The Opioid Epidemic and the Future of Public Health Emergencies

Sarah A. Wetter, J.D.*
James G. Hodge, Jr., J.D., LL.M.**
Danielle Chronister***
Alexandra Hess****

Center for Public Health Law and Policy,
Sandra Day O'Connor College of Law,
Arizona State University,
Phoenix, Arizona

Introduction

On October 26, 2017, after weeks of internal deliberations, President Donald Trump directed Acting Secretary of Health and Human Services (HHS) Eric Hargan to declare a national state of public health emergency (PHE) in response to the escalating opioid epidemic.[1] In so doing, the President classified the opioid epidemic as the deadliest PHE to ever be so designated since the nomenclature originated in 2001. Over the last two decades, overuse and abuse of prescription and illicit opioids have contributed to rampant morbidity and mortality across the country. Since 1999 over 600,000 deaths among all ages, sexes, races, and classes are attributable to opioid abuse.[2] Solutions to this "Medusa of epidemics"[3] are not easy, quick, or cheap. Absent enhanced and innovative public health interventions funded by a sizable infusion of resources, hundreds of thousands more may die by 2020.[4]

Like opioid-related declarations issued already by a half-dozen states and multiple tribal governments and localities,[5] the federal PHE declaration is a purposeful step. Alongside other interventions, it legally authorizes federal, state, tribal, and local authorities to allocate existing personnel and resources toward opioid prevention efforts, waives some key legal inhibitions, ramps up critical public health surveillance, and facilitates greater coordination across federal agencies.[6]

Still, HHS' declaration has generated considerable controversy. Some favor classifying the opioid epidemic as a PHE, but wish President Trump would have declared a full-blown national emergency to free up more resources.[7] Others seriously question the utility of labeling a long-term, complex epidemic of opioid abuse as an emergency at all.[8] They assert that PHEs are typically reserved for rapidly-escalating infectious disease threats or quick responses to humanitarian disasters.[9] Debating the utility of a PHE declaration in response to the opioid epidemic, however, is misplaced for several reasons: (1) PHEs have been declared in response to threats far less serious than the opioid epidemic; (2) while a PHE declaration may not solve the crisis, it can diminish its impacts; and (3) innovations undertaken during a PHE can become standard practice post emergency. The primary question is not whether the opioid epidemic qualifies as a PHE, but rather what other conditions might also constitute PHEs going forward. This article suggests a series of criteria designed to better clarify PHEs for the future.

Legal Scope and Range of Public Health Emergencies

The terrorist attacks of September 11, 2001 and ensuing anthrax exposures prompted public health law scholars at Johns Hopkins and Georgetown Universities to develop model legislation for state and local officials to rapidly respond to emergency events. The resulting Model State Emergency Health Powers Act (MSEHPA), disseminated in December 2001, has been adopted by legislatures and agencies in almost all states and D.C., and used to declare PHEs in response to acts of bioterrorism, emerging infectious diseases, or other threats posing a "high probability" of deaths, disabilities, or exposures to harm-causing agents.[10]

As illustrated in **Table 1** below, PHEs have been declared under diverse circumstances necessitating a heightened legal response to protect the public's health. Multiple PHEs have been issued to curb the spread of highly contagious, sometimes fatal diseases such as H1N1 (2009),

Ebola virus (2014), and Zika virus (2016) through strengthened medical countermeasures and enhanced authorizations of social distancing efforts. Humanitarian disasters, including Hurricanes Katrina (2005), Sandy (2009), and Harvey (2017), have sparked numerous other emergency declarations, allowing redirection of government funds and personnel to bolster local response efforts in devastated and overwhelmed regions.

Table 1 – Select Examples of PHE Declarations

Date	Jurisdiction	Declaring Entity	Event/Condition
5/6/08	Pima County (AZ)	County Board of Supervisors	Measles[11]
4/26/09	United States	Acting HHS Sec'y Charles Johnson	H1N1[12]
10/5/10	City of Oakland (CA)	Oakland City Council	Shortage of medical cannabis[13]
3/19/12	County of Hawai'i (HI)	Council of the County of Hawai'i	Food insecurity[14]
3/27/14	Commonwealth of Massachusetts	Gov. Deval Patrick	Opioid addiction[15]
10/7/14	State of Connecticut	Gov. Daniel Malloy	Ebola[16]
3/26/15	Scott County (IN)	Gov. Mike Pence	HIV[17]
12/15/15	City of Flint (MI)	Mayor Karen Weaver	Lead levels in drinking water[18]
8/12/16	Puerto Rico	HHS Sec'y Sylvia Burwell	Zika[19]
8/26/17	State of Texas	Gov. Greg Abbott	Hurricane Harvey[20]

Government officials[21] have increasingly issued PHEs for events or conditions less sudden and severe than deadly outbreaks or humanitarian disasters. For example, PHEs of limited scope have been declared for food insecurity in Hawai'i County (2012), seasonal influenza in New York (2013),[22] and homelessness in Seattle (2015).[23] Though dissimilar in origin and trajectory,

these conditions mirror traditional emergencies in their need for additional funding, medical countermeasures, and skilled personnel to curb imminent and preventable threats to morbidity and mortality.[24] Interventions proving successful during declared emergencies, such as allowing pharmacists to administer flu vaccines, can be incorporated long-term through routine public health practice.[25]

Qualifying the Opioid Epidemic as a Public Health Emergency

Like a deadly infectious disease outbreak, recent mortality related to opioid misuse surpasses historically low rates. Since 2010, annual opioid overdose deaths more than quadrupled, reaching 64,000 deaths in 2016[26] (and far exceeding comparable rates from motor vehicle crashes and gun violence over the same period).[27] Despite emerging policies to control opioid prescribing,[28] overdose mortalities continue to rise. This is due in part to increased trafficking of cheaper, illicit, and highly potent heroin and synthetic opioids such as fentanyl. These drugs are flooding the nation almost like agents of bioterrorism.[29] Public health repercussions of the opioid epidemic are extensive. Heightened transmission rates of HIV and hepatitis C, for example, are attributable to unsafe opioid injection practices.[30] Overwhelmed localities are in dire need of state and federal assistance to address preventable morbidity and mortality through additional funding, resources, and healthcare and addiction treatment personnel.

Six states and several tribes preceded HHS in declaring opioid emergencies to expedite essential interventions.[31] These include enhanced data collection efforts in Arizona,[32] naloxone standing orders in Alaska,[33] and major funds devoted to drug addiction treatment and prevention in Maryland.[34] In directing HHS to declare a nationwide PHE on October 26, 2017, President Trump promised increased Medicaid coverage for addiction treatment as well as actions against

prescription drug companies and illicit drug traffickers.[35] In its final report on November 1, 2017 the President's Commission on Combatting Drug Addiction and the Opioid Crisis further recommended increasing the affordability and accessibility of naloxone and additional criminal justice interventions such as drug court programs.[36]

Clarifying the Criteria for Future Public Health Emergencies

The opioid epidemic inarguably constitutes a national PHE consistent with model legal approaches and prior applications. However, its classification within the spectrum of PHEs necessitates clarification to better distinguish other types of multifarious health threats. In 2017, for example, 30 million Americans will likely abuse alcohol.[37] Millions will die of heart disease, cancers, stroke, and Alzheimer's disease.[38] Thirteen million American children will suffer food insecurity.[39] Nearly that many kids face obesity.[40] These and other serious conditions present real risks to human health, but classifying them as PHEs may (1) embroil legal and political controversies surrounding their legitimacy, (2) exhaust emergency resources, and (3) lead to unwarranted exercises of authority. How can PHE declarations be qualified to avoid these outcomes? **Table 2**, below, presents a series of criteria that can be used collectively to distinguish PHEs from non-emergencies.[41]

Table 2 – Criteria Underlying PHE Declarations

Criteria	A PHE May Be Justified . . .
Urgency	where preventable morbidity or mortality due to a public health threat are likely to continue unabated absent more substantial interventions
Escalation	when the ascendancy of a public health condition leads to morbidity and mortality rates surpassing historic lows
Imminence	to prevent a potential threat (e.g., prospective release of a bioterrorism agent) from developing into a mega-threat

Severity	in response to potential or actual impacts presenting serious or irreversible public health risks for affected populations
Scope	if public health threats may significantly impact subgroups (e.g., infants, elderly) or smaller regions or locations (e.g., daycares, schools, hospitals)
Interventions	to authorize interventions, including removal of legal obstacles, that may obviate negative public health repercussions
Efficacy	to facilitate proven, otherwise unavailable measures known to effectively address similar threats
Ethicality	in furtherance of efficacious interventions that may be ethically questionable outside an emergency
Duration	where emergency measures of limited duration can lead to the termination, diminishment, or control of the public health threat
Incorporation	to promote positive reforms of routine interventions through demonstrated successes of emergency measures

Urgency may be the most persistent commonality characterizing PHEs. Rapid deployment of countermeasures against slowly-developing conditions like obesity or heart disease may be disfavored over incremental interventions. In the context of the opioid crisis, however, expanding naloxone access could curb on average 100 overdose deaths each day. Unremitting patterns of *escalation* absent rapid intervention may further qualify a PHE, though some declarations may hinge on the *imminent potential* to cause widespread harm. Under either circumstance, severe risk to morbidity and mortality lays the groundwork for a PHE declaration. When Connecticut's Governor Dannell Malloy declared a PHE for Ebola virus in 2014,[42] the *imminence* of Ebola to impact local populations, combined with *severity* (e.g., a high risk of death for exposed persons), spurred the ramped-up response despite no reported cases in the state.

PHE declarations are less contentious when their classification is limited in *scope* to definitive populations or locations afflicted by the threat. PHEs may also be justified by the commitment of *interventions* with known or predicted effectiveness to address the emergency. A

national PHE allows the U.S. Food and Drug Administration (FDA) to issue an Emergency Use Authorization for an unapproved drug, device, or intervention if anticipated benefits determinedly outweigh the risks of the condition left untreated.[43] Aside from *efficacy*, PHE interventions must also be *ethical*. Unleashing a series of powers to address a perceived or known public health threat is untenable if those efforts are impractical, underfunded, or disproportionately encroaching on individual or community rights. Declaring PHEs to implement efficacious, legal, and ethical interventions augments public trust and confidence in public health authority.

By law, the national opioid PHE lasts 90 days (absent reauthorization). Temporary efforts made possible by declarations should hold promise to diminish or control the suspected or known threat. Limiting the *duration* of PHEs allows for strategic funneling of resources without disinheriting other public health priorities. Resolving emergencies like the opioid epidemic entails a coupling of immediate actions and long-term reforms. Interventions demonstrating efficacy during a PHE can be *incorporated* later into routine public health practice. Calls for the FDA to convert naloxone from a prescription to over-the-counter drug during the opioid emergency, for example, may result in a permanent reclassification if the drug is demonstrated safe and effective.

Conclusion

HHS' declaration of the national opioid PHE reflects a modern trend of utilizing emergency efforts to address a broad range of calamitous conditions. While there are no set rules guiding determinations of PHEs, re-examining criteria for their declarations is critical to meaningfully respond to future emergency-level crises. The factors presented above help identify

conditions where a PHE declaration is legally warranted. As public health threats evolve, emergency authority must adapt as well to protect and promote population-level health.

Acknowledgment: The authors gratefully acknowledge contributions of Jennifer Piatt, Senior Legal Researcher, Center for Public Health Law and Policy, Sandra Day O'Connor College of Law, Arizona State University.

*Research Scholar, Center for Public Health Law and Policy; Staff Attorney, Network for Public Health Law – Western Region Office, Sandra Day O'Connor College of Law, Arizona State University (ASU). This article is based in part on the following publication: James G. Hodge, Jr., Sarah A. Wetter, Danielle Chronister, Alexandra Hess & Jennifer Piatt, *Redefining Public Health Emergencies: The Opioid Epidemic*, 58 JURIMETRICS J. (forthcoming December 2017).
**Professor of Public Health Law and Ethics; Director, Center for Public Health Law and Policy; Director, Network for Public Health Law – Western Region Office, Sandra Day O'Connor College of Law, ASU.
***J.D. Candidate (2018), Senior Legal Researcher, Center for Public Health Law and Policy, Sandra Day O'Connor College of Law, ASU.
****J.D. Candidate (2018), Senior Legal Researcher, Center for Public Health Law and Policy, Sandra Day O'Connor College of Law, ASU.

[1] Press Release, The White House Office of the Press Sec'y, President Donald J. Trump Is Taking Action on Drug Addiction and the Opioid Crisis (Oct. 26, 2017), https://www.whitehouse. gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid- crisis.
[2] Lawrence O. Gostin, James G. Hodge, Jr. & Sarah A. Noe, *Reframing the Opioid Epidemic as a National Emergency*, 318 JAMA 1539, 1539 (2017).
[3] James G. Hodge, Jr., Sarah A. Wetter & Sarah A. Noe, *Emerging Legal Responses to Curb the Opioid Epidemic*, 45 J. L. MED. & ETHICS 460, 460 (2017).
[4] Gostin et al., *supra* note 2.
[5] James G. Hodge, Jr. & Sarah A. Wetter, Network for Pub. Health Law, Opioid Related Public Health Emergency Declarations, https://www.networkforphl.org/resources_collection/2017/07/20/912/fact_sheet_declared_states_of_emergency_-_opioid_crisis/ (Fact Sheet).
[6] Public Health Emergency Declaration, U.S. Dep't of Health & Human Servs. (Aug. 18, 2017), https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx.
[7] Dan Merica, *What Trump's Opioid Announcement Means – and Doesn't Mean,* CNN (Oct. 26, 2017), http://www.cnn.com/2017/10/26/politics/national-health-emergency-national-disaster/index.html.
[8] Joel Wolfman, *Does Trump's Health Emergency Declaration Do Enough to Address the Opioid Crisis?*, WHYY (Oct. 27, 2017), https://whyy.org/articles/trumps-health-emergency-declaration-enough-address-opioid-crisis/.
[9] James G. Hodge, Jr. & Madeline Morcelle, Network for Pub. Health Law, Emergency Legal Preparedness 2017 – Hurricanes Harvey, Irma, and Maria, https://www.networkforphl.org/_asset/rfg7c7/Hurricanes-Harvey--Irma---Network-Primer-v2.pdf.
[10] JAMES G. HODGE, JR., PUBLIC HEALTH LAW IN A NUTSHELL 353, 358 (3d ed. 2018) (quoting MODEL STATE EMERGENCY HEALTH POWERS ACT § 104(m) (CTRS. FOR LAW & THE PUB.'S HEALTH, Draft for Discussion 2001), https://www.aclu.org/sites/default/files/field_document/msehpa2.pdf .

[11] Jennifer Steinhauser, *SOUTHWEST; Arizona; Measles Outbreak,* N.Y. TIMES (May 3, 2008), http://query.nytimes.com/gst/fullpage.html?res=9C0CE1D91E30F930A35756C0A96E9C8B63.
[12] 42 U.S.C. § 247d (2012); U.S. Dep't of Health & Human Servs., Determination that a Public Health Emergency Exists (April. 26, 2009), https://www.phe.gov/emergency/news/healthactions/phe/Pages/h1n1.aspx.
[13] Oakland City Council. Res. No. 82994 (Oct. 5, 2010).
[14] Hawaii Cty., Haw., Bill 199 (Mar. 9, 2012).
[15] MASS. DEPT. OF PUB. HEALTH, PUBLIC HEALTH ADVISORY (Mar. 28, 2014), http://www.mass.gov/eohhs/docs/dph/140328-opiate-advisory.pdf.
[16] Dannel P. Malloy, *Letter of Termination of Public Health Emergency* (Apr. 1, 2016), http://www.ct.gov/dph/lib/dph/infectious_diseases/pdf_forms_/2016_04_01_termination_of_public_health_emergency_-_ebola.pdf.
[17] Declaration of Public Health Emergency in Scott Cty., Ind., Exec. Order No. 15-05 (Mar. 26, 2015).
[18] State and Federal Emergency Declarations for Flint Contaminated Water, U.S. Dep't of Health & Human Servs. (Dec. 12, 2016), https://www.phe.gov/emergency/events/Flint/Pages/declarations.aspx.
[19] Determination that a Public Health Emergency Exists in Puerto Rico as a Consequence of the Zika Virus Outbreak, U.S. Dep't of Health & Human Servs. (Aug. 12, 2016), https://www.phe.gov/emergency/news/healthactions/phe/pages/zika-pr.aspx.
[20] Determination that a Public Health Emergency Exists in Texas as the Result of Hurricane Harvey, U.S. Dep't of Health & Human Servs. (Aug. 26, 2017), https://www.phe.gov/emergency/news/healthactions/phe/Pages/harvey-25aug2017.aspx.
[21] Authority to declare a PHE varies across jurisdictions. Most states adopting the MSEHPA authorize their Governors to declare a PHE. However, some jurisdictions also allow the declaration to be made by officials such as state health officers or health agency directors. ASTHO LEGAL PREPAREDNESS SERIES, EMERGENCY AUTHORITY AND IMMUNITY TOOLKIT: EMERGENCY DECLARATIONS AND AUTHORITIES (2012).
[22] Press Release, New York State Pressroom, Governor Cuomo Declares State Public Health Emergency in Response to Severe Flu Season (Jan. 12, 2013), https://www.governor.ny.gov/news/governor-cuomo-declares-state-public-health-emergency-response-severe-flu-season.
[23] Seattle, Wash., Mayoral Proclamation of Civil Emergency (Nov. 2, 2015), http://murray.seattle.gov/wp-content/uploads/2015/10/Proclamation-of-Civil-Emergency.pdf.
[24] While the utility and political motive behind these less-traditional emergency declarations may have been questioned, none has garnered the level of controversy as the national PHE declared for the opioid crisis.
[25] Michael D. Hogue et al., *Pharmacist Involvement with Immunizations: A Decade of Professional Advancement*, 46 J. AM. PHARM. ASS'N 168,169-70 (2006).
[26] Overdose Death Rates, U.S. Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last updated Sep. 2017).
[27] Josh Katz, *Drug Deaths in America are Rising Faster than Ever*, N.Y. TIMES (June 5, 2017), https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html.
[28] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (2016).
[29] Casey Leins, *Controlling Prescriptions Isn't Enough to Stop West Virginia's Opioid Crisis*, U.S. NEWS & WORLD REP. (Nov. 20, 2017), https://www.usnews.com/news/best-states/articles/2017-11-20/controlling-prescriptions-isnt-enough-to-stop-the-opioid-crisis-in-west-virginia.
[30] Thomas J. Stopka, *Opioid Epidemic Causing Rise in Hepatitis C Infections and Other Serious Illnesses*, CHICAGO TRIB. (Sep. 26, 2017), http://www.chicagotribune.com/sns-opioid-epidemic-causing-rise-in-hepatitis-c-infections-and-other-serious-illnesses-82040-20170926-story.html.
[31] JAMES G. HODGE, JR. & SARAH A. WETTER, NETWORK FOR PUB. HEALTH LAW, OPIOID RELATED PUBLIC HEALTH EMERGENCY DECLARATIONS, https://www.networkforphl.org/_asset/tbpflo/Opioid-Emergencies---Network-Primer-12-15-17.pdf.
[32] Holly Ward, Press Release, Governor Ducey Issues Executive Order to Increase Reporting of Opioid-Related Data (June 13, 2017), http://www.azdhs.gov/director/public-information-office/index.php#news-release-061317.

[33] Jay C. Butler, Chief Med. Officer, Alaska Dep't of Health & Soc. Servs., Statewide Medical Standing Order to Distribute, Dispense, and Administer Opioid/Heroin Overdose Rescue Kits (Feb. 15, 2017), https://gov.alaska.gov/wp-content/uploads/sites/5/Standing-Order-Project-HOPE-signed.pdf.
[34] Bill Turque, *Maryland Governor Declares State of Emergency for Opioid Crisis*, WASH. POST (Mar. 1, 2017), https://www.washingtonpost.com/local/md-politics/hogan-declares-opioid-state-of-emergency/2017/03/01/5c22fcfa-fe2f-11e6-99b4-9e613afeb09f_story.html?utm_term=. 3d6fc59ce8f7.
[35] The White House Office of the Press Sec'y, *supra* note 1.
[36] WHITE HOUSE COMM'N ON COMBATING DRUG ADDICTION & THE OPIOID CRISIS, FINAL REPORT 73, 77 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[37] Bridget F. Grant et al., *Prevalence of 12-Month Alcohol Use, High-Risk Drinking and DSM-IV Alcohol Use Disorder in the United States, 2001-2002 to 2012-2013*, 74 JAMA PSYCHIATRY 911(Sep. 2017), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2647079.
[38] Leading Causes of Death, Ctrs. for Disease Control & Prevention (Mar. 17, 2017), https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm.
[39] NO KID HUNGRY, HUNGER DEVASTATES CHILDREN: FACTS ON CHILDHOOD HUNGER IN AMERICA (2016).
[40] Childhood Obesity Facts, Ctrs. for Disease Control & Prevention (Apr. 10, 2017), https://www.cdc.gov/obesity/data/childhood.html.
[41] For additional description of criteria, see James G. Hodge, Jr., Sarah A. Wetter, Danielle Chronister, Alexandra Hess & Jennifer Piatt, *Redefining Public Health Emergencies: The Opioid Epidemic*, 58 JURIMETRICS J. (forthcoming December 2017). MSEHPA authorizes an emergency declaration to confront an "imminent threat" believed to be caused by bioterrorism, infectious agent, or biological toxin; or a "high probability" of death, disability, or future harm. *Supra* note 10. However, MSEHPA does not otherwise describe emergency-level criteria. *Id*.
[42] Malloy, *supra* note 16.
[43] Emergency Use Authorization, Food & Drug Admin. (Nov. 17, 2017), https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.