Opioid-related Public Health Emergency Declarations
as of August 31, 2018

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Opioid Crisis Timeline

- **Mar 18 2016**: CDC publishes Opioid Prescribing Guidelines
- **Dec 30 2016**: CDC reports annual opioid overdose deaths hit record-high of >33,000
- **Mar 29 2017**: President Trump issues Executive Order establishing White House Commission on Combating Drug Addiction and the Opioid Crisis
- **Mar 29 2017**: Commission recommends national emergency declaration
- **July 31 2017**: President Trump states initial intention to declare emergency
- **Aug 10 2017**: Commission recommends national emergency declaration
- **Oct 26 2017**: President Trump announces HHS Public Health Emergency declaration
- **Nov 1 2017**: Final White House Commission Report issued
- **July 23 2018**: HHS PHE extended a third time for 90 more days
The Escalating Crisis

• From 2014-2015, death rates 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
• 146 Americans die every day from opioid-related overdoses
• 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 (47,232) were due to synthetic opioids (28,526)
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)
Reframing the Opioid Epidemic as a National Emergency

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. 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. 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. A declaration of a national emergency authorizes public health powers, mobilizes resources, and facilitates innovative strategies to curb a rapidly escalating public health crisis.

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

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

Determinations 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)
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Implementation (as of May 15, 2018)</th>
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<tbody>
<tr>
<td>Funding state opioid efforts</td>
<td>The spending bill passed by Congress in March included a $3.3 billion increase for opioid funding, some of which went to states’ efforts</td>
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<td>Media campaigns encouraging treatment</td>
<td>TBD</td>
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<td>Bolstering use of PDMPs</td>
<td>In February, 2018, Jeff Sessions announced a plan to use medical data from PDMPs to crack down on doctors and pharmacies dispensing large amounts of opioids</td>
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<td>Expanding drug courts for MAT</td>
<td>TBD</td>
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<tr>
<td>Developing prescribing standards</td>
<td>CDC recently issued clarification on prescribing guidelines. In April, CMS released final Medicare rule requiring pharmacists to contact prescribers and document discussions before filling prescriptions of over 90 mg of morphine</td>
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<td>Encouraging non-opioid pain treatment</td>
<td>TBD</td>
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<tr>
<td>Raising criminal penalties on drug trafficking</td>
<td>In January, President Trump signed the Interdict Act giving federal agents further tools for detecting synthetic opioids (e.g. fentanyl) at the border. In March, President Trump announced a plan to increase penalties for drug traffickers, including the death penalty</td>
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<tr>
<td>Naloxone co-prescribing programs</td>
<td>TBD</td>
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<tr>
<td>Increasing coverage of substance use treatment</td>
<td>Administration has continued prior policy of approving waivers to let Medicaid programs pay for addiction and mental health treatment in facilities &gt; 16 beds</td>
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Select Congressional Responses

6/15/18
The SITSA Act, introduced by Rep. Katko (R-NY), passed the House. It would classify synthetic opioids above CSA Schedule I and tighten importation checks.

6/22/18
The House passed the SUPPORT for Patients and Communities Act, combining numerous opioid bills for Senate consideration.

7/24/18
The 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
The John S. McCain National Defense Authorization Act was signed into law and contains 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.
Key Elements:

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

Criticism:

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

Passed with bipartisan support on September 26, 2018
Opioids in the Headlines

The Washington Post
New Illinois law allows medical marijuana pain prescriptions
8/29/18

The New York Times
Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017
8/15/18

npr
Justice Department Promises Crackdown On Supervised Injection Sites
8/30/18

THE WALL STREET JOURNAL
Trump Calls On Justice Department to Sue Opioid Companies
8/30/18

This doctor wrote 130 opioid prescriptions a day. She says she did nothing wrong.
9/26/18
Select Federal Agency Responses

July 18, 2018: ASPR’s planned reorganization creates an office to coordinate public health emergency responses across federal, state, tribal, territorial, local, and international entities.

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 published fact sheets to support clinical treatment of women with an opioid use disorder who are also pregnant or recent mothers.

September 19, 2018: CDC announced $155 million in new funding has been distributed to states and four territories to better characterize and address the opioid crisis.
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

- **Massachusetts**: Mar 27, 2014
- **Alaska**: Feb 14, 2017
- **Virginia**: Nov 16, 2016
- **Maryland**: Mar 1, 2017
- **Florida**: Mar 13, 2017
- **Arizona**: June 5, 2017
- **South Carolina**: Dec 18, 2017
- **Pennsylvania**: Jan 10, 2018
State, Tribal and Local Opioid Emergency Declarations

**State opioid emergency declarations**

- CA
- OR
- WA
- NV
- TX
- SC
- GA
- FL

**Tribal government declarations**

- White Earth Nation
- Leech Lake, Band of Chippewa
- Red Lake Nation
- Bad River Band of Lake Superior Chippewas
- White Earth Nation
- Red Lake Nation
- Bad River Band of Lake Superior Chippewas
- Leech Lake, Band of Chippewa

**Local government declarations**

- Erie County
- Broome County
- Summit County
- Anne Arundel County
- Bad River Band of Lake Superior Chippewas
- Leech Lake, Band of Chippewa
- Red Lake Nation

**Legend**

- AK – Alaska
- HI – Hawaii
- PR – (Puerto Rico)
- VI – (U.S. Virgin Islands)
# State Emergency Declaration Actions

<table>
<thead>
<tr>
<th>Action</th>
<th>MA</th>
<th>VA</th>
<th>AK</th>
<th>MD</th>
<th>FL</th>
<th>AZ</th>
<th>SC</th>
<th>PA</th>
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<tbody>
<tr>
<td>Naloxone Standing Order</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
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<td>First Responders Can Carry/Distribute Naloxone</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Enhanced PDMP Surveillance</td>
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<td>X</td>
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<td>X</td>
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<tr>
<td>Opioid Prescribing Restrictions</td>
<td>X*</td>
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<td>X</td>
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<tr>
<td>Increased Funding for Treatment</td>
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<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Interagency Coordination</td>
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<td>X</td>
<td>X</td>
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</table>

*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
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

*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
State of Maryland 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
Executive Order Number 17-146 was issued on May 3, 2017. The 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. The Governor is empowered to spend money immediately without legislative approval to expedite public health responses.
Declaration of Emergency and Notification of Enhanced Surveillance Advisory declared on June 5, 2017 (renewed for 60 days).

- Provides better coordination between state, local, and private-sector partners to distribute naloxone (and standing order)
- Enhances real-time surveillance for increased reporting of overdose deaths
- Develops guidelines to educate HCWs on responsible prescribing practices
- Generated 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.
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.
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 and 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, and has already cleared the state Senate.
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
Topical Legal Issues

**Product Liability:** Amidst numerous state, local, and tribal lawsuits alleging pharmaceutical companies’ role in the opioid epidemic, Perdue Pharma announces on Feb. 10 it will no longer actively market opioids to doctors.

**Joint Commission Liability:** Several counties in West Virginia sue the Joint Commission (for allegedly issuing misinformation to prescribers) and the WV Board of Pharmacy (for failing to report excessive orders for painkillers).

**Private Liability:** Tucson (AZ) Medical Center sued more than two dozen pharmaceutical companies for negligence, fraud, and conspiracy. Purdue Pharma published an open letter in Aug. 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 related to the wrongful or over-prescription opioids.
Good Samaritan Overdose Immunity Laws
(as of 6/5/17)

**Safe Injection Facilities (SIFs):** In Aug. 2018, the California Legislature approved a bill for a SIF pilot program in San Francisco, and was sent to the governor.

**Addressing Addiction:** On 3/28/18, Oregon passed legislation to increase funding, data sharing & other measures to prevent and treat addiction. Governor Kate Brown also declared addiction a public health crisis.

**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.

**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.

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**Overdose Prevention & Treatment**

**Safe Injection Facilities (SIFs):** In Aug. 2018, the California Legislature approved a bill for a SIF pilot program in San Francisco, and was sent to the governor.
**Increased Data Collection:** In 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.

**PDMP:** New York moved on 3/22/2018 to allow data sharing between its PDMP and 25 other states and Washington, D.C.

**Eased Data Sharing:** The House passed a bill on 6/20/18 to align privacy rules for substance use disorder records with the HIPAA Privacy Rule, easing data sharing w/out consent.

**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 the legislation.

**Privacy**
• Special thanks to Walter Johnson, MSTP, at ASU’s Sandra Day O’Connor College of Law for his research & assistance

• Ask the Network regarding questions or comments about this information

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