

Opioid Public Health Emergencies: A Primer

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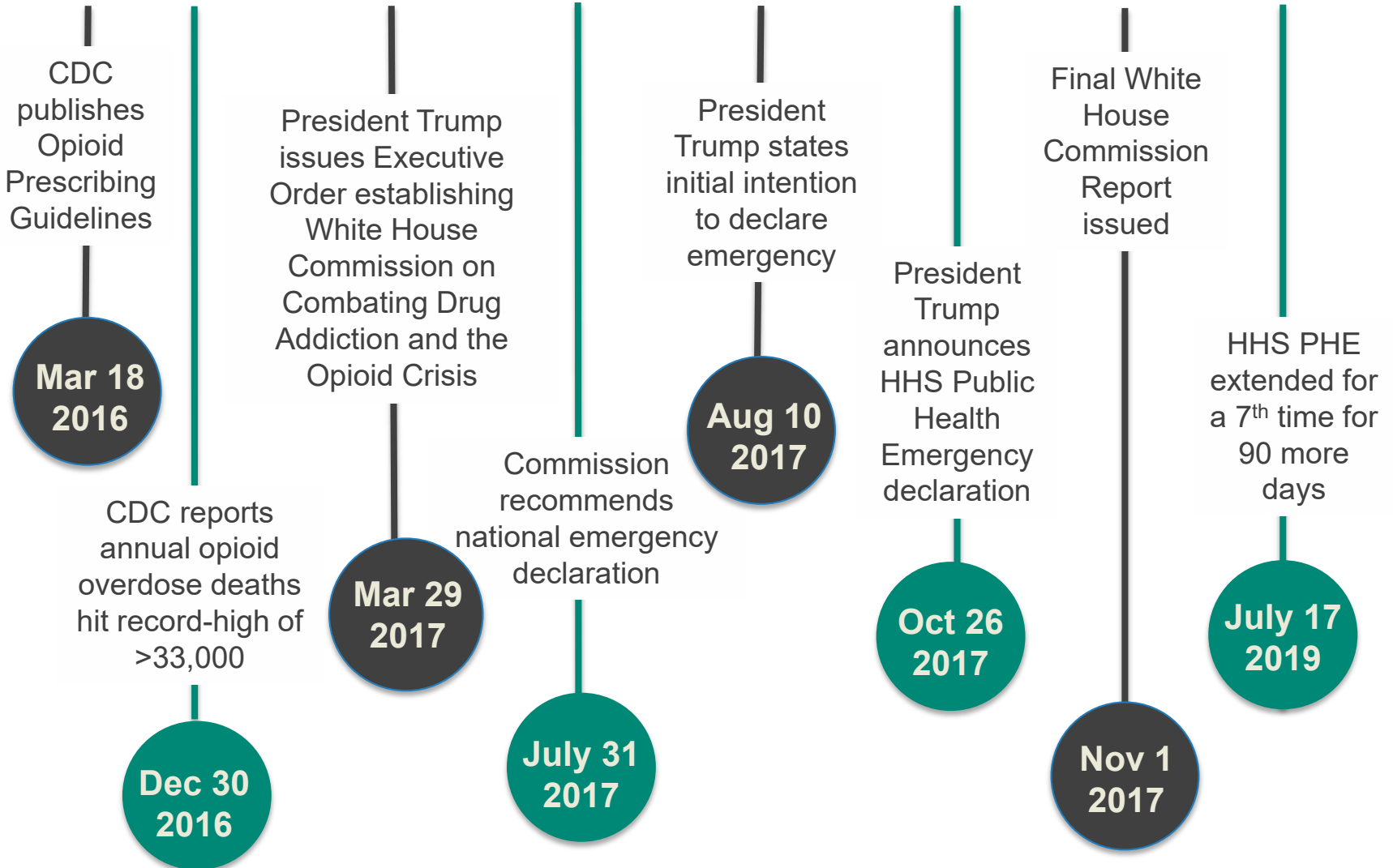
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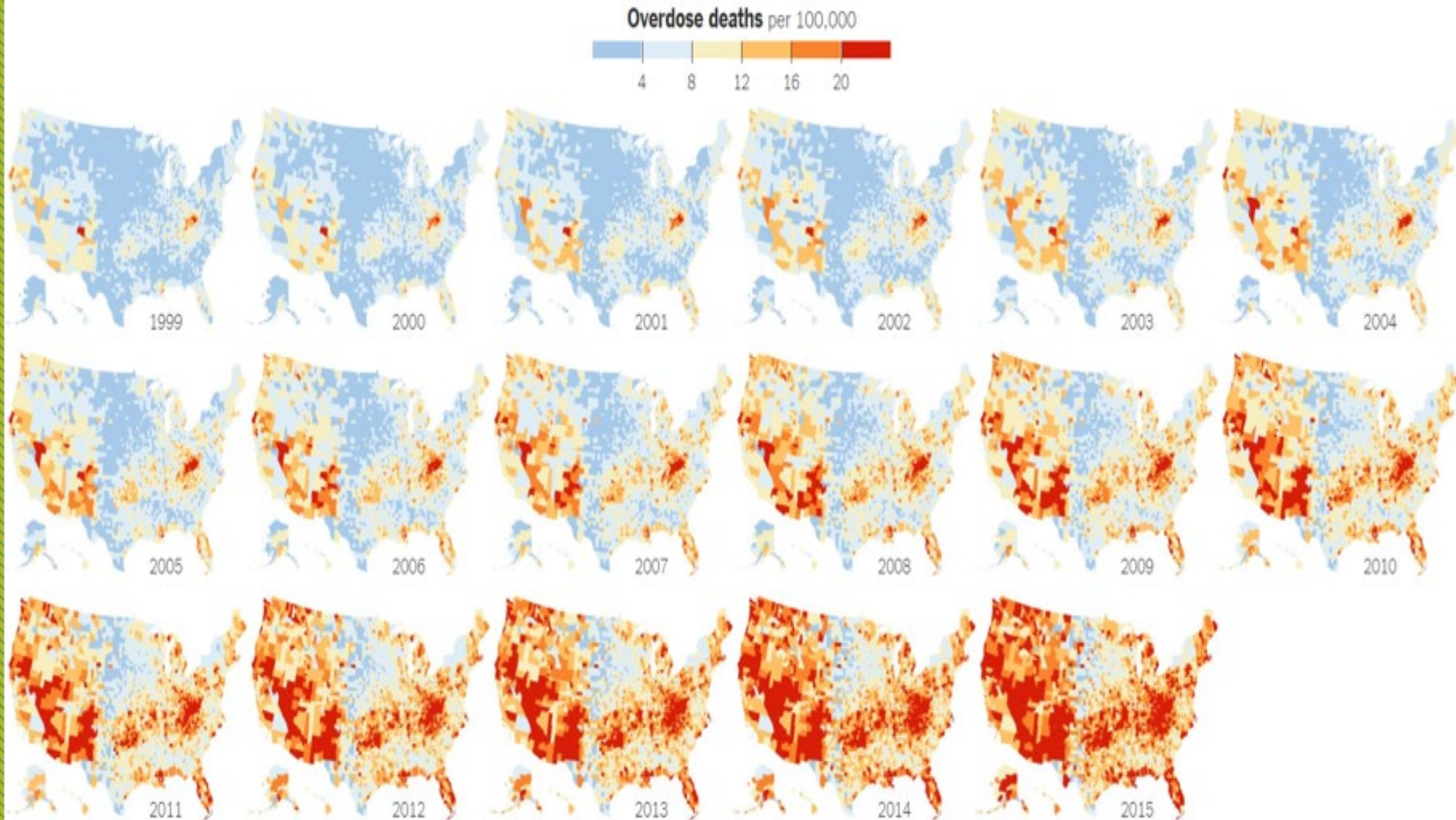
Opioid Crisis Timeline



An Escalating Crisis

- From 2014-2015, deaths from synthetic opioids (other than methadone) increased 72%; teen overdose deaths (15-19 years) increased ~ 20%
- About 4 of 5 new heroin users start by misusing prescription opioids
- Fentanyl and its analogs have been identified in over 70% of overdose deaths in 10 states
- 2016 deaths involving synthetic opioids (19,413) outnumbered those involving prescription opioids (17,087) and heroin (15,469)
- Over half of the 2017 opioid overdoses (49,068) were due to synthetic opioids (29,406)

Overdose Deaths 1999-2015



Profile of Opioid Deaths

20%

of deaths in
persons age
25-34 were
opioid-related
(2016)

67%

of fatal
overdoses are
among males
(2015)

82%

identify as
Caucasian/
Non-Hispanic
(2015)

45%

more fatal
overdoses
occur in rural
vs urban areas
(2015)

62%

are diagnosed
with chronic
pain in the last
year of life
(2017)

60%

of opioid
deaths involve
synthetic
opioids (2017)

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 receive prescription opioids such as oxycodone and acetaminophen/hydrocodone. Opioids are among the most heavily prescribed pharmaceuticals, and they are highly

opioid epidemic (health care, labor, and criminal justice costs) was estimated at \$92 billion in 2016 (an increase of 67% over a decade ago).⁸ 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.

This traditional model of public health emergencies, however, is beginning to change. In the past decade states and localities have declared emergencies

October 26, 2017: President Trump directs acting HHS Secretary Eric D. Hargan to declare the opioid crisis a national PHE to:

- Overcome IMD exclusions for Medicaid coverage
- Mobilize public and private organizations
- Provide best prescribing practices and training
- Remove high-risk opioids from the market
- Prevent overseas illicit drug trafficking
- Initiate lawsuits against drug companies
- Deploy NIH funding to fight drug addiction



DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the consequences of the opioid crisis affecting our Nation, on this date and after consultation with public health officials as necessary, I, Eric D. Hargan, Acting Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists nationwide.

January 19, 2018: Acting Sec. Hargan renews PHE (effective 1/23/18)

April 20, 2018: Sec. Azar renews PHE a second time (effective 4/24/18)

July 19, 2018: Sec. Azar renews PHE a third time (effective 7/23/18)

October 18, 2018: Sec. Azar renews PHE a fourth time (effective 10/21/18)

January 17, 2019: Sec. Azar renews PHE a fifth time (effective 1/19/19)

April 15, 2019: Sec. Azar renews PHE a sixth time (effective 4/19/19)

July 17, 2019: Sec. Azar renews PHE a seventh time (effective 7/18/19)

 **USA TODAY** 11/05/18

FDA approves opioid painkiller 1,000 times stronger than morphine

11/17/18 **TIME**

Florida Is Suing CVS and Walgreens Over Their Role in the Opioid Crisis

11/29/18

The New York Times

*'The Numbers Are So Staggering.'
Overdose Deaths Set a Record Last Year.*

1/15/19

The New York Times

02/25/19

The Washington Post

Family Behind Purdue Pharma Pushed Opioid Marketing, Massachusetts Says

FDA takes fresh look at whether opioids are effective for chronic pain

Select Congressional Responses

7/24/18

House Committee on Energy and Commerce held a hearing to investigate how the substance use treatment industry markets and obtains patient referrals

8/13/18

John S. McCain National Defense Authorization Act authorizes a pilot program to monitor and predict potential opioid misuse in the military health system

8/23/18

The House and Senate passed HR 6157 to grant \$250 million to NIDA for research in opioid addiction, alternatives, pain management, and addiction treatment

10/24/18

SUPPORT for Patients and Communities Act combines numerous opioid bills proposed by various lawmakers (see next slide)



10/26/18

The House bill, Combatting Illicit Fentanyl Act, calls for Presidential sanctions on individuals in China involved in fentanyl production and trafficking

Key Elements:

- ❖ Expansion of Medicare and Medicaid coverage and services
- ❖ Prevention, treatment, recovery grants and programs
- ❖ MAT prescribing changes
- ❖ FDA requirements for non-addictive drug development



Criticisms:

- ❖ Insufficient funding
- ❖ Lacks focus on root causes of opioid crisis
- ❖ No real increased access to naloxone and buprenorphine
- ❖ Weak guidance on FDA opioid packaging





August 30, 2018: U.S. Deputy Attorney General Rod Rosenstein releases statement maintaining that supervised drug injection sites violate federal law



September 20, 2018: SAMHSA publishes fact sheets to support clinical treatment of women with an opioid use disorder who are also pregnant or recent mothers



September 19, 2018: CDC announces \$155 million in new funding distributed to states and 4 territories to better characterize and address the opioid crisis



October 23, 2018: CMS announces a new Medicaid payment model for up to 12 states to better coordinate care for pregnant women and new mothers with opioid use disorder



October 25, 2018: HHS Office of Civil Rights announces an educational campaign to increase nondiscrimination law compliance in providing medication assisted treatment

Select FY2017 Appropriations



The [Consolidated Appropriations Act, 2017](#) provides HHS with \$20 million for CARA-authorized programs, including 2 opioid-specific programs



Congress provides \$103 million for “comprehensive opioid abuse reduction activities” from the DOJ [State and Local Law Enforcement Assistance](#) account

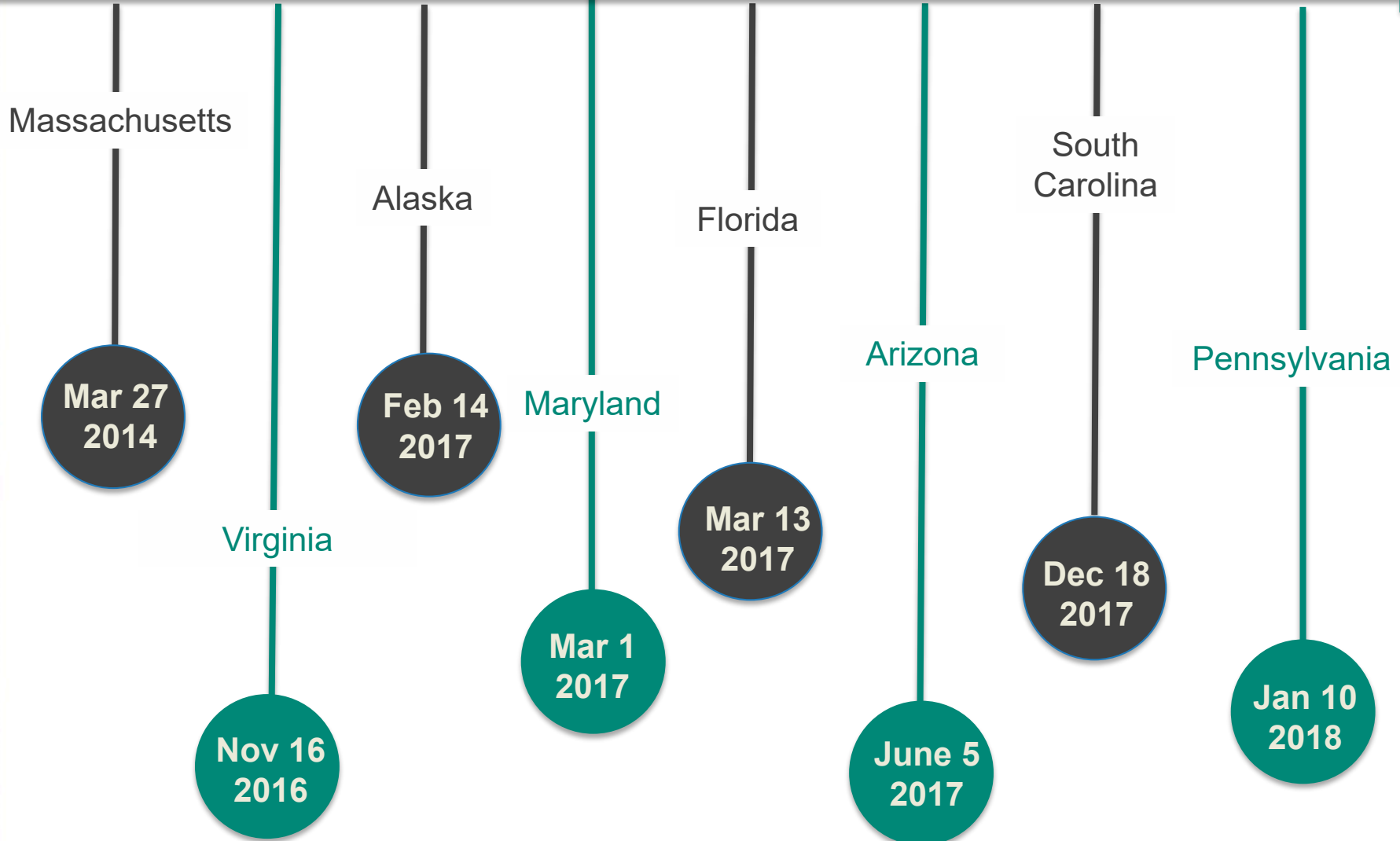


Under the [Department of Veterans Affairs](#), \$50 million was provided to bolster opioid and substance abuse prevention and treatment

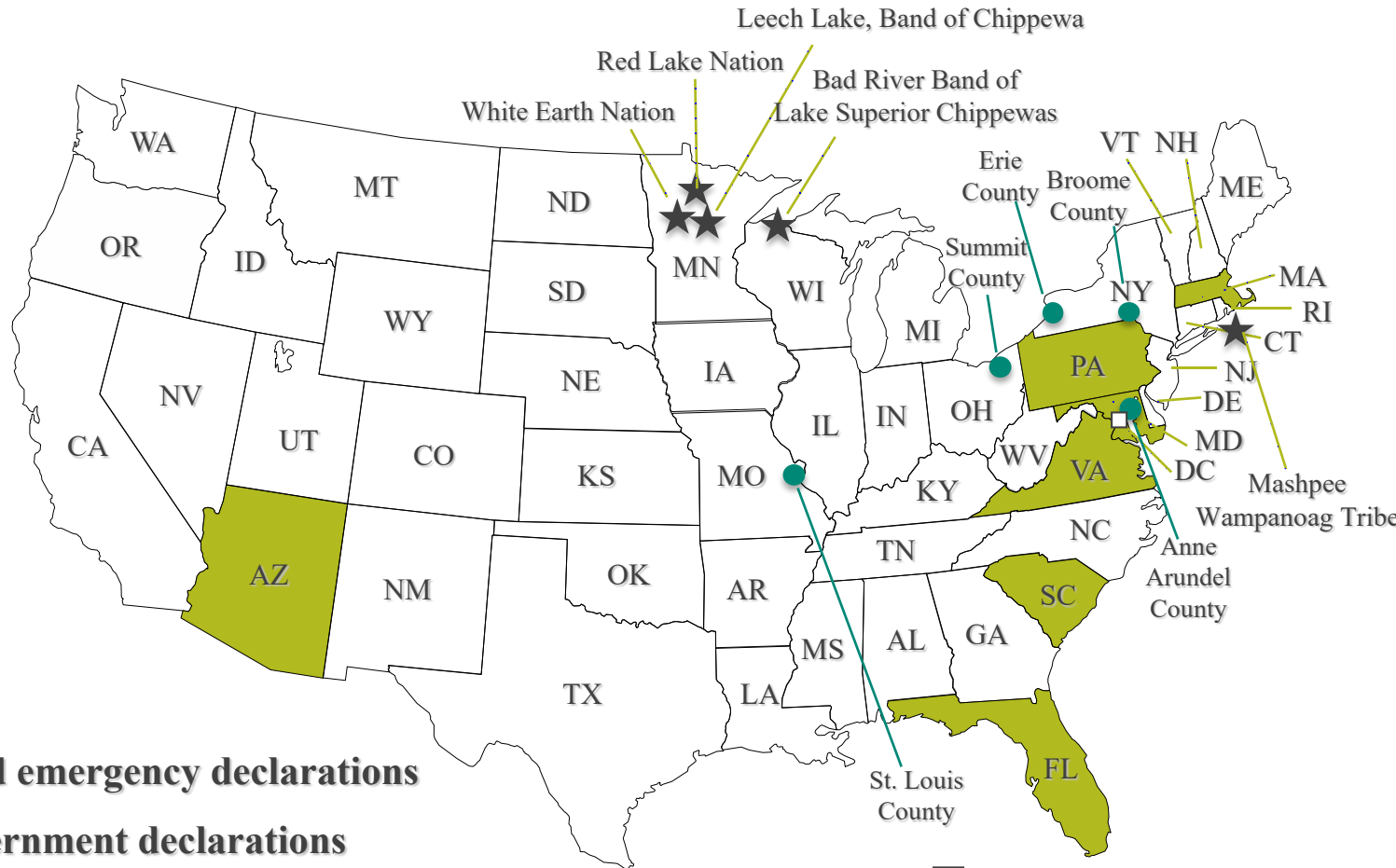


The explanatory statement accompanying the [Consolidated Appropriations Act, 2017](#) specifies \$56 million for SAMHSA’s Medication Assisted Treatment for Prescription Drug and Opioid Addiction program

State-based Emergency Declarations Timeline



State, Tribal and Local Opioid Emergency Declarations



- State opioid emergency declarations
- ★ Tribal government declarations
- Local government declarations

- AK – Alaska
- HI - Hawaii
- PR - (Puerto Rico)
- VI - (U.S. Virgin Islands)

State Emergency Declaration Actions

Action	MA	VA	AK	MD	FL	AZ	SC	PA
	3/27/14 – TBD	11/21/16 – TBD	2/14/17 – 2/14/18	3/1/17 – 4/30/17	5/3/17 – 10/27/17	6/5/17 – 5/29/18	12/18/17 – TBD	1/10/18 – 9/26/18
Naloxone Standing Order		X	X		X	X		
First Responders Can Carry/Distribute Naloxone	X		X		X	X		X
Enhanced PDMP Surveillance	X					X		X
Opioid Prescribing Restrictions	X*						X	
Increased Funding for Treatment				X	X			
Interagency Coordination				X		X	X	X

*Eventually overturned in court

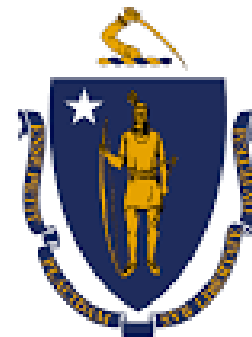
Massachusetts State of Public Health Emergency

Public Health Emergency declared on
March 27, 2014 which:

- Empowers Massachusetts' public health commissioner to use emergency powers to expand access to naloxone
- Requires physicians and pharmacists to check PDMPs in some situations
- Prohibits prescribing and dispensing of hydrocodone-only medication (subject to ongoing litigation)
- Created a task force to find new paths to treatment, reduce stigma, and impose prescription opioid limits



Former Governor Deval Patrick



On November 21, 2016, Marissa Levine, MD, Commissioner of Health, declared a public health emergency to address the opioid crisis, supported by Governor Terry McAuliffe*

- Allows the public to obtain naloxone in emergency situations
- Reduces stigma toward those suffering from addiction
- Attributed to slowing the rate of opioid-related deaths



Governor Terry McAuliffe



*The Commissioner [comments](#) on the declaration, noting it has no force of law and is not a Governor's emergency declaration

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)
- Issuance of a state-wide medical standing order allowing HCWs, first responders, and the public to dispense and administer naloxone
- Operationalizes state-wide incident command system



Governor Bill Walker



Maryland Governor Hogan issued [Executive Order 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
- Establishes 24 opioid intervention teams at local levels
- Encourages long-term system changes to improve the public's health
- Authorizes 70+ specific projects with key measurements for success



Governor Larry Hogan

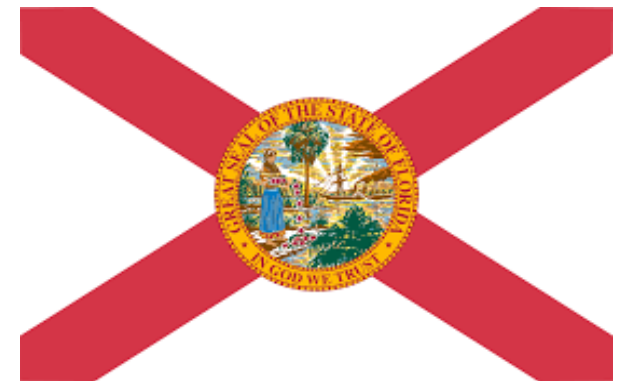


[Executive Order Number 17-146](#) issued on May 3, 2017

- 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 \$ 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.

- Provides better coordination between state, local and private-sector partners to distribute naloxone (including standing orders)
- Enhances real-time surveillance for increased reporting of overdose deaths
- Develops guidelines to educate HCWs on responsible prescribing practices
- Generates 12 point action plan
- Enables fast-track regulatory reforms

On January 25, 2018, the Arizona Legislature unanimously passed the Arizona Opioid Epidemic Act, establishing increased treatment funding, prescription limits, and Good Samaritan protections.



Governor Doug Ducey



South Carolina declared a Public Health Emergency on December 18, 2017

- Establishes the “Opioid Emergency Response Team” consisting of multiple stakeholders to optimize information gathering/sharing and reduce addiction-related stigma
- Directs the Response Team to hold monthly meetings and develop a strategic plan to address the statewide crisis
- Limits initial opioid prescriptions for acute and post-operative pain to a maximum of 5 days for state Medicaid recipients

On June 4, 2018, the S.C. legislature enacted 9 bills addressing prescription limits and fraud, naloxone access, addiction counselor licensing, confidentiality exceptions, and controlled substance scheduling



Governor Henry McMaster



Pennsylvania issued a [Declaration of Disaster](#) on January 10, 2018

- Waives regulations creating barriers to opioid addiction treatment and prevention
- Expands state agency access to PDMP
- Requires medical providers & medical examiners to report cases of overdose or neonatal abstinence syndrome
- Permits nurses to admit patients for drug addiction treatment
- Allows emergency responders to leave behind naloxone after responding to an overdose
- Tightens criminal penalties for fentanyl derivative

[Proposed legislation](#) in Pennsylvania would allow the Governor to specifically declare a public health emergency over opioids; currently cleared the state Senate.



Governor Tom Wolf



Tribal Emergency Declarations



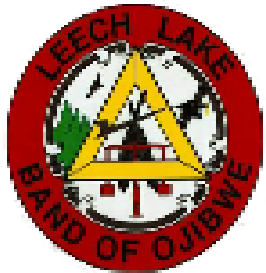
Red Lake Nation
2011 and 7/11/17

Public Health
Emergency



**Mashpee Wampanoag
Tribe**

7/16/16
Public Health Emergency



**Leech Lake, Band of
Chippewa Indians**
4/18/11

Public Health
Emergency



**Bad River Band of Lake
Superior Chippewas**

11/1/17
Public Health Emergency



White Earth Nation
2011

Public Health Emergency

Opioid Prescription

Limitation: Starting 1/1/18, a [North Carolina law](#) forbids doctors in the state from prescribing more than a 5-day supply of opioids for acute pain, or a 7-day supply following surgery

Supervised Injection

Facilities (SIFs): In Feb. 2019, [DOJ sued](#) a Philadelphia nonprofit, Safehouse, over its plans to open a SIF in the city. Multiple additional jurisdictions are also considering SIFs.

Overdose Prevention & Treatment

Medical Marijuana: New Jersey, New York, and Pennsylvania have added [opioid use disorder as a basis](#) for obtaining a medical marijuana license in their respective jurisdictions

Naloxone Access: Rhode Island was the 1st state to implement [NaloxBox](#) (a kit similar to an AED that contains naloxone nasal spray, masks, and medical gloves) in public spaces to [help increase naloxone access](#)

PDMP: New York moved in Mar. 2018 to allow data sharing between its PDMP and 25 other states and D.C. SUPPORT Act requires Medicaid providers to check state PDMPs beginning in Oct. 2021

Eased Data Sharing: SUPPORT Act removed the House provision aligning privacy rules for substance use disorder records (42 CFR Part II) with the HIPAA Privacy Rule

Privacy

HIPAA and Overdose Notification: A House proposal enabling providers to notify families and other providers of a patient's non-fatal overdose was removed from the Senate version of prior legislation

Increased Data Collection: Announcing the PHE on 10/26/17, President Trump indicated several forthcoming research partnerships that may result in increased collection of data related to addiction and overdose

Product Liability: In Nov. 2018, Purdue Pharma challenged a NY State law taxing opioid distributors and manufacturers, arguing the ongoing NY state lawsuit should first run its course

Distributor Liability: In Nov. 2018, Florida added CVS and Walgreens in its suit against opioid distributors for failing “to stop suspicious orders of opioids they received” and dispensing “unreasonable quantities of opioids from their pharmacies”

Liability

Private Liability: Tucson (AZ) Medical Center sued more than 2 dozen pharmaceutical companies for negligence, fraud, and conspiracy. Purdue Pharma published a letter in Aug. 2018 acknowledging the hazards of opioids

Federal Prosecution: DOJ’s Opioid Fraud and Abuse Detection Unit uses enhanced data analytics to identify and prosecute healthcare fraud cases of wrongful or over-prescription; 600 HCWs charged in June 2018

Purdue Settles for \$270 Million

March 26, 2019: Purdue Pharma settles with Oklahoma's Attorney General to resolve claims regarding its role in contributing to the opioid crisis.

- A large portion of the funds are devoted to a new addiction treatment center at Oklahoma State University.
- The settlement creates a benchmark for other states and cities in their lawsuits against drug companies.
- Purdue is considering filing for bankruptcy to consolidate and limit its potential liability.
- CMS is seeking a portion of settlement funds to remedy misspent Medicaid dollars.



July 11, 2019: DOJ announces the largest recovery in a case concerning opioids in U.S. history. DOJ secured a \$1.4 billion recovery from Reckitt Benckiser Group (suboxone seller).

- Resolves RB Group from potential criminal and civil liability
- 33 states expected to receive funding



**Reckitt
Benckiser**

- **Ask the Network regarding questions or comments:**

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