, reaching 3,057, and by June 2015 the number of Drug Courts reached 3,142 per the Department of Justice. Recently, some pioneering police departments began diverting individuals addicted to drugs directly to treatment in lieu of arrest. Many communities are adopting pre-arrest diversion programs and other law enforcement diversion and deflection models, in which those struggling with addiction can walk into a participating police station 24 hours a day for police-assisted rapid treatment entry. The Administration supports these innovative programs and will scale up support for State, Tribal, and local drug courts in order to provide offenders struggling with addiction access to evidence-based treatment as an alternative to or in conjunction with incarceration, or as a condition of supervised release.

Increasing Employment Opportunities for Those in Recovery

Americans in stable recovery from addiction deserve fair consideration for any job for which they are qualified. Today, millions of Americans from all walks of life are in recovery. Many of these individuals have past misdemeanor or felony drug-related criminal convictions that can impede or prevent them from securing employment for which they are fully qualified, even after having paid their debt to society and having emerged from the shadow of addiction. In addition to the obstacles created by a past criminal conviction, those in recovery can face long-lasting barriers to employment due to laws that prohibit the hiring of individuals with a past drug conviction in certain settings. These legal restrictions can create additional difficulties for those seeking to fully rejoin the community and sustain a life in recovery. The Administration will work across the Federal government and the private sector to increase hiring opportunities for those in recovery. This will include providing the best information to employers on the overall benefits of bringing these individuals back into our workforce, developing best practices to increase their employment prospects, and increasing the availability of safe housing that enables those in recovery to hold a full-time job and take their place in the American workforce.

Expanding Access to Peer Recovery Support Services

Peer recovery support services provide the bridge between formal systems and services and community-based support networks. When provided through a Recovery Community Organization (RCO), these services can be offered prior to, during, after, and sometimes in lieu of treatment. These RCOs and peer recovery support workers provide urgently needed services. The country needs to quickly increase the number of peer recovery support workers, including those who are in MAT and recovery programs. This workforce serves a dual function; it helps develop the national peer recovery support services infrastructure, and it provides employment opportunities for people in recovery who are well-suited to make this kind of contribution. Furthermore, while the number of Collegiate Recovery Programs (CRPs) on the campuses of large public universities, private higher education institutions, and community colleges has increased rapidly over the past decade, they are still the exception rather than the rule. Every higher

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education campus in America could potentially benefit from some type of CRP. Adolescent recovery support services are especially scarce and of tremendous value to youth, given the importance of peer networks to their social development. Recovery high schools and alternative peer group models hold great promise for meeting the needs of youth, either in active recovery or in encouraging youth to seek it, and we must encourage their increased use across the Nation.

Expanding the Scientific Understanding of Peer Recovery Support Services

While much is known about the process of addiction and about interventions to help address it, less is known about the recovery process and its various trajectories, components, and stages. A better understanding of this process will help in the design and targeting of both clinical and recovery support service interventions that are stage-and trajectory-specific. More research is needed to design and target clinical and recovery support interventions and strategies for long-term recovery. However, while the positive anecdotal evidence of the near-term effectiveness of recovery support service models is strong, rigorous, empirical research is required on their long-term effectiveness, the characteristics of those who benefit most from them, and peer recovery support services' role within and impact on broader systems and communities.

Reducing Stigma and Making Recovery Possible

Americans in recovery are a vital part of every community in the United States, and they seek the same things other Americans want and need—a good job, a safe place to live, the fellowship of a faith community, and the companionship of neighbors and friends. The millions of Americans in long-term recovery from addiction demonstrate that recovery is possible, and they share the message that while addiction is a chronic disease, treating it is possible. In doing so, they help lift the stigma, misunderstanding, and shame that prevent too many Americans from seeking help for substance use disorders. By promoting, supporting, and celebrating recovery, we can reduce stigma and offer hope and encouragement to those struggling with this incredibly difficult disease. Many people in recovery have also dedicated their lives to helping others affected by substance abuse as recovery coaches and counselors, a critically important and growing component of the addiction service workforce. The Administration will continue in its efforts to better educate the public, healthcare professionals, and policymakers on the science of addiction and the promise of recovery, and how stigma and misunderstanding can undermine efforts to reduce drug use and its consequences.

Conclusion

Untreated substance abuse can result in violence, crime, and risky behavior that jeopardizes the health and safety of individuals, families, and communities. The moment a person is ready and willing to enter treatment can be fleeting and infrequent. In addition to matching the individual with the most appropriate care model, efforts to expand treatment must include the capability to act quickly on the demand for treatment whenever and wherever the opportunity is presented. Anytime someone seeking help for addiction calls a treatment center, doctor's office, hospital, health clinic, or other medical facility,

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that person should immediately be referred to some level of assistance. Even if a treatment slot is not immediately available, recovery coaches, peer counseling groups, and families who have learned about addiction can provide help until the right treatment opportunity becomes available. It is in everyone's best interest—affected individuals, their families, and the Nation—for high-quality, evidence-based drug treatment to become more easily accessible. The current opioid crisis highlights the urgent need to encourage those who need treatment to seek it, rapidly increase treatment admissions for opioid addiction, improve treatment retention, and increase the number of individuals who successfully achieve sustained recovery. It is also essential to eliminate the stigma, misunderstanding, and legal and regulatory barriers that delay or prevent treatment access and impede recovery. In addition to saving lives and helping people in recovery achieve their full potential, these changes will help ensure that the significant public investment in treatment pays off in terms of long-term recovery.

REDUCING THE AVAILABILITY OF ILLICIT DRUGS IN THE UNITED STATES

Almost all of the illicit drugs causing American deaths are produced outside the United States and trafficked across the Nation's borders and, increasingly, through the international mail and express consignment carriers. Large and established Drug Trafficking Organizations (DTOs) and foreign producers shipping drugs into the United States threaten the health and safety of our communities by exposing our citizens to substances such as fentanyl, heroin, cocaine, and methamphetamine, which kill tens of thousands of Americans each year. The increased use of illicit drugs burdens the U.S. health care system and leads to lost productivity and civil engagement. Moreover, drug trafficking sustains a vast domestic and international criminal enterprise that enables corruption, undermines governance, has a destabilizing effect on our partner nations, and funds a range of illicit activities. Law enforcement agencies at all levels—Federal, state, local, and tribal—have achieved considerable success in combating drug trafficking and use, yet traffickers continue to refine their methods and adopt new techniques for delivering potent illicit drugs to our communities. Responding to the aggressive trafficking and distribution techniques of DTOs is an urgent national security and law enforcement priority.

The non-medical use of prescription drugs presents another dimension of the availability problem. Many active drug users report obtaining prescription drugs from friends, family members, and in some cases, healthcare providers. The overprescribing of prescription drugs, the diversion of prescription drugs for non-medical use, and the lack of accountability or oversight in prescribing practices increase the availability of prescription drugs in America's homes and workplaces, making it far too easy for them to fall into the wrong hands. Moreover, drug dealers exploit the demand for prescription medicines and traffic in counterfeit pills containing heroin, fentanyl, or one of its analogues. These drugs are difficult to distinguish from legitimate prescription medicines, and because they are most often milled and pressed in variable formulations in clandestine locations, increase the chance for accidental overdose.

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Disrupting, Dismantling, and Defeating Drug Traffickers and Their Supply Chains

While DTOs often are involved in poly-drug trafficking and other criminal activity, the unprecedented rise in deaths from the opioid crisis demands that we prioritize U.S. government efforts on the individuals and groups involved in the smuggling and sale of the most deadly drugs such as synthetic opioids and heroin. As these organizations continue to modify their techniques and operations in an attempt to reduce risk and maximize profit, we must anticipate and then respond to emerging changes in the drug trafficking environment, identify and exploit vulnerabilities in the illicit drug supply chain, and seize the initiative from drug traffickers in order to disrupt their activities and dismantle the infrastructure they use to sustain their illicit enterprise. Along with aggressive actions to prevent the further expansion of these criminal enterprises in our country, we must also work with foreign partners to attack criminal networks, principally those in the Western Hemisphere, whose drug trafficking and associated criminality directly impact migration and border security issues affecting the United States.

Working with International Partners

The U.S. Government will focus its diplomatic efforts to encourage partner nations to produce results that match the growing threat from illicit drugs. Consistent with the *National Security Strategy*, we will prioritize assistance with partners who are aligned with U.S. interests, are showing results, and building the capacity to address these threats independent of U.S. assistance programs. This will require partners' renewed commitment to disrupt the illicit supply chain through the interdiction and seizure of the illicit drug supply, illicit funds, and weapons; eradicate poppy and coca plants; find and dismantle the labs used for all illicit drug processing; develop and sustain robust law enforcement and justice systems; maintain the rule of law and ferret out corruption; and arrest and prosecute drug traffickers operating within their own land borders, territorial waters, and airspace. These efforts are not only important in their own right but will complement, and be informed by, a strong domestic public health response to the crisis aimed at reducing the use of these drugs in the United States. We will continue to work bilaterally with the primary drug producing and trafficking countries most affecting the United States, emphasizing our shared responsibility for today's drug problems and the strong desire for tangible progress in the years to come. Regional relationships will be an important part of our international approach going forward, allowing us to share information and harmonize our drug policies in the face of a constantly changing threat. Moreover, we will take full advantage of the strong multilateral framework that exists to address the global drug problem, particularly in terms of supporting the three international drug control conventions and providing leadership in the processes for internationally scheduling, controlling, and monitoring illicit drugs and their precursor chemicals.

Combating Illicit Internet Drug Sales

Over the past two years, illicit drug sales on both the clear and the dark web have further expanded the illicit drug market, allowing individuals to purchase dangerous drugs directly from their manufacturers instead of through established trafficking organizations, and have them shipped directly to their homes. We must disrupt the ability of drug traffickers to exploit the anonymity, distance, and financial trans-

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action reliability provided through internet sales by degrading the implicit trust between buyer and seller required for illicit on-line transactions. We must use existing authorities to their maximum effect to successfully target drug traffickers and their enablers by employing both passive and active measures to disrupt and exploit illicit drug related activities operating on both clear and dark webs. Contesting drug marketplaces in the cyber domain and disrupting the use of cryptocurrencies for illicit drug sales will require a coordinated and well-resourced framework of relationships, laws and regulations, procedures, and capabilities. This will allow us to identify and target the network of actors involved, and prosecute those who use the open or dark webs to market, sell, and purchase illicit drugs. Developing a drug cyber defense capability, and exercising it to achieve sustained effort against the internet drug market, will erode this implicit trust and disrupt illicit operations on the clear and dark webs over time.

Focusing Federal Government Effort Against Illicit Drug Delivery Through the Mail and Express Consignment Networks

We must complement our efforts against internet drug sales with a sustained effort to disrupt the flow of illicit drugs shipped through the international mail and express consignment environments. This requires developing the policy and regulations, international relationships, facility infrastructure upgrades, and technology required to aggressively target, detect, and intercept illicit drugs transported through the international mail and express consignment environments both internationally and domestically. We must work with our international partners to develop the ability to share Advance Electronic Data for all international shipments, in accordance with the *President's Opioid Initiative*, and continuously refine targeting algorithms to identify and interdict international shipments before they depart the source country and at U.S. Ports of Entry. We must help critical partner countries develop the ability to detect and intercept illicit drugs in their domestic mail and express consignment systems before those drugs depart for the United States and enter the U.S. mail or commercial carrier system. Finally, we must develop next generation technology and screening capabilities to increase our ability to detect illicit drugs once they enter the mail and express consignment systems within the country, and improve testing capability to determine the precise type and source of illicit drugs seized. This investment in science, technology, resources, and international relationships is necessary to determine the type, source region, production location, and route traveled for all illicit drugs seized by the United States and its international partners.

Interdicting the Flow of Drugs Across the Physical Borders and into the United States

Along with the new challenge of drug trafficking via internet sales and mail and express consignment delivery, drugs continue to flow across our land borders and through the maritime and air routes. Stopping these flows must remain part of our comprehensive interdiction efforts. The historically high levels of cocaine production in Colombia, along with heroin and methamphetamine production in Mexico, combined with the vast number of routes and conveyances into the United States, make the challenge of combating drug trafficking across our physical borders no less daunting than it has been for the past several decades. Federal agencies should expand efforts in the detection and monitoring of the air and maritime approaches to the United States; the detection of illicit drugs and precursor chem-

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icals being shipped in commercial containers; and interdiction of plant-based drugs such as heroin, cocaine, and marijuana, as well as synthetic drugs and their precursor chemicals, along the Nation's land borders. Moreover, this increased effort must be complemented by increased effort and cooperation from foreign partners who can contribute vital information on trafficking patterns and assets to seize drugs bound for the United States.

Disrupting and Dismantling the Illicit Drug Production Infrastructure

The United States and Mexico have expanded cooperation to address the common threat of illicit opioids, and both governments agree that reducing the supply of heroin, methamphetamine, and fentanyl is a shared responsibility. Mexico is increasing its efforts to eradicate poppy fields more effectively, destroy clandestine laboratories, and interdict heroin and other drugs before they reach the U.S. border. The U.S. Government provides training to Mexican law enforcement officers, analysts, chemists, and military personnel to identify and safely dismantle clandestine drug laboratories that produce heroin, methamphetamine, and fentanyl, and how to address the dangers synthetic drugs present to law enforcement.

Expanding coca cultivation and cocaine production in Colombia and the broader Andean region must continue to be addressed in a comprehensive manner. Key elements of cooperation with proven partners such as Colombia and Peru include increasing all forms of eradication, alternative development and economic opportunities, interdiction, investigation and prosecution, judicial support, and public health cooperation, all of which must be long-term and sustainable. Since coca fields differ in their level of productivity, this approach will be most successful if collectively focused in areas of high-yield coca cultivation. Unfortunately, these areas generally have limited government services and lingering security concerns, and will require concerted effort over several years to keep partner nations focused on the issue and turn the rising tide of cocaine production.

Within the United States marijuana cultivation on public lands, and within National Forest System lands in particular, is a significant issue. Cultivation activities not only sustain the illicit marijuana trade but also produce large volumes of hazardous materials that pose a significant risk to the public and the environment. Wildlife, soil, and vegetation are often contaminated by the various hazardous substances involved in the cultivation process. Personnel conducting enforcement, cleanup, and regulatory activities, as well as the public, are at considerable health risk from exposure to these chemicals. Continued firm action is required against the exploitation of the Nation's public lands through increased detection, disruption, reclamation, and prosecutions.

The majority of illicit synthetic drugs available in the United States are manufactured abroad. New illicit synthetic drugs and the precursor chemicals used to make them originate predominantly in China, although most of the methamphetamine available in the United States is manufactured in Mexico. Increased collaboration with Mexico, China, and other partners on shared drug priorities can help disrupt drug trafficking networks, along with the corrupt or compromised systems that support them, and reduce the availability of dangerous synthetic drugs in the United States. The United States will continue bilateral exchanges with China, Mexico, Colombia, and other source and transit countries to reduce production and trafficking of synthetic drugs destined for markets in the United States and support collaboration with international partners impacted by drugs from the very same sources.

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Leveraging the Full Capabilities of Multi-Jurisdictional Task Force Programs

The High Intensity Drug Trafficking Areas (HIDTA) Program provides assistance to law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. HIDTAs provide an umbrella to coordinate Federal, state, local, and tribal drug law enforcement agencies' investigations, and act as neutral centers to manage, de-conflict, analyze, provide intelligence, and execute drug enforcement activities in their respective regions. With the recent inclusion of Alaska, the first new HIDTA in 17 years, the 29 regional HIDTAs now include designated areas in all 50 states, Puerto Rico, the U.S. Virgin Islands, and the District of Columbia. The regional HIDTAs bring together more than 21,000 Federal, state, local, and tribal personnel from 500 agencies through 800 enforcement, intelligence, and training initiatives, all designed to disrupt illicit drug trafficking and dismantle criminal and drug trafficking organizations. The Administration will ensure strong support for counterdrug enforcement, including by supporting Federal participation in multi-jurisdictional task forces and enhancing support for information sharing at all levels. This will ensure that national data systems receive input from state, local, and tribal agencies, and that these agencies, in turn, have access to data compiled by Federal agencies that can prove vital to their own investigations.

Interrupting the Financial Activities of Drug Traffickers

Illicit drugs enter the United States from global suppliers as the result of a long and complex process involving manufacture, concealment, movement, purchase, and delivery. The illicit drugs may change hands several times during the process, and this often necessitates the transfer of money, either as payment for services or for delivery of the final product. Traditionally, street-level sales of illegal drugs are conducted with cash, creating immediately liquid assets that are almost impossible to track. As technology and money laundering methods have adapted over the years to circumvent Anti-Money Laundering regulations, drug traffickers have initiated many new techniques to enable the traditional method of hard currency transactions. Although some of these methods create additional investigative evidence, emerging technologies continue to outpace banking regulations and consistently provide drug traffickers the means to launder large amounts of their illicit proceeds.

Most of the revenue generated from illegal drug sales in the United States is maintained at the retail level of drug distribution. However, illicit proceeds that flow back to international sources of drug supply are most often used to finance other illegal activities or the next cycle of illegal drugs to be directed into our communities, posing a continual threat to the country. These funds also corrupt and weaken the government infrastructure of source and transit countries, limiting those governments' ability to combat Transnational Criminal Organizations (TCOs), escalating violence, and threatening the stability of the governments we partner with to counter illicit activity. We will combat this threat and target the drug proceeds that motivate criminal activity by attacking TCOs' financial capital; preventing the circulation, transfer, and concealment of their illicit proceeds; and ultimately decreasing their wealth and their incentive to function.

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Enhancing Law Enforcement Capacity

Success in reducing the availability of illicit drugs in our country requires building the capacity and tools to fully understand, and relentlessly respond to, the increased drug threat we face. As stated in our *National Security Strategy*, this capacity building includes national-level strategic intelligence and planning capabilities to improve the ability of departments and agencies to work together to combat TCOs, particularly those who traffic drugs at home and abroad. We must improve our capability to dismantle TCOs as a whole through greater coordination and focus, directly benefiting our counterdrug efforts. Improved strategic planning must be informed by better strategic intelligence on transnational organized crime and global criminal networks, fusing law enforcement and Intelligence Community information and intelligence to create the most complete picture available of criminal networks. We must use that information to identify and exploit vulnerabilities in drug trafficking networks using the full range of law enforcement capabilities including criminal prosecutions, financial disruption tools such as asset forfeiture proceedings, and security operations to remove the profits from crime. Moreover, we must maintain pressure on these organizations over time and prevent them from regenerating their capabilities. We must also emphasize both actions that lead to prosecutions—to reduce networks' ability to operate, through the investigation, arrest, and prosecution of critical personnel —and those that lead to the long-term disruption of network operations such as the seizures of illicit drugs, precursor chemicals, illicit funds, and weapons.

Our conventional focus on targeting high-level individuals within the hierarchy of well-organized and sophisticated DTOs must evolve toward identifying and targeting vulnerable critical components of more fluid and dynamic organizations such as financial facilitators, corrupt officials, and key transporters, to affect a significant disruption of DTO activities, targeting key nodes to attack the entire network through its enablers. Degrading and defeating criminal networks that have become more resilient because they are decentralized, redundant in capabilities and capacities, and compartmentalized, requires identifying the key nodes enabling DTO operations and simultaneously targeting them for maximum effectiveness over time. Agile interagency and international coordination will allow for better detection of changes in the trafficking supply chain, which will support intelligence-driven operations against identified vulnerabilities, from drug production to delivery to the end user.

Conclusion

The increased availability and use of illicit drugs is taking far too many American lives. It burdens the U.S. health care system and leads to lost productivity and civil engagement here at home, and global drug trafficking sustains a vast domestic and international criminal enterprise that enables corruption and destabilizes partner nations abroad. America's drug crisis has created a complex national security, law enforcement, and public health challenge for the Nation, and this challenge will remain with us for the foreseeable future. We must leverage the full capabilities of the U.S. intelligence and law enforcement communities, our military, domestic law enforcement and criminal justice capabilities, and sustained engagements with the governments of key partner nations and international organizations to stop the flow of these drugs across our borders and into our communities, and use that capability to posture ourselves for an ever-evolving drug trafficking environment. Our actions will include disrupting the evolving illicit supply chain, decreasing the volume of drugs being sold over the internet; decreasing

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the cultivation of illicit crops like poppy and coca as well as the volume of illicit drugs being produced for export to the United States; increasing the amount of illicit drugs seized before entering the United States; increasing the amount of forfeited assets; increasing the number of convictions for drug-related crimes; and increasing the pace of emerging dangerous substances being reviewed and scheduled for domestic and international controls.

Achieving the President's objective of reducing the number of Americans losing their lives to drug addiction in today's crisis, and preparing now to dominate the drug environment of the future, requires deliberate actions focused on clear priorities and tangible outcomes to reduce the availability of drugs in our Nation. However, lasting success requires those actions to complement, and be informed by, a strong domestic public health response to reduce the use of these drugs in the United States which makes possible enormous profits for drug traffickers and fuels the illicit drug market. Bold and decisive national security, law enforcement, and public health efforts are needed to lift the Nation from the shadow of drug use and move toward the President's goal of a stronger, healthier, and drug free society today and in the years to come.

METRICS

Because this *Strategy* focuses on outlining a high-level approach rather than enumerating all of the key tasks and activities that organizations at the Federal, State, local and Tribal levels must undertake in order to stem the tide of this crisis, it is important to employ some broad measures of performance and effectiveness to guide the *Strategy's* implementation. This not only ensures the necessary policies, priorities, and objectives of drug control agencies and interagency partners are adequately aligned and resourced to advance the President's drug control priorities, but also serves to identify those areas where a refinement of the *Strategy* may be necessary to close an identified gap, or areas where a shift in specific agency resources can attain greater effects in achieving the President's overarching strategic objective.

This requires that we focus on effects and not simply performance. While a performance measure represents the specific characteristic or aspect of the program or policy used to gauge successful performance of a specific task, effectiveness represents the aggregate progress, of multiple agencies contributing to achieving tangible improvement through their programs, initiatives, and policies. Doing so requires linking actions taken on the front end of the global supply chain to reduce the availability of illicit drugs in the United States with measurable effects on the health and safety of our communities.

Measures of Performance

- Educate the public, especially adolescents, about drug use, specifically opioids increase, mandatory prescriber education and continuing training on best practices and current clinical guidelines; and increase PDMP interoperability and usage across the country
- Encourage expanded access to evidence-based addiction treatment in every state, particularly Medication-Assisted Treatment for opioid addiction; support legislative changes to allow

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Medicaid to reimburse certain residential treatment at facilities with more than 16 beds; and encourage states to apply for state Medicaid demonstration projects that address barriers to inpatient treatment as a part of a comprehensive opioid/substance use disorder strategy

- Significantly reduce the availability of illicit drugs in the United States by preventing their production outside the United States, disrupt their sale on the internet, and stop their flow into the country through the mail and express courier environments, and across our borders

Measures of Effectiveness

- The number of Americans dying from a drug overdose is significantly reduced within five years
- Nationwide opioid prescription fills are reduced by one-third within three years, and within five years all healthcare providers have adopted best practices for opioid prescribing
- Evidence-based addiction treatment, particularly Medication-Assisted Treatment for opioid addiction, is more accessible Nationwide for those who need it
- The production of plant-based and synthetic drugs outside the United States has been significantly reduced, illicit drugs are less available in the United States as reflected in increased price and decreased purity, and drug seizures at all U.S. ports of entry increase each year over five years

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ONDCP-19-0922-A-000272_ONDCP042FY18043_000000098

CEPOP ALL-PARTICIPANTS TELECONFERENCE (MARCH 2019)

Date: Monday, March 25, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. ONDCP's National Drug Control Strategy – Tackling the Opioid Epidemic**
  The Honorable James W. Carroll, *Director, Office of National Drug Control Policy, Executive Office of the President*
- **B. EVERFI and the Prescription Drug Safety Network (link)**
  Kimberley Timpf, M.Ed., *Senior Director, Partner Education, EverFi*

III. Advocacy and Policy Priorities

- **A.** President's Proposed FY20 Budget & CEPOP Priorities
- **B.** FY2020 Appropriations

IV. Working Groups

- **A.** Prevention
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Upcoming Schedule
  - **i.** National Rx Drug Abuse & Heroin Summit – CEPOP Reception (April 23rd, 5:30pm – 7:30pm, Sway Restaurant)
  - **ii.** No April 2019 All-Participants Teleconference (reconvene in May)
- **B.** Seen and Heard
- **C.** Participant News

Next CEPOP All-Participants Teleconference:

Monday, May 27, 2019 (calendar appointment forthcoming)

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[EXTERNAL] Canceled: CEPOP Reception at the National Rx Drug Abuse and Heroin Summit

Where: Sway Restaurant (Hyatt Regency Atlanta, 265 Peachtree Street NW)

When: Tue Apr 23 17:30:00 2019 (America/New_York)

Until: Tue Apr 23 19:30:00 2019 (America/New_York)

Organiser: Whitney Taylor <(b)(6)

Required Attendees:

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"Jonah Cunningham (TFAH)" <(b)(6)

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Optional Attendees:

Frederick Ryan <(b)(6)
"Webb, Kevin J" <(b)(6)
Patrick Fogarty <(b)(6)
"Grove, Sean" <(b)(6)
"Lohman, Donald A" <(b)(6)
Jason Sundby <(b)(6)

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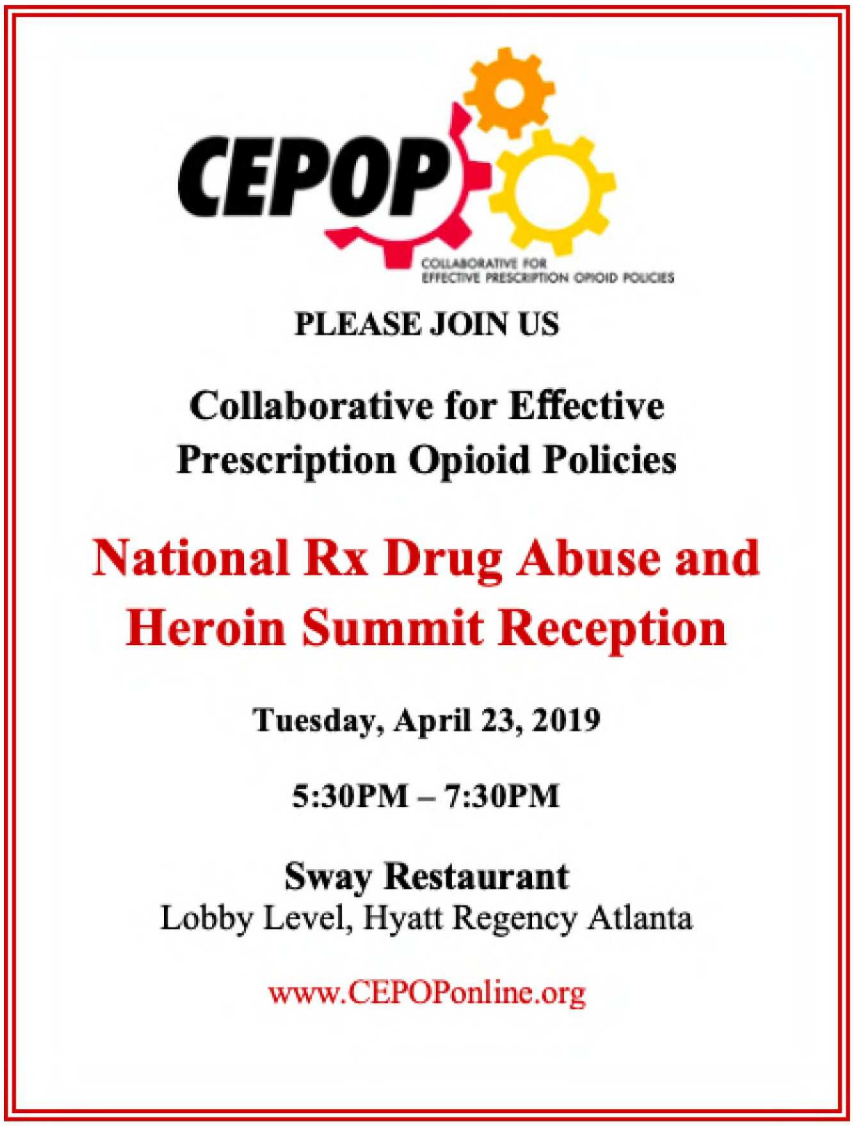

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PLEASE JOIN US

Collaborative for Effective Prescription Opioid Policies

National Rx Drug Abuse and Heroin Summit Reception

Tuesday, April 23, 2019

5:30PM – 7:30PM

Sway Restaurant
Lobby Level, Hyatt Regency Atlanta

www.CEPOPonline.org

AMERICAN OVERSIGHT

[EXTERNAL] CEPOP All-Participants Teleconference (May 2019)

From: Whitney Taylor <(b)(6)

To:
Addie Liles <(b)(6) (b)(6) (b)(6)
"Jonah Cunningham (TFAH)" <(b)(6)
(b)(6) (b)(6) "J. Nadine Gracia"
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Gabriella Witte <(b)(6) (b)(6)

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Ventimiglia <(b)(6) (b)(6)
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Cc: "Motu, Nick" <(b)(6) Jason Sundby
<(b)(6) "Lohman, Donald A" <(b)(6)
Claire Stroer <(b)(6) "Naten, Derek" <(b)(6)

Date: Fri, 17 May 2019 12:16:47 -0400

Attachments CEPOP All-Participants Meeting Agenda (May 2019).pdf (234.29 kB); not supported

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CEPOP All-Participants Teleconference (May 2019)

- To join via computer, please click here.

Conference Line: (b)(6)
Participant Code: (b)(6)

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AMERICAN OVERSIGHT

CEPOP ALL-PARTICIPANTS TELECONFERENCE (MAY 2019)

Date: Monday, May 20, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. The HEALing Communities Study – Developing Evidence to Prevent and Treat Opioid Addiction (link)**
  Dr. Redonna Chandler, *Director HEALing Communities Study, National Institute on Drug Abuse, National Institutes of Health*
- **B. Learnings from Scioto County, Ohio – Successes from the Community Level**
  Lisa Roberts, RN, *Program Coordinator, Scioto County Drug Action Team, Portsmouth, Ohio*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations
- **B.** FOA for Drug-Free Communities Grant Program (link)

IV. Working Groups

- **A.** Prevention
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Recap from Atlanta – The National Rx Drug Abuse and Heroin Summit
- **B.** Seen and Heard
- **C.** Participant News
  - **i.** Update on National Safety Council's Employer Survey and Toolkit
  - **ii.** CADCA Mid-Year Training Institute in Dallas, TX (July 14-18, 2019; link)

Next CEPOP All-Participants Teleconference:
Monday, June 24, 2019 (calendar appointment forthcoming)

www.CEPOPonline.org

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[EXTERNAL] CEPOP All-Participants Teleconference (May 2019)

From: Whitney Taylor <(b)(6)

To:
Addie Liles <(b)(6) (b)(6) (b)(6)
"Jonah Cunningham (TFAH)" <(b)(6)
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Claire Stroer <(b)(6) "Naten, Derek" <(b)(6)

Date: Fri, 17 May 2019 12:15:15 -0400

Attachments CEPOP All-Participants Meeting Agenda (May 2019-SCRIPT).pdf (219.82 kB);

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: CEPOP All-Participants Meeting Agenda (May 2019).pdf (234.29 kB); not supported calendar message.ics (18.77 kB)

CEPOP All-Participants Teleconference (May 2019)

- To join via computer, please click here.

Conference Line: (b)(6)
Participant Code: (b)(6)

AMERICAN OVERSIGHT

CEPOP ALL-PARTICIPANTS TELECONFERENCE (MAY 2019)

MARCH 2019 SPEAKER SCRIPT

Date: Monday, May 20, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA MEETING LEADER IS DEREK NATEN (Mallinckrodt; Steering Committee Member)

LEADER NOTE: The May 2019 CEPOP All-Participants teleconference is being held via WebEx for remote participation **only**. A copy of the agenda and relevant materials have been included in the calendar appointment for today's All-Participants meeting. If you are not speaking during any portion of the call, we ask that you please mute your line. With this meeting, you will not hear any sign-in tones when participants enter. **For those participants with a speaking role in today's meeting, we ask that you please sign into the WebEx using the leader pin: 190150.** This will help us easily identify those Steering Committee members, Working Group co-chairs, Focus Topic Speakers and others that have joined via phone. Should you have any questions, please do not hesitate to reach out to the FBDC team.

SPEAKER NOTE: *We ask that all Steering Committee members, Working Group chairs, and other Focus Topic Speakers please announce themselves upon joining the teleconference.*

Once all participants have gathered, we will welcome everyone to the May 2019 CEPOP All-Participants call and turn the call over to **DEREK NATEN,** Steering Committee member representing Mallinckrodt, who is leading this month's meeting.

I. Welcome **DEREK NATEN:** Thank you to everyone for joining our March 2019 CEPOP All-Participants teleconference. As always, we're pleased to share a full agenda with outstanding focus topic speakers and a series of updates. We'll move through the agenda to ensure we have time for discussion. ***And as always, a friendly reminder to mute your line when you're not speaking.***

Without further delay, we'd like to dive right in to this month's Focus Topic presentations, leading with a timely and impactful discussion with Dr. Redonna Chandler from NIDA's HEALing Communities Study. As outlined in further detail through the link provided in the agenda, the HEALing Communities Study is an exciting collaborative effort between NIH and SAMHSA around integrated community-based interventions aimed at combatting the opioid abuse epidemic. These interventions are implemented across various settings, covering areas such as healthcare, behavioral health, justice, and elsewhere. The goal of the study is to reduce overdose rates by 40% in three years across four key states and more than a dozen partners on the ground. States include: New York, Massachusetts, Kentucky and Ohio.

Dr. Chandler is the Director of the HEALing Communities Study at NIDA. She brings extensive

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scientific and organizational leadership, and recently served as the Deputy Director for the Division of Clinical Innovation at the National Center for Advancing Translational Sciences providing leadership to the Clinical and Translational Science Awards Program. Dr. Chandler has been at the NIH since 2002, serving in positions of increasing responsibility and leadership at the National Institute on Drug Abuse. Prior to joining NCATS, she served as the Acting Director for the NIDA's Division of Epidemiology, Services, and Prevention Research and Chief of the Services Research Branch. She worked for the Department of Justice from 1996-2002, directing large drug treatment programs. Her areas of expertise include research with individuals involved with the criminal justice system, clinical trials, improving adherence to drug abuse treatment and HIV care, health services research, and implementing evidence-based treatments into routine practice settings. She has authored numerous articles and book chapters. She earned her Ph.D. in psychology from the University of Kentucky and is a licensed psychologist. As a clinician she has treated those struggling with addiction use disorder and serious mental health issues. Welcome, Dr. Chandler, we look forward to your remarks.

II.

Focus Topic Discussions

A. The HEALing Communities Study – Developing Evidence to Prevent and Treat Opioid Addiction (link)
Dr. Redonna Chandler, *Director HEALing Communities Study*, *National Institute on Drug Abuse, National Institutes of Health*

DEREK NATEN will allot approximately 10 minutes for remarks from Dr. Chandler followed by a brief Q&A that he will facilitate, opening the call up to all CEPOP participants joining via WebEx for questions/comment.

Leading questions for consideration:

- How will data be recorded and disseminated? Will data be shared in a monthly fashion as we've seen historically with CDC MMWR reporting?
- Beyond tracking overdose deaths and other downstream metrics, is there any component of the HEALing Communities Study that will help to demonstrate efficacy or utility of primary prevention strategies?
- Do you anticipate the study to be broadened at any point to include additional partner cities?

Thank you, Dr. Chandler for your remarks. We will now turn our focus to the community level and will hear from Ms. Lisa Roberts from Scioto County, Ohio. Lisa is a Registered Nurse employed at the Portsmouth City Health Department in Scioto County, Ohio which is part of the Appalachian region. In 2010, Lisa helped form the Scioto County Drug Action Team Alliance—a community coalition that serves Scioto County. She has assisted Scioto County to receive a High Intensity Drug Trafficking Area (HIDTA) designation and also a Drug Free Communities (DFC) Support Program grant—both administered by the Office of National Drug Control Policy. Lisa currently administers the DFC Program which is now in its seventh year. The DFC program uses a data driven community-based coalition infrastructure to achieve population-level reductions in substance use and to mitigate the harms associated with substance abuse.

She has collaborated with local, state, and national leaders to seek innovative solutions to the opioid crisis. She has worked extensively in the area of opioid misuse and overdose prevention and has piloted multiple projects designed to address overprescribing, accidental drug overdoses, and the harms associated with opioid use disorder. We look forward to Ms. Roberts' remarks and are pleased to turn the call over to her at this time.

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B. Learnings from Scioto County, Ohio – Successes from the Community Level
Lisa Roberts, RN, *Program Coordinator, Scioto County Drug Action Team, Portsmouth, Ohio*

DEREK NATEN will allot approximately 10 minutes for remarks from Ms. Roberts followed by a brief Q&A that he will facilitate, opening the call to other CEPOP participants joining via WebEx.

Upon completion of our May 2019 focus topic discussions, **DEREK NATEN** will thank Dr. Chandler and Ms. Roberts for their participation in today's All-Participants teleconference and their ongoing leadership in combatting the opioid epidemic at various levels throughout the country. We will now turn the focus of the call over to the *Advocacy and Policy Priorities* section of the agenda followed by a brief update from our Working Groups. To lead this portion of the agenda, **DEREK NATEN** will turn the call over to **SUE THAU.**

III. Advocacy and Policy Priorities

A. FY2020 Appropriations – **SUE** will note the ongoing Appropriations and FY2020 budget process with the recent reporting of the Labor-HHS bill out of Committee. Sue will look to discuss the funding allotted towards to opioid epidemic, its alignment with CEPOP priorities, and related advocacy to help further efforts and grant programs of interest to the organization. (Sue may look to **ROB MORRISON** for additional thoughts or insight should he be able to join.)

B. FOA for Drug-Free Communities Grant Program – **SUE** will note the announcement of 2019 Drug-Free Communities Grant funding out of SAMHSA last week. Consistent with year's past these will be used to help establish and strengthen coalitions across the nation aimed at preventing and reducing substance use and abuse among youth. Approximately 150 coalitions will be chosen to receive up to $125,000 per year for up to five years.

DEREK NATEN will thank **SUE** (and ROB, if participating) for their continued leadership on the CEPOP policy agenda and will then transition the call into the Working Group portion of the agenda, to be led by **DAVE ZOOK**.

IV. Working Groups – **DAVE ZOOK** will thank **DEREK NATEN** for the introduction and remind participants of the restructuring of the CEPOP Working Groups. Should participants still wish to join in any of the three Working Groups, please contact **WHITNEY TAYLOR** and she will coordinate to add you to the appropriate distribution list. Each Working Group is in the process of coordinating an initial call to help develop an action plan and opportunities for implementation.

A. Prevention – This working group will be led by **CEPOP Steering Committee Members CADCA and NSC** and is set to convene for an initial meeting in the coming month.

B. Safe Disposal and Anti-Diversion – Co-chairs include **AmerisourceBergen** (Brad Tallamy) and **NHPCO** (Judi Lund-Person)

i. Consistent with CEPOP's longstanding emphasis on safe disposal of unused and unwanted opioids, including opportunities to deactivate and dispose of in the home, we are pleased to report that, following the Rx Summit, the FDA announced their *Remove the Risk* national public awareness campaign and revisions to the Drug Disposal webpage. This change includes a significant additional with respect to a note around other technologies available to help patients and caregivers safely dispose of unused and unwanted medications in the home, augmenting existing kitty litter/coffee ground suggestions.

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ii. CEPOP, in partnership with BD & BIOCOM, will be hosting a Capitol Hill briefing on acute care opioid safety on Wednesday, June 12th (5:00pm). Mary Bono will moderate. Additional information forthcoming. This builds out from a longstanding area of focus for CEPOP and builds upon our initial partnership with BD in March 2017 on this issue. Since that point, innovative technology solutions have been brought to market and are readily integrated into the healthcare delivery system to promote safe opioid management and dispensation. We look forward to seeing everyone there!

C. Safe Use –. Collegium (**Steve Passik)** is a co-chair; steering committee is determining second co-chair with shift of **NSC** to prevention. In the last several weeks, FDA and CDC have made significant steps to help clarify appropriate use/discontinuation of opioids. FDA announced an updated opioid label and drug safety communication focused on product tapering. Simultaneously, the CDC issued a letter in the New England Journal of Medicine referencing the misutilization of the Chronic Pain Opioid Guidelines and notes the agency's ongoing review of potential opportunities to correct that issue. The working group will also look to reconvene and continue discussions around the ongoing priority issue of access to abuse-deterrent opioids and the non-pharmacologic benefits from these products.

V. Organizational Updates: Sharing Intel, Participant News and Updates – **DEREK NATEN** will thank **the Working Group leaders** and turn the call agenda to remaining updates led by **MARY BONO**.

A. Recap from Atlanta – The National Rx Drug Abuse and Heroin Summit – **MARY BONO** will thank all CEPOP participants for joining us during the Rx Summit Reception just a few short weeks ago. This was the most successful and highly attended event to date! We look forward to continuing the tradition during next year's Rx Summit in Nashville, Tennessee.

B. Seen and Heard – **MARY BONO** will note that on June 26th, CEPOP will have an opportunity to participate in an event honoring longstanding epidemic response champion **HAL ROGERS** during a lunch. Additional information is forthcoming; however, this event will serve as a great opportunity to continue honoring a steadfast champion and strengthen our relationship with his office. **MARY** will allow CEPOP participants the opportunity to share what they are hearing from Hill staff, federal agency partners and others with respect to the opioid epidemic and items germane to the focus of CEPOP.

C. Participant News – **MARY** will then open the call to any additional updates from CEPOP participants on recent news or reports; noting that two Steering Committee members will be teed up and ready to discuss their relevant news and updates. **MARY** will turn the call over to **JULIAN HOFFMAN** at National Safety Council and his colleagues to briefly discuss their Employer Survey and Toolkit related to the opioid epidemic and some updates since last reported.

i. **Update on Employer Survey and Toolkit (link)**
National Safety Council

MARY will then turn the call briefly over to **GENERAL DEAN** to note CADCA's annual mid-year training in a few weeks.

ii. CADCA Mid-Year Training Institute in Dallas, TX (July 14-18, 2019; link)

Next CEPOP All-Participants Teleconference:
Monday, June 24, 2019 (calendar appointment forthcoming)

There being no further business in front of the group, **DEREK NATEN** will close out the May 2019 All-Participants teleconference by thanking everyone for joining us today. CEPOP looks forward to reconvening this group for our next All-Participants teleconference, scheduled for **Monday, June 24th**. A calendar appointment for

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this event will be circulated from **WHITNEY TAYLOR** following this call. Should there be any questions or comments, please refer them to any member of the Steering Committee. Once again, thank you for joining us.

[[END]]

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (MAY 2019)

Date: Monday, May 20, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. The HEALing Communities Study – Developing Evidence to Prevent and Treat Opioid Addiction (link)**
  Dr. Redonna Chandler, *Director HEALing Communities Study*, *National Institute on Drug Abuse, National Institutes of Health*
- **B. Learnings from Scioto County, Ohio – Successes from the Community Level**
  Lisa Roberts, RN, *Program Coordinator, Scioto County Drug Action Team, Portsmouth, Ohio*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations
- **B.** FOA for Drug-Free Communities Grant Program (link)

IV. Working Groups

- **A.** Prevention
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

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[EXTERNAL] CEPOP All-Participants Teleconference (May 2019)

From: Whitney Taylor <(b)(6)

To:
Addie Liles <(b)(6) (b)(6) (b)(6)
"Jonah Cunningham (TFAH)" <(b)(6)
(b)(6) (b)(6) "J. Nadine Gracia"
<(b)(6) Rob Morrison <(b)(6)
(b)(6) Sue Thau <(b)(6) Van Ingram
<(b)(6) Whitney Taylor <(b)(6)
(b)(6) Erica Webb-Belzer <(b)(6)
(b)(6) "Alexander, Tesfa" <(b)(6) Alice
Dembner <(b)(6) (b)(6)
(b)(6) Amy Callender <(b)(6)
(b)(6) Aryka Chapman
<(b)(6) (b)(6) Blaire Bryant
<(b)(6) "Tallamy, Brad" <(b)(6)
(b)(6) Brian Bowden <(b)(6)
(b)(6) Cara Moon <(b)(6)
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(b)(6) Dennis Brennan
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(b)(6) (b)(6) "Spitznas, Cecelia M.
EOP/ONDCP" <(b)(6)
(b)(6) (b)(6) "Dr. John Harrison"
<(b)(6) (b)(6) (b)(6)
(b)(6) Eli Briggs <(b)(6) (b)(6)
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Gabriella Witte <(b)(6) (b)(6)

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(b)(6) Ian Goldstein <(b)(6)
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(b)(6) Jeremiah Lindemann <(b)(6) Jessica Johnston
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[AAAP]" <(b)(6) (b)(6)
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(b)(6) Marcia Lee Taylor <(b)(6)
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(b)(6) Richard Hamburg <(b)(6)
"Norton, Rita" <(b)(6) (b)(6)
"Swift, Robin, DOH" <(b)(6) Samantha Arsenault
(b)(6) , Sarah Nerad <(b)(6)
(b)(6) (b)(6) Shelley Starkey
<(b)(6) (b)(6) Stephanie Pasternak
<(b)(6) Steve Passik
<(b)(6) Susan Thau <(b)(6) Susan
Awad <(b)(6) (b)(6) (b)(6)
(b)(6) (b)(6) (b)(6) Vince
Ventimiglia <(b)(6) (b)(6)
(b)(6)

Cc: "Motu, Nick" <(b)(6) Jason Sundby
<(b)(6) "Lohman, Donald A" <(b)(6)
Claire Stroer <(b)(6) "Naten, Derek" <(b)(6)
"Webb, Kevin J" <(b)(6)

Date: Mon, 20 May 2019 12:03:54 -0400

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Attachments:	CEPOP All-Participants Meeting Agenda (May 2019).pdf (234.29 kB); CEPOP Solutions to the Opioid Epidemic in Rural America.pdf (3.59 MB); CEPOP Presentation.5.20.2019.pptx (3.55 MB); not supported calendar message.ics (18.95 kB)

CEPOP All-Participants Teleconference (May 2019)

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A Rural Response to the Opioid Crisis in Scioto County, Ohio





Portsmouth City Health Department

Lisa Roberts RN / Program Coordinator Drug Free Communities Support Pro

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ONDCP-19-0022-A-001297_0000000067

Scioto County Data/ History and Risk Factors:

2010: First county in nation to declare public health emergency related to opioids
2017: The US declared a public health emergency



POLICY: Worked with state legislature to pass laws to regulate pain management, opioid prescribing, and improve access to naloxone

Risks:

Appalachian-Distressed County; populat
Ohio's original epicenter for opioid prob

- 2002- First pill mill established in Portsr
- Between 2002-2011 Home to a leading of oxycodone in the *nation-three differ*

2010: Scioto County saw 9.7M pain pills d (123 pills/person)-Highest in Ohio

Results:

- Highest fatal OD rate in state
- Highest opioid addiction rate in Ohio
- Highest rate of NAS
- Highest rate of drug incarcerations in O
- Huge increase in Hepatitis C rates-high

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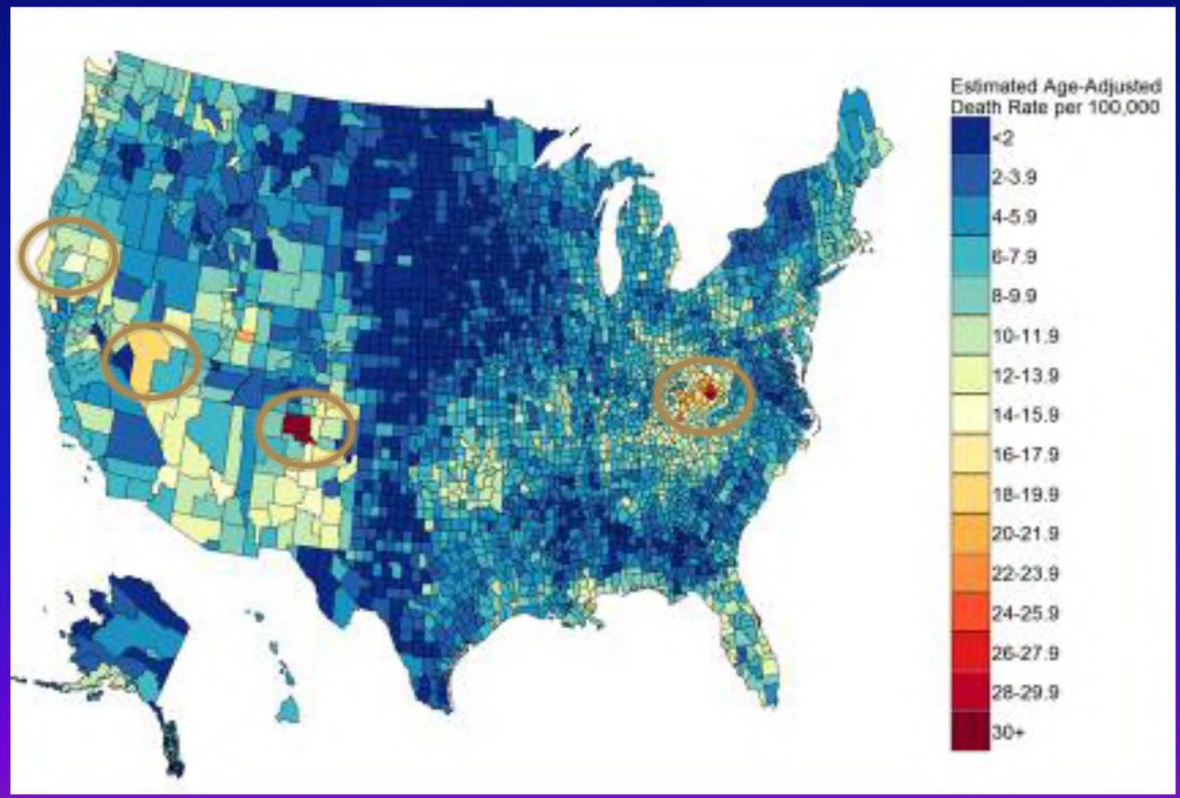
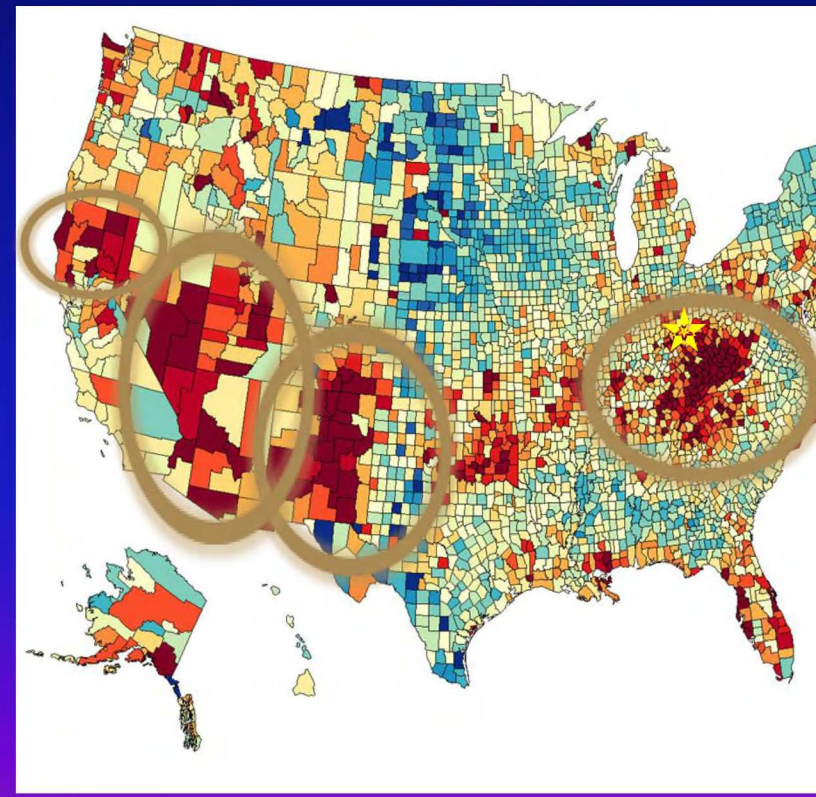
Fatal Drug Overdose Mortality U.S. 2002-2016
A 14 year span.....

2002



2016



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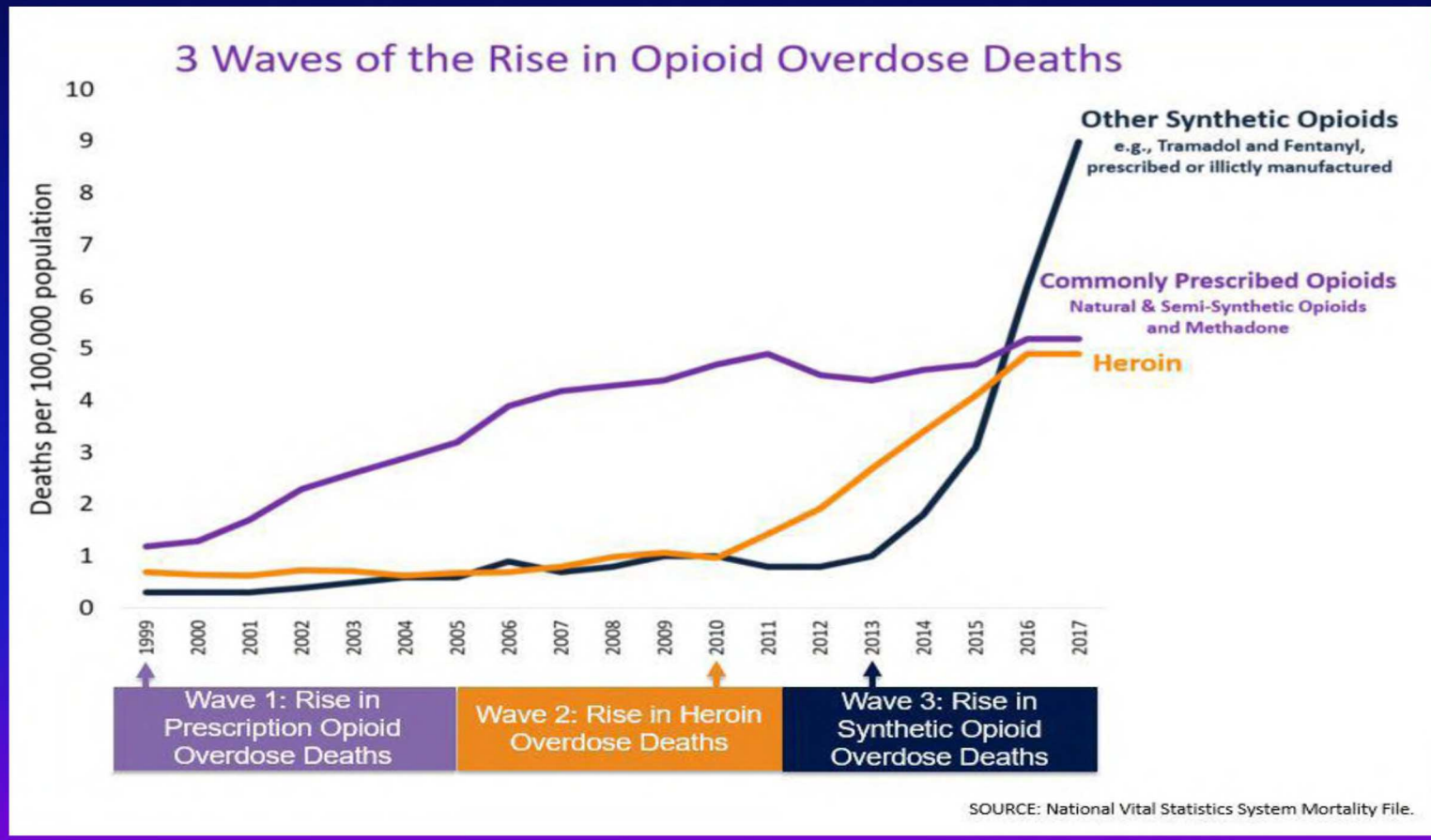
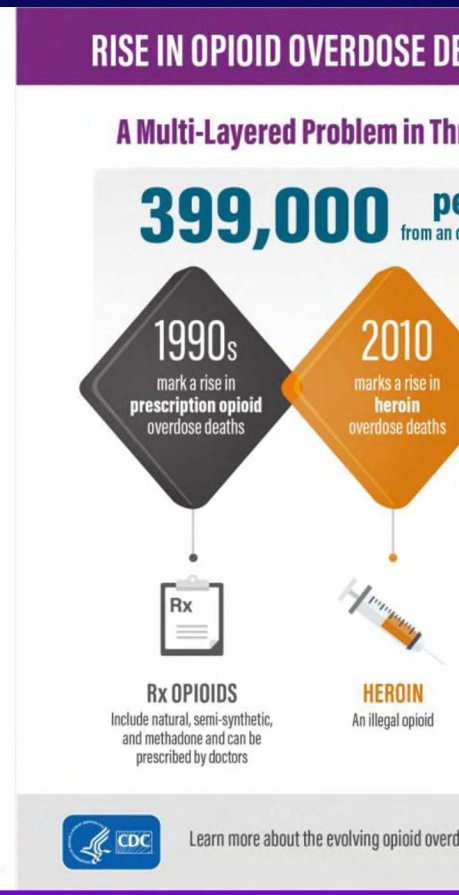
United States Opioid Related Overdose Deaths 1999-2017
Overlapping, Entangled, but Distinct Contributors to the Epidem





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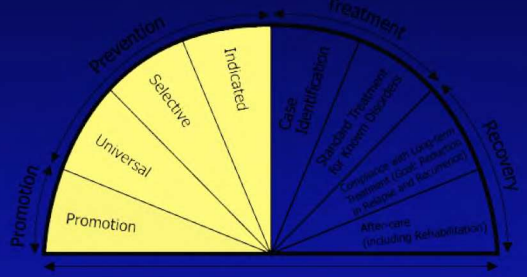
Scioto County organized: Coalition formed 2010



2012 -***"Drug Free Communities Support Program"*** from the W
Office of National Drug Control Policy (federal grant/ ***demand***
2012- ***HIDTA*** Designation by Congress (federal grant/ ***supply re***



Used the Strategic Prevention Framework:

Strategic Planning produced 3 priorities:

1. Prevent new initiates to opioid abuse
2. Reduce harms associated with Opioid Use Disorders (death,
3. Treat the addicted

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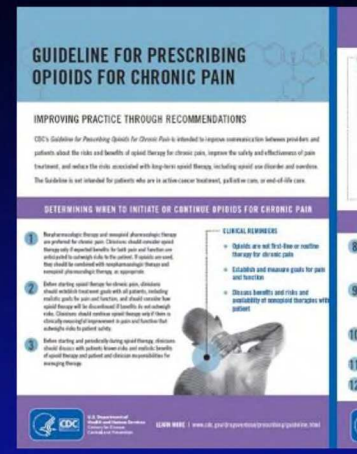
Strategy 1. Prevent new initiates to opioid abuse



- Improved opioid prescribing (Ohio's Opioid prescribing Guidelines (2013)
- Increased use of and enhancements to Prescription Monitoring Program
- Established Rx Drug disposal (Take Back Days and permanent Rx Drop Boxes
- Implemented adult and adolescent prevention initiatives







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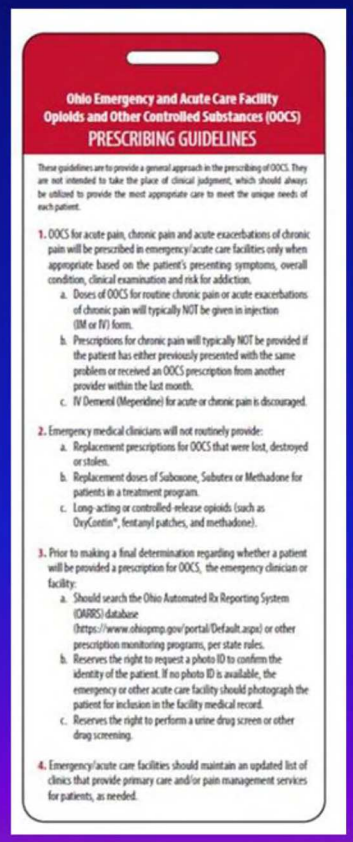
Outcomes: Scioto County- Opioid Consumption 2010-2018 (excluding treatment medications)

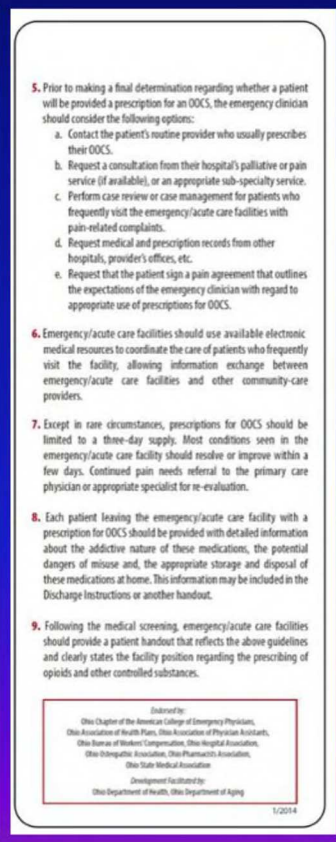


Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances (OOCS)

PRESCRIBING GUIDELINES

These guidelines are to provide a general approach in the prescribing of OOCS. They are not intended to take the place of clinical judgment, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient.

1. OOCS for acute pain, chronic pain and acute exacerbations of chronic pain will be prescribed in emergency/acute care facilities only when appropriate based on the patient's presenting symptoms, overall condition, clinical examination and risk for addiction.
   a. Doses of OOCS for routine chronic pain or acute exacerbations of chronic pain will typically NOT be given in injection (IM or IV) form.
   b. Prescriptions for chronic pain will typically NOT be provided if the patient has either previously presented with the same problem or received an OOCS prescription from another provider within the last month.
   c. IV Demerol (Meperidine) for acute or chronic pain is discouraged.
2. Emergency medical clinicians will not routinely provide:
   a. Replacement prescriptions for OOCS that were lost, destroyed or stolen.
   b. Replacement doses of Suboxone, Subutex or Methadone for patients in a treatment program.
   c. Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone).
3. Prior to making a final determination regarding whether a patient will be provided a prescription for OOCS, the emergency clinician or facility:
   a. Should search the Ohio Automated Rx Reporting System (OARRS) database (https://www.ohiopmp.gov/portal/Default.aspx) or other prescription monitoring programs, per state rules.
   b. Reserves the right to request a photo ID to confirm the identity of the patient. If no photo ID is available, the emergency or other acute care facility should photograph the patient for inclusion in the facility medical record.
   c. Reserves the right to perform a urine drug screen or other drug screening.
4. Emergency/acute care facilities should maintain an updated list of clinics that provide primary care and/or pain management services for patients, as needed.

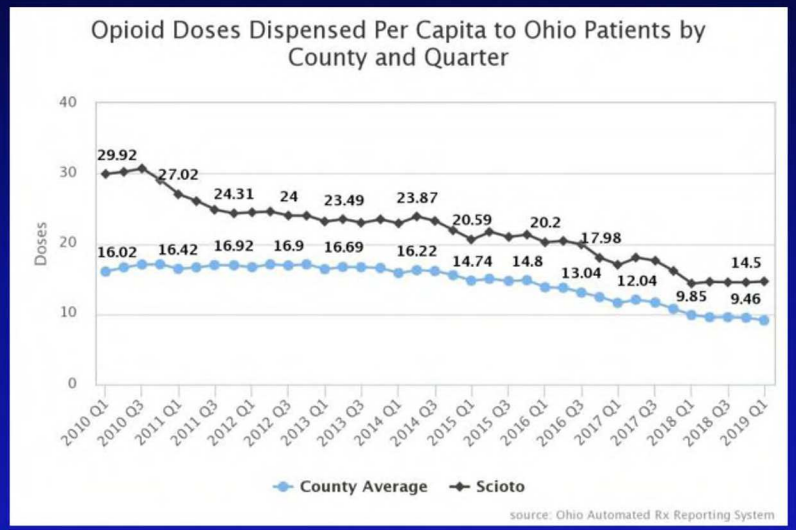


5. Prior to making a final determination regarding whether a patient will be provided a prescription for an OOCS, the emergency clinician should consider the following options:
   a. Contact the patient's routine provider who usually prescribes their OOCS.
   b. Request a consultation from their hospital's palliative or pain service (if available), or an appropriate sub-specialty service.
   c. Perform case review or case management for patients who frequently visit the emergency/acute care facilities with pain-related complaints.
   d. Request medical and prescription records from other hospitals, provider's offices, etc.
   e. Request that the patient sign a pain agreement that outlines the expectations of the emergency clinician with regard to appropriate use of prescriptions for OOCS.
6. Emergency/acute care facilities should use available electronic medical resources to coordinate the care of patients who frequently visit the facility, allowing information exchange between emergency/acute care facilities and other community-care providers.
7. Except in rare circumstances, prescriptions for OOCS should be limited to a three-day supply. Most conditions seen in the emergency/acute care facility should resolve or improve within a few days. Continued pain needs referral to the primary care physician or appropriate specialist for re-evaluation.
8. Each patient leaving the emergency/acute care facility with a prescription for OOCS should be provided with detailed information about the addictive nature of these medications, the potential dangers of misuse and, the appropriate storage and disposal of these medications at home. This information may be included in the Discharge Instructions or another handout.
9. Following the medical screening, emergency/acute care facilities should provide a patient handout that reflects the above guidelines and clearly states the facility position regarding the prescribing of opioids and other controlled substances.

Endorsed by:
Ohio Chapter of the American College of Emergency Physicians,
Ohio Association of Health Plans, Ohio Association of Physician Assistants,
Ohio Bureau of Workers' Compensation, Ohio Hospital Association,
Ohio Osteopathic Association, Ohio Pharmacists Association,
Ohio State Medical Association

Development Facilitated by:
Ohio Department of Health, Ohio Department of Aging

1/2014



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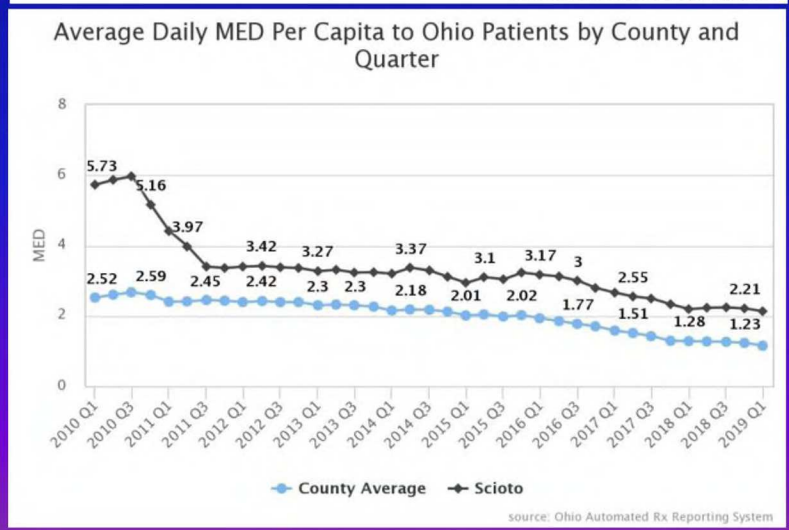

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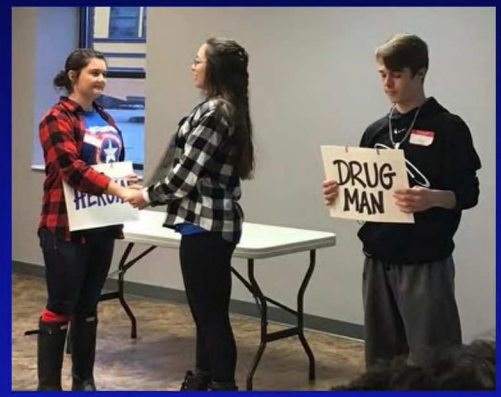
Primary Prevention in Schools:
Scioto County 6th Annual Drug-Free Youth Summit

















You Have the POWER to Be - Drug Free

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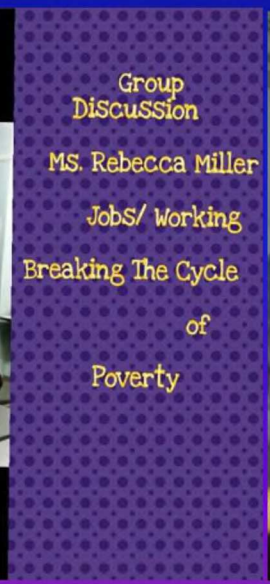
Indicated Prevention at CAPE School: Teens Linked to Care Pilot Project

- Only 3 in the United States funded by Conrad N. Hilton Foundation through the CDC Divis Adolescent and School Health
- Provides substance use, STD, and HIV prevention education, access to health services, saf supportive environments, and monitoring and evaluation for high-risk communities in Ke and Indiana.
- Youth-Led and focuses on high-risk youth (indicated prevention) at CAPE school









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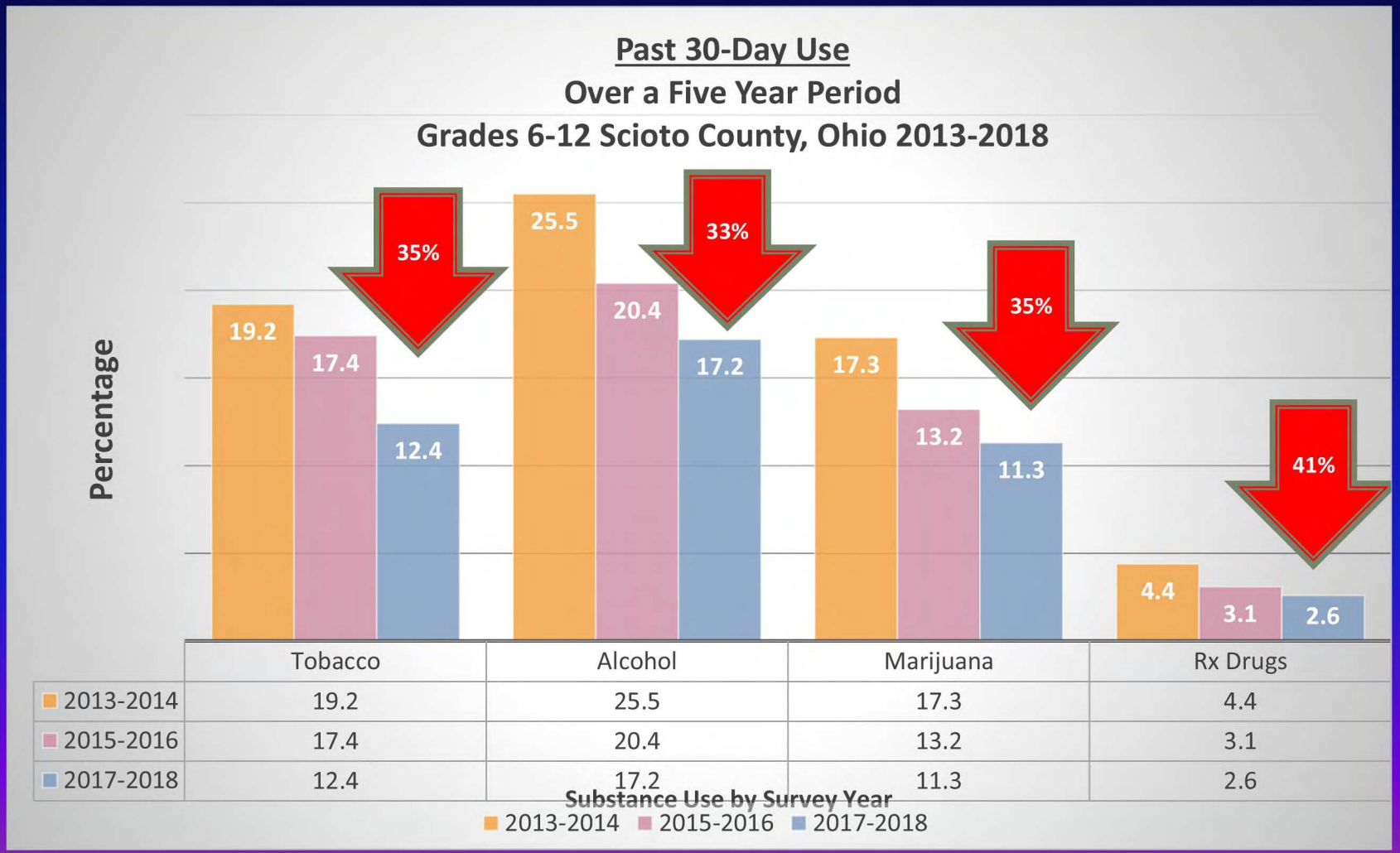
Outcomes: Scioto County High School Surveys 2013-2016

Teen substance use declined-largest reduction involved non-medi



	Tobacco	Alcohol	Marijuana	Rx Drugs
2013-2014	19.2	25.5	17.3	4.4
2015-2016	17.4	20.4	13.2	3.1
2017-2018	12.4	17.2	11.3	2.6

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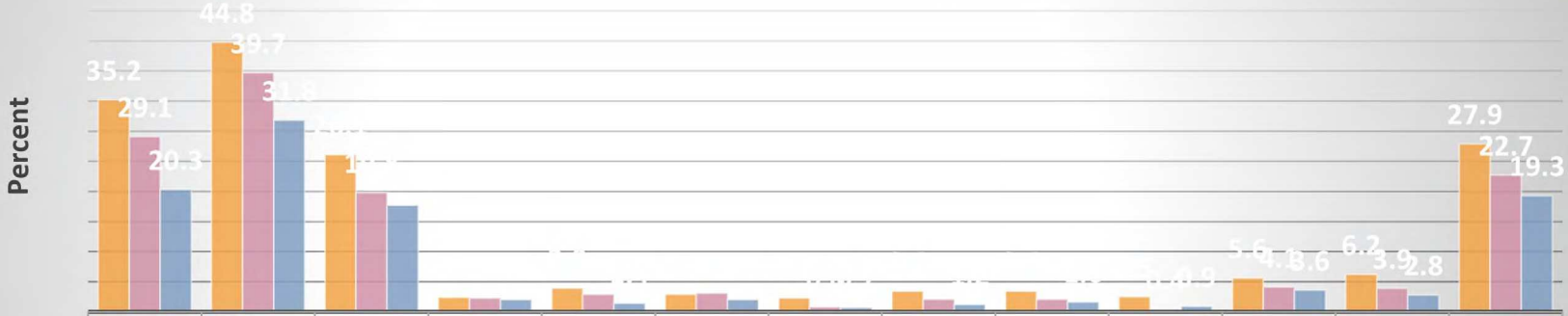
Outcomes : Frequency of Use/ Annual

Within the past year how often have you used these substances? Answe

Percentage of Scioto County youth in grades 7-12 who report using drugs annually/ by specific drug

Source: DFC Semi-Annual PRIDE Surveys 2013-2018



	Tobacco	Alcohol	Marijuana	Cocaine	Inhalants	Hallucinogens	Heroin	Steroids	Ecstacy	Meth	Prescription Drugs	OTC Drugs	Any Illicit Drug
2013-2014	35.2	44.8	26.1	2.4	3.9	2.9	2.3	3.4	3.4	2.5	5.6	6.2	27.9
2015-2016	29.1	39.7	19.8	2.3	2.9	3.1	0.8	2.1	2.1	0.4	4.1	3.9	22.7
2017-2018	20.3	31.8	17.7	2	1.4	2	0.7	1.2	1.6	0.9	3.6	2.8	19.3

Drug by Year

2013-2014 2015-2016 2017-2018

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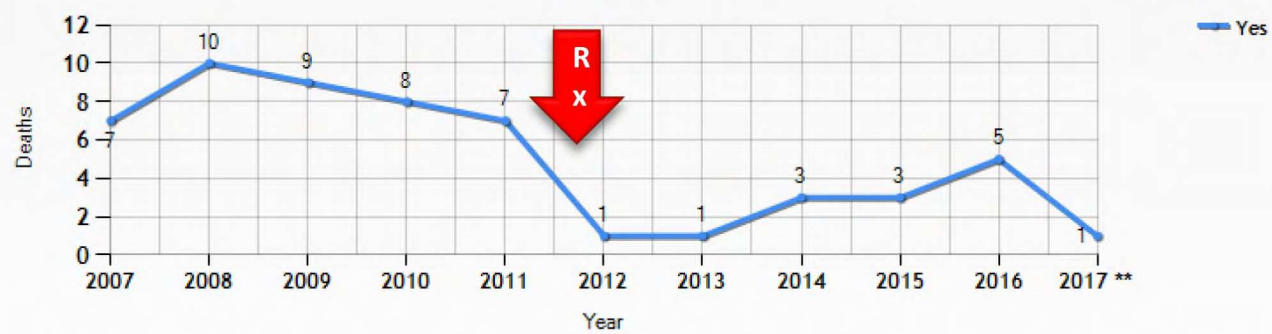
Outcomes:: Reductions in fatal OD due to *Rx Opioids*

Number of Prescription Opiate Related Drug Overdose Deaths by Year, Ohio

for External Injury Intent = (Unintentional) , External Injury Mechanism = (Drug Poisoning) , Res State = (OH) , County = (Scioto) , Fentanyl and Analogues = (No)

Year of death

Prescription Opiates Indicator



Deaths with ICD10 Code T402-T404, or T406

Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44)
Excludes deaths involving fentanyl and related drugs

N/A - Indicates rates have been suppressed for counts < 10 or where population counts are not available, rates based on counts < 20 are considered unreliable.Years with ** are incomplete and subject to change.

Chart created in the Ohio Public Health Data Warehouse on 1/12/2018 with data from 1/12/2018

The Ohio Department of Health specifically disclaims responsibility for any analysis, interpretations or conclusions.

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Strategy 2. Reduce the Harms Associated with Opioid Use Disorders

Billboards and PSA's/ State Public Awareness Campaign

- ♦ Ohio passed laws to increase and ease access
- ♦ 2016 Naloxone made available in select pharmacies through a medical protocol (*CVS and Kroger)
- ♦ Good Samaritan Law passed to encourage 911 calls and promote mass community utilization



Results: Since 2012 hundreds of overdose reversals in SCIOTO COUNTY and thousands acr
Ohio

ONDCP-19-00243_000000067

Annual Overdose Awareness Day August 31 (Hotspot



Partner with the "community hub"



Social Media Campaign



Mass public naloxone t



TV News "Top Story"



The Troops



Distribute "Rea
Angel" cup

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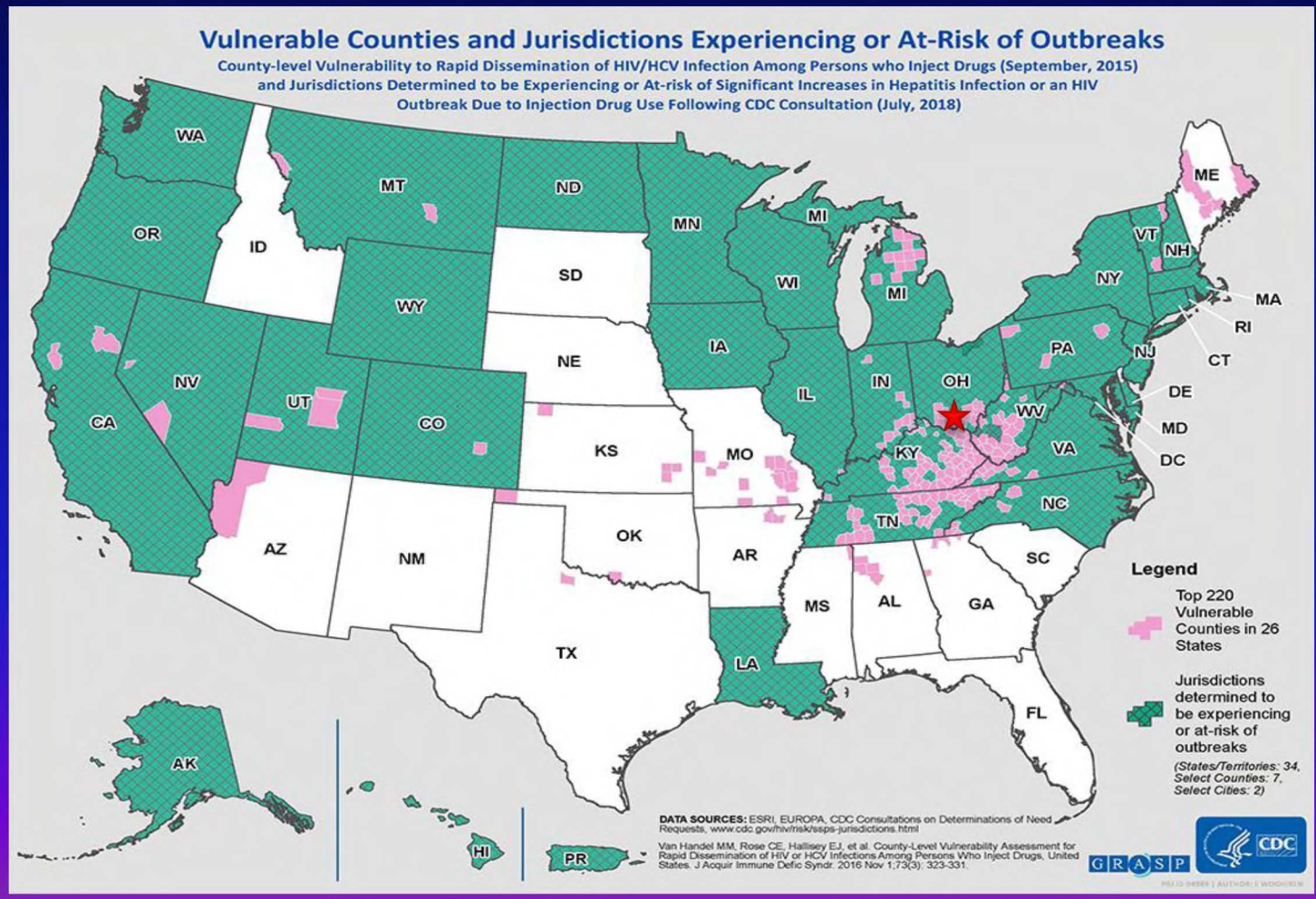
ONDCP-19-0224-000910_000000067

Top 220 US Counties for Hepatitis C Considered at risk for HIV Outbreaks-2018 Source: CDC



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"Prevention NOT Permission" SEP at the Portsmouth City Health Depa
Established 2011 as the first "rural" SEP in Ohio



State:

- Effective Sept. 2015, Ohio Boards of Health can establish a "Blood Born Pathogen Prevention Program" without declaring an emergency

Scioto County:

- Over 1,000 participants and over 300,000 syringes exchanged annually
- Allows ongoing access to a high-risk population and BBP Disease Testing/ Immunizations/ Narcan/ **HIV-Testing and disease containment**
- Partner with multiple Universities on Research studies to inform science



- **2018- began distributing Fentanyl Test Strips to determine presence in illicit drug supply and alert users**

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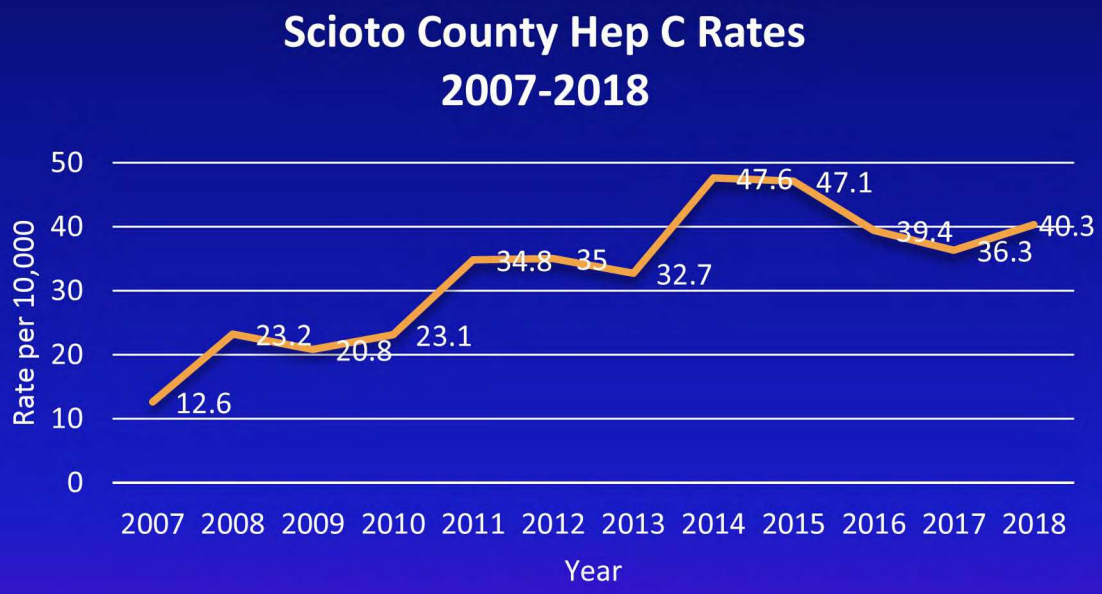
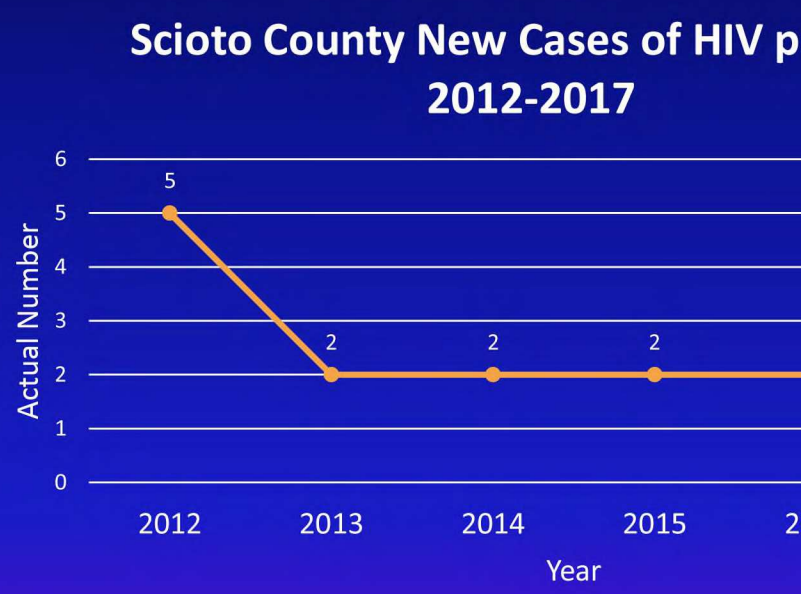
Outcomes: Too early to tell.....

but starting to see a slight decline in new HCV and HI

No longer highest in the state for HCV





* Beginning Jan. 2019, Ohio Medicaid will begin to cover the cost of care for individuals who have a fibrosis score, or F-score, of F0. They currently only cover care for F2-F4. A fibrosis score reflects how much damage has been done to the liver.

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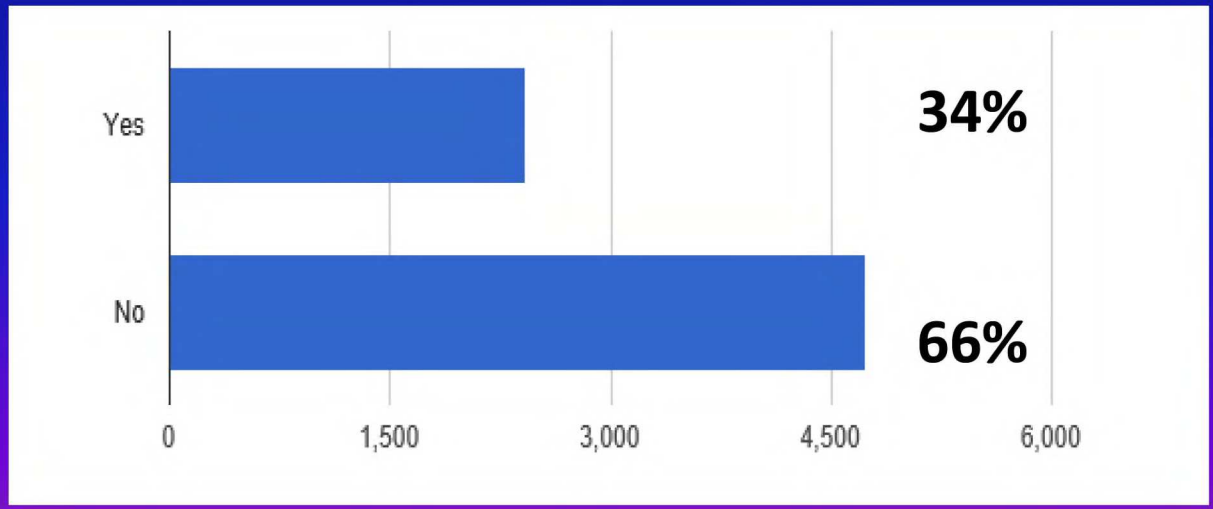
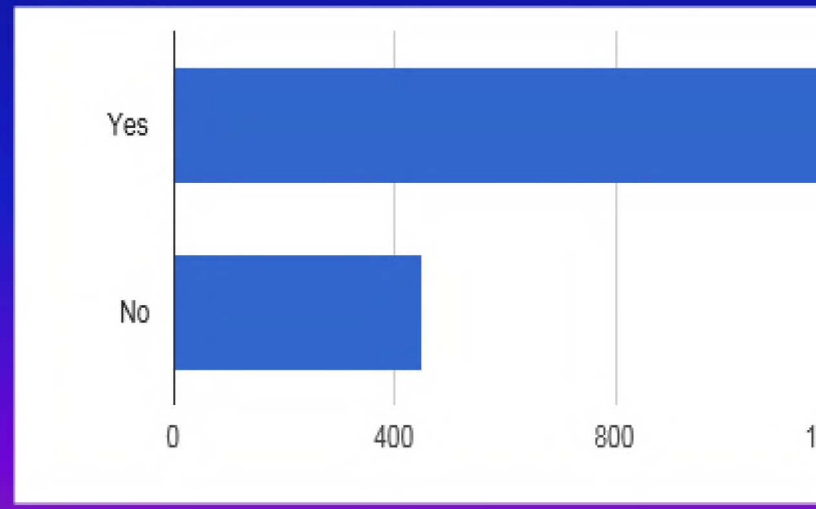
Outcomes: SEP Participants 2018
Overdose history and access to Narcan

REDCap
Research Electronic Data Capture

Have you ever overdosed?
(Decreased 9% in 1 year)



Do you currently have Narcan
(Increased 22% in 1 yr.)



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Strategy 3. Treat the Addicted

Outcomes:



- Established a Local Detox/ Crisis Unit (2014)
- Established Medical Stabilization Unit at hospital (2014)
- Expanded licensed addiction treatment facilities
- Conducted DATA2000-waiver training in 2018 (tripled our MAT providers)
- Getting our first SAMHSA-certified Opiate Treatment Practice this summer
- Established 4 Drug Courts including **JUVENILE/ FAMILY DRUG COURT**
- Established Overdose Response Teams in 2017
- Established a "hub and spoke" location with our Health Department serving as the "hub"
- County Health Commissioner now Board Certified in Addiction who is the Medical Directo Clinic located next door to our health department (immediate stabilization)

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The HEALing Communities Study

A Cooperative Agreement in partnership with the Substance Abuse and Mental Health Services Administration

Redonna K. Chandler, Ph.D.
Director HEALing Communities Study and AIDS Research Program
National Institute on Drug Abuse

May 20, 2019



NIH National Institutes of Health
Turning Discovery Into Health

ONDCP-19-00022-A-0003-043_000000068

The HEALing Communities Study: Primary Goal and Key Outcomes

Primary Goal:

- Develop an evidence-based integrated and comprehensive strategy that reduces opioid-related overdose fatalities by 40% in 3 years across communities highly affected by the opioid crisis

Key Outcomes:

- Reduce overdose fatalities and events
- Increase naloxone access
- Decrease incidence of OUD
- Increase the number of individuals:
  - receiving medication and behavioral treatment
  - retained in treatment beyond 6 months
  - receiving recovery support services

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The HEALing Communities Study: Settings

Healthcare

- Primary care
- Emergency departments
- Inpatient hospital care
- Behavioral health

Criminal Justice

- Jails
- Prisons
- Parole/Probation
- Drug courts

Commun

- Families
- Schools
- Police and f department
- Faith-based organizatio
- Housing & Employmen

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COMMUNITY ENGAGEMENT INTERVENTION

- **Get Started**
- **Get Organized**
- **Develop Community Profile**
- **Develop Data Driven Community Action Plan**
- **Implement and Evaluate Action Plan Activities & Impact**
- **Improve Action Plan as Indicated by Data**
- **Sustain Gains**

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The HEALing Communities Study: Continuum of Care

Prevention	Seek/Engage	Treat/Retain	Recovery	Structural
Primary	Those misusing opioids	Medication for OUD	Recovery Coaches	Better Prescribing
Secondary	OUD/never in care	Behavioral Interventions	Facilitated 12 Step	Increasing waivered providers
Tertiary	OUD/lost to care	Peer/Case Management	SMART Recovery	Increasing collaborations between justice and health care
	Lost tolerance	Smartphone Apps		

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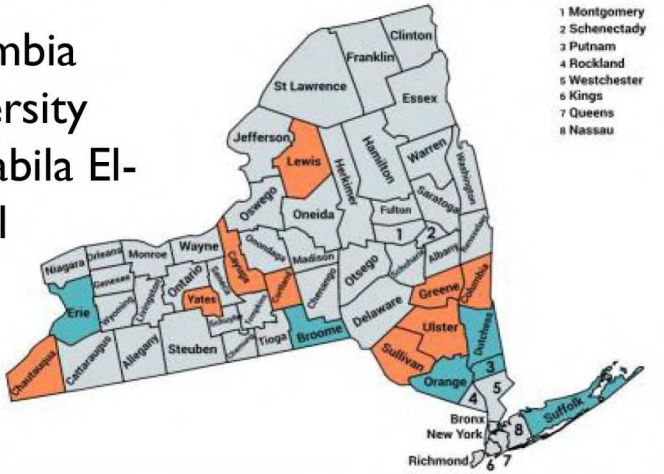
The HEALing Communities Study: Research Sites

Rural Communities | Urban Communities

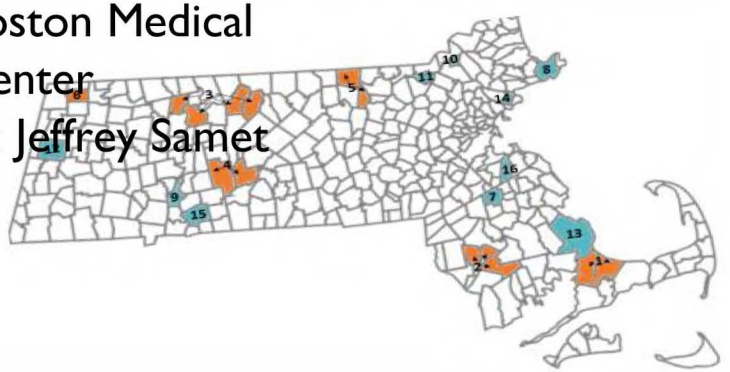
Ohio State University
PI: Rebecca Jackson



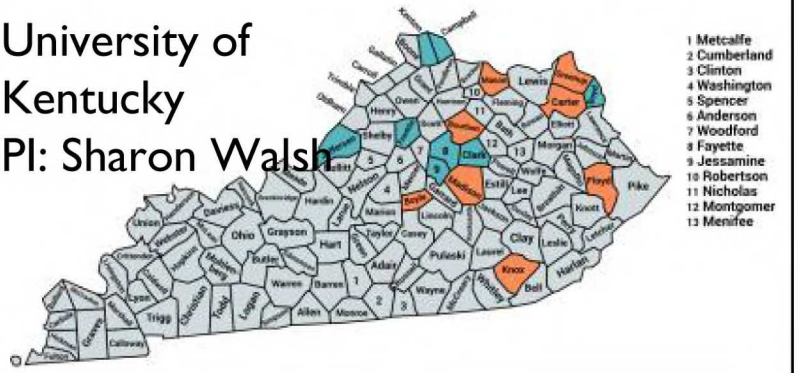
Columbia University
PI: Nabila El-Bassel



Boston Medical Center
PI: Jeffrey Samet



University of Kentucky
PI: Sharon Walsh



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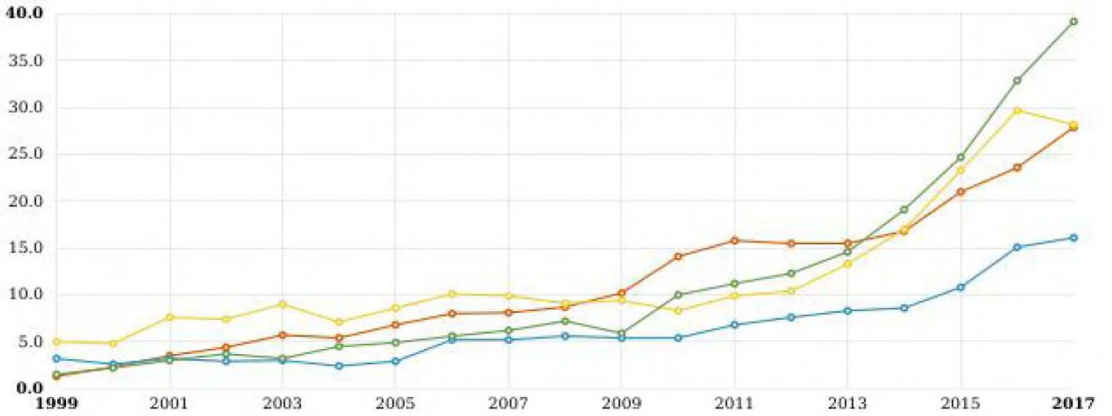
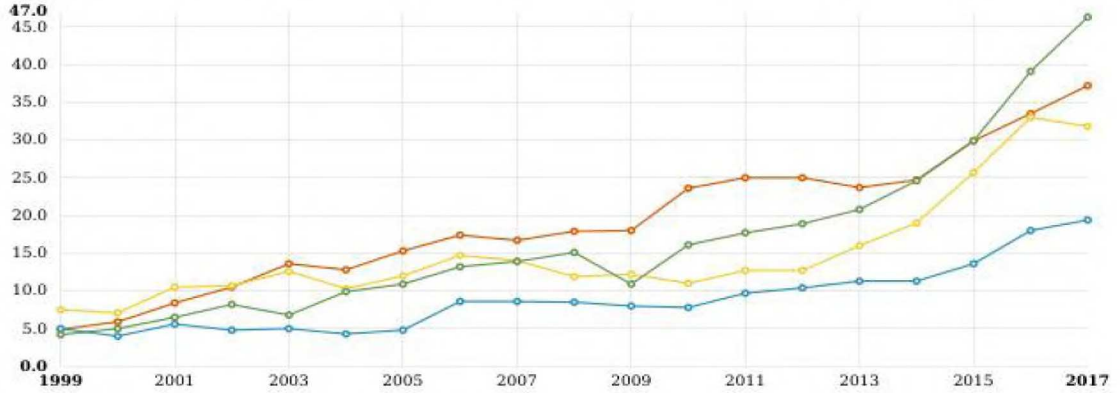
Overdose Rates per 100,000 Population (age-adjusted) in Research Site States

Opioid Overdose Deaths



All Drug Overdose Deaths



Kentucky | Massachusetts | New York | Ohio

Source: Kaiser Family Foundation

ONDCP-19-00022-A-0003-2043_000000068

Data Coordinating Center

- RTI International, North Carolina
- PIs: Rick Williams, Kevin Conway, and Gary Zarkin
- Data Collection and Data Analysis
- Health Economic Research
- Dissemination of Research Findings

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DISCUSSION

More information on drug abuse: www.drugabuse.gov

More information on NIH HEAL: www.nih.gov/heal-initiative

More information on the HEALing Communities Study:

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ONDCP-19-00022-A-00032043_000000068

[EXTERNAL] CEPOP All-Participants Teleconference (June 2019)

From: "Rubin, Matthew J." <(b)(6)

To: Addie Liles <(b)(6) "Derek Naten (MNK)" <(b)(6) "Gen. Arthur Dean" <(b)(6) Julian Hoffman <(b)(6) "Kevin Webb (MNK)" <(b)(6) Mary Bono <(b)(6) Richard Hamburg <(b)(6) Rob Morrison <(b)(6) "Sue Thau (Gmail)" <(b)(6) Van Ingram <(b)(6) "Whitney Taylor (Integritas)" <(b)(6) "Zook, David R." <(b)(6) Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) "Amber Landis (Spectrum Health)" <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach (b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) David May <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)"

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<(b)(6) Dennis Brennan
<(b)(6) "Donald A. Lohman (MNK)"
<(b)(6) Donald Hoppert <(b)(6) "Dr.
Anita Gupta" <(b)(6) "Spitznas, Cecelia M. EOP/ONDCP"
<(b)(6) "Dr. Elizabeth Salisbury-Afshar"
<(b)(6) "Dr. Jack Stein" <(b)(6) "Dr.
John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6)
"Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli
Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emily Diehl
(NASADAD)" <(b)(6) Erika Long <(b)(6)
"Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)"
<(b)(6) Gabrielle de la Gueronniere (b)(6) (b)
(6) Gary Mendell <(b)(6) shatterproof.org>, "Gena Fitzgerald (SAFE
Project)" <(b)(6) Hadi Sedigh <(b)(6) "Hanson,
Roberta J." <(b)(6) "Ian Goldstein (NACCHO)"
<(b)(6) James Appleby <(b)(6) Jane Terry
<(b)(6) Jason Sundby <(b)(6) Jeremiah
Lindemann (b)(6) "Jessica Johnston (BD)"
<jessica(b)(6) John Donahue <(b)(6) Judi Lund
Person (b)(6) Karen Tracy <(b)(6) Kate Berry
<(b)(6) Kate McFadyen <(b)(6) Kathleen O'Conner
<(b)(6) "Kathryn L. Cates-Wessel" <(b)(6)
"Kevin Roy (Shatterproof)" (b)(6), Kevin Walker
<(b)(6) Keysha Brooks-Coley (b)(6)
"KJ Hertz (March of Dimes)" <(b)(6) Kristi
Thompson <(b)(6) Lorraine Yarde
<(b)(6) "Lynette Bradley-Baker (AACP)" <(b)(6)
Marcia Lee Taylor <(b)(6) Mary Winnefeld
<(b)(6) Melissa Ough <(b)(6) Michael
DeGeorge <(b)(6) Mike Smith
<(b)(6) Nick Motu <(b)(6) Nicole Burda
<(b)(6) "Patel, Beena S." <(b)(6) Patricia
Bruckenthal <(b)(6) Patricia D'Antonio
<(b)(6) Patricia Farley <(b)(6) "Patty
McCarthy (FaVoR)" <(b)(6) Paul Ross
<(b)(6) "Rachel Rivera

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([redacted] <[redacted] Rebecca Farley <[redacted] Rebecca Slater Abbott <[redacted] Rita Norton <[redacted] Robert Forman <[redacted] "Robin Swift ([redacted] <[redacted] Samantha Arsenault <[redacted], "Sarah Nerad (Alkermes)" <[redacted] Scott Proescholdbell <[redacted] Shalini Wickramatilake <[redacted] Shelley Starkey <[redacted] Sonya Clay <[redacted] "Stephanie Pellitt (NCBH)" <[redacted] Steve Passik <[redacted] Sue Thau <[redacted] Susan Awad <[redacted] Teresa Baker <[redacted] "Terry Malefant (RCOA)" <[redacted] "Terry McGeeney, MD, MBA" <[redacted] "Tom Supinka (NSC)" <[redacted] Tracie Thomas <[redacted] "Valerie Brankovic (NACo)" <[redacted] Vince Ventimiglia <[redacted] Wade Delk <[redacted] "William Hibbs (Alkermes)" <[redacted]

Date: Wed, 29 May 2019 14:55:13 -0400

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Agenda and related materials forthcoming.

CEPOP All-Participants Teleconference (June 2019)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** [redacted]
  - **Participant Code:** [redacted]

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[EXTERNAL] CEPOP All-Participants Teleconference (June 2019) - AGENDA ATTACHED

From: "Rubin, Matthew J." <(b)(6)

To: Brian Bowden <(b)(6) Ed Kaleta <(b)(6) Nick Motu <(b)(6) "Gen. Arthur Dean" <(b)(6) Patricia Farley <(b)(6) "Donald A. Lohman (MNK)" <(b)(6) David May <(b)(6) Jeremiah Lindemann <(b)(6) "Alexander, Tesfa" <(b)(6) "Dr. Elizabeth Salisbury-Afshar" <(b)(6) Paul Ross <(b)(6) "Sarah Nerad (Alkermes)" <(b)(6) Rita Norton <(b)(6) Kate McFadyen <(b)(6) Kathleen O'Conner <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) Julian Hoffman <(b)(6) "Kevin Roy (Shatterproof)" <(b)(6) Nicole Burda <(b)(6) "Dr. Renan Castillo" <(b)(6) Michael DeGeorge <(b)(6) Patricia Bruckenthal <(b)(6) Sonya Clay <(b)(6) Tracie Thomas <(b)(6) Lorraine Yarde <(b)(6) "Dr. Anita Gupta" <(b)(6) Sue Thau <(b)(6) "Valerie Brankovic (NACo)" <(b)(6) Courtney Hunter <(b)(6) "Terry Malefant (RCOA)" <(b)(6) "Jessica Johnston (BD)" <jessica(b)(6) Andrew kessler <(b)(6) "Whitney Taylor (Integritas)" <(b)(6) "Robin Swift (b)(6) <(b)(6) Addie Liles <(b)(6) Rebecca Slater Abbott <(b)(6) Judi Lund Person (b)(6) Mary Winnefeld <(b)(6) "Cara Moon (Egalet)" <(b)(6) Wade Delk <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) Karen Tracy <(b)(6) Carol Thornton <(b)(6) "Sue Thau (Gmail)" <(b)(6) "Dr. Stuart Gitlow" <(b)(6) Steve Passik <(b)(6) Charlie Cichon <(b)(6) "Terry McGeeney, MD, MBA" <(b)(6) "Dr. Jack

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Baker <(b)(6) Patricia D'Antonio <(b)(6) "Carrier

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	Latimer (Hirons)" <(b)(6) Robert Forman <(b)(6) Mike Smith <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) "Kathryn L. Cates-Wessel" <(b)(6) Jane Terry <(b)(6) "Tom Supinka (NSC)" <(b)(6) "Patel, Beena S." <(b)(6) Scott Proescholdbell <(b)(6) Amanda Sears <(b)(6) Kevin Walker <(b)(6) "Amber Landis (Spectrum Health)" <(b)(6) Chuck Ingoglia <(b)(6) Hadi Sedigh <(b)(6) "Patty McCarthy (FaVoR)" <(b)(6) Brad Tallamy <(b)(6) "Rachel Rivera (b)(6) <(b)(6) Richard Hamburg <(b)(6) Marcia Lee Taylor <(b)(6) Blair Clark-Schoeb <(b)(6) Kate Berry <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Lynette Bradley-Baker (AACP)" <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6)
Cc:	Perry Flowers <(b)(6) (b)(6) "Rodman, Christopher" <(b)(6) Karen Heldrich <(b)(6) Thomas Utech <(b)(6)
Date:	Mon, 24 Jun 2019 09:00:11 -0400
Attachments:	CEPOP All-Participants Meeting Agenda (June 2019).pdf (29.77 kB); BD Hospital Drug Diversion Report.pdf (2.19 MB); not supported calendar message.ics (18.32 kB)

CEPOP Participants – In advance of our upcoming CEPOP All-Participant Teleconference, please find the agenda and related materials. We are pleased to have ***Mr. Perry Flowers,* MS, RPh, *VP, Medical Affairs, Enterprise Medication Management, BD,*** join to discuss the role of integrated technological solutions to help address acute care diversion of prescription opioids and BD's recently issued report on the topic. These remarks will build upon the June 12th congressional briefing that CEPOP held alongside BD and Biocom on the topic.

We look forward to a productive discussion this afternoon. Please do not hesitate to reach out with any questions.

CEPOP All-Participants Teleconference (June 2019)

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:

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- **Conference Line:** (b)(6)
- **Participant Code:** (b)(6)

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CEPOP ALL-PARTICIPANTS TELECONFERENCE (JUNE 2019)

Date: Monday, June 24, 2019

Time: 3:00pm – 4:00pm EST

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Integrated Technology and Analytics within Acute Care Medication Management**
  Perry Flowers, MS, RPh, *VP, Medical Affairs, Enterprise Medication Management, BD*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations

IV. Working Groups

- **A.** Prevention
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Seen and Heard
- **B.** Participant News

Next CEPOP Quarterly In-Person All-Participants Meeting:

Monday, July 29, 2019 (3:00pm – 5:00pm) (calendar appointment forthcoming)

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Health Care's Hidden Epidemic

A Call to Action on Hospital Drug Diversion

BD

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ONDCP-19-0922-A-000333_000000011

New analysis shares perspectives from thought leaders and more than 650 health care executives and providers on hospital drug diversion and its causes, barriers and solutions.

The national opioid epidemic has reached unprecedented depths, with Americans now more likely to die from opioid overdoses than car accidents – nearly 200 people a day, on average, according to a 2019 analysis by the National Safety Council.[1] While other aspects of this devastating public health crisis have caught mainstream attention, drug diversion in U.S. hospitals remains an underreported contributor to the opioid epidemic.

Between 10 and 15% of the general population misuses substances in their lives, including health care providers with access to controlled substances.[2] Hospital drug diversion, when a health care worker "diverts" opiates and other controlled substances away from patients for personal use or sale, remains a significant, and largely underdiscussed, challenge. Left undetected, diversion can imperil patient safety, harm diverters and generate significant risks for hospitals.

Because hospital drug diversion has been understudied, the BD Institute for Medication Management Excellence commissioned a new national survey of more than 650 hospital executives and providers to better understand health care diversion perceptions, behaviors and solutions.

The following report seeks to shed light on one of the opioid epidemic's hidden issues, integrating survey findings with personal insights from key opinion leaders to highlight causes, barriers and solutions. We hope to foster a national conversation about this silent crisis – with the goals of spurring additional research and resources for those on the frontlines.



Perry Flowers, RPh, MS

Vice President of Medical Affairs at BD



Kelly Robke, MBA, MS, RN

Vice President of Thought Leadership at BD

Contents

Exposing Hospital Drug Diversion	3	Consolidating Anti-Diversion Tools	9
Key Findings	4	Closing Thoughts: A Safety-Focused Culture	11
Survey Methods	4	Meet the Experts	12
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ONDCP-19-0922-A-000334_ONDCP042FY18043_000000011

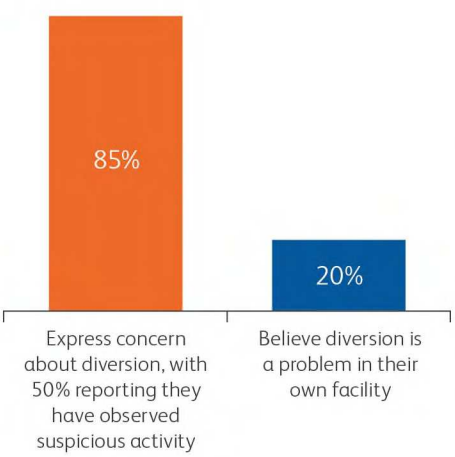
Exposing Hospital Drug Diversion

Most of what we know about drug diversion is extrapolated from isolated cases and anecdotal evidence. Little research is publicly available. Much of the work that has been done is quite dated.

In early 2019, the BD Institute for Medical Management Excellence commissioned KRC Research, a global public opinion research consultancy, to survey health care executives and providers to better understand their perspectives, gain new insights into the problem and identify potential solutions.

Those surveyed recognize diversion is a problem, with one eye-opening caveat: not in their own hospital.

Diversion Recognised as Problem with Major Caveat



Health care executives and providers acknowledge preventing diversion is challenging, and say the tools they are using are only somewhat effective.

- Yet, despite these sentiments, 63% of executives and 59% of providers feel their hospitals are spending the right amount to prevent diversion.

The survey also confirms anecdotal observations that health care providers are often stressed beyond their ability to cope, making them vulnerable to substance use disorder.

Many are high achievers who suffer from long hours, emotional strain and heavy patient volume.

- The survey showed 78% of providers know a peer who may be stressed "to the breaking point." And while the vast majority of participants acknowledge they have resources to help manage stress, fewer than half have accessed that support.
- This stressful work environment may put hospital staff at great risk, particularly nurses, pharmacists and anesthesiologists with access to drugs.

Many respondents also feel inadequate detection tools are a major barrier.

- They cite the need for better information resources, including more accurate data to reduce false positives, as well as machine learning and advanced analytics capabilities.

In the end, most hospital professionals in the survey said they are confident that, with adequate resources and attention, they can enhance diversion detection efforts in their facilities.

Crises Visible and Hidden

Addiction to prescription narcotics in the United States has reached epidemic proportions. In 2015, according to the National Survey of Drug Use and Health, 97.5 million Americans took prescription pain relievers.[3]

Embedded in this larger crisis, hospital providers face their own opioid and substance use problems. According to the Drug Diversion Digest, nearly 19 million pills were diverted in the first six months of 2018.[4]

Anecdotal stories indicate a serious issue that endangers patients, but hardly quantify the problem:

- In April 2019, 60 health care professionals in multiple states were indicted for a diversion scheme.[5]
- At a cancer center, several people developed infections when a diverting hospital worker replaced narcotics with water and injected patients.[6]
- An academic medical center paid a $4.3 million settlement to the Drug Enforcement Administration over diversion.[7]
- A hospital medical technician was sentenced to 39 years in prison after his diversion infected dozens of patients with hepatitis C.[8]

As noted, between 10 and 15% of the general population will misuse substances in their lives, including health care providers with access to controlled substances. According to the Bureau of Labor Statistics, there are nearly 3 million nurses, around 300,000 pharmacists and more than 30,000 anesthesiologists in the U.S. – even at the lower range, an extrapolating 10-15% of this workforce data indicates a potentially significant problem.[9, 10, 11]

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ONDCP-19-0922-A-000333_ONDCP042FY18043_000000011

Key Findings

Diversion Is Somebody Else's Problem: The Not-In-My-Backyard (NIMBY) Effect

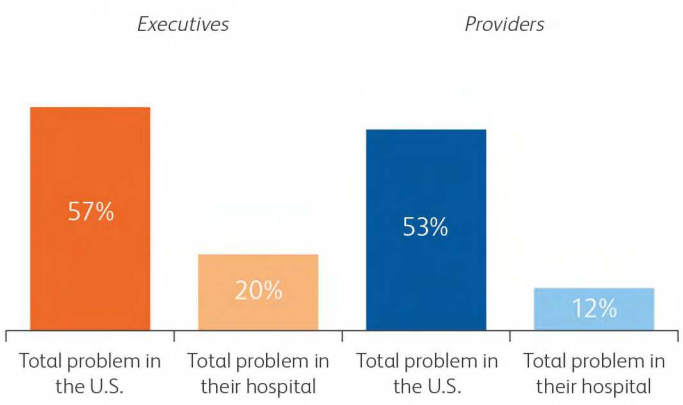
The initial interviews with thought leaders indicated diversion is a growing concern in hospitals but often does not get the attention it deserves. Diversion may be flying under the radar because it's a taboo subject, budgets are impacted and there's risk to hospital reputation and staff morale.

The survey picked up another possible barrier: Denial about substance misuse itself. While health care providers and executives said they think substance use disorder is a major challenge, they believe it's less of a problem in hospitals in general and specifically in their own facilities.

When asked whether substance use disorder in U.S. hospitals occurs more than, the same as or less than the general population, 26% of executives and 29% of providers believe it is less in hospitals, while 49%/47% believe it is less in their own facility.

Among C-suite executives, 89% said substance use disorder is a significant problem in the U.S.; 53% feel it's a significant problem in hospitals; and 17% feel it's a big problem in their hospital. Among pharmacists, the numbers are 99%/59%/16%. Among nurses, it's 97%/70%/13%. And, among anesthesiologists, 97%/48%/13%.

Perceived Problem of Hospital Diversion in U.S. Hospitals vs. Their Own



Despite diversion being a large problem in U.S. hospitals, few health care professionals view diversion as a problem in their own hospital.

Survey Methods

KRC Research, a global public opinion research consultancy, was commissioned by BD Institute For Medication Management Excellence to shed light on this hidden health care crisis. To prepare the survey, KRC Research conducted eight in-depth phone interviews with seven thought leaders in pharmacy, anesthesiology and nursing.

They then surveyed 651 health care executives and providers online between February 20 and February 29, 2019. The sample was randomly drawn from a large group of U.S. health care professionals.

The pool included 100 health care professionals who self-identified as hospital executives with quality, risk and/or compliance and diversion oversight, as well as 151 provider diversion managers who self-identified as nurses, pharmacists or anesthesiologists. This group is responsible for overall diversion prevention or creating and enforcing diversion policies.

Among frontline providers, KRC Research queried 101 anesthesiologists, 139 pharmacists or pharmacy technicians and 160 nurses. The latter included: registered nurses, charge nurses, nurse managers, licensed vocational nurses and certified registered nurse anesthetists.

This research sought to uncover perceptions and attitudes of health care executives and providers towards workplace stress, substance use disorder and diversion; describe the current state of diversion programs and perceived efficacy; quantify perception differences between health care executives, diversion managers and frontline providers, as well as between nurses, anesthesiologists and pharmacists; and identify solutions.

As with all surveys, results should be interpreted within the context of study limitations, which include limited generalizability outside of the specific populations surveyed in this study. The sample of respondents were randomly selected from a large consumer panel of health care providers and screened to determine if they qualified to participate. Coverage bias may be a limitation, as the panel from which the sample was randomly drawn does not include every U.S. health care provider. Non-response bias may represent a limitation because those who responded may have different perceptions than those who did not respond. While social desirability bias may be a limitation of surveys on sensitive topics, an anonymous and confidential online research approach was coupled with neutrally written and carefully ordered survey questions to minimize measurement error.

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As noted in the graph above, attitudes about diversion dovetail with those about substance use disorder. While the majority of surveyed executives and providers recognize diversion is a problem in U.S. hospitals, relatively few believe it's a problem in their own facility.

Among executives, 57% acknowledge the overall problem, while only 20% feel it is an issue in their own facility. Among providers, the breakdown is 53% to 12%.

Overall concern about diversion in their own hospitals is 83% among executives and 65% percent among providers. Among executives, this concern is mostly focused on patient care and safety, followed by employee health, compliance, reputational damage, lawsuits and employee morale.

Circling back to the initial interviews with thought leaders, this disconnect may reflect an unwillingness among health care staff to suspect their colleagues. However, the survey shows 50% of providers have witnessed a suspicious act and 45% have been concerned about a peer.

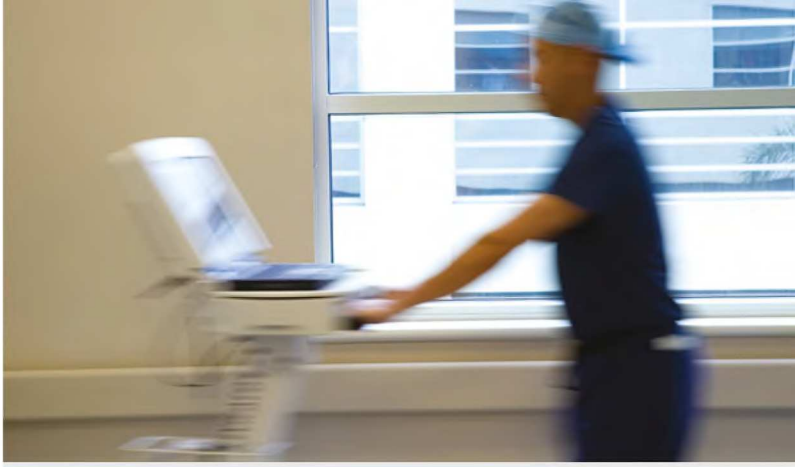
While health care executives and providers do not believe there is significant diversion in their hospitals, they do feel that some level of diversion is going undetected. In the survey, 63% of executives and 54% of providers believe diversion has happened in their hospital within the past year. In addition, 57%/64% think it goes undetected.

This cognitive dissonance is visible throughout the survey. When asked if diversion is difficult to detect, 80% of executives and 60% of providers say it is very or somewhat difficult to detect. On the other hand, 92%/90% feel the diversion detection tools their hospitals are currently using are very or somewhat effective. In addition, majorities in both groups (63%/59%) feel their hospitals are investing the appropriate resources to fight diversion.

Underlying Causes: Work-related Stress

The reasons behind hospital diversion are complicated; however, thought leaders in the early interviews said demanding work, combined with access to narcotic drugs, creates a risky environment.

The survey affirmed pre-survey interviews, which painted many providers as driven to perform at a high level. Among providers, 100% agree with the statement: *I am a high achiever and set high standards for myself.* 86% strongly agree.



A Path to Diversion

Rodrigo Garcia, APN-BC, MSN, CRNA, MBA

CEO of Parkdale Center for Professionals and Parkdale Solutions

As a chief certified registered nurse anesthetist, I was at the top of my specialty. But as much as I loved my work, it was highly stressful. There were long hours, and I missed my family. Eventually, I found myself sacrificing my mental, physical and emotional health in order to do my job.

I broke my ankle playing baseball and, for the first time in my life, began taking prescription opioid painkillers. When I returned to work, I soon realized I was dependent on the medications. I tried weaning myself off several times, but failed. I asked my doctors to renew my prescriptions, but they turned me down. Without the medication, it was nearly impossible to physically make it through each day.

One day, I was reconciling the waste medications that I didn't use for patients and started thinking: I feel horrible and I can barely function, let me see if this helps. I squirted some of the waste medication under my tongue, and within five minutes, not only had the withdrawal completely gone away, but my anxiety, stress, depression and lethargy were also gone.

Over time, I escalated from placing the medication under my tongue to injecting it intravenously. My wife knew something was wrong. Suspicious pharmacy audits earned me several interrogations, but I talked my way out of them each time. They caught me because I stopped trying to avoid the inevitable. I finally said: "I need help. Just stop this insanity, because I can't stop it on my own."

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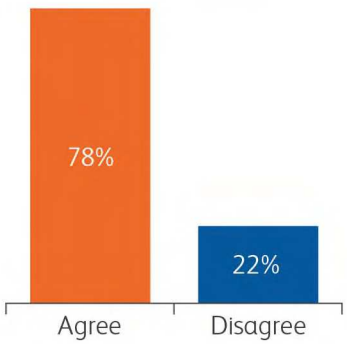
58% of nurses and 52% of anesthesiologists say their jobs are highly stressful. In addition, 78% of all providers have known a peer who has appeared to be stressed nearly *to the breaking point.*

Agree/Disagree: I Am Aware of Colleagues Who Seem Stressed to the Breaking Point

(Among all providers)



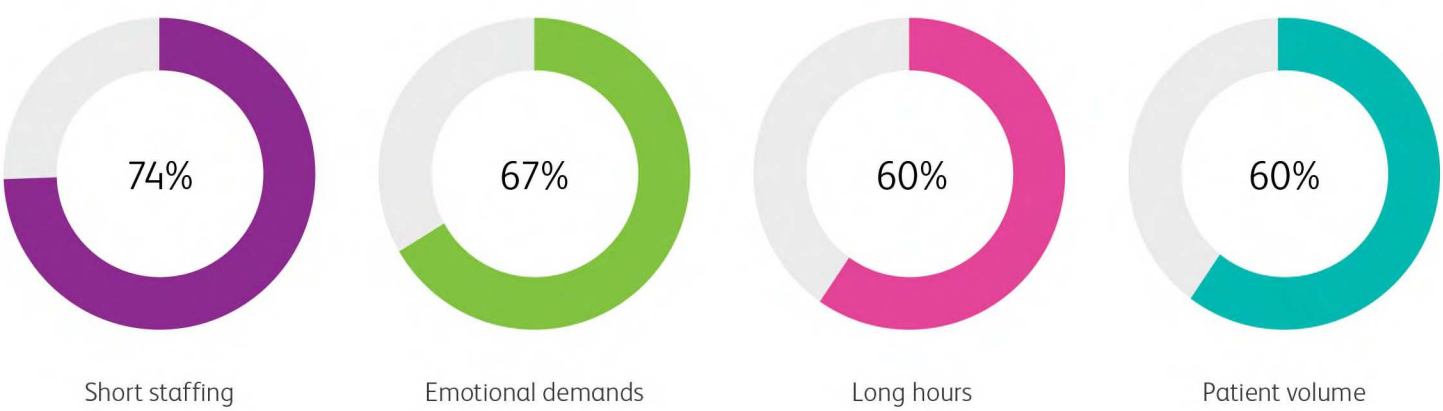
Hospital executives recognize this issue: 98% feel the hospital environment is challenging, while 96% say patient care is stressful. Major stressors include: short staffing, emotional demands, long hours and patient volume.

I was unemployable for a few years. After attending an intensive drug rehabilitation program, I returned to school with my wife and we obtained our MBA degrees. As a result, we are co-founders of Parkdale Center for Professionals in Chesterton, Indiana, a treatment center that assists health care professionals in recovering from both substance use disorders and from the professional consequences associated with the impaired health care provider. Since 2015, more than 450 professionals from around the country have successfully completed the program.

Hospitals have many ways to address diversion, such as moving sharp boxes, placing cameras in vulnerable locations, changing reporting requirements and conducting training and education. We see significant improvements when hospitals make diversion a priority and put the appropriate programs in place. I believe a successful hospital diversion program is based on a proactive rather than a reactionary approach. The challenge is sometimes trying to understand the difference.

What Are the Primary Reasons for Stress in a Hospital?

(Among all providers)



Chief among reasons for stress are short staffing and emotional demands, coupled with long hours and high patient volume.

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A strong majority of providers agree stress is difficult to manage. While support is available, providers say they don't always take advantage of it. Among providers, 86% believe they have peer support, 68% feel they have organizational support and 82% know where to get help. And while 74% are comfortable seeking help to manage stress, only 39% of all respondents have actually sought assistance.

Training and Communication

Thought leaders who were interviewed pre-survey said diversion is a taboo subject. However, in the survey, 89% of providers say they are somewhat or very comfortable discussing diversion at work. Among executives, 67% feel their employees are comfortable talking about it at work.

Among all providers who say they are uncomfortable discussing diversion at work, 67% think bringing up diversion sounds accusatory, 51% are concerned it raises suspicions and 40% believe it makes peers distrust them.

The majority of executives say their hospitals have formal drug diversion prevention programs: 40% note their pharmacy departments spearhead anti-diversion efforts, while 26% report it's the executive leadership team.

A Nurse's Perspective

Carol Mallia, RN, MSN

Associate Director, Division of Nursing, Massachusetts Nurses Association



I help manage a peer program for nurses trying to overcome substance misuse. Over the years, I have heard countless stories about diversion.

The source of the problem is pain – physical, mental, emotional. And then it becomes unhealthy coping with the pain. And then it becomes the pressure to get to work in pain. That starts the vicious cycle.
Of the 19 years I've been answering this helpline, the majority of calls start with: "I hurt my neck" or "I hurt my back" or "I had to have surgery" or "I didn't have surgery."

But there's also the day-to-day stressors: lack of staffing, feeling overworked and the compassion fatigue that comes from caring for patients with traumatic injuries or terminal diseases.

I've heard good analogies from experienced nurses saying you just get a little chip to your heart every time you have one of these situations, and you have to just swallow it down. That's what you do, you swallow it down. I can tell you clearly the times I've had to swallow some horrible sad situations in my career, and to this day if I start to talk about it... I tear-up and re-live the trauma.

In order to be effective as a nurse, to choke it down, it's survival.

We are working to support nurses and help them avoid diversion. I think education about the risk factors is huge. We can show our nurse colleagues what the risk factors are and why they are personally at risk. There's also the need to help nurses who have been injured. For many, it can be disconcerting, and depressing, to be away from work.

While nurses are out on injury leave, we can proactively keep them engaged. They can come to staff meetings. They can be part of a team, and they don't have to feel disconnected from the unit.

We also want to change the culture to make it more acceptable for people to self-report. The first part of enforcement is making it acceptable for people to seek help and offer recovery support and be more in tune with helping nurses gain recovery.

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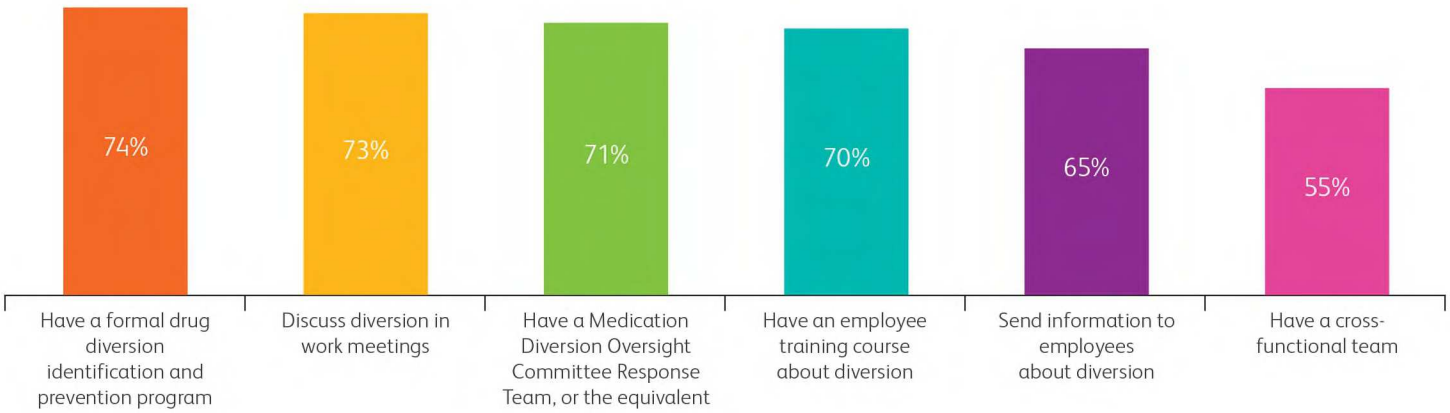
Hospital Diversion Best Practices and Activities

(Among all executives)



Most executives report their hospitals have a formal drug diversion identification and prevention program and a diversion oversight committee response team.

The majority report their hospitals have between one and five full-time employees dedicated to diversion detection and enforcement. The number of diversion-focused FTEs appears unrelated to hospital size.

Nearly 60% of providers have either taken a formal diversion training course, talked about it in a work meeting and/or received information from their hospital. However, 40% report they have not had any formal training, and more than a third have not received diversion information from their hospital or discussed the topic in a work setting.

This highlights another perception gap among executives, who say – at their hospital – 95% of employees with access to controlled substances, and 87% of clinical staff, have taken a diversion training course.

Among those who participated in diversion training or discussion, the vast majority found it helpful. In addition, among those who had not received any training or communication, 60% would like that to change.

Current hospital diversion communication, according to providers, is focused on raising awareness about the problem, ways to get help, reporting suspicious activity and potential consequences.

Current Anti-Diversion Efforts

Among survey respondents, 65% of executives and 58% of providers acknowledge diversion prevention is difficult, and the tools they are using to combat it are only somewhat effective.

When a diversion incident is confirmed, facilities shape their responses case-by-case, depending on the severity of the offense, negative effects it might have on patients or the facility and the diverter's willingness to cooperate.

Most hospitals surveyed use electronic medical records, automated dispensing cabinets (ADCs) and internal controlled substance audits. Seventy-one percent of respondents said they also had diversion prevention committees in place. Just over half say they use internal inventory systems. Few use ADC reports, machine learning, advanced analytics or wholesaler purchasing systems.

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The majority utilize electronic medical records, internal controlled substance audits, automated dispensing machines and internal inventory systems.

The majority of surveyed executives and providers believe these tools are only somewhat effective: 67%/66%. The biggest perceived barriers to timely enforcement are inadequate real-time detection and reliable tools.

Consolidating Anti-Diversion Tools

Katelyn Hipwell, PharmD, MPH

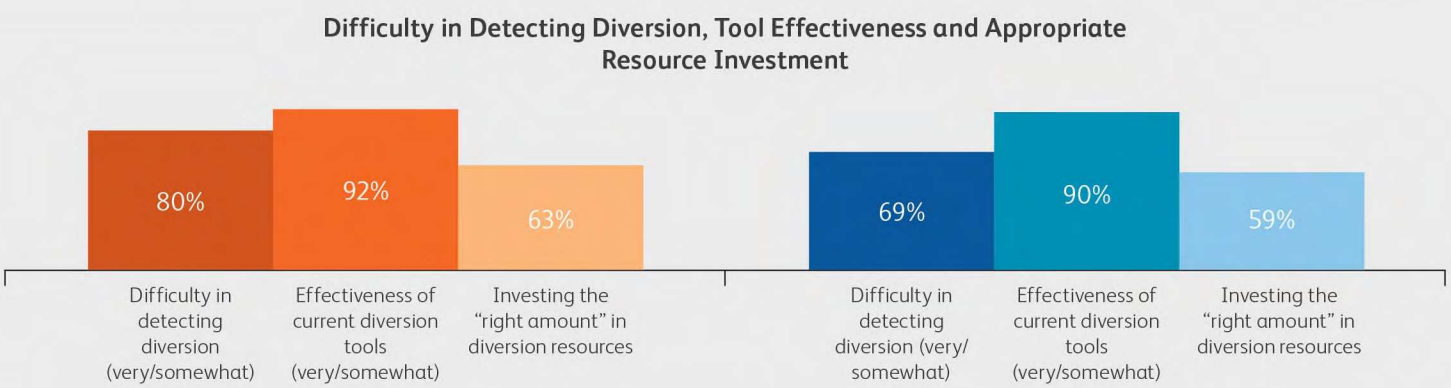
Pharmacy Clinical Operations Manager for the University of Virginia Health System

Day-to-day, I receive a variety of reports tracking drugs through automated dispensing cabinets, electronic health records, waste, and other sources. We use these reporting tools to alert us to issues, but they're all separate. We have to look at them individually and try to link and trend across locations and transactions within the entire health system.

While it's quite possible the data produces enough evidence to manage diversion, it becomes a numbers game – how much time can we spend on reconciling these disparate reports at the expense of other tasks? We have to make hard choices about what we believe is going to give us the biggest bang for our buck. What report, what kind of trending am I going to do? And what am I not going to be able to get to because we only have two people allocated to do this?

I have complicated feelings about false positives. On one hand, I would like to be proven wrong. However, I also don't want anyone slipping through the cracks.

Given the magnitude of the opiate problem in the general population, I believe this problem has to also be significant in hospitals. If a hospital is not finding cases, it may be because they're just not looking hard enough.



There is wide agreement that diversion is difficult to detect, yet nearly all say that their current tools to combat diversion are effective.

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Solutions

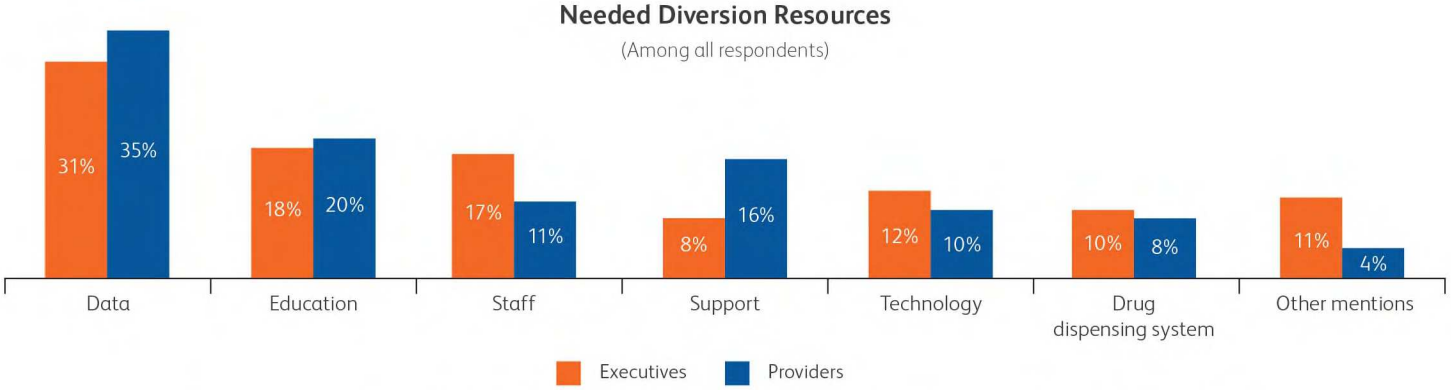
Health care executives and providers cite a variety of tools that could help them, including: better drug dispensing systems, improved technology, increased staff and more robust education.

However, they say their greatest need is for more accurate data, machine learning technology and advanced analytics.

There are many points where diversion may occur and many diversion methods. Tight control is needed through process checks and balances, diligent surveillance and timely interventions to prevent, promptly identify and investigate suspected diversion.

Needed Diversion Resources

(Among all respondents)



The biggest need to prevent, detect, and control diversion, according to health care professionals unaided, is data resources.

Surveyed executives are split on whether their facility will increase its diversion budget, with 42% believing it will go up and 46% thinking it will stay the same. A significant majority – 63% of executives and 59% of providers – believe their hospitals are spending the right amount. About a third think they are spending too little.

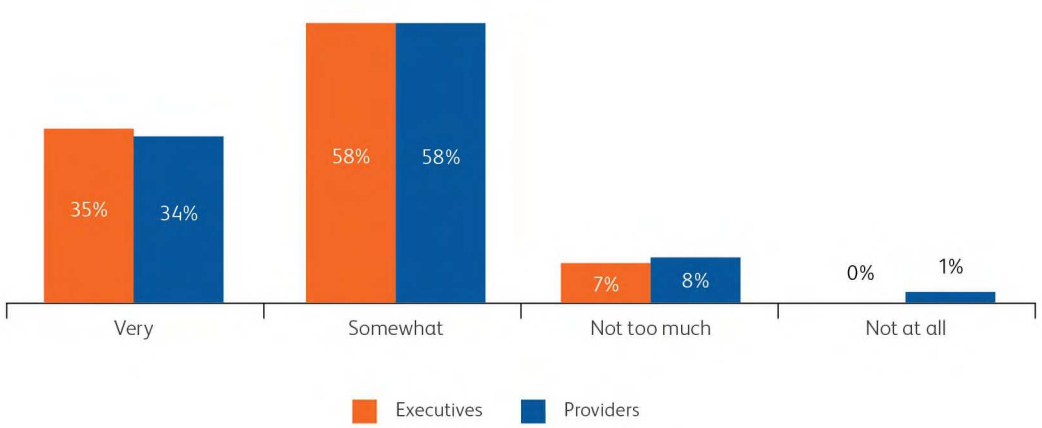
However, many executives say they are spending too little on specific measures, such as: random drug screenings; more accurate data to reduce false positives, machine learning, advanced analytics and mandatory diversion training.

The University of Virginia Health System, for example, has been moving towards a system that automatically reconciles the information, putting it on a single screen rather than different reports. The system makes it easier to put together information from multiple sources and has the potential to streamline detection.

The vast majority of both executives and providers believe that, with enough resources, they can mitigate diversion risk.

Optimism That Drug Diversion in Hospitals Can Be Controlled

(Among all respondents)



Most executives are somewhat optimistic that with adequate resources and attention, drug diversion in hospitals can be controlled. A third are very confident.

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Closing Thoughts: A Safety-Focused Culture

Hospital drug diversion is complicated. Enforcement can be difficult because suspected diverters are good at avoiding detection and peers are reluctant to accuse friends. Few people want a dedicated colleague to lose their career. In addition, enforcement efforts can produce negative consequences. False positives can lead to wrongful accusations, which can impair staff morale in an already-stressed workplace.

The interviews that informed this survey, and the survey itself, illustrate an environment where providers can be vulnerable to diverting drugs. In some cases, it could be just one injury away.

On the other hand, diversion reduces public faith in the health care system and can impose financial burdens on hospitals. Ultimately, it's a safety issue – for patients and staff.

One challenge is a lack of readily adoptable best practices. These might include multidisciplinary teams tightly focused on diversion, closing subtle gaps in chains of custody, advanced data techniques and improved education and training.

Education, in particular, may have great potential to move hospital cultures to actively reduce diversion by reinvigorating their focus on safety. Sharing information can also build loyalty within the workforce.

During initial survey interviews, several health care professionals cited the need to aggressively communicate a rehabilitation pathway. They noted that many diverters, once caught, express relief. If given an honorable opportunity to self-report, they may take it.

With so many believing diversion is a problem – just not in their hospital – these survey findings show an obvious, and possibly dangerous, disconnect. What is the motivation to commit resources to a problem they don't believe exists in their own facility? Once again, education and training can help correct these misconceptions.

Institutions must embrace new approaches to ensure diversion does not fly under the radar. Like diversion itself, this must be a dynamic process.

This survey should not be the last word on diversion. Rather, it should spark a national conversation, spur much-needed research and ultimately lead hospitals and health systems to adopt comprehensive diversion prevention programs. Through technology, communication and training, cultural shifts and other means, diversion risk can be addressed in a meaningful way.

The time has come to shine a light on hospital drug diversion and develop solutions.

For more information, insights and tools, please visit the:
BD Institute for Medication Management Excellence

About the BD Institute for Medication Management Excellence

The BD Institute for Medication Management Excellence is helping to advance the safe and efficient management of medications across the care continuum. The Institute works with customers and industry thought leaders to transform medication management in meaningful ways and engages others to join the effort. The goal of the Institute is to identify and support evolutionary – and revolutionary – advancements by encouraging new ways of thinking, new methods, processes, guidelines and best practices to create a foundation for measurable improvements.

The institute strives to consistently deliver high impact thought leadership initiatives. It also works to engage with health systems, clinicians, technology partners, regulatory organizations and thought leaders to create a forum for insightful research and best practices to directly impact patient safety.

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Meet the Experts



W. Perry Flowers, RPh, MS

As vice president of Medical Affairs and Enterprise Medication Management at BD, Perry Flowers has a deep clinical understanding of diversion and potential solutions. Prior to joining BD, Flowers was vice president, Acute Care and Infusion Pharmacy Programs at Kaiser Permanente. Before that, he was system executive, Patient Care Support & System Pharmacy at Memorial Hermann Healthcare System in Houston.



Rodrigo Garcia, APN-BC, MSN, CRNA, MBA

Rodrigo Garcia has been a provider in emergency management, intensive care, education, surgical services, and anesthesia for more than 20 years. He has extensive experience in addiction, treatment, management, advocacy and recovery. He is currently the CEO of Parkdale Center for Professionals and Parkdale Solutions, a diversion consulting program for health care facilities.



Katelyn Hipwell, PharmD, MPH

Katelyn Hipwell is manager of Pharmacy Clinical Operations at the University of Virginia Health System, where diversion enforcement is one of her main responsibilities. She was a Health System Pharmacy Administration resident at Allegheny General Hospital in Pittsburgh, Pennsylvania. She earned her PharmD at the West Virginia University School of Pharmacy.



Carol Mallia, RN, MSN

Carol Mallia has worked as a registered nurse for over 30 years, delivering care in high acuity settings as a Staff Nurse, Clinical Leader Clinical Specialist in acute and critical care units. She is currently an Associate Director at the Massachusetts Nurses Association (MNA) and leads the MNA efforts to support nurses suspected of diversion. She also leads the MNA Peer Assistance program, a novel program that allows impacted nurses the opportunity to confidentially self-report into a rigorous rehabilitation program that aligns with Alternative to Discipline programs.



Kelly Robke, MBA, MS, RN

Kelly Robke is vice president of Thought Leadership at BD, where she leverages her experience as a frontline provider to find solutions for diversion and other issues. Prior to this role, she was Director of Product Management for Dispensing Technologies at BD. Robke earned her BSN at West Virginia University, an MBA from the University of Houston and MS in Regulatory Sciences from the University of Southern California.

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Appendix

Survey Method

KRC Research, a global public opinion research consultancy, conducted a national quantitative survey among 651 health care executives and providers from February 20 to February 29, 2019. The survey sample was randomly drawn from a large U.S. panel of health care professionals, who were screened to qualify for this study. The survey was conducted online and required an average of twenty minutes to complete.

Hospital Executives, 251

- 100 C-Suite Executives
  This group self-identified as hospital executives with oversight for quality, risk and/or compliance and diversion oversight.
- 151 Provider Diversion Managers
  This groups self-identified as nurses, pharmacists or anesthesiologists.

Both groups are responsible for diversion programs, or are key decision-makers, creating and enforcing diversion policies at their hospitals.

Hospital Providers, 400

- 101 Anesthesiologists
- 139 Pharmacists – pharmacists or pharmacy technicians
- 160 Nurses – Registered Nurses, Charge Nurses, Nurse Managers, Licensed Vocational Nurses or Certified Registered Nurse Anesthetists.

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[EXTERNAL] CEPOP Quarterly In-Person All-Participants (July 2019)

From: "Rubin, Matthew J." <(b)(6)

To: Addie Liles <(b)(6) "Derek Naten (MNK)" <(b)(6) "Gen. Arthur Dean" <(b)(6) Julian Hoffman <(b)(6) "Kevin Webb (MNK)" <(b)(6) Mary Bono <(b)(6) Richard Hamburg <(b)(6) Rob Morrison <(b)(6) "Sue Thau (Gmail)" <(b)(6) Van Ingram <(b)(6) "Whitney Taylor (Integritas)" <(b)(6) "Zook, David R." <(b)(6) Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) "Amber Landis (Spectrum Health)" <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Brian Bowden <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Cara Moon (Egalet)" <(b)(6) Caren Kagan Evans <(b)(6) Carol Thornton <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Celia Hagan (NILA)" <(b)(6) Charlie Cichon <(b)(6) Chris Zimmerman <(b)(6) "Christian, Jeanine M" <(b)(6) Chuck Ingoglia <(b)(6) "Clay Alspach ((b)(6) <(b)(6) Courtney Hunter <(b)(6) "Cristi L. Schwarcz" <(b)(6) Dan Buffington <(b)(6) Daniel Raymond <(b)(6) "Danna Droz (NABP)" <(b)(6) "David Bilardello (Spectrum Health)" <(b)(6) David May <(b)(6) "Deana Haworth (Hirons)" <(b)(6) "Deb Waugh (Affiliated Monitors)"

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John Harrison" <(b)(6) "Dr. Renan Castillo" <(b)(6)
"Dr. Stuart Gitlow" <(b)(6) Ed Kaleta <(b)(6) Eli
Briggs <(b)(6) Elizabeth Solhtalab <(b)(6) "Emily Diehl
(NASADAD)" <(b)(6) Erika Long <(b)(6)
"Evans, Daniel F." <(b)(6) "Gabriella Witte (APHA)"
<(b)(6) Gabrielle de la Gueronniere (b)(6)
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Roberta J." <(b)(6) "Ian Goldstein (NACCHO)"
<(b)(6) James Appleby <(b)(6) Jane Terry
<(b)(6) "Jasey Cardenas (AAAP)" <(b)(6) Jason
Sundby <(b)(6) Jeremiah Lindemann
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Bruckenthal <(b)(6) Patricia D'Antonio
<(b)(6) Patricia Farley <(b)(6) "Patty
McCarthy (FaVoR)" <(b)(6) Paul Ross

AMERICAN OVERSIGHT

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(b)(6) <(b)(6) Rebecca
Farley <(b)(6) Rebecca Slater Abbott
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<(b)(6) Wade Delk <(b)(6) "William Hibbs
(Alkermes)" <(b)(6)

Date: Mon, 01 Jul 2019 15:25:35 -0400

Attachments: not supported calendar message.ics (17.26 kB)

Formal agenda and related materials forthcoming.

Meeting Location (July 2019)
Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

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Optional Attendees:	"Motu, Nick" <(b)(6)
	"Abbott, Rebecca" <(b)(6)
	"Rachael Cooper (NSC)" <(b)(6)

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CEPOP Participants – Please see attached for the July 2019 Quarterly In-Person All-Participants Agenda. We're pleased to have a robust agenda covering a wide array of different topics and longstanding CEPOP priorities. Additional information will be shared as available. Our Focus Topic Speakers for this month's meeting include:

- **Peter Fise, Counsel for U.S. Senator Jeanne Shaheen,** to discuss the recently introduced *Turn the Tide Act* (S. 2102);
- **Dr. Vanila Singh, Chairwoman for the Pain Management Best Practices Inter-Agency Task Force**, to discuss the final report issued in May 2019; and
- **Dr. Michael Barnett, Assistant Professor at Harvard T.H. Chan School of Public Health,** to discuss his recent research around access barriers to treatment for opioid use disorder.

We look forward to a productive discussion! Should there be any questions, please reach out to the Steering Committee.

Meeting Location (July 2019)

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Washington, DC 20001

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AMERICAN OVERSIGHT

CEPOP QUARTERLY IN-PERSON ALL-PARTICIPANTS MEETING

Date: Monday, July 29, 2019

Time: 3:00pm – 5:00pm EST

Location: Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

WebEx: To join via computer, please click here.
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AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Turn the Tide Act (S. 2102) – Combatting and Preventing the Epidemic through SUPPORT**
  Peter Fise, *Counsel, U.S. Senator Jeanne Shaheen (D-NH)*
- **B. Readout: The Final Report from HHS on Pain Management Best Practices (link)**
  Dr. Vanila M. Singh, *Chairwoman, Pain Management Best Practices Inter-Agency Task Force*
- **C. Identifying Continued Barriers to Accessing SUD/OUD Treatment Services (link)**
  Dr. Michael Barnett, *Assistant Professor of Health Policy and Management, Harvard T.H. Chan School of Public Health*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations

IV. Working Groups

- **A.** Prevention
  - **i.** Survey Result Readout
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Seen and Heard
- **B.** Participant News

Next Monthly CEPOP All-Participants Teleconference: Monday, September 23, 3:00pm – 4:00pm

Calendar Appointment Forthcoming.

Should you have any questions, please contact Matt Rubin at (b)(6)

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July 2019

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Blair Clark-Schoeb <(b)(6)

David May <(b)(6)

Judi Lund Person (b)(6)

Patricia Bruckenthal <(b)(6)

"Stephanie Pellitt (NCBH)" <(b)(6)

Sue Thau <(b)(6)

Erika Long <(b)(6)

Carol Thornton <(b)(6)

"Zook, David R." <(b)(6)

Gabrielle de la Gueronniere <(b)(6)

Hadi Sedigh <(b)(6)

Rebecca Slater Abbott <(b)(6)

Courtney Hunter <(b)(6)

"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)

"Lynette Bradley-Baker (AACP)" <(b)(6)

Dennis Brennan <(b)(6)

"Whitney Taylor (Integritas)" <(b)(6)

Optional Attendees:

"Rachael Cooper (NSC)" <(b)(6)

Richard Cesar-Meyers <(b)(6)

"Motu, Nick" <(b)(6)

"Abbott, Rebecca" <(b)(6)

AMERICAN OVERSIGHT

CEPOP Participants – Please see attached for the July 2019 Quarterly In-Person All-Participants Agenda. We're pleased to have a robust agenda covering a wide array of different topics and longstanding CEPOP priorities. Additional information will be shared as available. Our Focus Topic Speakers for this month's meeting include:

- **Peter Fise, Counsel for U.S. Senator Jeanne Shaheen,** to discuss the recently introduced *Turn the Tide Act* (S. 2102);
- **Dr. Vanila Singh, Chairwoman for the Pain Management Best Practices Inter-Agency Task Force**, to discuss the final report issued in May 2019; and
- **Dr. Michael Barnett, Assistant Professor at Harvard T.H. Chan School of Public Health,** to discuss his recent research around access barriers to treatment for opioid use disorder.

We look forward to a productive discussion! Should there be any questions, please reach out to the Steering Committee.

Meeting Location (July 2019)

Faegre Baker Daniels Consulting Offices

1050 K Street NW, Suite 400

Washington, DC 20001

For those unable to attend in-person, a WebEx has been made available for individuals to participate remotely.

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP QUARTERLY IN-PERSON ALL-PARTICIPANTS MEETING

Date: Monday, July 29, 2019

Time: 3:00pm – 5:00pm EST

Location: Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Turn the Tide Act (S. 2102) – Combatting and Preventing the Epidemic through SUPPORT**
  Peter Fise, *Counsel, U.S. Senator Jeanne Shaheen (D-NH)*
- **B. Readout: The Final Report from HHS on Pain Management Best Practices (link)**
  Dr. Vanila M. Singh, *Chairwoman, Pain Management Best Practices Inter-Agency Task Force*
- **C. Identifying Continued Barriers to Accessing SUD/OUD Treatment Services (link)**
  Dr. Michael Barnett, *Assistant Professor of Health Policy and Management, Harvard T.H. Chan School of Public Health*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations

IV. Working Groups

- **A.** Prevention
  - **i.** Survey Result Readout
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Seen and Heard
- **B.** Participant News

Next Monthly CEPOP All-Participants Teleconference: Monday, September 23, 3:00pm – 4:00pm

Calendar Appointment Forthcoming.

Should you have any questions, please contact Matt Rubin at (b)(6)

www.CEPOPonline.org
July 2019

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PAIN MANAGEMENT

BEST PRACTI

Vanila M. Singh, MD, MACM

Task Force Chairperson

Collaborative for Effective Prescription Opioid Policies

July 29, 2019

ONDCP-19-0922-A-001867_000000003

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CARA Act and Task Force Membership

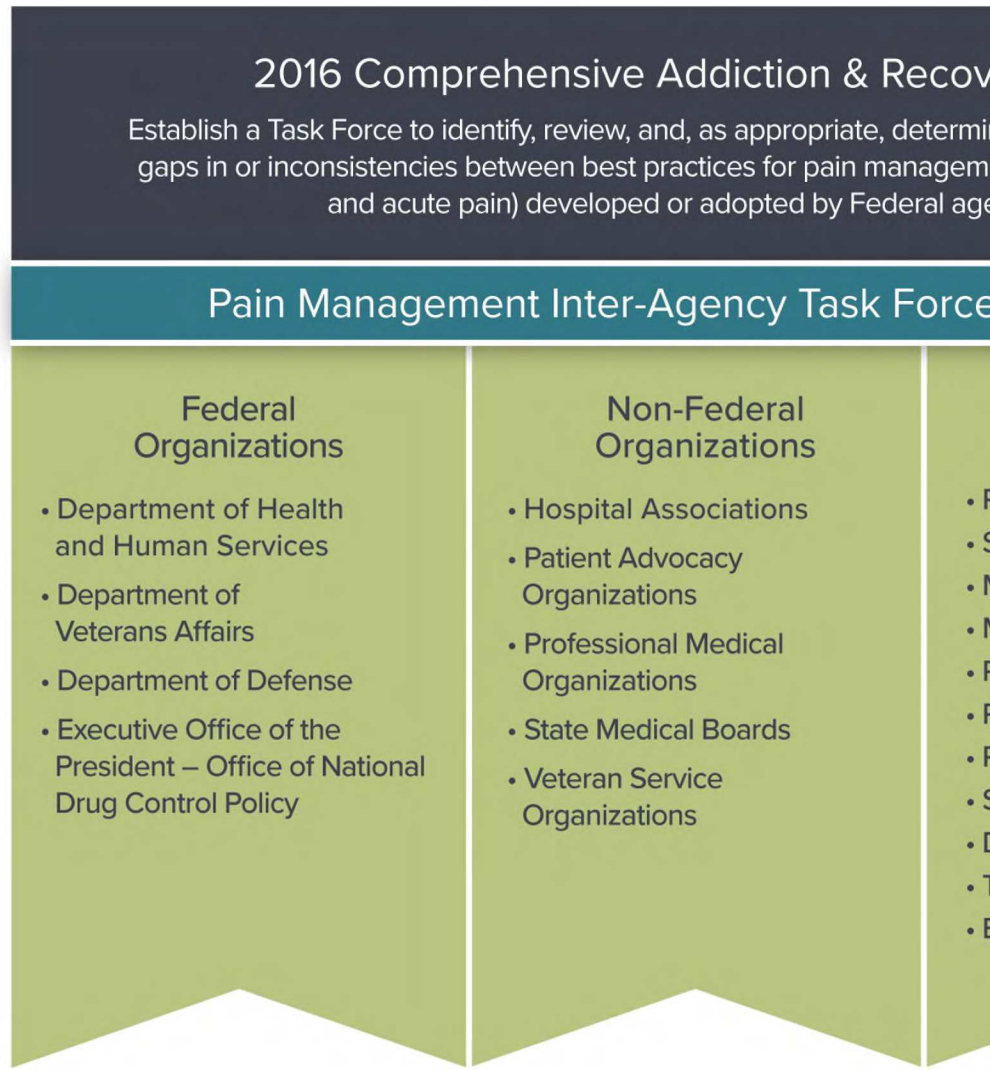
Task Force charge:

- To identify **gaps in best practices** for pain management
- Propose **recommendations to address these gaps**

Task Force members included:

- Representatives from Federal and non-Federal organizations
- Expertise across areas relevant to acute and chronic pain management

Task Force received **over 9,000 public comments**.



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Task Force Report Overview: 5 Broad Treatment Categories a 4 Cross Cutting Themes to Provide Framework for Best Practi

Task Force Report calls for:

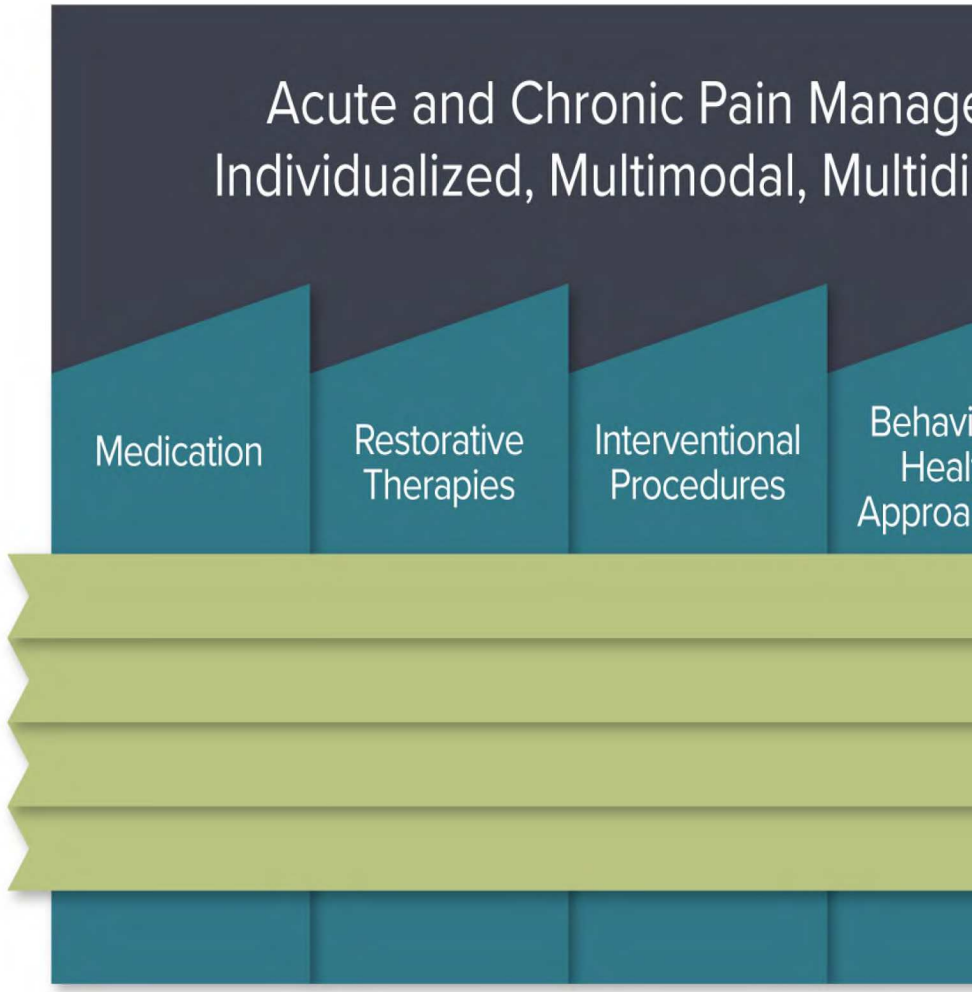
- **Individualized, multimodal, multidisciplinary approach to pain management**

Five major treatment approaches:

- Medication
- Restorative therapies
- Interventional procedures
- Behavioral health
- Complementary and integrative health

Four cross cutting topics need to be addressed to ensure best practices:

- Risk Assessment
- Stigma
- Access to Care
- Education



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Medication Approaches to Pain Include Opioid and Non-opioid

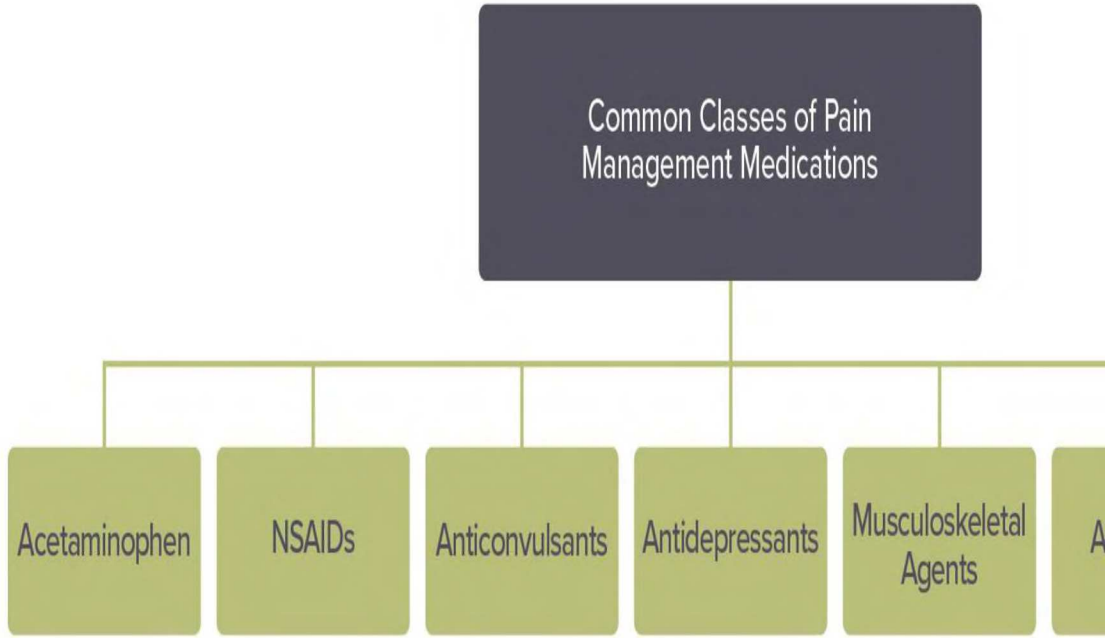
Risk-benefit analysis always recommended for any medication

2 Broad categories of medications used for pain management:

- Non-opioids
- Opioid classes of medications

Common non-opioid medications:

- Acetaminophen,
- NSAIDs
- Antidepressants (e.g., SNRIs, TCAs)
- Anticonvulsants,
- Musculoskeletal agents,
- Biologics,
- Topical analgesics and
- Anxiolytics



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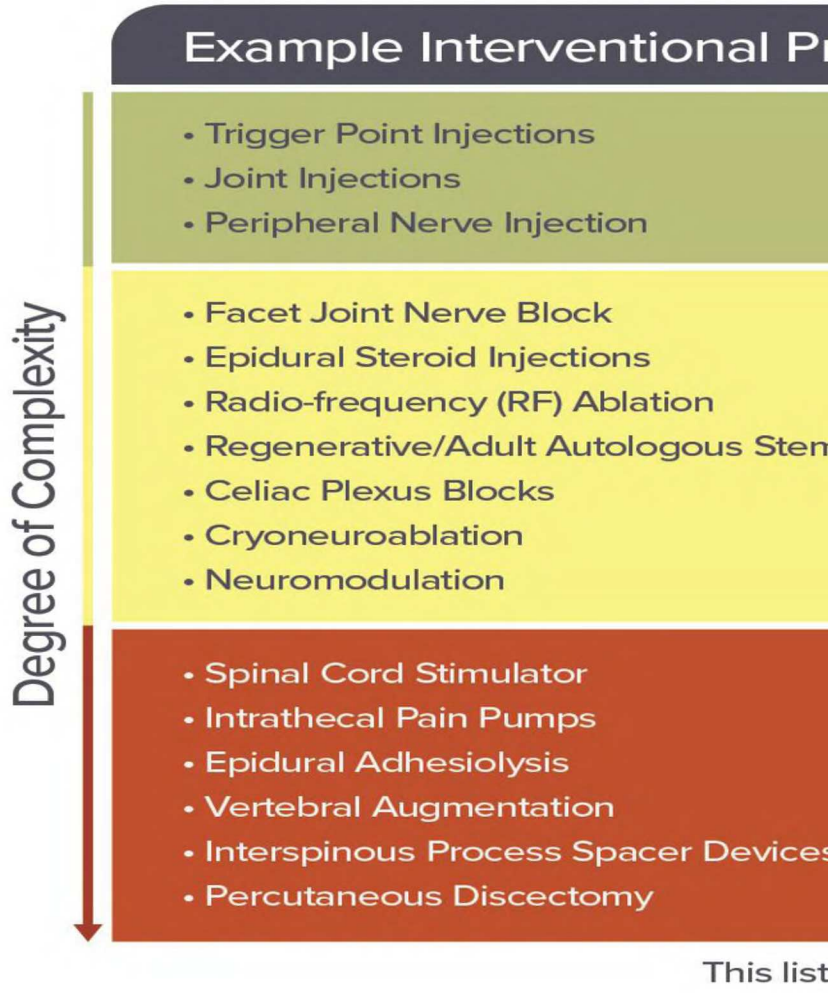
Interventional Procedures Vary by Degree of Complexity and Invasiveness

- Need: **well-researched interventional pain guidelines**
- Need: **Clinical research** to establish how interventional procedures work with other approaches
- Establish **criteria-based guidelines** for properly credentialing clinicians
- Encourage CMS and private payers:
  - Provide consistent and timely insurance coverage for interventional procedures



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Overcoming Barriers to Behavioral Health Approaches

Addressing barriers to **access to care** is essential to quality pain management:

- Clinical barriers (e.g. treatment access, provider attitudes)
- Health care system-related barriers (e.g. cost and reimbursement issues)
- Patient-related barriers (e.g. stigma, attitudinal variables).

When access and costs are limiting factors:

- Employ evidence-based, low-cost scalable approaches
  - E.g. **Telehealth and internet technologies**



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Complementary and Integrative Health Approaches

Complementary and Integrative Health (CIH) Approaches:

- Mind-body behavioral interventions
- Acupuncture
- Massage
- Meditative movement therapies (e.g., yoga, tai chi)
- Natural products

Need to address **barriers to acceptance** of CIH for pain:

- Improve reimbursement policies
- Improve education for medical professionals
- Greater workforce of pain management specialists



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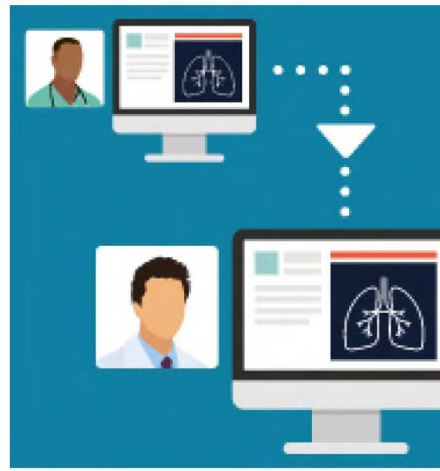
Innovative Delivery Systems, Research, and Special Populat

- **Innovative** solutions: e.g. telemedicine, tele-mentoring, mobile apps
- **Research** needed: mechanisms of pain, preventive measures, innovative medical devices and medications
- **Special populations:** pediatric, women, older adults, American Indians/Alaskan Natives, active duty soldiers/veterans, sickle cell disease (as an example of a chronic relapsing condition)





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Overdose Prevention & Naloxone, Medication Safe Storage Disposal, Acute Pain Guidelines, and Review of CDC Guide

- **Naloxone** use and preventing overdose
- **Safe Storage and Disposal** of medication, medication **shortages**
- **Guidelines** needed for acute pain and common surgeries
- **CDC Guideline** review: Recognize utility and contribution to mitigating opioid exposure. Also recognize misapplication and misinterpretation of guideline, including forced tapers and patient abandonment





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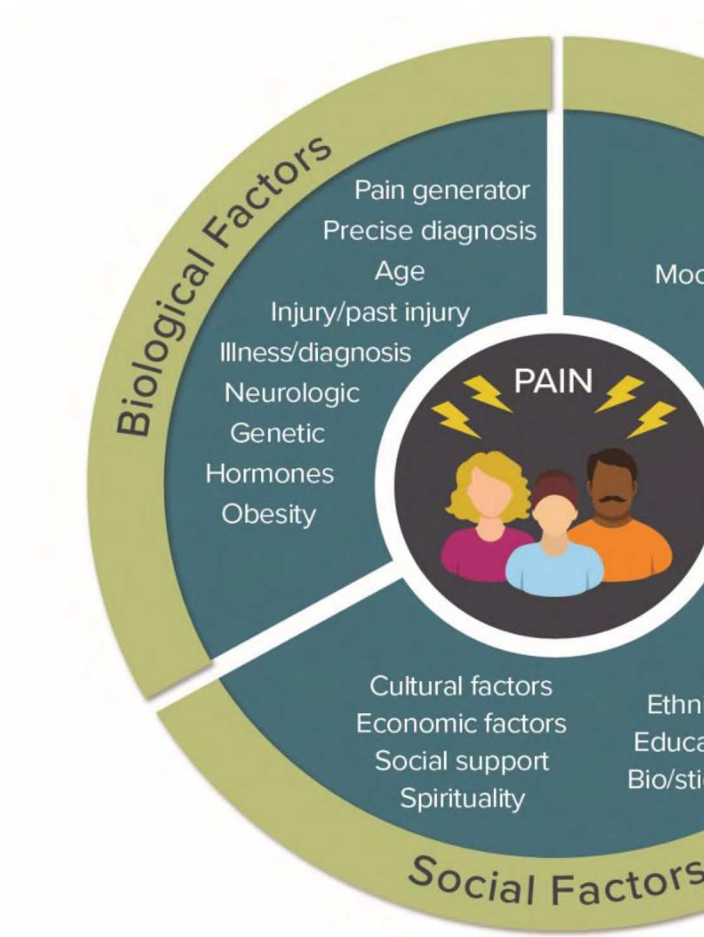
Approach to Pain Management: The Biopsychosocial Model of Pain Management

Key components of the **biopsychosocial model**:

- Biological Factors (e.g. diagnosis, age)
- Psychological factors (e.g. mood, stress)
- Social factors (e.g. social support, spirituality)

Aim to improve:

- Overall pain experience
- Physical functioning,
- Activities of daily living
- Quality of life (QOL)



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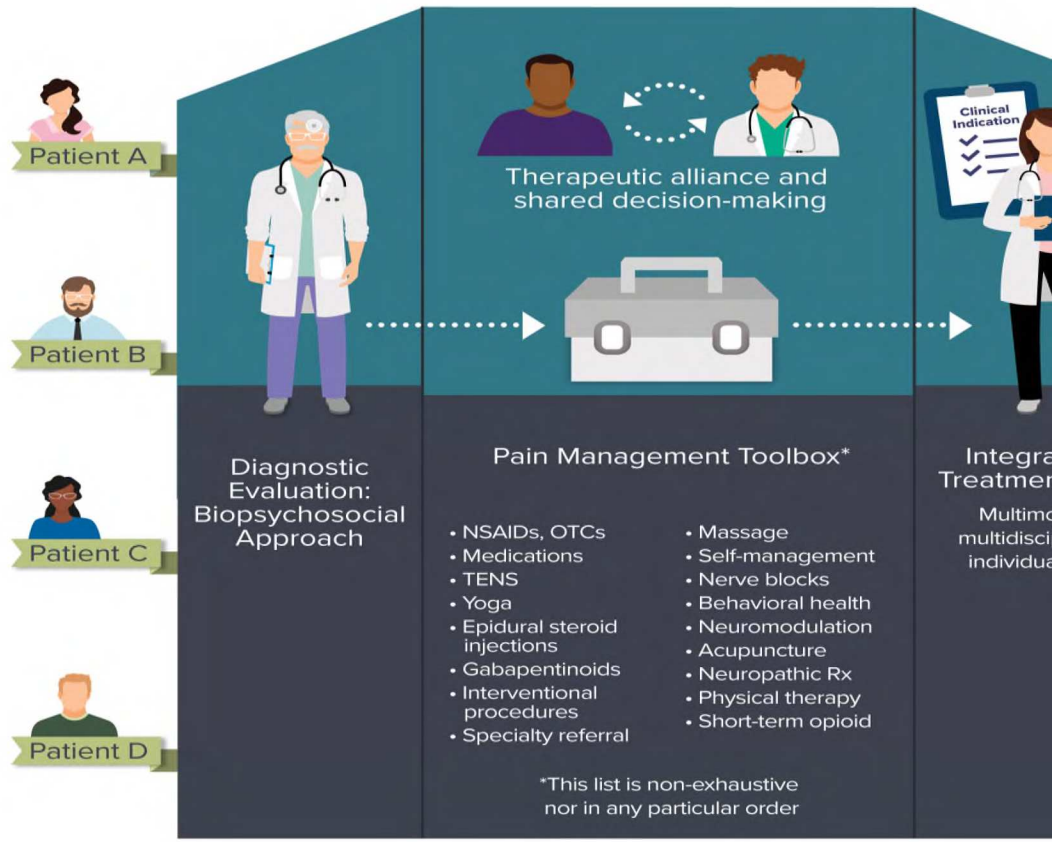
Individualized Patient Care for All Treatment Options

Individualized, patient-centered care best achieved:

- Diagnostic evaluation
- Biopsychosocial approach
- Access to needed treatment approaches

Resulting treatment plan, tailored to the specific needs of individuals requires a strong **patient-clinician relationship**:

- Mutual trust and respect
- Empathy
- Compassion
- Resulting in therapeutic alliance



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Public Comments to the Task Force Affirm the Barriers Stigma Creates

I have gone through, and exhausted all of the other drug and non-drug treatment options over the past 13 years. Still, I have pain. I hate that I am being treated like a drug abuser when I am just trying to make my life more manageable on a daily level. I try to participate in being part of our family, making a contribution to society, but it's hard. Not everyone who needs pain relief is an abuser.

- April 2019



How can a person be in pain for many years, unable to do the things he or she used to do without becoming depressed? Why does everyone assume the person was depressed or anxious first? Try having a serious heart condition knowing if you go to an ER for chest pain with or without extremely high blood pressure they probably will think you are seeking drugs

- June 2018





I was sent to a doctor after the last pain clinic in my county closed. He yelled at me, shamed me, and dehumanized me right in of front two other people.

- September 2018





My wife has Cervical Spinal Stenosis with Myelopathy. She was forced to taper in January of 2018. Within one month she was bed ridden and had talked to her employer explaining why she may have to quit her accounting job. I can't tell you how demoralizing this experience has been. We were immediately treated like second class citizens, accused of seeking drugs and the reason for the crippling, illicit, drug epidemic taking place on our streets.

- January 2019

I understand the abuse of pain meds, but not all of those who deal with chronic pain abuse them. I have always abided by pain contracts, been willing to submit UAS and yet still have had some pain doctors treat me as an addict because of the number of years I have been on pain meds. Trust is vital between a pain patient and their physician.

- May 2018



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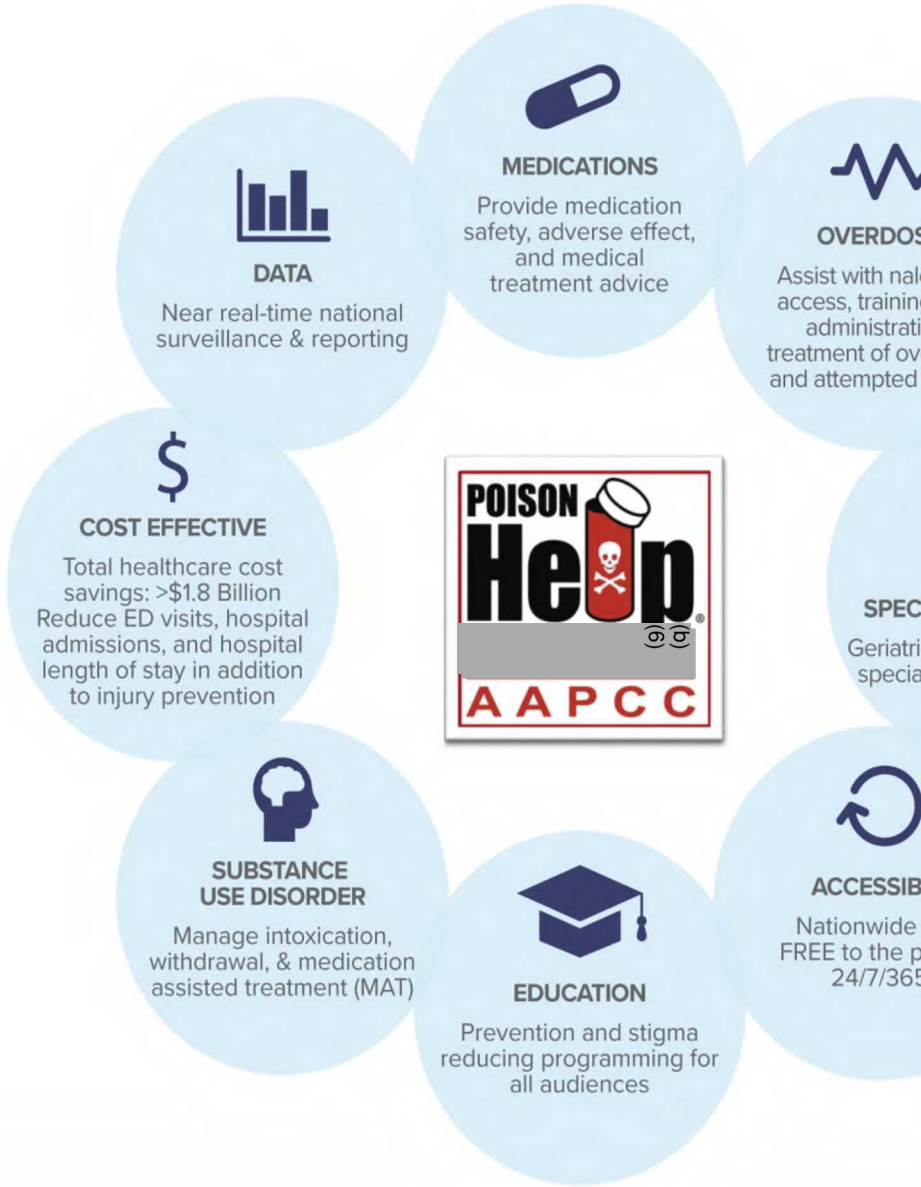
Value of Poison Control Centers

- Important for **patient safety**
- Available **24/7**
- Answer questions about:
  - Medication interactions,
  - Adverse effects,
  - Assess the need for emergency health care resources



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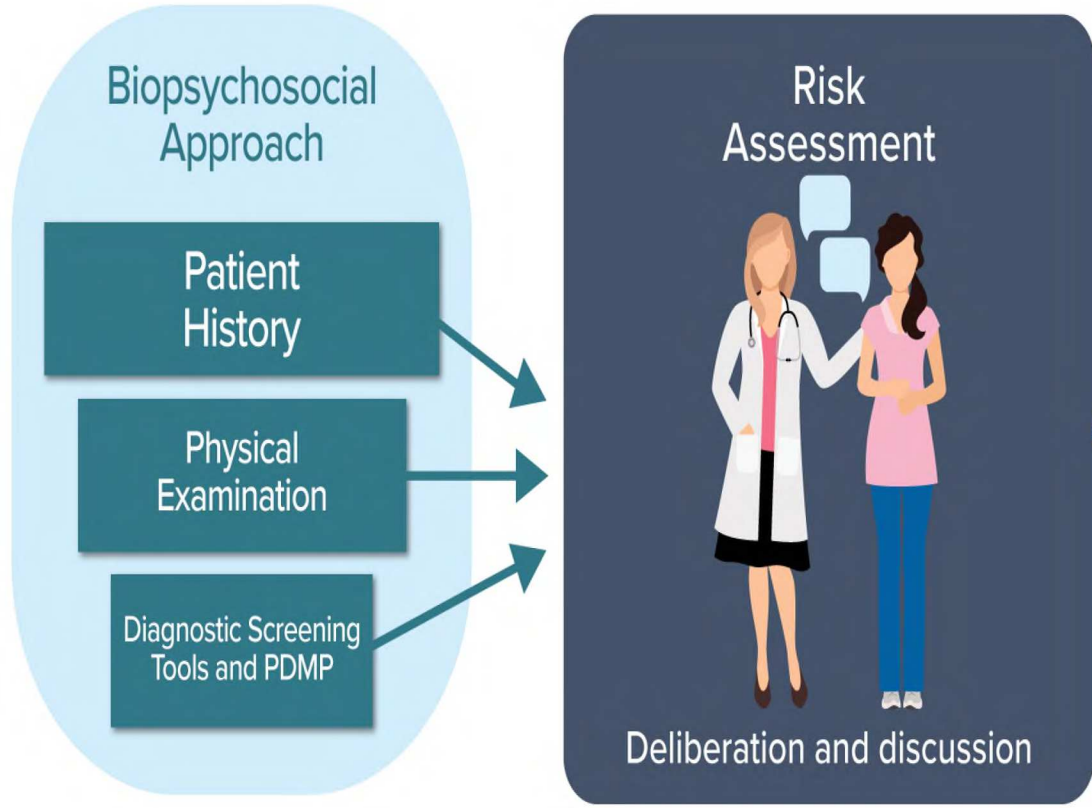
Risk Assessment for Risk-Benefit Analysis

Risk assessment:

- Comprehensive review of patient history
- Physical examination
- Diagnostic screening tools
- PDMPs

Patients and their Clinicians:

- Discuss potential **risks and benefits**
- Need **therapeutic alliance** to achieve best outcomes



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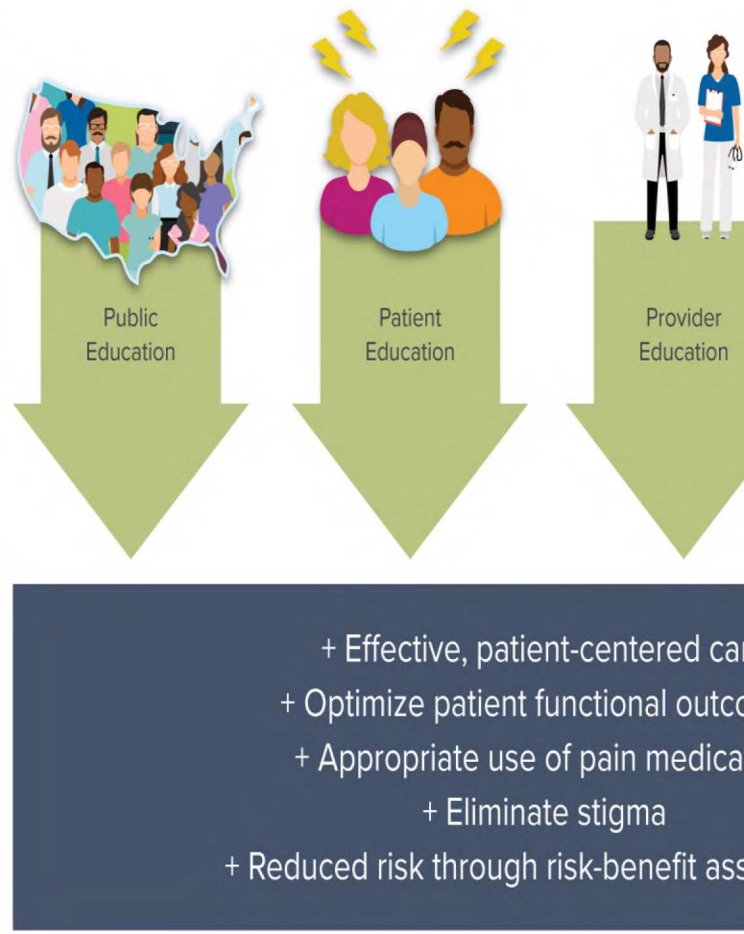
Education Is Critical to the Delivery of Effective Patient-Centered Pain Care

- Effective **education and training at all levels of clinician training**, including:
  - Undergraduate educational curricula
  - Graduate professional training
  - Continuing professional education

- **Public and patient education** helps reduce barriers to treatment, including stigma

- **Education for policymakers** ensures future legislation properly addressing issues related to pain management, including:
  - Payment mechanisms
  - Controlled medications



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Get Involved & Stay Connected!

- The Task Force Report emphasizes the importance of **individu**
  patient-centered care that is relevant to a wide range of stake
  invested in helping patients with acute and chronic pain achie
  best quality of life.
- **It's Time to Implement.** The report is comprehensive and info
  yet approachable. There are items of interest for all stakehold

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Access to office-based buprenorph
treatment: a secret shopper stu

Michael L. Barnett, MD, MS, Harvard Chan School of Public H

CEPOP Quarterly Meeting, July 29, 2019, Washingto

(b)(6) ml_barnett

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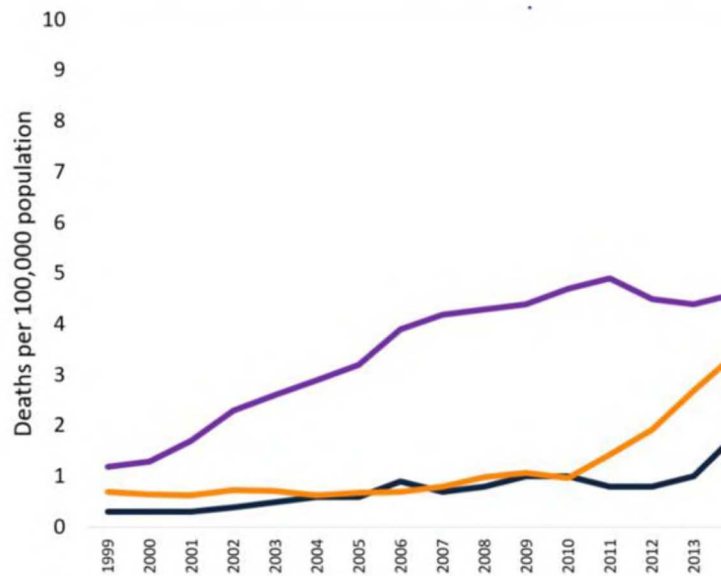
Background

- The opioid crisis continues to rage on
- Opioid substitution with buprenorphine or methadone can cut mortality from opioid use disorder (OUD) by over 50%
- But:
  - 80% of Americans with OUD have not received treatment in past year
  - Of those receiving treatment, 34% receive medication for OUD
- Therefore, improving access to medications for OUD is a public health priority



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Evidence Gap

- We know little about the real-world barriers patients seeking buprenorphine treatment face
  - Is it wait time?
  - Providers accepting new patients?
  - Providers accepting Medicaid?
- We know even less about *how* buprenorphine prescribers offer appointments to initiate buprenorphine
  - Ideally, should be offered ASAP without required contingency of intake appointment first



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Objective

Assess real-world access to buprenorphine treatmen
uninsured and Medicaid-covered patients reporting cu
heroin use

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Methods

- "Secret Shopper" audit survey of buprenorphine-waivered providers
  - Simulated patients seeking buprenorphine treatment for heroin use
  - Providers were each called twice:
    - 1) Uninsured/Cash-Pay patient
    - 2) Medicaid-covered patient
- Called publicly-listed providers on SAMHSA's website with unique p address combinations
- Sampled prescribers from 6 states with the highest opioid overdose in 2016
  - MA, NH, WV, OH, MD, DC

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Methods: Caller Script

- **Callers**: Two females called each clinic once on each payer arm
- **Patient Profiles**: 30 yrs. old, uses intravenous heroin daily, last use v prior, no medical or psychiatric history, no current medications
- **Script:** Asked to make appointment to start suboxone, if insurance accepted, when first opening is, whether it is possible to start medic same day
  - *No appointments were held* when getting off phone

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Methods: Outcomes Captured

1. Rates of new appointments offered
2. Wait times
3. Induction possibility at first visit
4. Cost for uninsured

- Outcome heterogeneity by patient and provider characteristics
  - Medicaid-Covered vs Uninsured / Cash-Pay
  - Provider credentials: MD vs NP/PA
  - Provider waiver status: 30, 100, & 275 patient capacity
  - Urban vs. rural location

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Results: Cohort Flow Diagram



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Results: Appointment Availability

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Offered Appointment n (%)	Total Contacts	Offered Appointme n (%)
Total	432	233 (54%)	417	258 (62%
Waiver Status				
30 (NP or PA)	114	80 (70%)	111	65 (59%)
30 (Physicians)	62	25 (40%)	55	26 (47%)
100	151	66 (44%)	146	91 (62%)
275	105	62 (59%)	105	76 (72%)
Location				
Urban	328	183 (56%)	316	203 (64%
Rural	104	50 (48%)	101	55 (54%

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Results: Induction Possible at First Visit

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Offered Appointment n (%)	Total Contacts	Offered Appointme n (%)
Total	432	117 (27%)	417	169 (41%
Waiver Status				
30 (NP or PA)	114	38 (33%)	111	37 (33%
30 (Physicians)	62	9 (15%)	55	10 (18%)
100	151	28 (19%)	146	59 (40%)
275	105	42 (40%)	105	63 (60%)
Location				
Urban	328	94 (29%)	316	127 (40%
Rural	104	23 (22%)	101	42 (42%

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Results: Wait Times

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Wait Time in Days, Median (IQR)	Total Contacts	Wait Time in Median (IQ
Total	432	6 (2, 10)	417	5 (1, 9)
Waiver Status				
30 (NP or PA)	114	4 (1, 9)	111	4 (1, 7)
30 (Physicians)	62	3 (1, 10)	55	4 (3, 10)
100	151	7 (2, 11)	146	5 (2, 11)
275	105	7 (3, 11)	105	5 (1, 11)
Location				
Urban	328	6 (2, 10)	316	5 (1, 9)
Rural	104	6 (2, 11)	101	5 (1, 9)

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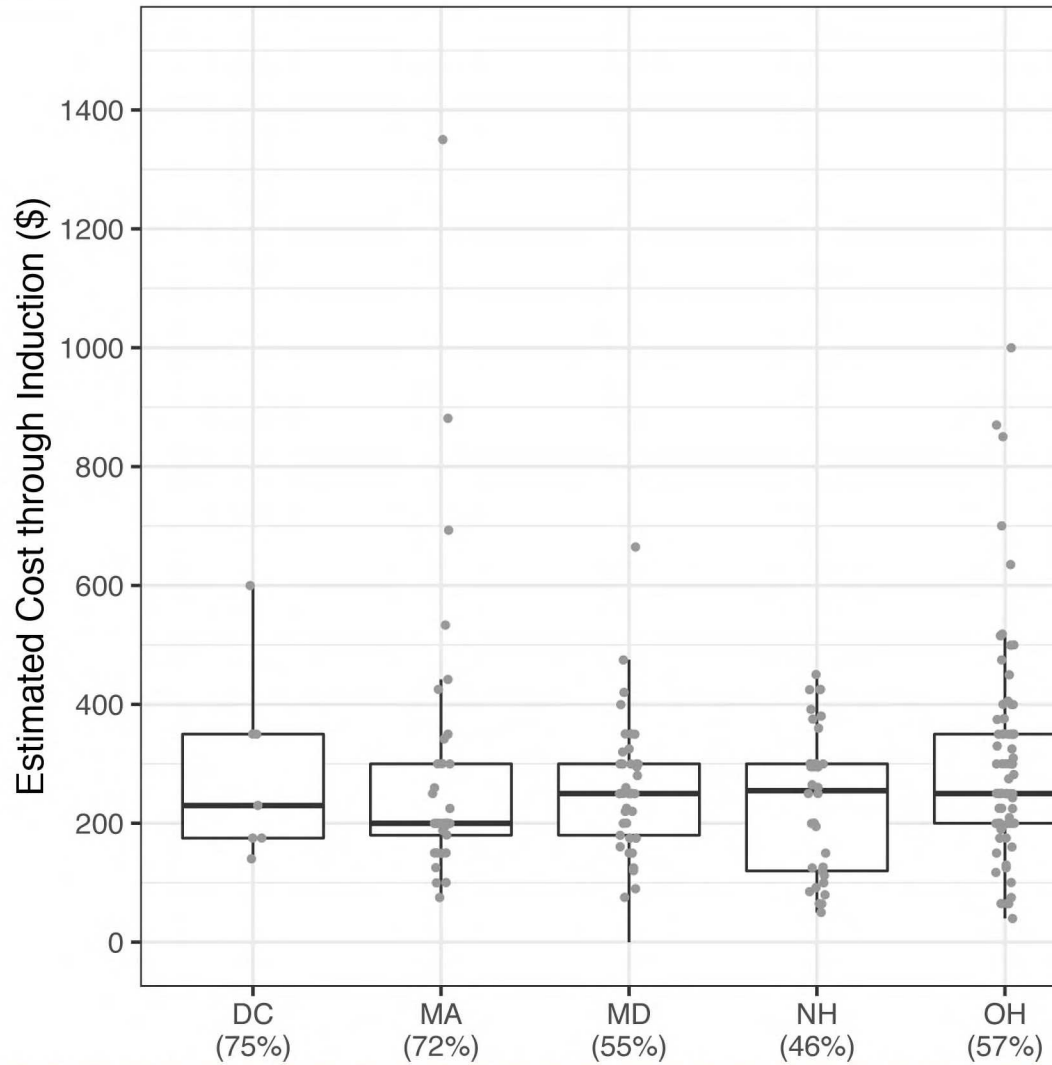
Results: Cash-Pay Cost

- Median price for cash-pay appointment was $250
- 5% of clinics had >$500 cost
- Little variation across states
- 54% of clinics had unknown additional lab charges



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Results Summary

- In 6 states with high opioid-related mortality, 38-46% of clinicians wi buprenorphine waivers not accepting new patients
  - Better access with NP/PAs and 275-patient waivered clinicians
  - The situation was worse for patients with Medicaid and in rural areas
- Of those accepting patients, only 50-66% allowed the possibility of ir on the first visit
- Surprisingly, among those accepting patients, wait times were genera than a week
- If paying with cash, visits are very expensive

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Conclusions and Policy Implications

- Simply finding a prescriber willing to take new patients is a significan
  - A second challenge is getting the prescription given that many prescribers prescribe on the first visit
- Among those accepting patients, wait times are not long, implying ur capacity

Policy implications

- We need improved methods to connect patients with prescribers, e enhanced online directories
- Paying more for addiction treatment would likely increase Medicaid acceptance

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Thank you! Any questions?

- [redacted]
- [redacted]t
- Grant Support:
  - National Institute on Aging
  - National Institute on Drug Abuse
- Thanks to co-authors:
  - Tamara Beetham (HSPH → Yale)
  - Brendan Saloner (Johns Hopkins)
  - Sarah Wakeman (MGH)
  - Marema Gaye (HSPH)

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Appendix

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	Number of Contacts with Response per Provider, n (%)			Total
	0	1	2	
Waiver Capacity				
30 (NP or PA)	19 (13%)	22 (15%)	109 (73%)	150
30 (Physician)	27 (29%)	11 (12%)	55 (59%)	93
100	21 (11%)	39 (20%)	132 (69%)	192
275	10 (9%)	17 (15%)	84 (76%)	111
State				
Washington DC	12 (32%)	8 (22%)	17 (46%)	37
Massachusetts	12 (11%)	20 (19%)	73 (70%)	105
Maryland	20 (20%)	13 (13%)	69 (68%)	102
New Hampshire	6 (8%)	14 (19%)	53 (73%)	73
Ohio	16 (12%)	23 (17%)	98 (72%)	137
West Virginia	11 (12%)	11 (12%)	70 (76%)	92
Urban/Rural Location[1]				
Urban	66 (16%)	72 (17%)	286 (67%)	424
Rural	11 (9%)	17 (14%)	94 (77%)	122
Years Since Initial Waiver for Physicians				
Below median (<6)	27 (15%)	34 (19%)	118 (66%)	179
Median and greater(≥6)	31 (14%)	33 (15%)	153 (71%)	217
Total	77 (14%)	89 (16%)	380 (70%)	546

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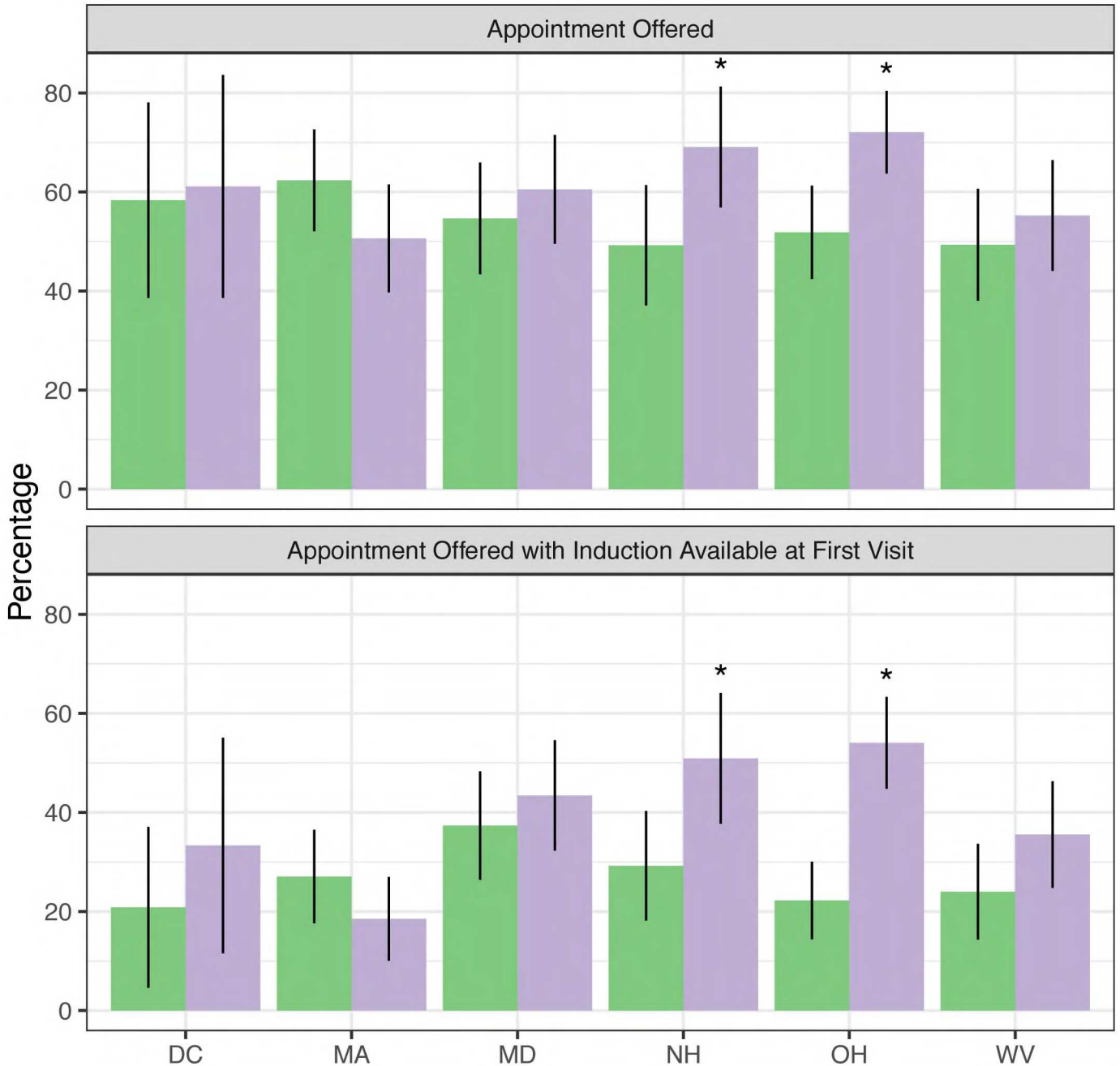

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No Appointment Reasons by State

State	Payer Status Not Accepted (n, %)	Not Accepting New Patients (n, %)	Waitlist (n, %)	Other (n, %)	Total (n)
Total	158 (44%)	130 (36%)	61 (17%)	9 (3%)	358
Washington DC	5 (29%)	12 (71%)	0 (0%)	0 (0%)	17
Massachusetts	31 (43%)	30 (42%)	8 (11%)	3 (4%)	72
Maryland	35 (55%)	23 (36%)	5 (8%)	1 (2%)	64
New Hampshire	14 (28%)	25 (50%)	7 (14%)	4 (8%)	50
Ohio	50 (60%)	23 (28%)	9 (11%)	1 (1%)	83
West Virginia	23 (32%)	17 (24%)	32 (44%)	0 (0%)	72

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VIA ELECTRONIC DELIVERY

The Honorable Richard Shelby
Chairman
Committee on Appropriations
United States Senate
304 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Patrick Leahy
Ranking Member
Committee on Appropriations
United States Senate
437 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Roy Blunt
Chairman
Subcommittee on Labor, Health and Human Services, Education and Related Agencies
United States Senate
260 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Subcommittee on Labor, Health and Human Services, Education and Related Agencies
United States Senate
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Washington, D.C. 20510

The Honorable Jerry Moran
Chairman
Subcommittee on Commerce, Justice, Science and Related Agencies
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Washington, D.C. 20510

The Honorable Jeanne Shaheen
Ranking Member
Subcommittee on Commerce, Justice, Science and Related Agencies
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Washington, D.C. 20510

The Honorable John Kennedy
Chairman
Subcommittee on Financial Services and General Government
United States Senate
416 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Christopher Coons
Ranking Member
Subcommittee on Financial Services and General Government
United States Senate
218 Russell Senate Office Building
Washington, D.C. 20510

Thursday, July 25, 2019

Dear Chairmen and Ranking Members:

As participants in the Collaborative for Effective Prescription Opioid Policies (CEPOP; www.CEPOPonline.org), we are writing in support of robust funding for the below programs to address the national opioid epidemic. Together, these programs will increase access to comprehensive prevention, treatment and recovery services and will help save lives.

CEPOP is a diverse group of more than 80 stakeholders – interested in the manufacture, distribution, appropriate use of opioid and non-opioids medications, non-pharmacologic interventions, medication-assisted treatment and

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disposal of unused and unwanted prescription drugs – who have joined together to work toward a comprehensive and balanced policy strategy to prevent misuse, abuse, diversion and promote treatment and recovery options. We support effective programs, strategies and policies to help prevent prescription painkiller misuse and overdose while ensuring patients' access to safe effective pain treatment.

The opioid epidemic continues to devastate American communities from coast to coast. This continued devastation highlights the need for further investment in prevention as well as treatment if we are to turn the tide. Opioid overdoses (including prescription opioids, heroin and fentanyl) led to the deaths of more than 47,600 Americans in 2017, eclipsing any year on record. That is nearly six times higher than the number of opioid overdose deaths in 1999 (8,048). An average of 130 people a day die from an opioid overdose. While preliminary data for 2018 indicates the first decline in overdose deaths in nearly three decades, we cannot be stagnant in our response as much work is yet to be done.

We appreciate the Committee's ongoing commitment to providing much needed resources to address the opioid epidemic. As you work to craft FY 2020 appropriations legislation, we respectfully urge you to consider the following recommendations:

Labor-HHS-Education and Related Agencies Appropriations Act (LHHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)[1]:

- **Substance Abuse Prevention and Treatment (SAPT) Block Grant:** The Substance Abuse Prevention and Treatment (SAPT) Block Grant Program serves as the foundation of the publicly funded prevention, treatment and recovery system. In particular, the SAPT Block Grant distributes funds to 60 eligible states, territories, the District of Columbia, and the Red Lake Band of Chippewa Indians of Minnesota to support critical substance abuse prevention, treatment and recovery support services for the nation's most vulnerable. Federal investments in the SAPT Block Grant have not kept up with inflation. We urge the Committee to provide an increase for the SAPT Block Grant in FY20 over the FY19 level of $1.858 billion to help states meet the increasing need for prevention, treatment, and recovery strategies and services.
- **Center for Substance Abuse Treatment (CSAT):** SAMHSA's Center for Substance Abuse Treatment is dedicated to expanding access to high quality treatment and recovery services, including access to Medication Assisted Treatment when appropriate. According to the National Survey on Drug Use and Health, 21.5 million people aged 12 or older needed treatment for an alcohol or illicit drug use problem in 2014. During the same year, more than 4 million received treatment for such a problem. That means 17.5 million Americans needed but did not receive services for a substance use problem. We urge the Committee to provide, at a minimum, the House-passed level of $405.4 million (level funding) for CSAT in FY20.
- **Center for Substance Abuse Prevention (CSAP):** SAMHSA's Center for Substance Abuse Prevention (CSAP) brings evidence-based prevention programs and strategies to every state and sub-state regions nationwide. Its discretionary grant programs target states, communities, organizations, workplaces and families to promote resiliency, promote protective factors, and reduce risk factors for substance use. We urge the Committee to provide, at a minimum, the House-passed level of $$212,469,000 for CSAP in FY20, as we must increase our efforts to address effective prevention to stop misuse before it ever starts.

[1] All requested levels of funding should not be taken out of other existing Substance Abuse and Mental Health Services Administration line items that support individuals living with mental illness or substance abuse, including those with co-occurring disorders.

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- **State Opioid Response (SOR) Grants:** Congress authorized (via the 21st Century Cures Act) and reauthorized (via the SUPPORT for Patients and Communities Act) grants to States to enhance prevention, treatment and recovery programs and services to address the opioid crisis. States are required to outline gaps in services, identify evidence-based implementation strategies and report progress on categories such as opioid related overdose deaths. We urge the Committee to provide the House-passed level of $1.5 billion in FY20.

Centers for Disease Control and Prevention (CDC), Injury Center: The CDC uses data and prevention strategies to help track trends in the epidemic, identify problem areas, and help states strengthen and evaluate prevention efforts. CDC is also equipping health care providers with data and tools needed for appropriate opioid prescribing. Through the Opioid Prevention in States effort, CDC works with 45 states and the District of Columbia. CDC provides scientific expertise, enhanced surveillance activities, and support resources to quickly report fatal and non-fatal overdoses; identifies hot spots and responds with targeted resources; and identifies risk factors for overdoses and shares data to improve prevention responses. We are pleased that as part of the FY18 Omnibus appropriations package, the CDC received a $350 million funding increase, with specific mention around CDC promotion of PDMP use and expansion of efforts to make PDMPs "more interconnected, real-time, and usable for public health surveillance and clinical decision making." In FY20 we request the House-passed $475.5 million.

National Institute on Drug Abuse (NIDA): The National Institute on Drug Abuse (NIDA), within the National Institutes of Health (NIH), seeks to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. NIDA is investing resources in a variety of initiatives in order to help address the opioid crisis. This includes support of research related to medication assisted treatment (MAT), the misuse of prescription opioid pain relievers by high schoolers, addressing opioid use disorders in the criminal justice system. In addition, NIDA has a critical role in implement the NIH-HEAL Initiative (Helping to End Addiction Long-Term) initiative which seeks to accelerate research-based solutions to the opioid crisis. We recommend the House-passed level of $1.489 billion for NIDA in FY20.

Commerce-Justice-Science Appropriations Act

Hal Rogers PDMP Grant Program: PDMPs are a critical tool for addressing prescription drug abuse, yet PDMP capabilities vary widely by state. The Rogers PDMP Program is a discretionary, competitive grant program administered through the Justice Department, Bureau of Justice Assistance. The Rogers grants are intended to enhance the capacity of regulatory and law enforcement agencies and public health officials to collect and analyze controlled substance prescription data and other scheduled chemical products through a centralized database administered by an authorized state agency. We recommend at minimum the House-passed level of $30 million (level funding) for the Rogers PDMP program in FY20.

Edward Byrne Memorial Justice Assistance Grant (JAG) Program: The JAG program provides states and local governments with funding necessary to support a range of program areas including law enforcement, prosecution and court programs including indigent defense, prevention and education programs, corrections and community corrections, drug treatment and enforcement, and planning, evaluation and technology improvement programs. States are investing in strategies to improve outcomes for justice-involved individuals with mental illness and substance use disorders. Yet funding for the Byrne JAG program has dropped by about one-third in recent years. We recommend at least the House-passed level of $530 million for this critical program.

Drug Enforcement Administration (DEA): The DEA is a key federal agency in the effort to reverse the opioid epidemic for prescription drug abuse, misuse, and diversion. CEPOP supports the agency's engagement in the

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National Take-Back Initiative, as well as the innovative 360 Strategy program. We recommend that the Committee include, at minimum, the House-passed level of $2.36 billion in FY20.

Financial Services and General Government Appropriations Act

Drug-Free Communities (DFC) Grant Program: The Drug-Free Communities Grant Program (DFC) is administered by the Office of National Drug Control Policy and provides support for communities to identify and respond to all local substance use and misuse issues. DFC grantees have reduced substance use and misuse in funded communities throughout the country to levels lower than national averages because they are organized, data driven and take a comprehensive, multi-sector approach to solving and addressing these issues. DFC coalitions are uniquely situated to deal with emerging drug trends, such as prescription drug abuse, because they have the infrastructure in place to effectively address any drug related issues within their communities. We recommend, at a minimum, the House-passed level of $100.5 million for the DFC program in FY20.

Community-Based Coalition Enhancement Grants: CARA's prevention provision, Section 103, is purposefully drafted to build on the effective DFC community-based infrastructure to help communities address local opioid crises. DFC grantees are maximally prepared and proven effective in preventing and addressing all alcohol, tobacco, and drug issues, as they engage in evidence-based, comprehensive, multi-component strategies across all community sectors to achieve population-level decreases in substance use rates. Providing enhancement grants to existing DFC grantees to specifically deal with stopping opioid initiation before it ever starts is critical because DFC grantee coalitions already have the necessary infrastructure and expertise to most cost-effectively prevent prescription drug misuse from ever starting. We request at a minimum, the House-passed level of $5 million in FY 2020, which is the full authorized level for this program.

Together, these programs will help expand prevention efforts to reduce opioid misuse and promote access to life-saving treatment and recovery services, rescue medications and other resources integral to the national effort to combat the opioid epidemic. A comprehensive approach is the only way we will reverse the substance misuse epidemic. Please do not hesitate to leverage the undersigned organizations as resources in the future. Thank you for your consideration of these comments.

Sincerely,

[Insert Undersigned Organizations]

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[EXTERNAL] CEPOP Quarterly In-Person All-Participants (July 2019) - AGENDA ATTACHED

Where:	FBDC Offices (1050 K Street NW, Suite 400) - Conference Room 4D; WebEx Available
When:	Mon Jul 29 15:00:00 2019 (America/New_York)
Until:	Mon Jul 29 17:00:00 2019 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	Dan Buffington <(b)(6) "Dr. John Harrison" <(b)(6) "Robin Swift ((b)(6) <(b)(6) Julian Hoffman <(b)(6) "Carrier Latimer (Hirons)" <(b)(6) "Gen. Arthur Dean" <(b)(6) Marcia Lee Taylor <(b)(6) "Kathryn L. Cates-Wessel" <(b)(6) Addie Liles <(b)(6) Eli Briggs <(b)(6) Kate McFadyen <(b)(6) "Brooke Goldberg (SAFE Project US)" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Kathleen O'Conner <(b)(6) Jeremiah Lindemann (b)(6) Amanda Sears <(b)(6) Robert Forman <(b)(6) Mary Winnefeld <(b)(6) Patricia Farley <(b)(6) Brad Tallamy <(b)(6) Van Ingram <(b)(6) Andrew kessler <(b)(6) Chris Zimmerman <(b)(6) "Deb Waugh (Affiliated Monitors)" <(b)(6) "KJ Hertz (March of Dimes)" <(b)(6)

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"Kevin Roy (Shatterproof)" (b)(6)
"Cara Moon (Egalet)" <(b)(6)
Karen Tracy <(b)(6)
Amy Callendar <(b)(6)
Kevin Walker <(b)(6)
Scott Proescholdbell <(b)(6)
Susan Awad <(b)(6)
"Jasey Cardenas (AAAP)" <(b)(6)
"Ian Goldstein (NACCHO)" <(b)(6)
Melissa Ough <(b)(6)
Gary Mendell (b)(6)
"Sarah Nerad (Alkermes)" <(b)(6)
"Donald A. Lohman (MNK)" <(b)(6)
"Brandee Izquierdo (SAFE Project)" <(b)(6)
"Derek Naten (MNK)" <(b)(6)
Shalini Wickramatilake <(b)(6)
"Valerie Brankovic (NACo)" <(b)(6)
Charlie Cichon <(b)(6)
"Gena Fitzgerald (SAFE Project)" <(b)(6)
"Amber Landis (Spectrum Health)" <(b)(6)
Ed Kaleta <(b)(6)
Caren Kagan Evans <(b)(6)
Lorraine Yarde <(b)(6)
Kristi Thompson <(b)(6)
Tracie Thomas <(b)(6)
Rob Morrison <(b)(6)
Michael DeGeorge <(b)(6)
Daniel Raymond <(b)(6)
Patricia D'Antonio <(b)(6)
"Terry Malefant (RCOA)" <(b)(6)
Mary Bono <(b)(6)
Keysha Brooks-Coley <(b)(6)
Jason Sundby <(b)(6)
Donald Hoppert <(b)(6)
"Patel, Beena S." <(b)(6)
"Dr. Anita Gupta" <(b)(6)

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Samantha Arsenault (b)(6)
Nicole Burda <(b)(6)
"Tom Supinka (NSC)" <(b)(6)
John Donahue <(b)(6)
"Emily Diehl (NASADAD)" <(b)(6)
"Gabriella Witte (APHA)" <(b)(6)
Teresa Baker <(b)(6)
Steve Passik <(b)(6)
"Celia Hagan (NILA)" <(b)(6)
"Danna Droz (NABP)" <(b)(6)
"David Bilardello (Spectrum Health)" <(b)(6)
Kate Berry <(b)(6)
Brian Bowden <(b)(6)
"Jessica Johnston (BD)" (b)(6)
James Appleby <(b)(6)
"Christian, Jeanine M" <(b)(6)
"Dr. Stuart Gitlow" <(b)(6)
"Deana Haworth (Hirons)" <(b)(6)
Mike Smith <(b)(6)
"Terry McGeeney, MD, MBA" <(b)(6)
"Evans, Daniel F." <(b)(6)
"Blaire Bryant (NACo)" <(b)(6)
Paul Ross <(b)(6)
Wade Delk <(b)(6)
Alice Dembner <(b)(6)
"Clay Alspach (b)(6) <(b)(6)
Rebecca Farley <(b)(6)
Jane Terry <(b)(6)
"Patty McCarthy (FaVoR)" <(b)(6)
Rita Norton <(b)(6)
"Alexander, Tesfa" <(b)(6)
"Dr. Elizabeth Salisbury-Afshar" <(b)(6)
"Sue Thau (Gmail)" <(b)(6)
"Cristi L. Schwarcz" <(b)(6)
Chuck Ingoglia <(b)(6)
Aiken Hackett <(b)(6)

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Aryka Chapman <(b)(6)
Sonya Clay <(b)(6)
Richard Hamburg <(b)(6)
"William Hibbs (Alkermes)" <(b)(6)
Vince Ventimiglia <(b)(6)
"Rachel Rivera (b)(6)
<(b)(6)
"Dr. Jack Stein" <(b)(6)
Elizabeth Solhtalab <(b)(6)
Shelley Starkey <(b)(6)
Nick Motu <(b)(6)
"Hanson, Roberta J." <(b)(6)
"Dr. Renan Castillo" <(b)(6)
Blair Clark-Schoeb <(b)(6)
David May <(b)(6)
Judi Lund Person (b)(6)
Patricia Bruckenthal <(b)(6)
"Stephanie Pellitt (NCBH)" <(b)(6)
Sue Thau <(b)(6)
Erika Long <(b)(6)
Carol Thornton <(b)(6)
"Zook, David R." <(b)(6)
Gabrielle de la Gueronniere <(b)(6)
Hadi Sedigh <(b)(6)
Rebecca Slater Abbott <(b)(6)
Courtney Hunter <(b)(6)
"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)
"Lynette Bradley-Baker (AACP)" <(b)(6)
Dennis Brennan <(b)(6)
"Whitney Taylor (Integritas)" <(b)(6)

Optional Attendees:

"Rachael Cooper (NSC)" <(b)(6)
Richard Cesar-Meyers <(b)(6)
"Motu, Nick" <(b)(6)
"Abbott, Rebecca" <(b)(6)

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CEPOP Participants – Please see attached for the July 2019 Quarterly In-Person All-Participants Agenda. We're pleased to have a robust agenda covering a wide array of different topics and longstanding CEPOP priorities. Additional information will be shared as available. Our Focus Topic Speakers for this month's meeting include:

- **Peter Fise, Counsel for U.S. Senator Jeanne Shaheen,** to discuss the recently introduced *Turn the Tide Act* (S. 2102);
- **Dr. Vanila Singh, Chairwoman for the Pain Management Best Practices Inter-Agency Task Force**, to discuss the final report issued in May 2019; and
- **Dr. Michael Barnett, Assistant Professor at Harvard T.H. Chan School of Public Health,** to discuss his recent research around access barriers to treatment for opioid use disorder.

We look forward to a productive discussion! Should there be any questions, please reach out to the Steering Committee.

Meeting Location (July 2019)

Faegre Baker Daniels Consulting Offices

1050 K Street NW, Suite 400

Washington, DC 20001

For those unable to attend in-person, a WebEx has been made available for individuals to participate remotely.

- To join WebEx, please **CLICK HERE**.
- Or, to join via conference call:
  - **Conference Line:** (b)(6)
  - **Participant Code:** (b)(6)

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CEPOP QUARTERLY IN-PERSON ALL-PARTICIPANTS MEETING

Date: Monday, July 29, 2019

Time: 3:00pm – 5:00pm EST

Location: Faegre Baker Daniels Consulting Offices
1050 K Street NW, Suite 400
Washington, DC 20001

WebEx: To join via computer, please click here.
Conference Line: (b)(6)
Participant Code: (b)(6)

AGENDA

I. Welcome

II. Focus Topic Discussions

- **A. Turn the Tide Act (S. 2102) – Combatting and Preventing the Epidemic through SUPPORT**
  Peter Fise, *Counsel, U.S. Senator Jeanne Shaheen (D-NH)*
- **B. Readout: The Final Report from HHS on Pain Management Best Practices (link)**
  Dr. Vanila M. Singh, *Chairwoman, Pain Management Best Practices Inter-Agency Task Force*
- **C. Identifying Continued Barriers to Accessing SUD/OUD Treatment Services (link)**
  Dr. Michael Barnett, *Assistant Professor of Health Policy and Management, Harvard T.H. Chan School of Public Health*

III. Advocacy and Policy Priorities

- **A.** FY2020 Appropriations

IV. Working Groups

- **A.** Prevention
  - **i.** Survey Result Readout
- **B.** Safe Disposal and Anti-Diversion
- **C.** Safe Use

V. Organizational Updates: Sharing Intel, Participant News and Updates

- **A.** Seen and Heard
- **B.** Participant News

Next Monthly CEPOP All-Participants Teleconference: Monday, September 23, 3:00pm – 4:00pm

Calendar Appointment Forthcoming.

Should you have any questions, please contact Matt Rubin at (b)(6)

www.CEPOPonline.org
July 2019

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PAIN MANAGEMENT BEST PRACTI

Vanila M. Singh, MD, MACM

Task Force Chairperson

Collaborative for Effective Prescription Opioid Policies

July 29, 2019

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CARA Act and Task Force Membership

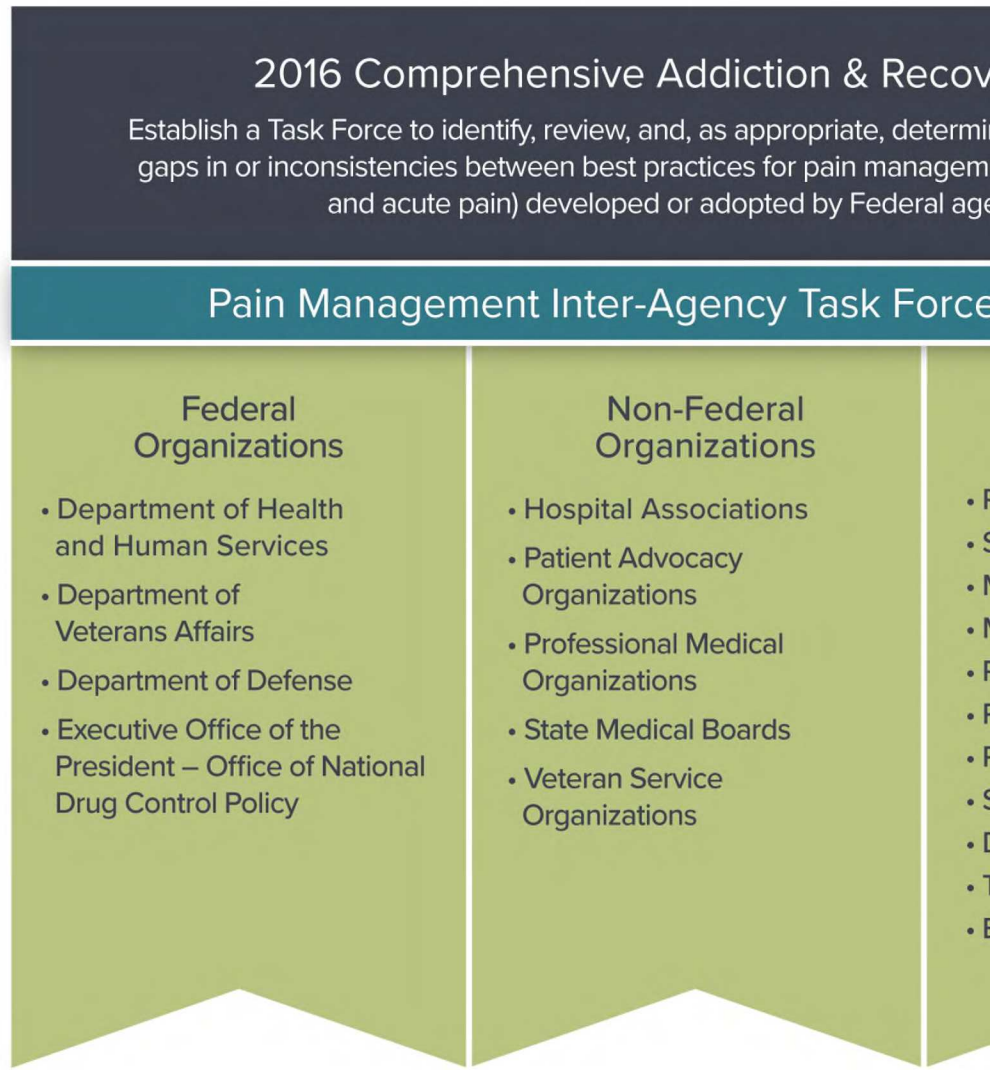
Task Force charge:

- To identify **gaps in best practices** for pain management
- Propose **recommendations to address these gaps**

Task Force members included:

- Representatives from Federal and non-Federal organizations
- Expertise across areas relevant to acute and chronic pain management

Task Force received **over 9,000 public comments**.



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Task Force Report Overview: 5 Broad Treatment Categories a
4 Cross Cutting Themes to Provide Framework for Best Practi

Task Force Report calls for:

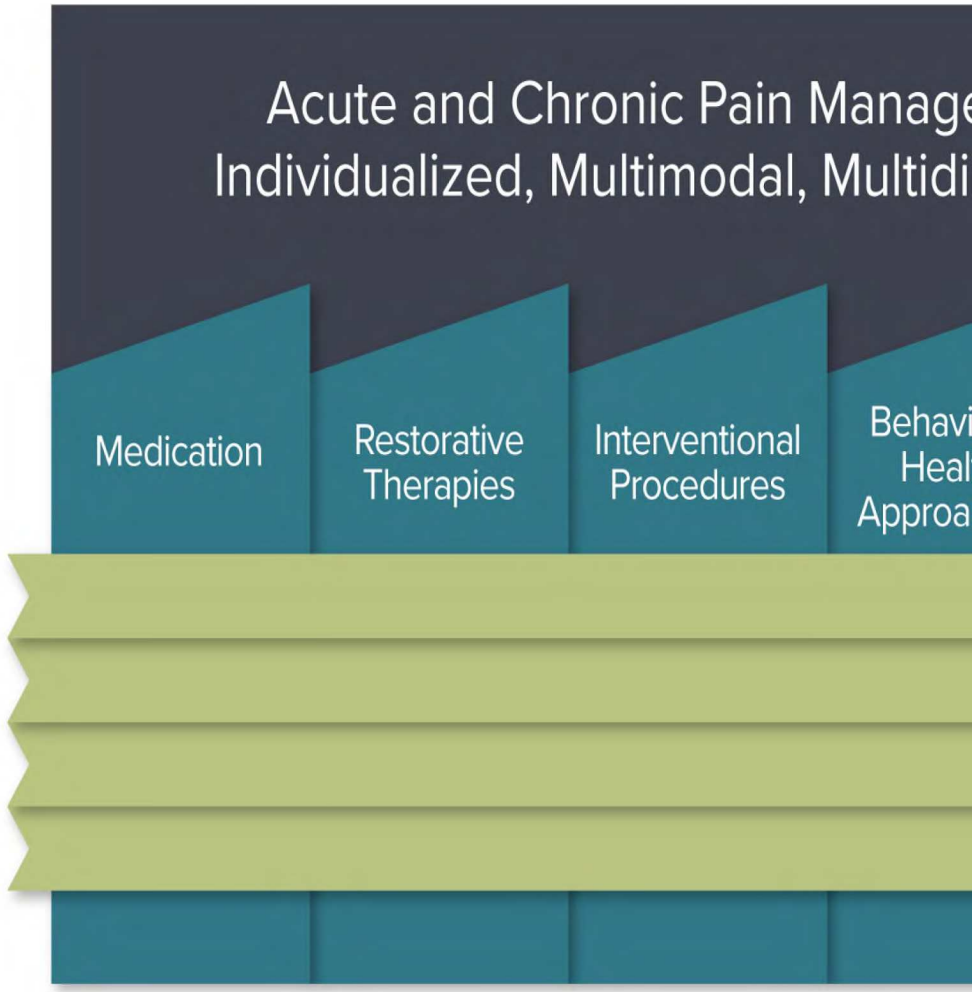
- **Individualized, multimodal, multidisciplinary approach to pain management**

Five major treatment approaches:

- Medication
- Restorative therapies
- Interventional procedures
- Behavioral health
- Complementary and integrative health

Four cross cutting topics need to be addressed to ensure best practices:

- Risk Assessment
- Stigma
- Access to Care
- Education



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Medication Approaches to Pain Include Opioid and Non-opioid

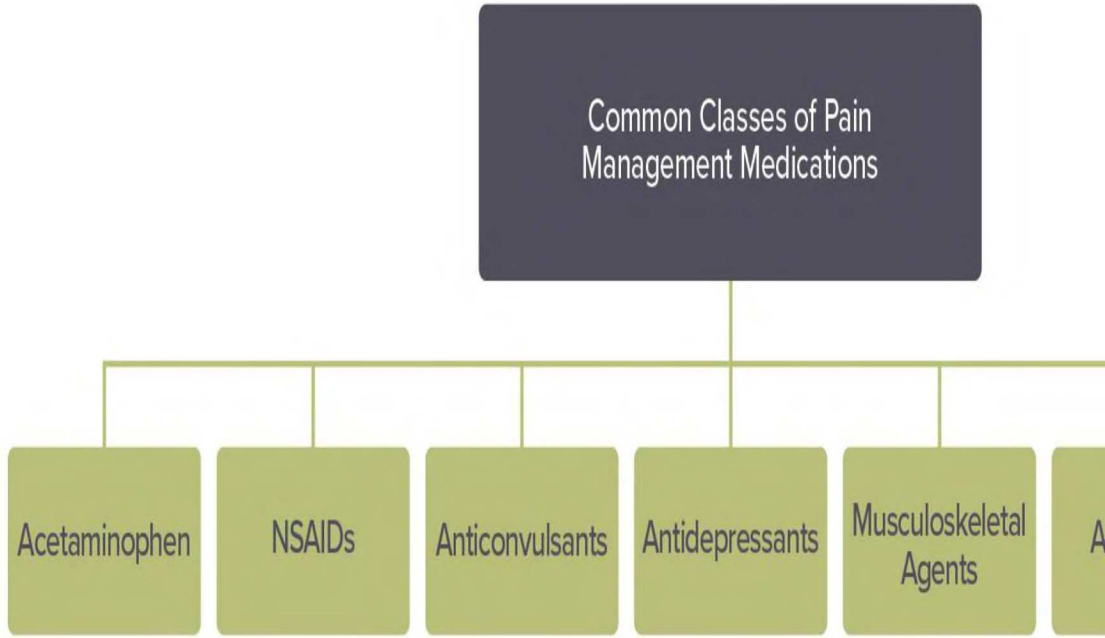
Risk-benefit analysis always recommended for any medication

2 Broad categories of medications used for pain management:

- Non-opioids
- Opioid classes of medications

Common non-opioid medications:

- Acetaminophen,
- NSAIDs
- Antidepressants (e.g., SNRIs, TCAs)
- Anticonvulsants,
- Musculoskeletal agents,
- Biologics,
- Topical analgesics and
- Anxiolytics



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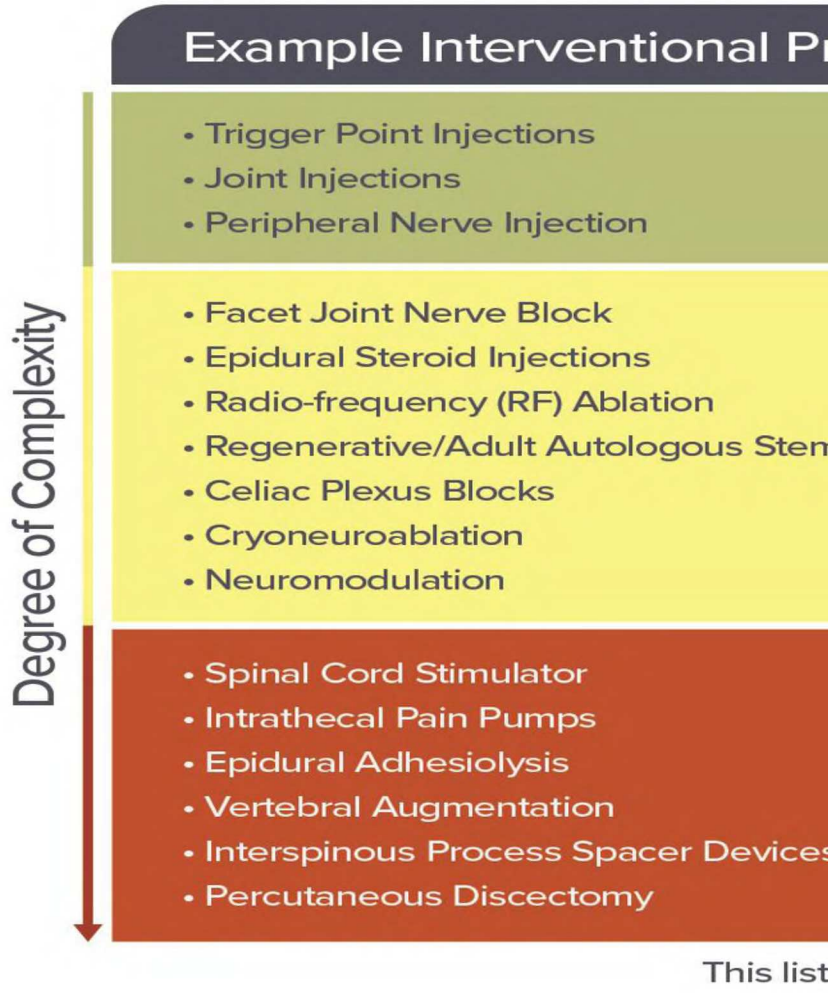
Interventional Procedures Vary by Degree of Complexity and Invasiveness

- Need: **well-researched interventional pain guidelines**
- Need: **Clinical research** to establish how interventional procedures work with other approaches
- Establish **criteria-based guidelines** for properly credentialing clinicians
- Encourage CMS and private payers:
  - Provide consistent and timely insurance coverage for interventional procedures



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Overcoming Barriers to Behavioral Health Approaches

Addressing barriers to **access to care** is essential to quality pain management:

- Clinical barriers (e.g. treatment access, provider attitudes)
- Health care system-related barriers (e.g. cost and reimbursement issues)
- Patient-related barriers (e.g. stigma, attitudinal variables).

When access and costs are limiting factors:

- Employ evidence-based, low-cost scalable approaches
  - E.g. **Telehealth and internet technologies**



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Complementary and Integrative Health Approaches

Complementary and Integrative Health (CIH) Approaches:

- Mind-body behavioral interventions
- Acupuncture
- Massage
- Meditative movement therapies (e.g., yoga, tai chi)
- Natural products

Need to address **barriers to acceptance** of CIH for pain:

- Improve reimbursement policies
- Improve education for medical professionals
- Greater workforce of pain management specialists



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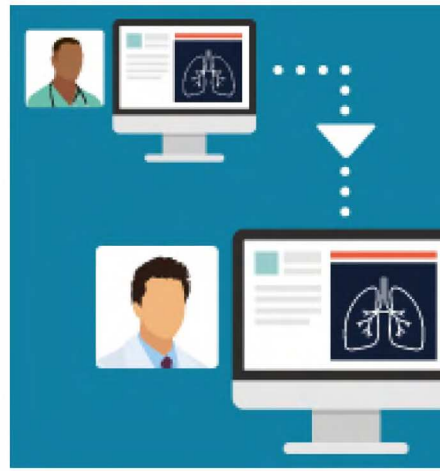
Innovative Delivery Systems, Research, and Special Populat

- **Innovative** solutions: e.g. telemedicine, tele-mentoring, mobile apps
- **Research** needed: mechanisms of pain, preventive measures, innovative medical devices and medications
- **Special populations:** pediatric, women, older adults, American Indians/Alaskan Natives, active duty soldiers/veterans, sickle cell disease (as an example of a chronic relapsing condition)





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Overdose Prevention & Naloxone, Medication Safe Storage Disposal, Acute Pain Guidelines, and Review of CDC Guide

- **Naloxone** use and preventing overdose
- **Safe Storage and Disposal** of medication, medication **shortages**
- **Guidelines** needed for acute pain and common surgeries
- **CDC Guideline** review: Recognize utility and contribution to mitigating opioid exposure. Also recognize misapplication and misinterpretation of guideline, including forced tapers and patient abandonment





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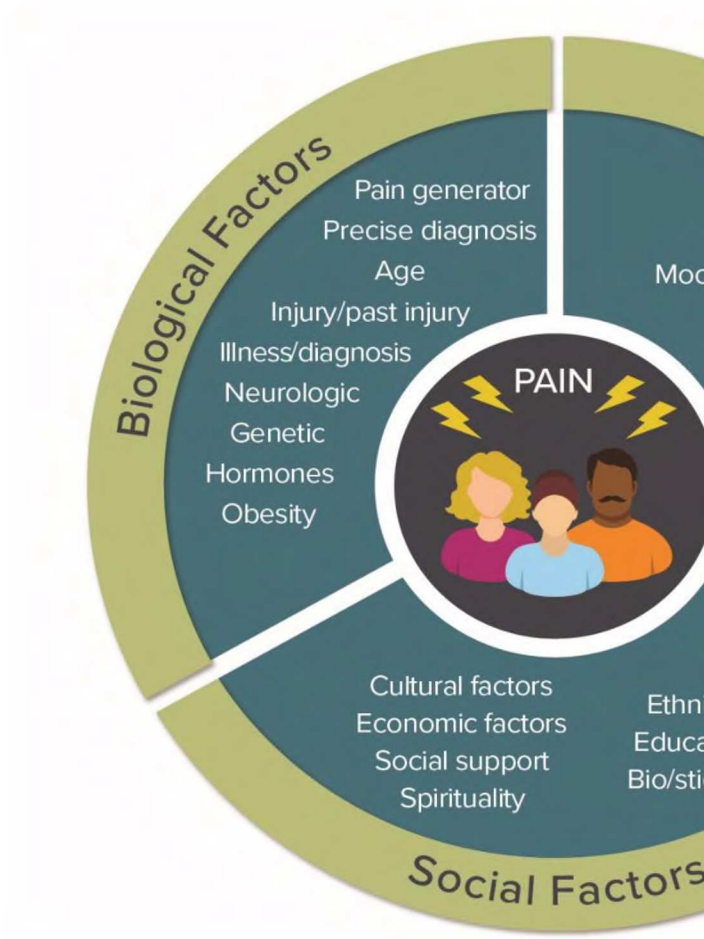
Approach to Pain Management: The Biopsychosocial Model of Pain Management

Key components of the **biopsychosocial model**:

- Biological Factors (e.g. diagnosis, age)
- Psychological factors (e.g. mood, stress)
- Social factors (e.g. social support, spirituality)

Aim to improve:

- Overall pain experience
- Physical functioning,
- Activities of daily living
- Quality of life (QOL)



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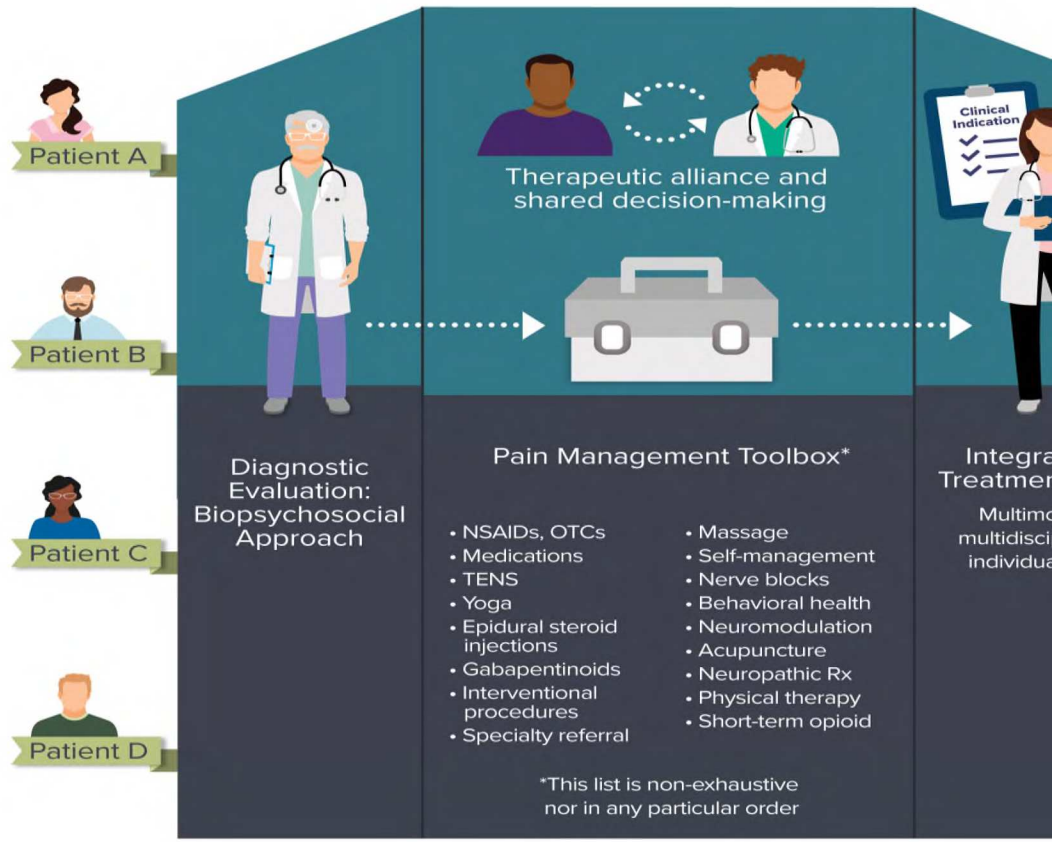
Individualized Patient Care for All Treatment Options

Individualized, patient-centered care best achieved:

- Diagnostic evaluation
- Biopsychosocial approach
- Access to needed treatment approaches

Resulting treatment plan, tailored to the specific needs of individuals requires a strong **patient-clinician relationship**:

- Mutual trust and respect
- Empathy
- Compassion
- Resulting in therapeutic alliance



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Public Comments to the Task Force Affirm the Barriers Stigma Creates

I have gone through, and exhausted all of the other drug and non-drug treatment options over the past 13 years. Still, I have pain. I hate that I am being treated like a drug abuser when I am just trying to make my life more manageable on a daily level. I try to participate in being part of our family, making a contribution to society, but it's hard. Not everyone who needs pain relief is an abuser.

- April 2019



How can a person be in pain for many years, unable to do the things he or she used to do without becoming depressed? Why does everyone assume the person was depressed or anxious first? Try having a serious heart condition knowing if you go to an ER for chest pain with or without extremely high blood pressure they probably will think you are seeking drugs

- June 2018





I was sent to a doctor after the last pain clinic in my county closed. He yelled at me, shamed me, and dehumanized me right in of front two other people.

- September 2018





My wife has Cervical Spinal Stenosis with Myelopathy. She was forced to taper in January of 2018. Within one month she was bed ridden and had talked to her employer explaining why she may have to quit her accounting job. I can't tell you how demoralizing this experience has been. We were immediately treated like second class citizens, accused of seeking drugs and the reason for the crippling, illicit, drug epidemic taking place on our streets.

- January 2019

I understand the abuse of pain meds, but not all of those who deal with chronic pain abuse them. I have always abided by pain contracts, been willing to submit UAS and yet still have had some pain doctors treat me as an addict because of the number of years I have been on pain meds. Trust is vital between a pain patient and their physician.

- May 2018



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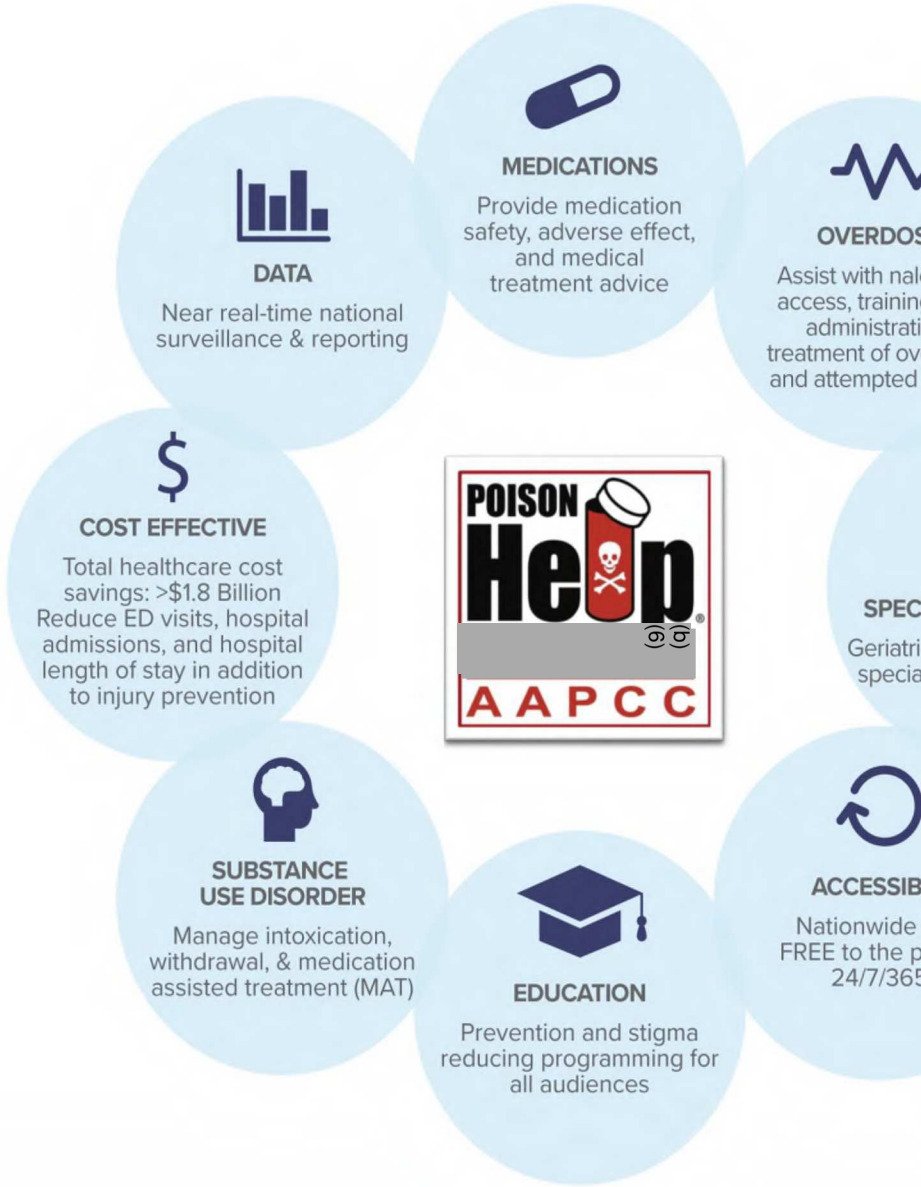
Value of Poison Control Centers

- Important for **patient safety**
- Available **24/7**
- Answer questions about:
  - Medication interactions,
  - Adverse effects,
  - Assess the need for emergency health care resources



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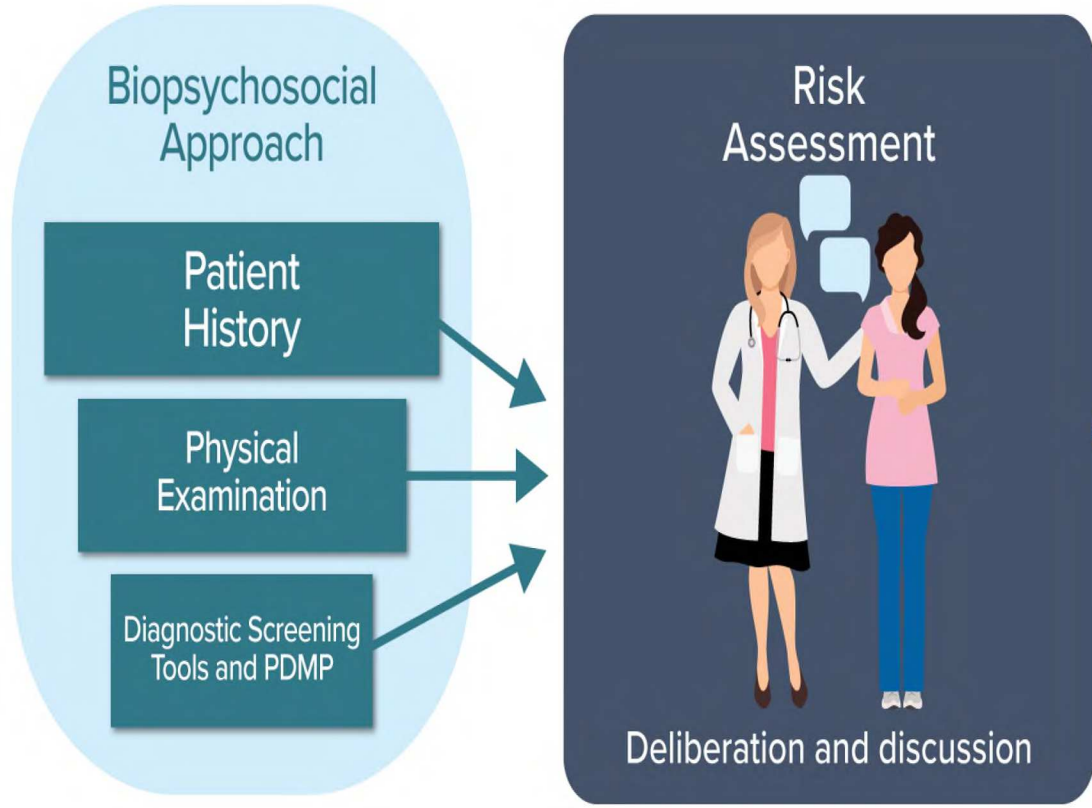
Risk Assessment for Risk-Benefit Analysis

Risk assessment:

- Comprehensive review of patient history
- Physical examination
- Diagnostic screening tools
- PDMPs

Patients and their Clinicians:

- Discuss potential **risks and benefits**
- Need **therapeutic alliance** to achieve best outcomes



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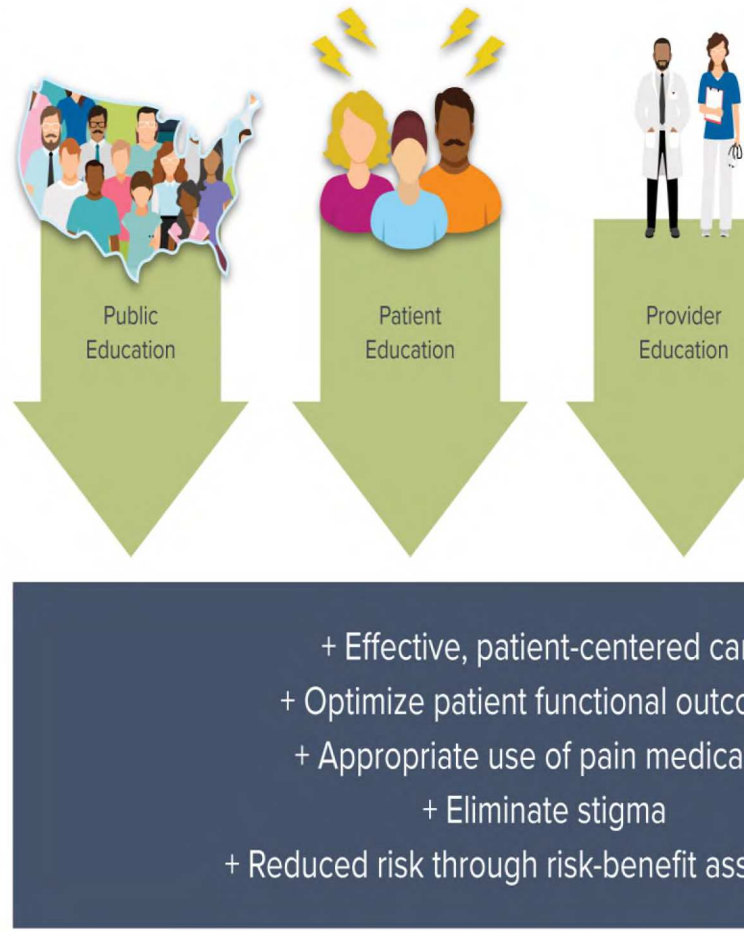
AMERICAN OVERSIGHT

Education Is Critical to the Delivery of Effective Patient-Centered Pain Care

- Effective **education and training at all levels of clinician training**, including:
  - Undergraduate educational curricula
  - Graduate professional training
  - Continuing professional education
- **Public and patient education** helps reduce barriers to treatment, including stigma
- **Education for policymakers** ensures future legislation properly addressing issues related to pain management, including:
  - Payment mechanisms
  - Controlled medications



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Get Involved & Stay Connected!

- The Task Force Report emphasizes the importance of **individu**
  patient-centered care that is relevant to a wide range of stake
  invested in helping patients with acute and chronic pain achie
  best quality of life.
- **It's Time to Implement.** The report is comprehensive and info
  yet approachable. There are items of interest for all stakehold

ONDCP-19-00243_000000021

AMERICAN OVERSIGHT

Access to office-based buprenorph
treatment: a secret shopper stu

Michael L. Barnett, MD, MS, Harvard Chan School of Public H

CEPOP Quarterly Meeting, July 29, 2019, Washingto

(b)(6) ml_barnett

ONDCP-19-00243_000000022

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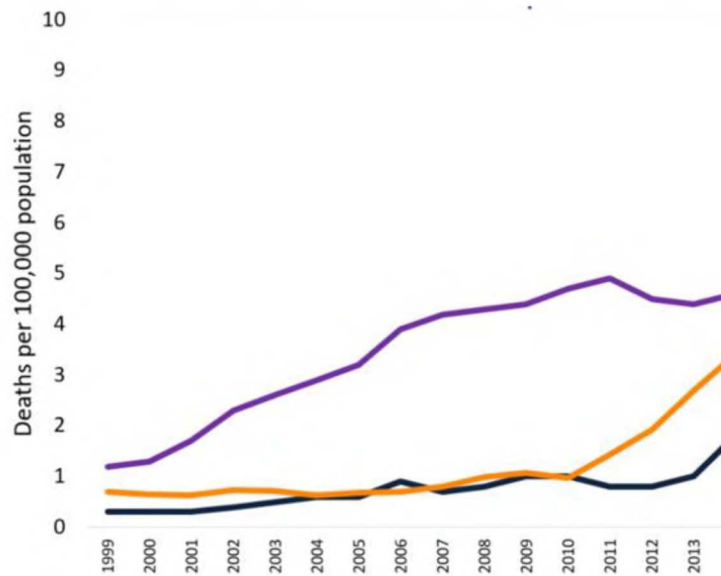
Background

- The opioid crisis continues to rage on
- Opioid substitution with buprenorphine or methadone can cut mortality from opioid use disorder (OUD) by over 50%
- But:
  - 80% of Americans with OUD have not received treatment in past year
  - Of those receiving treatment, 34% receive medication for OUD
- Therefore, improving access to medications for OUD is a public health priority



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Evidence Gap

- We know little about the real-world barriers patients seeking buprenorphine treatment face
  - Is it wait time?
  - Providers accepting new patients?
  - Providers accepting Medicaid?
- We know even less about *how* buprenorphine prescribers offer appointments to initiate buprenorphine
  - Ideally, should be offered ASAP without required contingency of intake appointment first



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Objective

Assess real-world access to buprenorphine treatmen
uninsured and Medicaid-covered patients reporting cu
heroin use

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Methods

- "Secret Shopper" audit survey of buprenorphine-waivered providers
  - Simulated patients seeking buprenorphine treatment for heroin use
  - Providers were each called twice:
    - 1) Uninsured/Cash-Pay patient
    - 2) Medicaid-covered patient
- Called publicly-listed providers on SAMHSA's website with unique p address combinations
- Sampled prescribers from 6 states with the highest opioid overdose in 2016
  - MA, NH, WV, OH, MD, DC

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Methods: Caller Script

- **Callers**: Two females called each clinic once on each payer arm
- **Patient Profiles**: 30 yrs. old, uses intravenous heroin daily, last use v prior, no medical or psychiatric history, no current medications
- **Script:** Asked to make appointment to start suboxone, if insurance accepted, when first opening is, whether it is possible to start medic same day
  - *No appointments were held* when getting off phone

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Methods: Outcomes Captured

1. Rates of new appointments offered
2. Wait times
3. Induction possibility at first visit
4. Cost for uninsured

- Outcome heterogeneity by patient and provider characteristics
  - Medicaid-Covered vs Uninsured / Cash-Pay
  - Provider credentials: MD vs NP/PA
  - Provider waiver status: 30, 100, & 275 patient capacity
  - Urban vs. rural location

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Results: Cohort Flow Diagram



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Results: Appointment Availability

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Offered Appointment n (%)	Total Contacts	Offered Appointme n (%)
Total	432	233 (54%)	417	258 (62%
Waiver Status				
30 (NP or PA)	114	80 (70%)	111	65 (59%)
30 (Physicians)	62	25 (40%)	55	26 (47%)
100	151	66 (44%)	146	91 (62%)
275	105	62 (59%)	105	76 (72%)
Location				
Urban	328	183 (56%)	316	203 (64%
Rural	104	50 (48%)	101	55 (54%

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Results: Induction Possible at First Visit

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Offered Appointment n (%)	Total Contacts	Offered Appointme n (%)
Total	432	117 (27%)	417	169 (41%
Waiver Status				
30 (NP or PA)	114	38 (33%)	111	37 (33%
30 (Physicians)	62	9 (15%)	55	10 (18%)
100	151	28 (19%)	146	59 (40%)
275	105	42 (40%)	105	63 (60%)
Location				
Urban	328	94 (29%)	316	127 (40%
Rural	104	23 (22%)	101	42 (42%

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Results: Wait Times

	Medicaid		Uninsured/Self-Pay	
Clinician Characteristics	Total Contacts	Wait Time in Days, Median (IQR)	Total Contacts	Wait Time in Median (IQ
Total	432	6 (2, 10)	417	5 (1, 9)
Waiver Status				
30 (NP or PA)	114	4 (1, 9)	111	4 (1, 7)
30 (Physicians)	62	3 (1, 10)	55	4 (3, 10)
100	151	7 (2, 11)	146	5 (2, 11)
275	105	7 (3, 11)	105	5 (1, 11)
Location				
Urban	328	6 (2, 10)	316	5 (1, 9)
Rural	104	6 (2, 11)	101	5 (1, 9)

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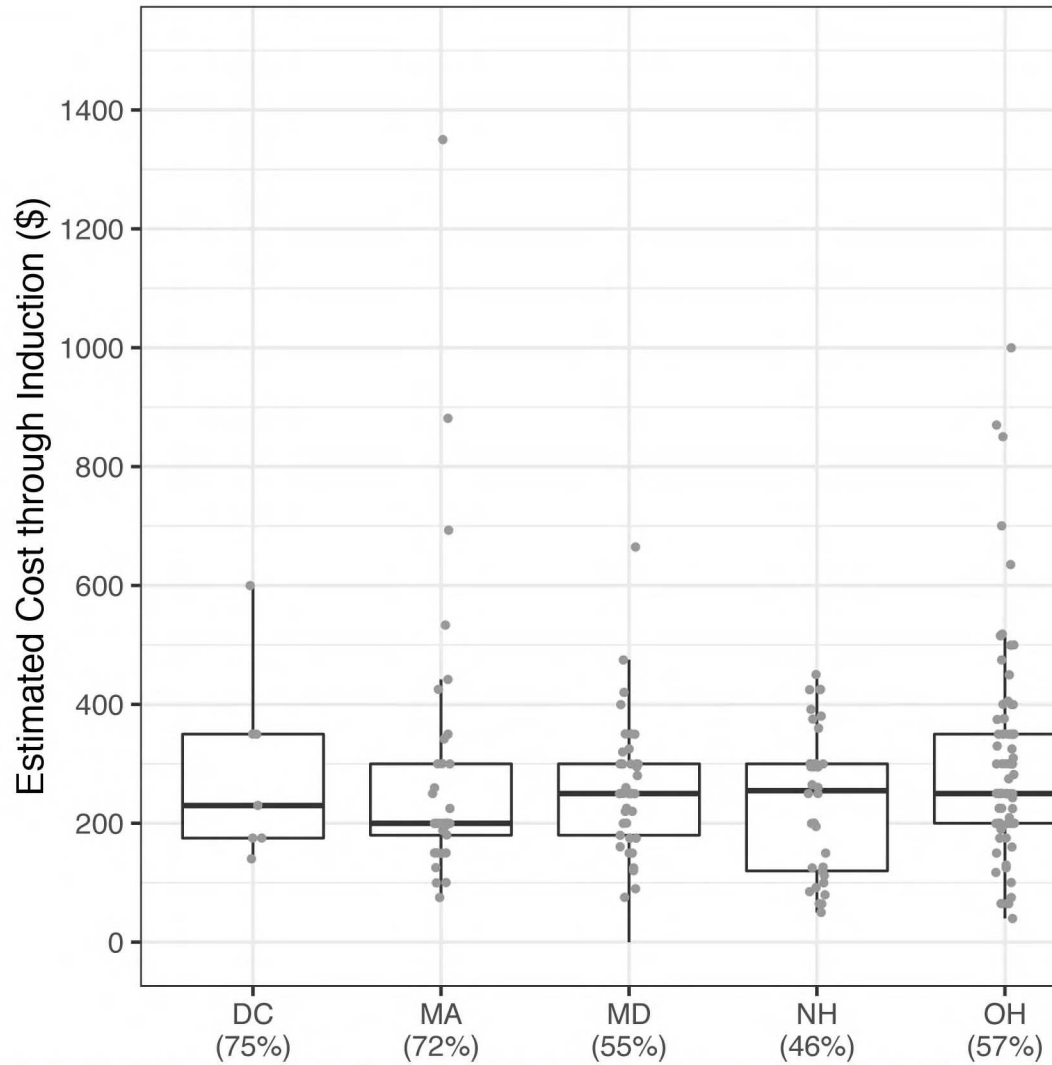
Results: Cash-Pay Cost

- Median price for cash-pay appointment was $250
- 5% of clinics had >$500 cost
- Little variation across states
- 54% of clinics had unknown additional lab charges



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Results Summary

- In 6 states with high opioid-related mortality, 38-46% of clinicians wi buprenorphine waivers not accepting new patients
  - Better access with NP/PAs and 275-patient waivered clinicians
  - The situation was worse for patients with Medicaid and in rural areas
- Of those accepting patients, only 50-66% allowed the possibility of ir on the first visit
- Surprisingly, among those accepting patients, wait times were genera than a week
- If paying with cash, visits are very expensive

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Conclusions and Policy Implications

- Simply finding a prescriber willing to take new patients is a significan
  - A second challenge is getting the prescription given that many prescribers prescribe on the first visit
- Among those accepting patients, wait times are not long, implying ur capacity

Policy implications

- We need improved methods to connect patients with prescribers, e enhanced online directories
- Paying more for addiction treatment would likely increase Medicaid acceptance

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Thank you! Any questions?

- [redacted]
- [redacted]t
- Grant Support:
  - National Institute on Aging
  - National Institute on Drug Abuse
- Thanks to co-authors:
  - Tamara Beetham (HSPH → Yale)
  - Brendan Saloner (Johns Hopkins)
  - Sarah Wakeman (MGH)
  - Marema Gaye (HSPH)

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Appendix

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	Number of Contacts with Response per Provider, n (%)			Total
	0	1	2	
Waiver Capacity				
30 (NP or PA)	19 (13%)	22 (15%)	109 (73%)	150
30 (Physician)	27 (29%)	11 (12%)	55 (59%)	93
100	21 (11%)	39 (20%)	132 (69%)	192
275	10 (9%)	17 (15%)	84 (76%)	111
State				
Washington DC	12 (32%)	8 (22%)	17 (46%)	37
Massachusetts	12 (11%)	20 (19%)	73 (70%)	105
Maryland	20 (20%)	13 (13%)	69 (68%)	102
New Hampshire	6 (8%)	14 (19%)	53 (73%)	73
Ohio	16 (12%)	23 (17%)	98 (72%)	137
West Virginia	11 (12%)	11 (12%)	70 (76%)	92
Urban/Rural Location[1]				
Urban	66 (16%)	72 (17%)	286 (67%)	424
Rural	11 (9%)	17 (14%)	94 (77%)	122
Years Since Initial Waiver for Physicians				
Below median (<6)	27 (15%)	34 (19%)	118 (66%)	179
Median and greater(≥6)	31 (14%)	33 (15%)	153 (71%)	217
Total	77 (14%)	89 (16%)	380 (70%)	546

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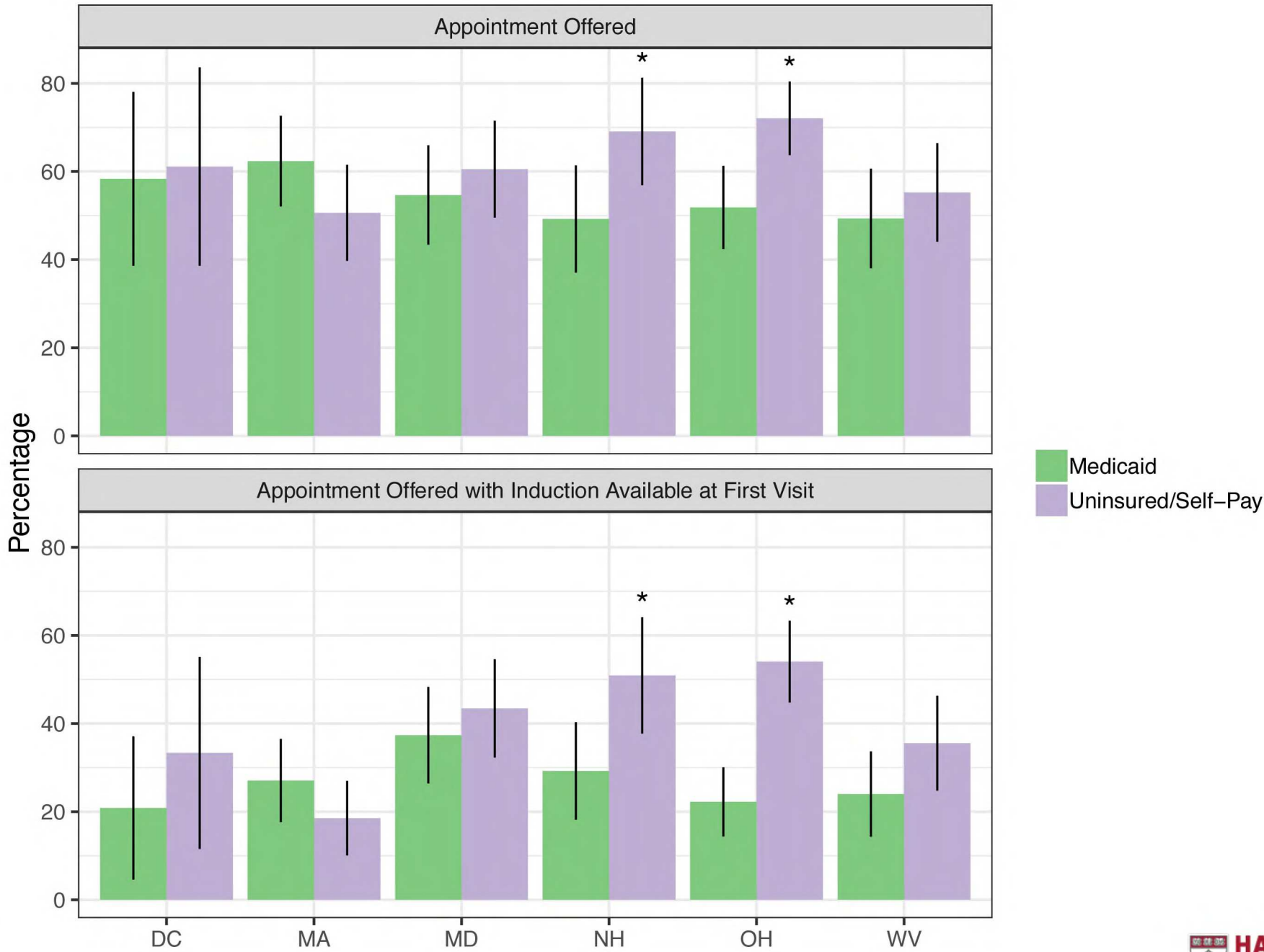

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No Appointment Reasons by State

State	Payer Status Not Accepted (n, %)	Not Accepting New Patients (n, %)	Waitlist (n, %)	Other (n, %)	Total (n)
Total	158 (44%)	130 (36%)	61 (17%)	9 (3%)	358
Washington DC	5 (29%)	12 (71%)	0 (0%)	0 (0%)	17
Massachusetts	31 (43%)	30 (42%)	8 (11%)	3 (4%)	72
Maryland	35 (55%)	23 (36%)	5 (8%)	1 (2%)	64
New Hampshire	14 (28%)	25 (50%)	7 (14%)	4 (8%)	50
Ohio	50 (60%)	23 (28%)	9 (11%)	1 (1%)	83
West Virginia	23 (32%)	17 (24%)	32 (44%)	0 (0%)	72

ONDCP-19-00243_000000022

CEPOP
COLLABORATIVE FOR
EFFECTIVE PRESCRIPTION OPIOID POLICIES

VIA ELECTRONIC DELIVERY

The Honorable Richard Shelby
Chairman
Committee on Appropriations
United States Senate
304 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Patrick Leahy
Ranking Member
Committee on Appropriations
United States Senate
437 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Roy Blunt
Chairman
Subcommittee on Labor, Health and Human Services, Education and Related Agencies
United States Senate
260 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Subcommittee on Labor, Health and Human Services, Education and Related Agencies
United States Senate
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Jerry Moran
Chairman
Subcommittee on Commerce, Justice, Science and Related Agencies
United States Senate
521 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Jeanne Shaheen
Ranking Member
Subcommittee on Commerce, Justice, Science and Related Agencies
United States Senate
506 Hart Senate Office Building
Washington, D.C. 20510

The Honorable John Kennedy
Chairman
Subcommittee on Financial Services and General Government
United States Senate
416 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Christopher Coons
Ranking Member
Subcommittee on Financial Services and General Government
United States Senate
218 Russell Senate Office Building
Washington, D.C. 20510

Thursday, July 25, 2019

Dear Chairmen and Ranking Members:

As participants in the Collaborative for Effective Prescription Opioid Policies (CEPOP; www.CEPOPonline.org), we are writing in support of robust funding for the below programs to address the national opioid epidemic. Together, these programs will increase access to comprehensive prevention, treatment and recovery services and will help save lives.

CEPOP is a diverse group of more than 80 stakeholders – interested in the manufacture, distribution, appropriate use of opioid and non-opioids medications, non-pharmacologic interventions, medication-assisted treatment and

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disposal of unused and unwanted prescription drugs – who have joined together to work toward a comprehensive and balanced policy strategy to prevent misuse, abuse, diversion and promote treatment and recovery options. We support effective programs, strategies and policies to help prevent prescription painkiller misuse and overdose while ensuring patients' access to safe effective pain treatment.

The opioid epidemic continues to devastate American communities from coast to coast. This continued devastation highlights the need for further investment in prevention as well as treatment if we are to turn the tide. Opioid overdoses (including prescription opioids, heroin and fentanyl) led to the deaths of more than 47,600 Americans in 2017, eclipsing any year on record. That is nearly six times higher than the number of opioid overdose deaths in 1999 (8,048). An average of 130 people a day die from an opioid overdose. While preliminary data for 2018 indicates the first decline in overdose deaths in nearly three decades, we cannot be stagnant in our response as much work is yet to be done.

We appreciate the Committee's ongoing commitment to providing much needed resources to address the opioid epidemic. As you work to craft FY 2020 appropriations legislation, we respectfully urge you to consider the following recommendations:

Labor-HHS-Education and Related Agencies Appropriations Act (LHHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)[1]:

- **Substance Abuse Prevention and Treatment (SAPT) Block Grant:** The Substance Abuse Prevention and Treatment (SAPT) Block Grant Program serves as the foundation of the publicly funded prevention, treatment and recovery system. In particular, the SAPT Block Grant distributes funds to 60 eligible states, territories, the District of Columbia, and the Red Lake Band of Chippewa Indians of Minnesota to support critical substance abuse prevention, treatment and recovery support services for the nation's most vulnerable. Federal investments in the SAPT Block Grant have not kept up with inflation. We urge the Committee to provide an increase for the SAPT Block Grant in FY20 over the FY19 level of $1.858 billion to help states meet the increasing need for prevention, treatment, and recovery strategies and services.
- **Center for Substance Abuse Treatment (CSAT):** SAMHSA's Center for Substance Abuse Treatment is dedicated to expanding access to high quality treatment and recovery services, including access to Medication Assisted Treatment when appropriate. According to the National Survey on Drug Use and Health, 21.5 million people aged 12 or older needed treatment for an alcohol or illicit drug use problem in 2014. During the same year, more than 4 million received treatment for such a problem. That means 17.5 million Americans needed but did not receive services for a substance use problem. We urge the Committee to provide, at a minimum, the House-passed level of $405.4 million (level funding) for CSAT in FY20.
- **Center for Substance Abuse Prevention (CSAP):** SAMHSA's Center for Substance Abuse Prevention (CSAP) brings evidence-based prevention programs and strategies to every state and sub-state regions nationwide. Its discretionary grant programs target states, communities, organizations, workplaces and families to promote resiliency, promote protective factors, and reduce risk factors for substance use. We urge the Committee to provide, at a minimum, the House-passed level of $$212,469,000 for CSAP in FY20, as we must increase our efforts to address effective prevention to stop misuse before it ever starts.

[1] All requested levels of funding should not be taken out of other existing Substance Abuse and Mental Health Services Administration line items that support individuals living with mental illness or substance abuse, including those with co-occurring disorders.

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- **State Opioid Response (SOR) Grants:** Congress authorized (via the 21st Century Cures Act) and reauthorized (via the SUPPORT for Patients and Communities Act) grants to States to enhance prevention, treatment and recovery programs and services to address the opioid crisis. States are required to outline gaps in services, identify evidence-based implementation strategies and report progress on categories such as opioid related overdose deaths. We urge the Committee to provide the House-passed level of $1.5 billion in FY20.

Centers for Disease Control and Prevention (CDC), Injury Center: The CDC uses data and prevention strategies to help track trends in the epidemic, identify problem areas, and help states strengthen and evaluate prevention efforts. CDC is also equipping health care providers with data and tools needed for appropriate opioid prescribing. Through the Opioid Prevention in States effort, CDC works with 45 states and the District of Columbia. CDC provides scientific expertise, enhanced surveillance activities, and support resources to quickly report fatal and non-fatal overdoses; identifies hot spots and responds with targeted resources; and identifies risk factors for overdoses and shares data to improve prevention responses. We are pleased that as part of the FY18 Omnibus appropriations package, the CDC received a $350 million funding increase, with specific mention around CDC promotion of PDMP use and expansion of efforts to make PDMPs "more interconnected, real-time, and usable for public health surveillance and clinical decision making." In FY20 we request the House-passed $475.5 million.

National Institute on Drug Abuse (NIDA): The National Institute on Drug Abuse (NIDA), within the National Institutes of Health (NIH), seeks to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. NIDA is investing resources in a variety of initiatives in order to help address the opioid crisis. This includes support of research related to medication assisted treatment (MAT), the misuse of prescription opioid pain relievers by high schoolers, addressing opioid use disorders in the criminal justice system. In addition, NIDA has a critical role in implement the NIH-HEAL Initiative (Helping to End Addiction Long-Term) initiative which seeks to accelerate research-based solutions to the opioid crisis. We recommend the House-passed level of $1.489 billion for NIDA in FY20.

Commerce-Justice-Science Appropriations Act

Hal Rogers PDMP Grant Program: PDMPs are a critical tool for addressing prescription drug abuse, yet PDMP capabilities vary widely by state. The Rogers PDMP Program is a discretionary, competitive grant program administered through the Justice Department, Bureau of Justice Assistance. The Rogers grants are intended to enhance the capacity of regulatory and law enforcement agencies and public health officials to collect and analyze controlled substance prescription data and other scheduled chemical products through a centralized database administered by an authorized state agency. We recommend at minimum the House-passed level of $30 million (level funding) for the Rogers PDMP program in FY20.

Edward Byrne Memorial Justice Assistance Grant (JAG) Program: The JAG program provides states and local governments with funding necessary to support a range of program areas including law enforcement, prosecution and court programs including indigent defense, prevention and education programs, corrections and community corrections, drug treatment and enforcement, and planning, evaluation and technology improvement programs. States are investing in strategies to improve outcomes for justice-involved individuals with mental illness and substance use disorders. Yet funding for the Byrne JAG program has dropped by about one-third in recent years. We recommend at least the House-passed level of $530 million for this critical program.

Drug Enforcement Administration (DEA): The DEA is a key federal agency in the effort to reverse the opioid epidemic for prescription drug abuse, misuse, and diversion. CEPOP supports the agency's engagement in the

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National Take-Back Initiative, as well as the innovative 360 Strategy program. We recommend that the Committee include, at minimum, the House-passed level of $2.36 billion in FY20.

Financial Services and General Government Appropriations Act

Drug-Free Communities (DFC) Grant Program: The Drug-Free Communities Grant Program (DFC) is administered by the Office of National Drug Control Policy and provides support for communities to identify and respond to all local substance use and misuse issues. DFC grantees have reduced substance use and misuse in funded communities throughout the country to levels lower than national averages because they are organized, data driven and take a comprehensive, multi-sector approach to solving and addressing these issues. DFC coalitions are uniquely situated to deal with emerging drug trends, such as prescription drug abuse, because they have the infrastructure in place to effectively address any drug related issues within their communities. We recommend, at a minimum, the House-passed level of $100.5 million for the DFC program in FY20.

Community-Based Coalition Enhancement Grants: CARA's prevention provision, Section 103, is purposefully drafted to build on the effective DFC community-based infrastructure to help communities address local opioid crises. DFC grantees are maximally prepared and proven effective in preventing and addressing all alcohol, tobacco, and drug issues, as they engage in evidence-based, comprehensive, multi-component strategies across all community sectors to achieve population-level decreases in substance use rates. Providing enhancement grants to existing DFC grantees to specifically deal with stopping opioid initiation before it ever starts is critical because DFC grantee coalitions already have the necessary infrastructure and expertise to most cost-effectively prevent prescription drug misuse from ever starting. We request at a minimum, the House-passed level of $5 million in FY 2020, which is the full authorized level for this program.

Together, these programs will help expand prevention efforts to reduce opioid misuse and promote access to life-saving treatment and recovery services, rescue medications and other resources integral to the national effort to combat the opioid epidemic. A comprehensive approach is the only way we will reverse the substance misuse epidemic. Please do not hesitate to leverage the undersigned organizations as resources in the future. Thank you for your consideration of these comments.

Sincerely,

[Insert Undersigned Organizations]

DRAFT

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ONDCP-19-0922-A-000450_ONDCP042FY18043_000000023

[EXTERNAL] CEPOP All-Participants Teleconference (September 2019)

Where:	WebEx; (b)(6) // 627 917 857
When:	Mon Sep 23 15:00:00 2019 (America/New_York)
Until:	Mon Sep 23 16:00:00 2019 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	"Rubin, Matthew J." <(b)(6) "Derek Naten (MNK)" <(b)(6) "Gen. Arthur Dean" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Mary Bono <(b)(6) "Rachael Cooper (NSC)" <(b)(6) Richard Hamburg <(b)(6) Rob Morrison <(b)(6) "Sue Thau (Gmail)" <(b)(6) Van Ingram <(b)(6) "Whitney Taylor (Integritas)" <(b)(6) "Zook, David R." <(b)(6) Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) "Amber Landis (Spectrum Health)" <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Brian Bowden <(b)(6)

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"Stephanie Pellitt (NCBH)" <(b)(6)
Steve Passik <(b)(6)
Sue Thau <(b)(6)
Susan Awad <(b)(6)
Teresa Baker <(b)(6)
"Terry Malefant (RCOA)" <(b)(6)
"Terry McGeeney, MD, MBA" <(b)(6)
"Tom Supinka (NSC)" <(b)(6)
Tracie Thomas <(b)(6)
"Valerie Brankovic (NACo)" <(b)(6)
Vince Ventimiglia <(b)(6)
Wade Delk <(b)(6)
"William Hibbs (Alkermes)" <(b)(6)

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CEPOP All-Participants Meeting Logistics (September 2019)

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  - **Participant Code:** (b)(6)

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[EXTERNAL] CEPOP All-Participants Teleconference (September 2019)

Where:	WebEx; (b)(6) // 627 917 857
When:	Mon Sep 23 15:00:00 2019 (America/New_York)
Until:	Mon Sep 23 16:00:00 2019 (America/New_York)
Organiser:	"Rubin, Matthew J." <(b)(6)
Required Attendees:	"Derek Naten (MNK)" <(b)(6) "Gen. Arthur Dean" <(b)(6) "Kevin Webb (MNK)" <(b)(6) Mary Bono <(b)(6) "Rachael Cooper (NSC)" <(b)(6) Richard Hamburg <(b)(6) Rob Morrison <(b)(6) "Sue Thau (Gmail)" <(b)(6) Van Ingram <(b)(6) "Whitney Taylor (Integritas)" <(b)(6) "Zook, David R." <(b)(6) Aiken Hackett <(b)(6) "Alexander, Tesfa" <(b)(6) Alice Dembner <(b)(6) Amanda Sears <(b)(6) "Amber Landis (Spectrum Health)" <(b)(6) Amy Callendar <(b)(6) Andrew kessler <(b)(6) Aryka Chapman <(b)(6) Blair Clark-Schoeb <(b)(6) "Blaire Bryant (NACo)" <(b)(6) Brad Tallamy <(b)(6) "Brandee Izquierdo (SAFE Project)" <(b)(6) Brian Bowden <(b)(6) "Cara Moon (Egalet)" <(b)(6)

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Caren Kagan Evans <(b)(6)
Carol Thornton <(b)(6)
"Carrier Latimer (Hirons)" <(b)(6)
"Celia Hagan (NILA)" <(b)(6)
Charlie Cichon <(b)(6)
Chris Zimmerman <(b)(6)
"Christian, Jeanine M" <(b)(6)
Chuck Ingoglia <(b)(6)
"Clay Alspach (b)(6) <(b)(6)
Courtney Hunter <(b)(6)
"Cristi L. Schwarcz" <(b)(6)
Dan Buffington <(b)(6)
Daniel Raymond <(b)(6)
"Danna Droz (NABP)" <(b)(6)
"David Bilardello (Spectrum Health)" <(b)(6)
David May <(b)(6)
"Deana Haworth (Hirons)" <(b)(6)
"Deb Waugh (Affiliated Monitors)" <(b)(6)
"Deni Carise (RCoA)" <(b)(6)
Dennis Brennan <(b)(6)
"Donald A. Lohman (MNK)" <(b)(6)
Donald Hoppert <(b)(6)
"Dr. Anita Gupta" <(b)(6)
"Spitznas, Cecelia M. EOP/ONDCP" <(b)(6)
"Dr. Elizabeth Salisbury-Afshar" <(b)(6)
"Dr. Jack Stein" <(b)(6)
"Dr. John Harrison" <(b)(6)
"Dr. Renan Castillo" <(b)(6)
"Dr. Stuart Gitlow" <(b)(6)
Ed Kaleta <(b)(6)
Eli Briggs <(b)(6)
Elizabeth Solhtalab <(b)(6)
"Emily Diehl (NASADAD)" <(b)(6)
Erika Long <(b)(6)
"Evans, Daniel F." <(b)(6)
"Gabriella Witte (APHA)" <(b)(6)

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Gabrielle de la Gueronniere <(b)(6)
Gary Mendell (b)(6)
"Gena Fitzgerald (SAFE Project)" <(b)(6)
Hadi Sedigh <(b)(6)
"Hanson, Roberta J." <(b)(6)
"Ian Goldstein (NACCHO)" <(b)(6)
James Appleby <(b)(6)
Jane Terry <(b)(6)
"Jasey Cardenas (AAAP)" <(b)(6)
Jason Sundby <(b)(6)
Jeremiah Lindemann (b)(6)
"Jessica Johnston (BD)" (b)(6)
John Donahue <(b)(6)
Josie Beets <(b)(6)
Judi Lund Person (b)(6)
Julian Hoffman <(b)(6)
Karen Tracy <(b)(6)
Kate Berry <(b)(6)
Kate McFadyen <(b)(6)
Kathleen O'Conner <(b)(6)
"Kathryn L. Cates-Wessel" <(b)(6)
"Kevin Roy (Shatterproof)" (b)(6)
Kevin Walker <(b)(6)
Keysha Brooks-Coley <(b)(6)
"KJ Hertz (March of Dimes)" <(b)(6)
Kristi Thompson <(b)(6)
"Lisa Luskin (Recovery COA)" <(b)(6)
Lorraine Yarde <(b)(6)
"Lynette Bradley-Baker (AACP)" <(b)(6)
"Malka Berro (NCBH)" <(b)(6)
Marcia Lee Taylor <(b)(6)
Mary Winnefeld <(b)(6)
Melissa Ough <(b)(6)
Michael DeGeorge <(b)(6)
Mike Smith <(b)(6)
Nick Motu <(b)(6)

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Nicole Burda <(b)(6)
"Patel, Beena S." <(b)(6)
Patricia Bruckenthal <(b)(6)
Patricia D'Antonio <(b)(6)
Patricia Farley <(b)(6)
"Patty McCarthy (FaVoR)" <(b)(6)
Paul Ross <(b)(6)
"Rachel Rivera (<(b)(6)
<(b)(6)
Rebecca Farley <(b)(6)
Rebecca Slater Abbott <(b)(6)
Rita Norton <(b)(6)
Robert Forman <(b)(6)
"Robin Swift (<(b)(6) <(b)(6)
Samantha Arsenault <(b)(6)
"Sarah Nerad (Alkermes)" <(b)(6)
Scott Proescholdbell <(b)(6)
Shalini Wickramatilake <(b)(6)
Shelley Starkey <(b)(6)
Sonya Clay <(b)(6)
"Stephanie Marshall (ACPM)" <(b)(6)
"Stephanie Pellitt (NCBH)" <(b)(6)
Steve Passik <(b)(6)
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