

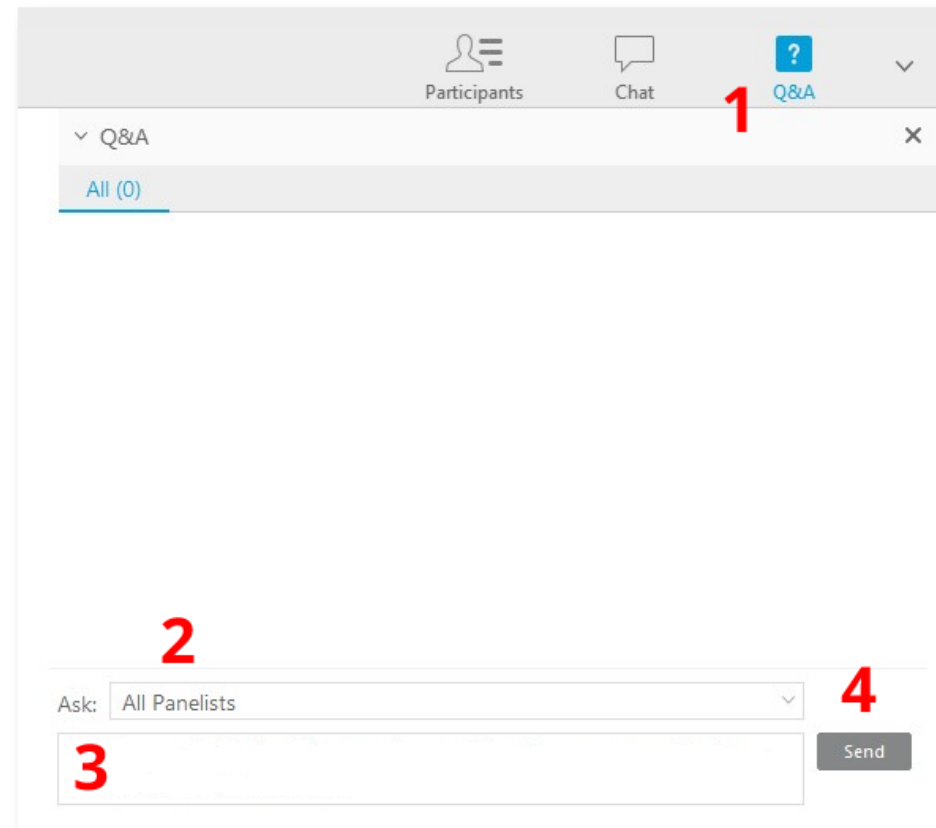
Emergency Declarations to Address the Opioid Crisis: Assessing Impact and Identifying Gaps

September 19, 2017

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 - Health information exchange
 - Obesity prevention and control
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 - Alcohol and drug abuse prevention
 - Affordable Care Act and Medicaid

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 - Public health licensing
 - Disease control



Emergency Declarations to Address the Overdose Crisis

Corey Davis

September 19, 2017

Background

- » Opioids can be beneficial for some post-surgical pain, cancer pain, HIV pain, palliative care
- » Extremely useful for treatment of opioid addiction
- » Limited, no, or negative evidence for opioid therapy for chronic back pain, osteoarthritis, rheumatoid arthritis, chronic non-cancer pain, headache, fibromyalgia
- » For most people, opioids are not superior to non-opioid therapy for most chronic and some acute pain



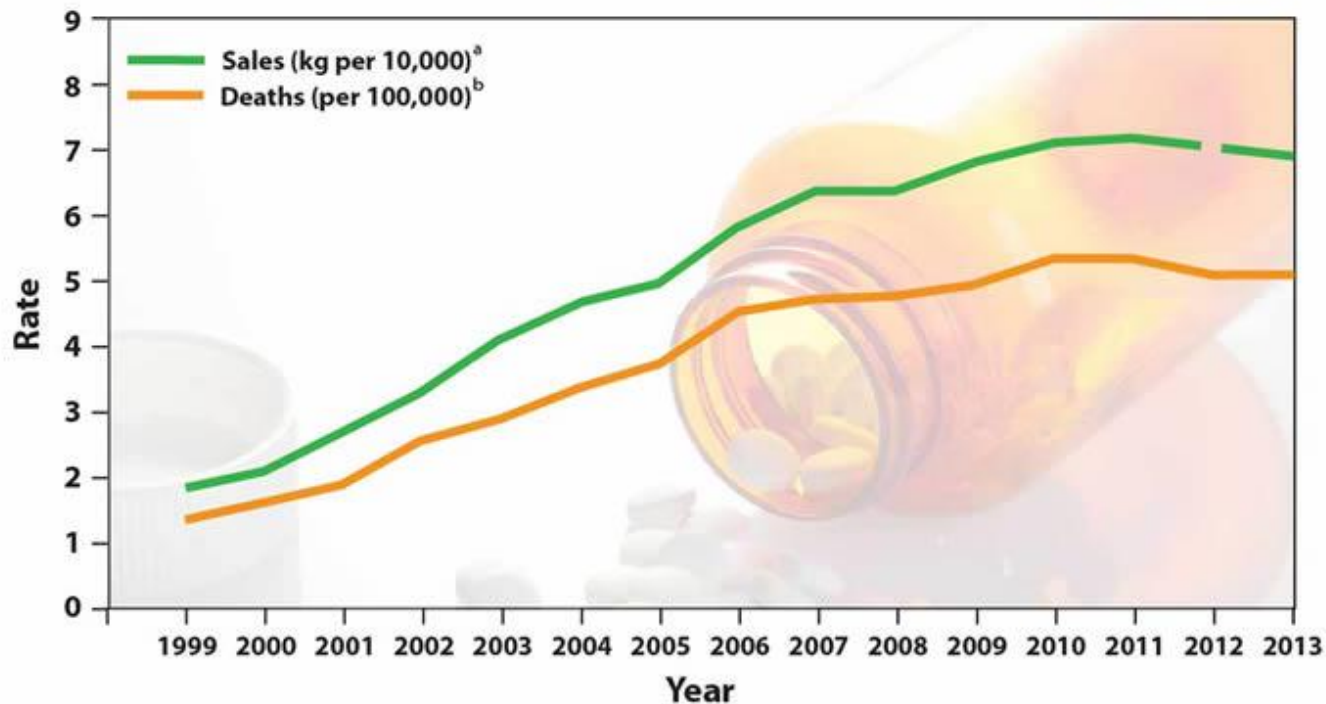
Pain and OD-related inequities

- » Women report higher rates of pain than men
- » Lower-income Americans more likely to be injured OTJ, and less likely to be insured
- » Hispanic and Latino Americans 22% less likely to be prescribed opioid analgesics than Whites; African-Americans 29% less likely
- » POC less likely to be insured, more likely than whites to be arrested and convicted for drug crimes
- » Pain is important! Problem is opioids are often not a great solution.



More opioids = More opioid OD

Prescription Painkiller Sales and Deaths



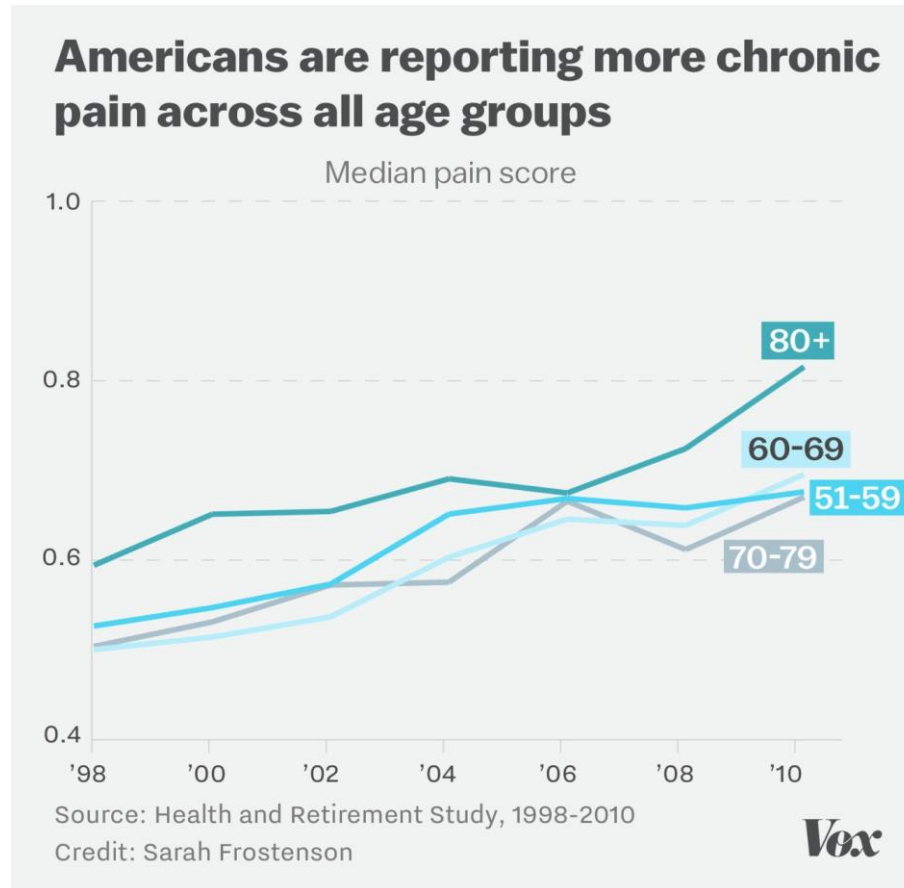
Sources:

^aAutomation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2012 data not available.

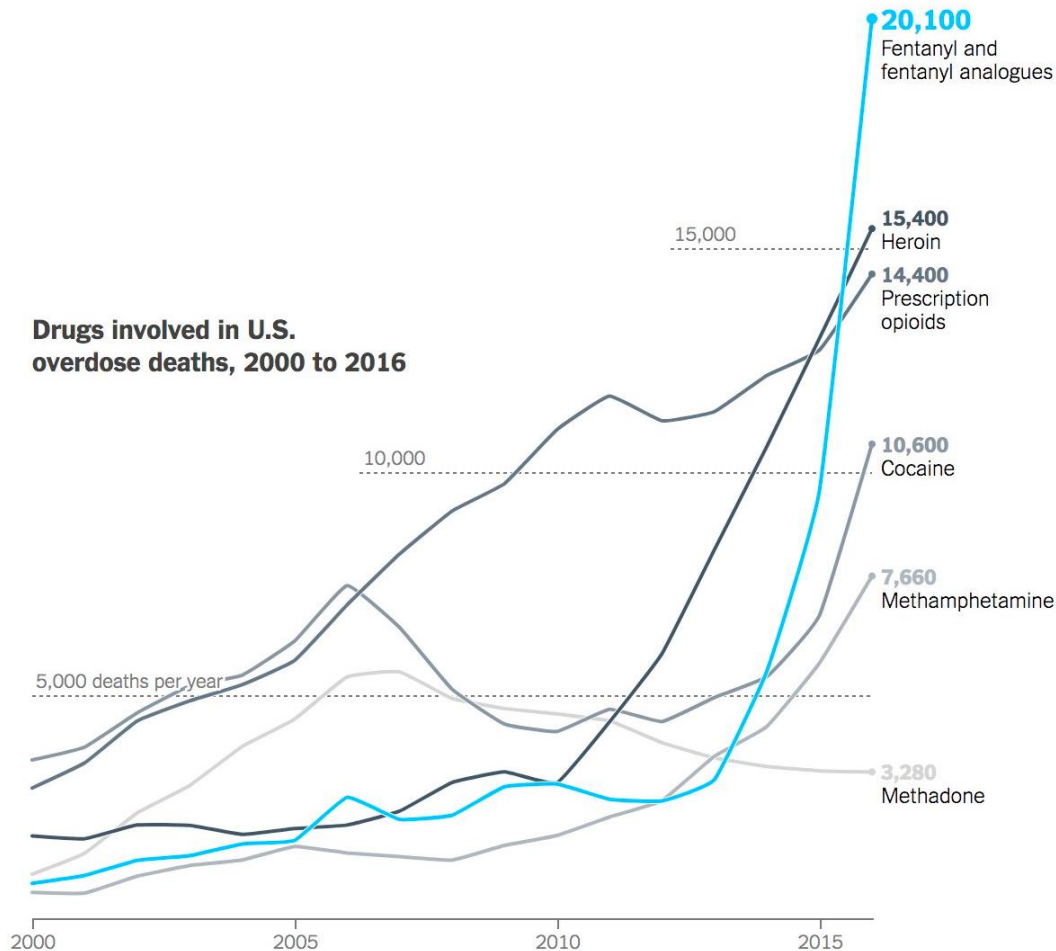
^bCenters for Disease Control and Prevention. National Vital Statistics System mortality data. (2015) Available from URL:

<http://www.cdc.gov/nchs/deaths.htm>.

Pain going up



Deaths going up



Law and policy matter.. But it's complicated.

- » Data aren't that great
Although they're getting better
- » Lots of signaling, but powerful actors aligned against meaningful change
Remember, smoking still kills 480k/yr in US
- » Backdrop of American health and political systems
- » CARA, CURES, ACA all helping – but small % of overall spending

CURES Act

\$1 billion in grants to states for FYs 2017 and 2018

| Program Name | Funding Appropriated | Period | Purpose |
|---|---------------------------------------|-----------|--|
| Priority Mental Health Needs of Regional and National Significance Program | \$394.550 million | 2018-2022 | Support of prevention, treatment, and rehabilitation of mental health services |
| Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program | \$333.806 million | 2018-2022 | Improvement of quality and availability of treatment and rehabilitation services for SUD services in targeted areas |
| Community Mental Health Services Block Grant | \$532.571 million | 2018-2022 | Provision of community mental health services for individuals with serious mental illness and emotional disorders |
| Substance Abuse Prevention and Treatment Block Grant | \$1.858079 billion | 2018-2022 | Training for SUD prevention and treatment professionals on trends in drug abuse and evidence-based practices |
| Grants for Jail Diversion Programs | \$4.269 million for each fiscal year | 2018-2022 | Development and implementation of jail diversion programs to divert individuals with mental illness from the criminal justice system to community-based services |
| Projects for Assistance in Transition from Homelessness | \$64.635 million for each fiscal year | 2018-2022 | Provision of services to homeless individuals with serious mental illness and SUD |
| Youth Suicide Early Intervention and Prevention Strategies Grant | \$30 million for each fiscal year | 2018-2022 | Initiation of youth suicide prevention activities and provision of resources to reduce the burden of suicidal behaviors among youth |

Law and policy matter

» **Do PDMPs work?**

Maybe, but it's complicated

» **Does naloxone work?**

Yes, but it costs money (and PWUD are icky)

» **Does evidence-based tx work?**

Yes, but it costs even more money

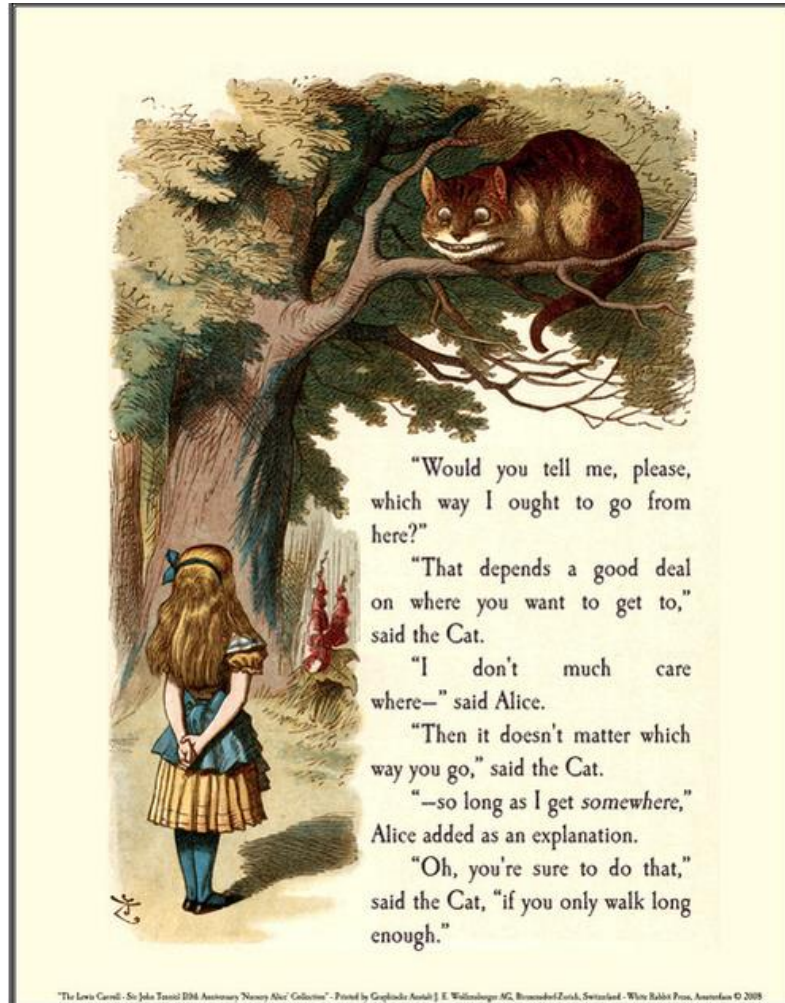
» **Does arresting people work?**

No, but Americans love putting humans in cages

» **Do lawsuits work?**

Dunno, do you think the MSA worked?

Where are we trying to go?



Policy Intervention Continuum

Reduce improper prescribing

- Prescriber and dispenser education
- Insurance changes
- Professional regulation
- PDMPs?
- Prescribing guidelines?
- Marketing restrictions
- Maybe put some execs in jail?
- Develop non-opioid analgesics

Treat SUD/Addiction

- Increased \$ and insurance coverage for evidence-based treatment and non-opioid pain therapy
- Ban ineffective “treatment”
- Increase number of adx/mh providers
- Stop arresting patients
- Expand medicaid/parity reqs

Improve access to overdose care

- Naloxone access laws
- Good Samaritan 911 laws
- Community education
- Reduce naloxone cost
- OTC naloxone?

Summary

- » If this is really a public health crisis, it needs public health solutions
- » No magic bullets – coordinated, evidence-based approaches necessary
- » We don't always know what works, and it's ok to pursue interventions w/ strong logic model
- » We do know some things that don't work, and we should stop doing them
- » Data are important, but only if used for good



Opioid-related Public Health Emergency Declarations

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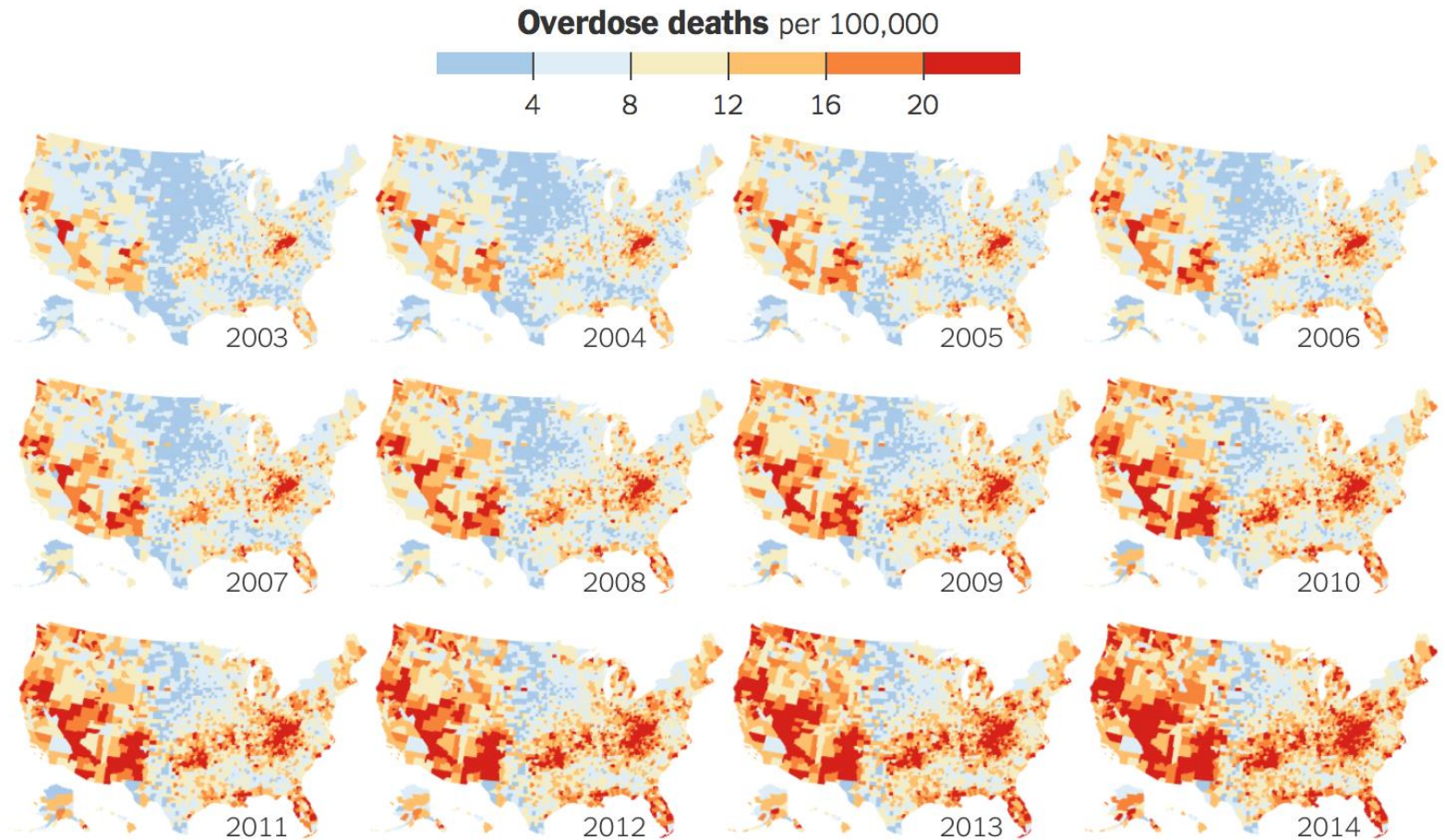
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- Escalating Opioid Crisis
- National Emergency
Declarations/Proposals
- State/Tribal Level Emergencies
- Specific Issues of Law and
Policy

The Escalating Crisis

- As many as 25% of persons receiving opioids for long-term non-cancer pain become addicted
- About 4 of 5 new heroin users start by misusing prescription opioids
- From 2014-2015, death rates from synthetic opioids (other than methadone) increased 72% and overdose deaths for teens (15-19 years) increased about 20%
- More than 12.5 million people misused prescription opioids in 2015
- On average 142 Americans die every day from opioid-related overdoses; > 160,000 more deaths by 2020
- Rural overdose death rate exceeds urban rates by 45%
- Economic impacts (healthcare, emergency care, related costs) exceed \$92 billion in 2016

Overdose Deaths 2003-2014

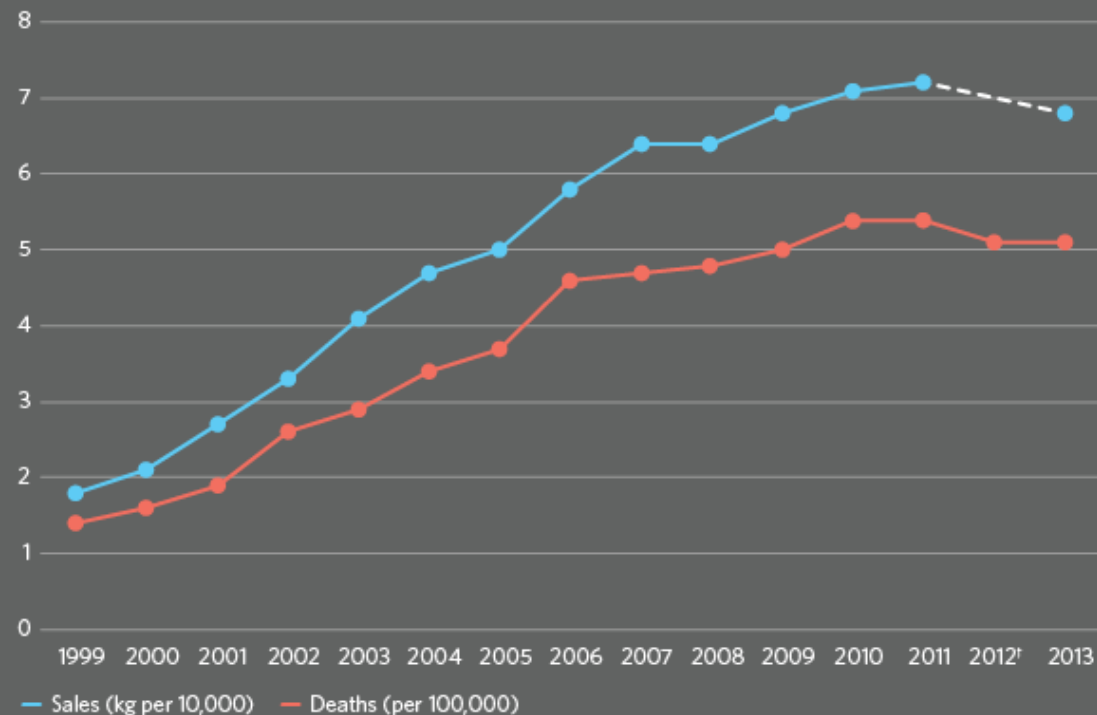


Source: <https://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html>

Prescription Opioid Sales and Overdose Deaths

Painkiller Sales and Overdose Deaths

The nation's rising overdose death rate from painkillers such as Vicodin, Percocet and OxyContin closely parallels an increase in opioid prescription sales over the past 15 years.



† Sales data is unavailable for 2012.

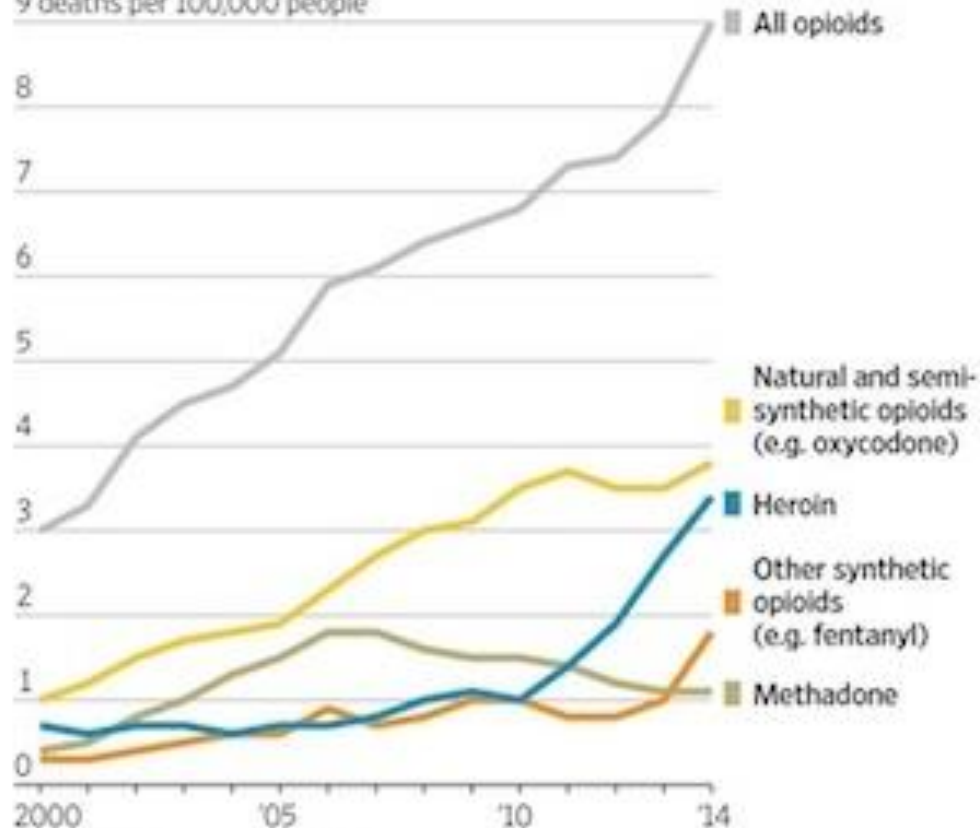
Source: U.S. Drug Enforcement Administration and Centers for Disease Control and Prevention
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Heroin and Synthetic Opioid Overdose

Escalating Drug Crisis

The rate of overdose deaths in the U.S. involving opioids, both prescription painkillers and heroin, has surged in recent years.

9 deaths per 100,000 people



Note: Death rates are age adjusted

Source: Centers for Disease Control and Prevention

THE WALL STREET JOURNAL.

VIEWPOINT

Reframing the Opioid Epidemic as a National Emergency

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On August 10, 2017, President Trump announced his intention to declare a national emergency following the recommendation of the President's Commission on Combating Drug Addiction and the Opioid Crisis.¹ Opioid abuse is among the most consequential preventable public health threats facing the nation. More than 600 000 deaths have occurred to date, with 180 000 more predicted by 2020.² Of the 20.5 million US residents 12 years or older with substance use disorders in 2015, 2 million were addicted to prescription pain relievers.³ A declaration of a national emergency authorizes public health powers, mobilizes resources, and facilitates innovative strategies to curb a rapidly escalating public health crisis.

The Opioid Crisis

Approximately one-third of individuals in the United States report experiencing chronic pain, and many re-

portedly use opioids to manage their pain. The economic burden of the opioid epidemic (health care, labor, and criminal justice costs) was estimated at \$92 billion in 2016 (an increase of 67% over a decade ago).⁴ Enhanced public health prevention nationally not only would reduce death and morbidity, but would likely also be highly cost-effective.

Expanding Conceptions of Public Health Emergencies

Modern public health emergency declarations typically focus on rapidly spreading infectious diseases such as West Nile virus (2002), severe acute respiratory syndrome (2003), H1N1 influenza (2009), Ebola virus (2014), and Zika virus (2016). They are also understood to include biosecurity threats such as anthrax (2001) or smallpox. Humanitarian disasters in the United States, such as hurricanes Katrina (2005) and Sandy (2012), have also triggered public health emergency declarations, particularly at the state level.

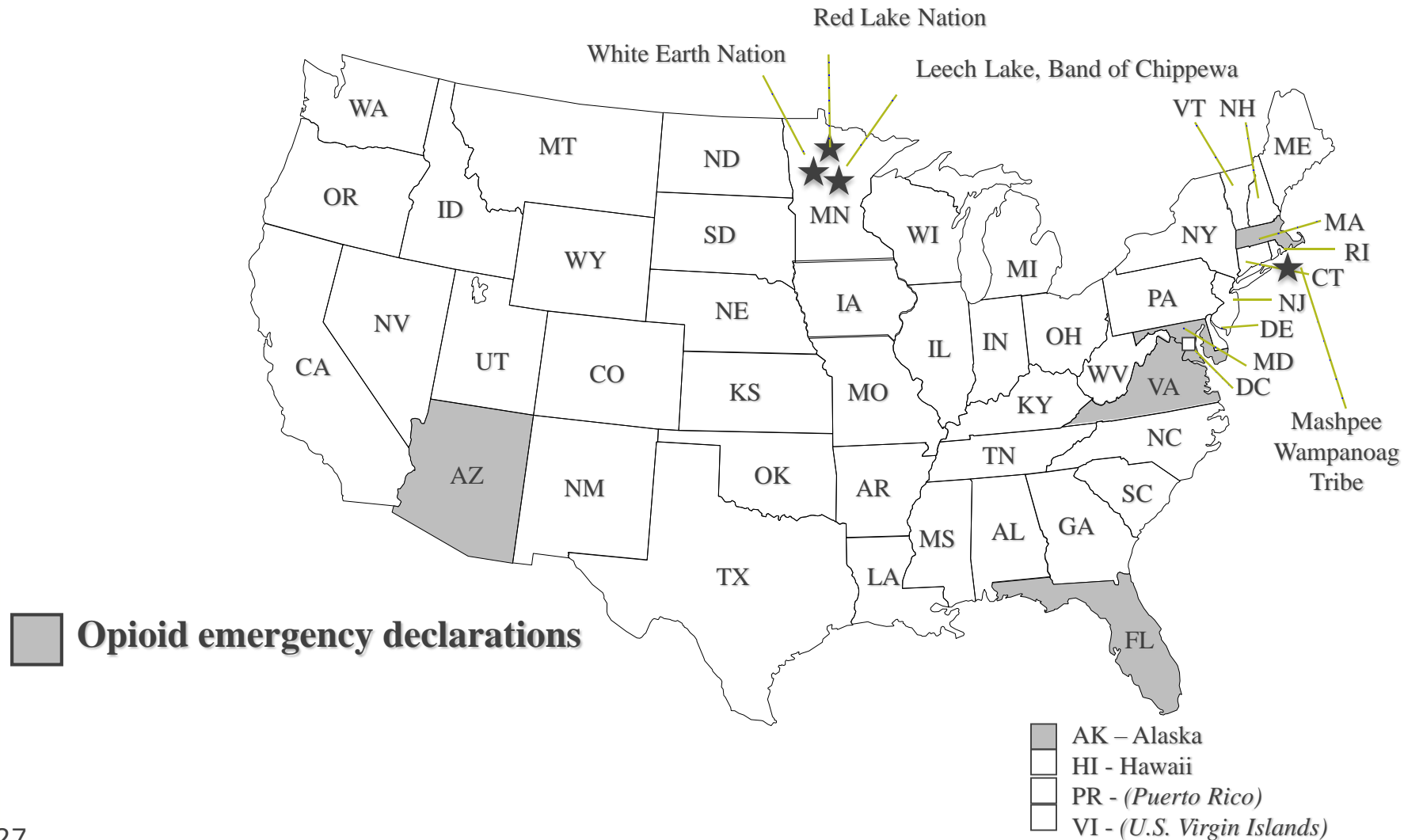
<http://jamanetwork.com/journals/jama/fullarticle/2652445>

Declaration of National Emergency

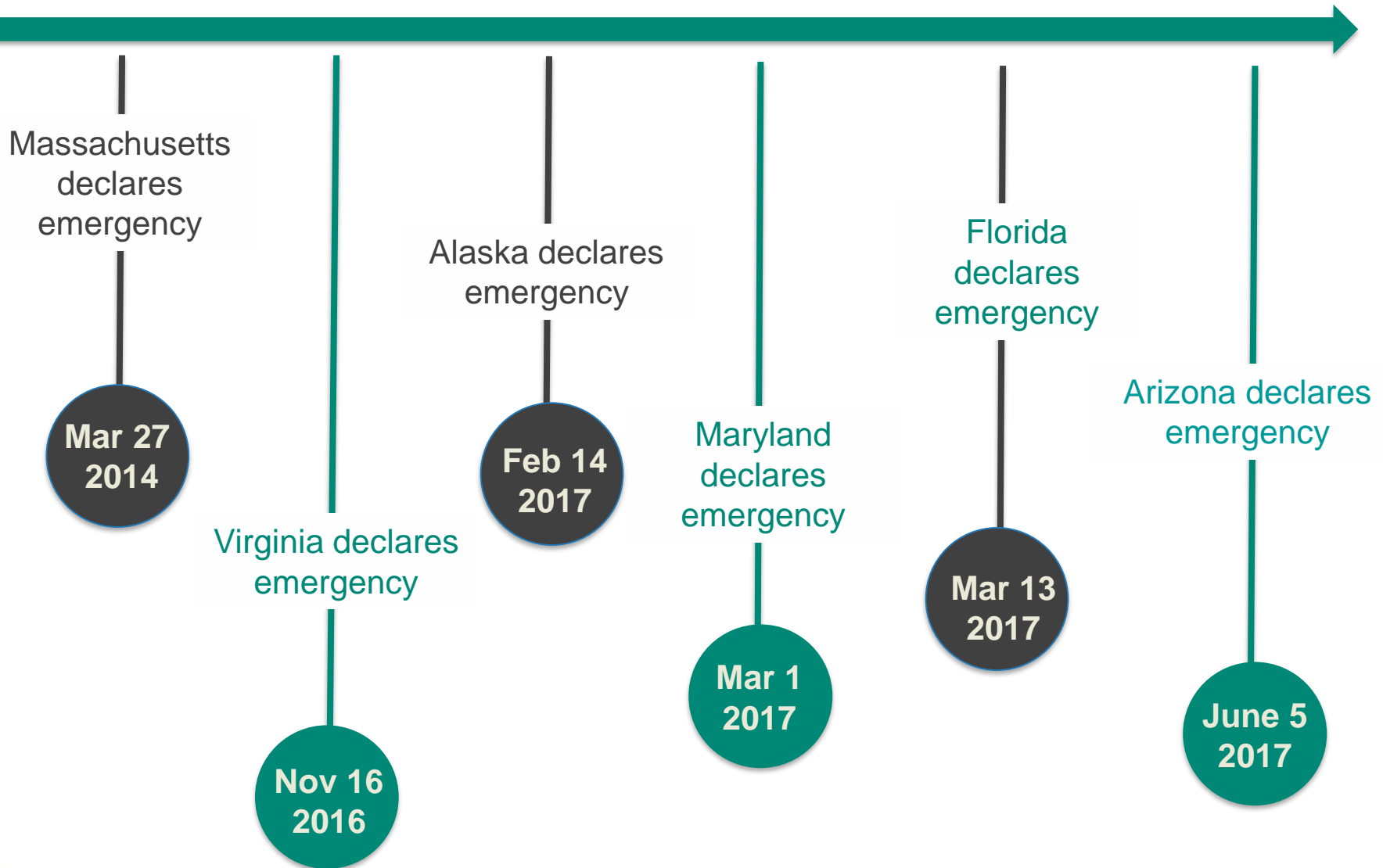
- On July 31, 2017, the [White House Commission](#) recommended that President Trump declare a national state of emergency in response to the opioid epidemic in part to:
 - reimburse state Medicaid programs to cover treatment facilities;
 - require doctors prescribing opiates to receive instruction in pain treatment;
 - expand access to medication-assisted treatment;
 - provide law enforcement officials and residents with naloxone;
 - authorize doctors to prescribe naloxone along with opioids; and
 - change health information privacy laws to ensure data regarding opioid abuse disorders are available to HCWs treating and prescribing medication to patients.
- On [August 8, 2017](#), President Trump and HHS Sec'y Price declined to issue any federal emergency declaration.
- On [August 10, 2017](#), President Trump reversed course, suggesting a national emergency will be declared.
- To date, no formal emergency declaration has been issued at the federal level.



State and Tribal Opioid Emergency Declarations

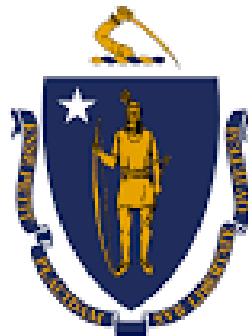


State-based Emergency Declarations Timeline



Massachusetts State of Public Health Emergency

- Public Health Emergency declared on March 27, 2014
- Empowers Massachusetts' public health commissioner to use emergency powers to expand access to naloxone
- Requires physicians and pharmacists to check Prescription Drug Monitoring Programs (PDMPs) in some situations
- Prohibits prescribing and dispensing of hydrocodone-only medication



Former Governor Deval Patrick

Virginia State of Emergency

- On November 21, 2016, Marissa Levine, MD, Commissioner of Health, declared a public health emergency to address the opioid crisis, which is supported by Governor Terry McAuliffe*
- Allows the public to obtain naloxone in emergency situations
- Lowers stigma toward those suffering from addiction



Governor Terry McAuliffe

Alaska State of Emergency

- Alaska issued a [Declaration of Disaster Emergency](#) on February 14, 2017
- Authorizes the Commissioner and State Medical Officer of the Department of Health and Social Services to coordinate a statewide Overdose Response Program (ORP)
- Authorizes the issuance of a state-wide medical standing order allowing healthcare officials, first responders, and the public to dispense and administer naloxone



Governor Bill Walker

- State of Maryland issued [Executive Order 01.01.2017.02 regarding the Heroin, Opioid, and Fentanyl Overdoes Crisis Declaration of Emergency](#) on March 1, 2017
- Committed \$50 million in new spending over 5 years coordinated by state emergency management authority with local jurisdictions to ensure community involvement
- Expands and coordinates resources to combat the opioid epidemic

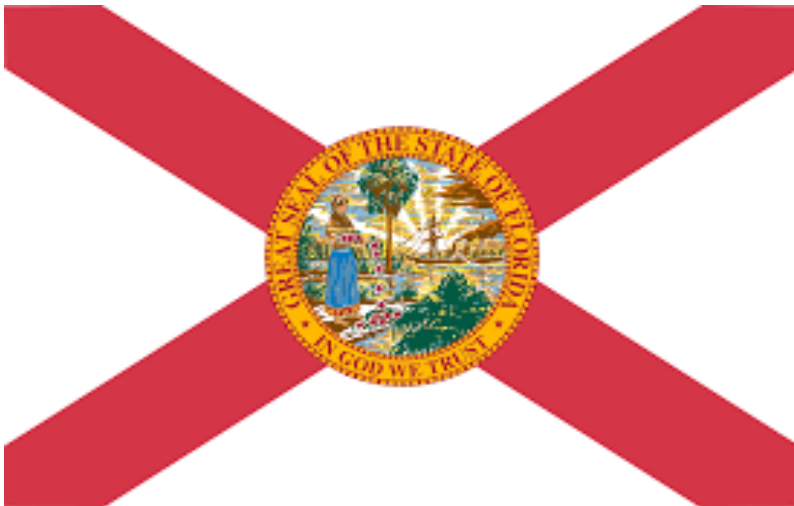


Governor Larry Hogan



Florida State of Emergency

- [Executive Order Number 17-146](#) was issued on May 3, 2017
- Department of Children and Families, Department of Health, and Department of Law Enforcement can suspend any statute, rule, ordinance, or order to procure necessary supplies, services, and temporary premises
- Governor is empowered to spend money immediately without legislative approval to expedite public health responses



Governor Rick Scott

- Declaration of Emergency and Notification of Enhanced Surveillance Advisory declared on June 5, 2017 (and renewed for 60 more days on August 11).
- Provides better coordination between state, local, and private-sector partners to distribute naloxone throughout the community
- Enhances surveillance for increased reporting of overdose death from health care entities
- Develops guidelines to educate healthcare providers on responsible prescribing practices



Governor Doug Ducey

Naloxone Expansion:

Arizona's emergency declaration includes naloxone distribution for communities and law enforcement statewide

Statewide Standing Order:

On 11/21/16 VA Health Commissioner issued statewide standing order authorizing pharmacists to dispense naloxone.

Overdose Prevention and Treatment

Naloxone Limitation: In June 2017, Middletown, Ohio city councilmember proposed a 'three-strikes' policy for people who repeatedly overdose, limiting access to emergency medical attention and overdose reversal.

Prescription Drug Monitoring Program (PDMP): In 2016, Massachusetts passed legislation requiring prescribers to report and query opioid prescribing practices.

Law Enforcement PDMP Access: Proposed New Jersey legislation would allow law enforcement to access PDMP database without a court order to investigate doctor-shopping.

Privacy

HIPAA and Overdose 'Notification:' In June 2017, White House Commission discussed possible requirement to inform family members when a person is revived with nalox-one after an opioid overdose.

Good Samaritan Statutes:

At least 40 states and D.C. have implemented immunity from arrest for drug possession when a person dials 911 or seeks medical attention during an instance of opioid overdose.

Product Liability: 8/30/17: Arizona

filed a lawsuit against Insys for deceptive marketing of Subsys, a synthetic opioid spray 50x stronger than heroin. The suit alleges the company and its executives bribed doctors to prescribe large quantities to non-cancer patients.

Liability

Medical Professional

Liability: Maryland, like many states, provides stronger legal protections from civil and professional liability for medical professionals who prescribe and dispense naloxone.

- Special thanks to **Alex Hess** at ASU's Sandra Day O'Connor College of Law for her research & assistance
- Ask the Network concerning questions or comments relating to this information
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- Sarah Wetter - swetter@networkforphl.org

Arizona's Opioid Epidemic Executive Order & Interventions

Leveraging Time-Sensitive Executive Authority to
Improve Public Health

September 19, 2017

Will Humble, MPH
Executive Director,
Arizona Public Health Association



Learning Objective

- Be able to describe 4 opportunities a Governor's Executive Order can be leveraged bills to change public health policy to improve health outcomes



Enhance Public Health Surveillance

- Public health surveillance for poisonings and deaths from opioid poisonings are generally tied to slow systems like:
 - Hospital discharge data (quarterly)
 - Emergency Department data (quarterly or monthly)
 - Medical Examiner information (depends on jurisdiction)
 - Death Certificates

The slow response and limited granularity of these reporting systems limits their usefulness in developing policy interventions



Enhance Public Health Surveillance

- Executive Orders & Emergency Declarations can give health departments time limited opportunities to improve data collection and analysis to build policy interventions
 - Quick data from the emergency medical services system
 - Real-time emergency department data
 - Real-time inpatient hospitalization data
 - Biosample results which can identify the type of opiate (street v. pills)
 - Quicker results from death certificates
 - Granular information about provider behavior
 - Access to prescription monitoring data (depends on jurisdiction)



Improve & Focus Regulatory Authority

- Executive Orders & Emergency Declarations can give health departments time limited opportunities to change their regulation of healthcare institutions
- Most state health departments have leverage via their licensing authority for hospitals, skilled nursing, assisted living, behavioral health clinics and outpatient treatment clinics
- Emergency declarations and EO's gives health departments a unique opportunity to overhaul their Administrative Code w/o economic impact evaluations & rule review board oversight
- First Responder use of Naloxone can be addressed as well as pharmacy licensing regulations



Leverage Medicaid Programs

- Executive Orders & Emergency Declarations can provide a unique opportunity for Medicaid programs to alter their contracts and payments with payer contractors
 - Contract alterations can be made mid-contract as an amendment
 - Provides political cover to the Medicaid agency
 - Can provide a long-term intervention that changes provider behavior with financial incentives rather than regulation
 - For example, AZ's Medicaid, in response to a 2016 Executive order, limited payments to providers to 7 days worth of opioids (for non cancer pain patients)



Provides Executive Support for New Legislation

- Executive Orders & Emergency Declarations send a message to state legislators that the governor supports new legislation
- Proposals made “under the cover” of a governor signed executive order make their passage more likely
- Stakeholder resistance can be muted when they know the governor has hooked his or her “brand” to the issue



Arizona's Case Study

- Arizona's Governor issued an Executive Orders on June 5 ordering the state health department to develop an action plan for addressing AZ's opioid epidemic
- Order included additional authority to require more timely and granular reporting
- Provided exempt rulemaking authority to modify their Administrative Code for the licensing and regulation of healthcare institutions
- Ordered the agency to produce an action plan of additional measures, including changes to state policy, new legislation, and recommendations to change federal regulations

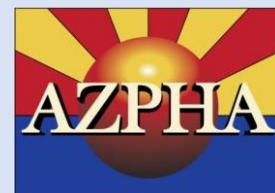


Arizona's Case Study

- Arizona health department issued [Opioid Overdose Epidemic Response Report](#). Intervention recommendations are included for:
 - state opioid legislation;
 - federal interventions;
 - youth prevention;
 - law enforcement;
 - medical education curriculum;
 - insurance parity;
 - regulatory boards;
 - correctional facilities;
 - continuity of care; educating the public; and
 - controlled substances prescription monitoring program improvements.



Arizona's Case Study



- There are literally dozens of recommendations, but here are a few of the more interesting ones:
 - Impose a 5-day limit on all first fills for opioid naïve patients for all payers (Medicaid is implementing w/o legislation);
 - Limit morphine milligram equivalents to 90 (MME) and require provider tapering to that level;
 - Require pharmacists to check the CSPMP prior to dispensing an opioid;
 - Require different labeling and packaging for opioids (“red caps”);
 - Require 3 hours of opioid-related CME for all professions that prescribe or dispense opioids;
 - Establish an all payers claims database for better surveillance data;
 - Eliminate dispensing of controlled substances by prescribers (e.g. samples);

Arizona's Case Study



- AZ Recommendations cont'd:
 - Regulate pain management clinics to prohibit “pill mill” activities;
 - Establish enforcement mechanisms for pill mills and illegal opioid dispensing;
 - Enact a good Samaritan law to allow bystanders to call 911 for a potential opioid overdose;
 - Allow Medicaid to pay for substance abuse treatment in correctional facilities (federal);
 - Remove the IMD exclusion to allow facilities to receive reimbursement for substance abuse treatment (federal);
 - Remove the pain satisfaction score completely from the CMS HCHAP (patient satisfaction) score (federal); and
 - Require federal health care facilities to maintain state licensure (e.g. VA, IHS) (federal).

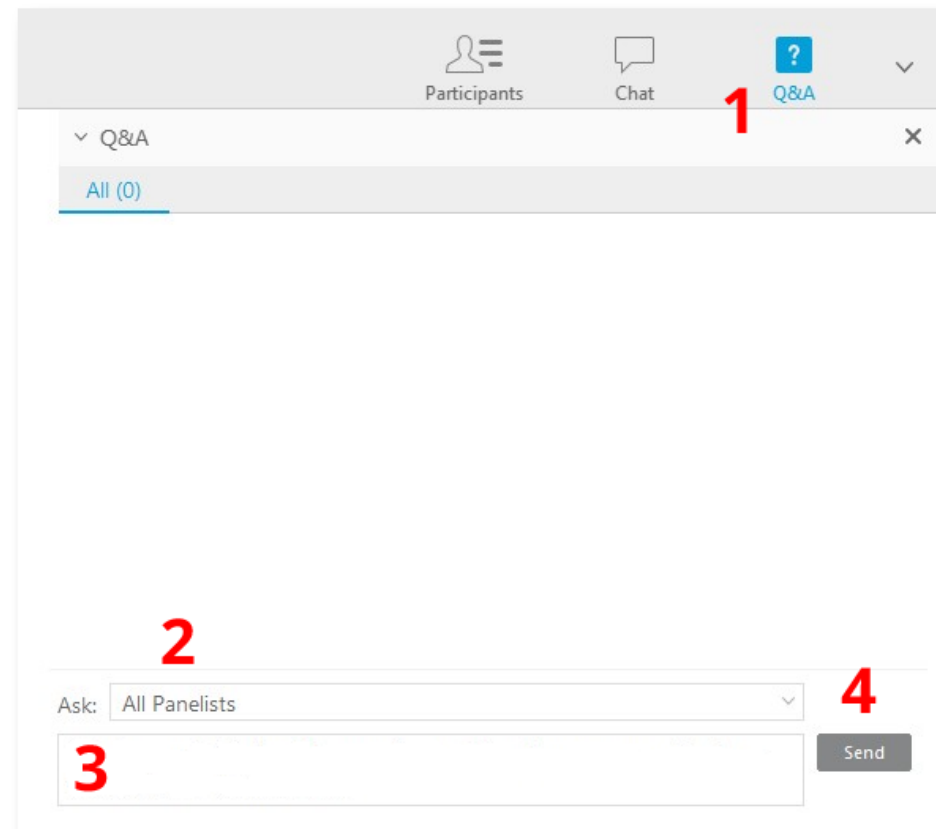
Summary



- Executive Orders and Emergency Declarations provide state health department and the entire executive branch a unique opportunity to quickly intervene:
 - Enhanced data collection and surveillance to develop better policy and legislative proposals
 - Can provide exempt rulemaking authority to change Administrative Code for licensed facilities (and other areas of state government if crafted that way)
 - Increases leverage for Medicaid programs to amend payer contracts
 - Sends a message to legislators about the executive branch priorities for new laws to address

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