Opioid-related Public Health Emergency Declarations
as of 11/17/17

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Brief Contents

• Opioid Crisis Timeline
• Escalating Opioid Crisis
• National Public Health Emergency Declaration
• State/Tribal/Local Level Emergencies
• Specific Issues of Law and Policy
The Escalating Crisis

- 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%**; overdose deaths for teens (15-19 years) increased about **20%**.
- More than 12.5 million people **misused** prescription opioids in 2015.
- **142 Americans die every day** from opioid-related overdoses.
- Economic impacts (health/emergency care costs) **exceed $92 billion** in 2016.
- In at least 10 states, fentanyl and its analogs have been identified in over 70% of **overdose deaths**.
Overdose Deaths 2003-2014

Profile of Opioid Deaths

- **45-54**
  - age range with highest fatal overdose rate

- **65%**
  - of fatal overdoses are among males (2015)

- **25%**
  - of persons on opioids for chronic pain become addicted

- **45%**
  - more fatal overdoses occur in rural vs urban areas

- **82%**
  - identify as Caucasian/Non-Hispanic (2015)

- **10%**
  - received prior addiction treatment (2016)
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 (kg per 10,000) — Deaths (per 100,000)

† Sales data is unavailable for 2012.

Source: U.S. Drug Enforcement Administration and Centers for Disease Control and Prevention
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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. 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.

The Opioid Crisis
Approximately one-third of individuals in the United States report experiencing chronic pain, and many report opioid epidemic (health care, labor, and criminal justice costs) was estimated at $92 billion in 2016 (an increase of 67% over a decade ago). 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

• July 31, 2017: White House Commission recommended that President Trump declare a national state of emergency or public health emergency to:
  • reimburse state Medicaid programs to cover treatment facilities;
  • require doctors prescribing opiates to be instructed on pain treatment;
  • expand access to medication-assisted treatment (MAT);
  • 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.
• August 8, 2017: President Trump and former HHS Sec’y Price declined to issue any federal emergency declaration.
• August 10, 2017: The President reversed course, suggesting a national emergency will be declared.
• October 16, 2017: President Trump indicated that a national emergency would soon be declared.
October 26, 2017: President Trump directed acting HHS Secretary Eric D. Hargan to declare the opioid crisis a national Public Health Emergency (PHE) to:

- Overcome the IMD exclusion that precludes patients at certain addiction treatment facilities from Medicaid coverage
- Mobilize governments, communities and private organizations on emergency response efforts
- Provide best prescribing practices and requiring training for prescribers
- Remove a high-risk opioid from the market
- Direct the U.S. Postal Service, DHS, and DOJ to prevent overseas illicit drug trafficking
- Initiate federal lawsuits against drug companies and others contributing to the opioid crisis
- Authorizing NIH to develop resources, including non-addictive painkillers, to fight drug addiction
Section 319 of the Public Health Service Act empowers HHS’ Secretary to declare a PHE for a period of 90 days (subject to multiple renewals). The PHE declaration authorizes HHS to:

- respond via grants, contracts, and investigations into the cause, impacts, and viability of interventions
- access the PHE fund (which is virtually empty) and redirect other funds toward emergency response efforts
- temporarily appoint and reassign personnel to address the PHE
- waive or modify certain Medicare, Medicaid, HIPAA, or prescribing requirements that may impede emergency response efforts (subject to additional legal maneuvers)
- issue Emergency Use Authorizations (EUAs) via FDA
November 1, 2017: White House Commission released its final report recommending:

- Increasing federally funded initiatives to support opioid-related efforts at the state level
- Media campaigns encouraging affected individuals to seek treatment
- Removing legal barriers to use of PDMPs
- Expanding drug courts nationwide to embrace MAT
- Developing opioid prescribing guidelines, regulations, and education
- Ensuring greater health care coverage of substance use treatment
- Encouraging non-opioid pain treatment
- Raising criminal penalties for illicit drug trafficking, especially for fentanyl
- Implementing naloxone co-prescribing programs and EMT best practices
Select Congressional Responses

- **10/25/17**
  Sen. King (I-ME) introduced legislation seeking to invest $45 billion into substance abuse programs and negotiate naloxone pricing.

- **10/26/17**
  Sens. Rob Portman (R-OH) and Sherrod Brown (R-OH) praised the PHE declaration, calling for immediate federal action to increase access to treatment.

- **10/26/17**
  Sens. Elizabeth Warren (D-MA) & Lisa Murkowski (R-AK) urged President Trump to secure funding and appoint an HHS Secretary to carry out emergency response efforts.

- **11/14/17**
  Sens. Shaheen (D-NH), Hassan (D-NH), Manchin (D-VA), and Moore Capito (R-VA) introduced a bill to prioritize grant funding for states with highest mortality rates of opioid overdose.
Select Federal Agency Responses

October 26, 2017: NIH Director issued a statement on the importance of combating the opioid crisis through biomedical research

October 26, 2017: Acting Secretary Duke highlighted ongoing efforts to dismantle transnational criminal organizations and reduce supply of illicit opioids

October 27, 2017: CDC released its first report on data that tracks fentanyl in cases of overdose death

October 30, 2017: FDA Commissioner announced efforts to prevent and deter opioid misuse by changing packaging, storage, and disposal of opioids
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 declares emergency**
  - Mar 27, 2014

- **Alaska declares emergency**
  - Feb 14, 2017

- **Virginia declares emergency**
  - Nov 16, 2016

- **Maryland declares emergency**
  - Mar 1, 2017

- **Florida declares emergency**
  - Mar 13, 2017

- **Arizona declares emergency**
  - June 5, 2017
State, Tribal and Local Opioid Emergency Declarations

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

- White Earth Nation
- Leech Lake, Band of Chippewa
- Red Lake Nation
- Summit County
- Erie County
- Broome County
- Anne Arundel County
- Mashpee Wampanoag Tribe

[Map showing states and declarations]
## State Emergency Declaration Actions

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*Eventually overturned in court*
Former Governor Deval Patrick

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
Governor Larry Hogan

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
• 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
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 (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

Governor Doug Ducey
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

White Earth Nation
2011
Public Health Emergency
Topical Legal Issues

**Good Samaritan Statutes:** Multiple states (see next slide) have implemented immunity from arrest for drug possession when a person dials 911 or seeks medical attention during an instance of opioid overdose.

**Joint Commission Liability:** Several counties in West Virginia sue the Joint Commission (which accredits hospitals and other entities) for allegedly issuing misinformation to prescribers on the addictive nature of opioids.

**Product Liability:** 8/30/17: Arizona *sues* Insys for deceptive marketing of Subsys, a synthetic opioid spray 50x more potent than heroin, alleging the company bribed doctors to prescribe large quantities to non-cancer patients.

**Insurance Coverage:** Insurance companies *are limiting coverage* of less addictive opioid alternatives because they are more costly, thus exposing more patients to an increased risk of opioid misuse or abuse.
Good Samaritan Overdose Immunity Laws

Federal Naloxone Expansion: In announcing the PHE on 10/26/17, President Trump indicated that first responders would be better equipped with life-saving overdose meds.

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.

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.

Overdose Prevention & Treatment

Federal Naloxone Expansion: In announcing the PHE on 10/26/17, President Trump indicated that first responders would be better equipped with life-saving overdose meds.
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.

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

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

PDMP: In 2016, Massachusetts passed legislation requiring prescribers to report opioid prescribing practices.
• Special thanks to Alex Hess at ASU’s Sandra Day O’Connor College of Law for her research & assistance
• Ask the Network regarding questions or comments about this information
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