



441 G St. N.W.
Washington, DC 20548

September 26, 2018

Congressional Requesters

Opioid Crisis: Status of Public Health Emergency Authorities

Opioid misuse and related deaths are a serious, growing public health problem in the United States. According to the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), over 42,000 people died from opioid-involved overdoses in 2016. The federal government has launched a number of initiatives to combat the opioid crisis, and HHS issued a five-point Opioid Strategy in April 2017 to guide the department's efforts.¹ We and others have reported on ongoing federal actions to address opioid issues.²

On October 26, 2017, the Acting Secretary of HHS declared the opioid crisis a public health emergency under section 319 of the Public Health Service Act and the declaration was renewed in January, April, and July 2018.³ A public health emergency triggers the availability of certain authorities under federal law that enable federal agencies to take actions such as accessing the Public Health Emergency Fund, temporarily reassigning certain state and local personnel, and waiving certain administrative requirements. These authorities may allow the federal government to increase support to and reduce administrative burdens on state and local governments and federal grantees affected by or responding to the public health emergency. They may also supplement other federal efforts that are ongoing to address the emergency. While the Secretary of HHS may declare a public health emergency, the use of some authorities requires coordination with other agencies, including the Department of Justice (Justice) and the Department of Labor (Labor). The October 2017 declaration was the first time that a public health emergency declaration was made for the opioid crisis. Public health emergencies have

¹The Opioid Strategy's five priority areas are: 1) better access to prevention, treatment, and recovery services; 2) better data on the epidemic; 3) better pain management; 4) better targeting of overdose-reversing drugs; and 5) better research on pain and addiction.

²See, for example, GAO, *Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries*, [GAO-18-585T](#) (Washington D.C.: May 29, 2018); *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts*, [GAO-18-205](#) (Washington, D.C.: March 29, 2018); *Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment*, [GAO-18-44](#) (Washington, D.C.: Oct. 31, 2017); *Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome*, [GAO-18-32](#) (Washington D.C.: Oct. 4, 2017); and *Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm*, [GAO-18-15](#), (Washington D.C.: Oct. 6, 2017).

³A declaration is in effect until the Secretary declares the emergency no longer exists, or 90 days after the declaration, whichever occurs first. A declaration that expires may be renewed by the Secretary. The then-Acting Secretary made the determination for the October 2017 public health emergency declaration for the opioid crisis and the January 2018 renewal of this declaration. The current Secretary made the determination for the April and July 2018 renewals of the declaration.

previously been declared for infectious disease outbreaks, such as the Zika and the H1N1 influenza virus outbreaks, as well as for hurricanes and other weather events.⁴

You asked us to review the decision to declare a public health emergency for the opioid crisis, and what actions have been taken under the declaration. In this report, we describe:

1. the factors HHS indicated as affecting its decision to declare and renew the public health emergency for the opioid crisis, and
2. the public health emergency authorities the federal government has used to address the opioid crisis.

To address these objectives, we reviewed relevant HHS statements and decision documents and interviewed HHS officials about the basis for declaring a public health emergency for the opioid crisis. These officials included those from the Substance Abuse and Mental Health Services Administration (SAMHSA), the agency within HHS that leads public health efforts focused on reducing the negative effects of substance abuse and mental illness. In addition, we reviewed the Public Health Service Act and related statutory and regulatory provisions to identify the authorities that become available during a public health emergency. We also reviewed HHS, Labor, and Justice documents and interviewed agency officials to determine which of the available authorities have been used and their status, including reasons that some authorities were not used. In addition, we reviewed information from HHS about other recently declared federal public health emergencies where these authorities were last used. This report focuses on public health emergency authorities and does not examine other federal efforts to combat the opioid crisis.

We conducted this performance audit from March 2018 to September 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

Increasing rates of opioid-related deaths and opioid use disorder were the primary factors for the declaration of a public health emergency for the opioid crisis on October 26, 2017, and for its renewal on January 19, 2018, according to HHS officials. Officials cited still-increasing rates of opioid-related deaths in 2017 for the declaration's renewal on April 20, 2018, as well as the consideration that a nationwide public health emergency underscores the urgency of ongoing federal, state, and local efforts to combat the opioid crisis. More recently in July, HHS again renewed the declaration due to the continued consequences of the opioid crisis.

Since declaring the opioid crisis a public health emergency, the federal government has used three available authorities. According to HHS officials, one of them allowed HHS to quickly field a survey of more than 13,000 providers to assess prescribing trends for a medication used to treat opioid use disorder and any barriers to prescribing it. HHS used another authority to waive the public notice period for approval of two state Medicaid demonstration projects related to substance use disorder treatment, which is intended to speed up implementation of these

⁴See GAO, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, [GAO-17-445](#) (Washington, D.C.: May 23, 2017) and *Influenza Pandemic: Lessons from the H1N1 Pandemic Should be Incorporated into Future Planning*, [GAO-11-632](#) (Washington, D.C.: June 27, 2011).

projects. HHS also took steps to expedite support for research on opioid use disorder treatments and to disseminate information on opioid misuse and addiction, as required by another authority. In addition to these 3 authorities, we identified 14 other authorities that became available as a result of the public health emergency and have not been used.⁵

According to HHS officials, these additional authorities have not been used for a variety of reasons: for example, HHS officials determined that many are not relevant to the circumstances presented by the opioid crisis. Officials told us they will continue to review the authorities as the opioid crisis evolves and in the context of HHS's other efforts to address the opioid crisis.

Background

Opioids, such as hydrocodone, oxycodone, morphine, and methadone, can be prescribed to treat both acute and chronic pain. Because many opioids have a high potential for abuse and may lead to severe psychological or physical dependence, many of them are classified as Schedule II drugs under the Controlled Substances Act.⁶ The misuse of opioids has been associated with serious consequences, including addiction, overdose, and death. Recently, there has been a rise in opioid use in the United States involving both the misuse of prescription drugs and illicit opioids, such as heroin.

The federal government has taken certain actions to address the crisis. For example, we reported on efforts by HHS to expand access to medication-assisted treatment for those who misuse or are addicted to opioids—a condition known as opioid use disorder.⁷ Medication-assisted treatment, which combines behavioral therapy and the use of certain medications (methadone, buprenorphine, and naltrexone), has been shown to reduce opioid use and to increase treatment retention compared with abstinence-based treatment, where patients are treated without medication.⁸ We also recently reported on federal efforts to combat synthetic opioids, such as by limiting their availability and expanding prevention programs and treatment options.⁹ Synthetic opioids, including fentanyl, often have very high potency that can increase the risk of overdose.

In March 2017, the President issued Executive Order 13784 establishing a commission to study the scope and effectiveness of the federal response to drug addiction and the opioid crisis.¹⁰ The President's Commission on Combating Addiction and the Opioid Crisis issued a final report in November 2017, making a number of recommendations to the President to enhance the

⁵We identified authorities that become available as a result of a public health emergency declaration under section 319 of the Public Health Service Act, as well as other authorities that become available when there is a public health emergency, but that do not require a declaration. For the purposes of this report, we refer to these authorities collectively as authorities triggered by a public health emergency.

⁶Under the Controlled Substance Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their currently accepted medical use, potential for abuse, and risk of dependence.

⁷[GAO-18-44](#).

⁸Methadone and buprenorphine suppress withdrawal symptoms in detoxification therapy and control the craving for opioids in maintenance therapy. Both drugs are opioids that activate opioid receptors and carry risks of misuse. Both drugs can also be used to treat pain. Naltrexone is used for relapse prevention because it suppresses the euphoric effects of opioids, and it carries no known risk of misuse.

⁹[GAO-18-205](#).

¹⁰Executive Order No. 13784 of March 29, 2017, 82 Fed. Reg. 16,283 (Apr. 3, 2017).

federal government's response to the opioid problem. Further, on October 26, 2017, the President directed the Acting Secretary of HHS to declare the opioid crisis to be a public health emergency.

Under section 319 of the Public Health Service Act, the Secretary of HHS may declare a public health emergency if the Secretary determines, in consultation with other public health officials as may be necessary, that (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.¹¹ Section 319 does not specify any additional requirements or procedures that the Secretary must follow to declare a public health emergency. Under section 319, the Secretary of HHS can take appropriate action in response to a public health emergency, including making grants, providing awards for expenses, entering into contracts, and conducting and supporting investigations into the cause, treatment, or prevention of the underlying disease or disorder. In addition, section 319 includes specific authorities that can be used for such things as extending deadlines for any report required to be submitted under any law administered by HHS and temporary reassignment of state and local personnel whose positions are funded, at least in part, under programs authorized under the Public Health Service Act. Public health emergency declarations also trigger the availability of other authorities outside of section 319. In addition, other authorities may become available when there is a public health emergency but do not require a declaration. The use of these authorities in previous public health emergencies has varied, and some authorities have not been used. Enclosure I lists the authorities available when there is a public health emergency.

The federal government has declared public health emergencies for infectious disease outbreaks, such as the Zika and the H1N1 influenza virus outbreaks, and for hurricanes, such as Hurricane Maria in Puerto Rico, and for other weather-related events. Enclosure II lists other recent public health emergencies.

HHS Officials Cited Increasing Rates of Opioid-Related Deaths and Opioid Use Disorder as Primary Factors for Declaring and Renewing the Public Health Emergency

According to HHS officials, the primary factors for declaring and renewing the public health emergency for the opioid crisis were the increasing rates of opioid-related overdose deaths and opioid use disorder, especially the increase in overdoses as a result of synthetic opioids such as fentanyl.¹² The public health emergency for the opioid crisis was first declared on October 26, 2017, by the Acting Secretary of HHS, who also renewed the declaration in January 2018.¹³ In April 2018, SAMHSA recommended that the Secretary of HHS again renew the public health emergency declaration for the opioid crisis, noting specifically the provisional 2017 estimates

¹¹Distinct from a public health emergency declaration are two declarations available to the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act): a major disaster declaration and an emergency declaration. The President can issue either type of declaration under the Stafford Act at the request of the governor of an affected state or a chief executive of an affected Indian Tribe. The President may also declare a national emergency under the National Emergencies Act, which authorizes the President to activate existing emergency authorities in other statutes. The President did not make these declarations for the opioid crisis.

¹²Synthetic opioids are man-made opioids, such as fentanyl and fentanyl analogues. An analogue is a drug molecule that shares structural similarities with the original compound. It may also share pharmacological similarities. For more information about synthetic opioids and federal agencies' efforts to combat them, see GAO, *Illicit Opioids: Office of National Drug Control Policy and Other Agencies Need to Better Assess Strategic Efforts*, [GAO-18-569T](#) (Washington D.C.: May 17, 2018), and [GAO-18-205](#).

¹³This renewal was declared on January 19, 2018, and effective January 24, 2018.

from CDC indicating that opioid-related overdose deaths continued to increase in 2017.¹⁴ In addition, SAMHSA's April recommendation cited a March 2018 CDC report stating that emergency department visits due to opioid overdoses—a measure of opioid-related morbidity—had increased significantly in the past year, increasing almost 30 percent from the third quarter (July through September) of 2016 to the third quarter of 2017.¹⁵ In particular, among approximately 91 million emergency department visits captured from July 2016 through September 2017 in the National Syndromic Surveillance Program, a total of 142,557 (15.7 per 10,000 visits) were suspected opioid overdoses.¹⁶ HHS officials told us that in addition to CDC's provisional estimates for opioid-related mortality and the emergency department visit data on suspected opioid-related overdoses, HHS relied on multiple other data sources to inform the public health burden of the opioid crisis.¹⁷

SAMHSA officials noted that the existence of a nationwide public health emergency has spurred additional action across HHS and underscores the urgency of federal, state, and local efforts to combat the opioid crisis, many of which were ongoing prior to the declaration, such as efforts to expand access to medication-assisted treatment. Further, SAMHSA stated that renewing the public health emergency declaration provided HHS additional time to consider how the public health emergency authorities might be used to supplement ongoing federal efforts. More recently, the Secretary of HHS again renewed the declaration on July 19, 2018, and stated that the renewal was due to the continued consequences of the opioid crisis.¹⁸

The Federal Government Has Used Three Public Health Emergency Authorities to Help Address the Opioid Crisis

Since declaring the opioid crisis a public health emergency, the federal government has used three public health emergency authorities to help address the crisis, as of July 2018. Specifically, these are:

- **Waiver of Paperwork Reduction Act requirements.** This authority allows the Secretary of HHS to waive requirements under the Paperwork Reduction Act for the voluntary collection of information when necessary to prepare for and respond to a public health emergency.¹⁹ HHS officials told us that, by using this authority, they were

¹⁴This renewal was declared on April 20, 2018, and effective April 24, 2018.

¹⁵Vivolo-Kantor, A.M., Seth, P., Gladden, R.M., et al. "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017." *Morbidity and Mortality Weekly Report* vol. 67:279–285 (2018).

¹⁶The National Syndromic Surveillance Program promotes the development of a syndromic surveillance system for the timely exchange of syndromic data. Syndromic surveillance uses syndromic data and statistical tools to detect and monitor unusual activity for further public health investigation or response. Syndromic data include patient encounter data from emergency departments, urgent care, ambulatory care, and inpatient healthcare settings, as well as pharmacy and laboratory data. These data are monitored in near real-time as potential indicators of an event, a disease, or an outbreak of public health significance.

¹⁷The additional data included, among others, data on opioid misuse and use disorder from SAMHSA's National Survey on Drug Use and Health, rising rates of injection drug use among treatment admissions reported into SAMHSA's Treatment Episode Data Set, the Agency for Healthcare Research and Quality's Healthcare Costs and Utilization Project hospitalization and emergency department data, and CDC's data on rising rates of hepatitis C.

¹⁸This renewal was declared on July 19, 2018, and effective July 23, 2018.

¹⁹The Paperwork Reduction Act was enacted, in part, to minimize the burden for individuals, small businesses, and others resulting from the collection of information by or for the federal government. Among other things, the Act requires federal agencies to justify any collection of information from the public by establishing the need for and intended use of the information, estimating the burden that the collection will impose on the respondents, and

quickly able to field a critical survey of more than 13,000 providers to assess prescribing trends of a medication, buprenorphine, used to treat opioid use disorder and any barriers to prescribing it. According to officials, they were able to streamline the survey review process, including bypassing a review by the Office of Management and Budget that is typically required, which allowed HHS officials to deploy the survey in March 2018 and collect more current data in a much shorter timeframe than they would have without the authority. As of April 2018, officials reported receiving over 5,000 responses. Officials told us the results of the survey will inform policy and programmatic decisions related to increasing access to substance abuse treatment.

- **Waiver of public notice procedures for section 1115 Medicaid demonstrations.** This authority allows HHS’s Centers for Medicare & Medicaid Services (CMS) to waive federal and state public notice procedures to expedite a decision on a proposed Medicaid section 1115 demonstration project that addresses a public health emergency.²⁰ These demonstrations allow states to test and evaluate new approaches for delivering Medicaid services.²¹ Generally, after receipt of an application from a state to begin or extend a demonstration, CMS must provide for a 30-day public comment period and wait at least 45 days before making a final decision.²² HHS officials reported that they waived the public notice requirements for two states—Louisiana and New Hampshire in February 2018 and July 2018, respectively—for the submission of demonstration applications related to substance use disorder treatment.
- **Expedited support for research.** When a public health emergency is in effect, the Secretary of HHS, acting through the Director of the National Institutes of Health (NIH), is required under one of the authorities to take steps to expedite support for research on the disease or disorder underlying the public health emergency and disseminate information on the cause, prevention, and treatment of the disease or disorder.²³ In December 2017, NIH announced expedited procedures for research funding on medication development for opioid use disorder and overdoses. In addition, according to HHS officials, NIH is disseminating information on opioid misuse and addiction through a website about the research goals and funding opportunities of its Helping to End Addiction Long-term (HEAL) initiative, launched in April 2018, and by updating related publications.

In addition to these 3 authorities, we identified 14 other authorities available under a public health emergency. As of July 2018, these 14 authorities have not been used under the public

showing that the collection is the least burdensome way to gather the information. Paperwork Reduction Act of 1995, Pub. L. No. 104-13, 109 Stat. 163 (1995).

²⁰Medicaid is a joint federal-state program that finances health care coverage for low-income and medically needy populations. Section 1115(a) of the Social Security Act allows the Secretary of HHS to waive certain federal Medicaid requirements and allow federal funding for items and services that would not otherwise be eligible for federal funding for experimental, pilot, or demonstration projects that, in the Secretary’s judgment, are likely to promote Medicaid objectives. The Secretary has delegated the approval and administration of Medicaid section 1115 demonstrations to CMS.

²¹GAO, *Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures*, [GAO-18-220](#), (Washington, D.C.: Jan. 19, 2018).

²²See 42 C.F.R. §§ 431.416(b) and (e) (2017).

²³Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (codified as amended at 42 U.S.C. § 289c).

health emergency declaration for the opioid crisis. HHS officials provided reasons for why they were not using these authorities, and we categorized these reasons in table 1 below. (See enclosure I for a list of the 17 available authorities, the source and description of each authority, the reasons agency officials provided for why some authorities were not used during the public health emergency for the opioid crisis, and the last public health emergency declaration during which agency officials identified using the authority.)

Table 1: Reasons Cited by Agency Officials That Certain Public Health Emergency Authorities Have Not Been Used for the Opioid Crisis, as of July 2018

Reason authorities were not used	Number of authorities
Officials determined authority was not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged	5
Officials reported that no eligible entities, such as states, requested the use of this authority	3
Officials determined that other authorities could be used, rather than public health emergency authorities	3 ^a
Officials expressed concerns that use of authority could increase the risk of diversion of medications for improper use	2 ^a
Officials determined authority was not applicable because dependent upon use of the Public Health Emergency Fund, which has not been used	1
Officials determined that the statutory conditions for using the authority have not been met	1

Source: GAO analysis of information from Department of Health and Human Services, Department of Justice, and Department of Labor. | GAO-18-685R

^aOne of the authorities is listed under two reasons.

Examples of the authorities, and the reasons that agency officials provided for why they have not been used, include the following:

- **Access to National Dislocated Worker Grants.** This authority allows the Secretary of Labor to award grants to states or other local areas that have been impacted by emergencies, disasters, or major economic dislocations. These grants provide funding to create temporary employment opportunities to assist with clean-up and recovery efforts, among other things. Labor officials reported that no eligible entities have submitted applications for these grants during the public health emergency for the opioid crisis, as of July 2018.²⁴ Officials noted that a number of factors might have affected why potential grantees have not submitted applications for these grants, including that another grant option is available—the National Health Emergency Dislocated Worker Demonstration Grants—which was established to help communities address the economic and workforce-related impacts of the opioid crisis.²⁵
- **Application extensions and waiver of requirements for block grant funding.** This authority allows the Secretary of HHS to provide an application extension for or waive

²⁴The National Dislocated Worker Grant authority was last used in September 2016 while the public health emergency declaration for the Zika virus in Puerto Rico was in effect. On September 28, 2016, Labor awarded a \$6 million National Dislocated Worker Grant to the Puerto Rico Department of Labor and Human Resources, to employ temporary workers to assist with recovery efforts to address the Zika outbreak.

²⁵In July 2018, Labor announced more than \$22 million in National Health Emergency Dislocated Worker Demonstration Grant funding to six state grantees. The grants will be used to provide reemployment services for individuals impacted by the health and economic effects of widespread opioid use, addiction, and overdose.

compliance with requirements for mental health and substance abuse block grant funding during a public health emergency.²⁶ HHS officials told us this provision is not relevant to the public health emergency for the opioid crisis, as it is generally used when a local or state health department building is destroyed by a natural disaster, such as an earthquake or hurricane, and grant data is lost.²⁷

- **Modifications to the practice of telemedicine.** During a public health emergency, this authority allows the Secretary of HHS, with concurrence of the Attorney General, to reduce restrictions on the use of telemedicine when prescribing controlled substances, including those used in the treatment of opioid use disorder.²⁸ HHS officials stated that they have not used this authority because federal law provides for other circumstances under which these restrictions do not apply, thereby allowing the use of telemedicine. Officials also expressed concerns about increasing the risk of diversion of medications for improper use and maintaining high quality of care.²⁹
- **Access to the Public Health Emergency Fund.** The Secretary of HHS may access the Public Health Emergency Fund to take action to respond to a public health emergency, including making grants, providing awards for expenses, and entering into contracts for conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder presenting a public health emergency. According to documents provided by HHS, the Public Health Emergency Fund has a balance of about \$57,000. According to HHS officials, HHS has not requested that Congress appropriate money to the Fund for the current public health emergency and, instead, has used other sources of federal funds to address the opioid crisis.³⁰

HHS officials told us they will continue to assess the relevancy of these and other authorities as the opioid overuse issue evolves across the country, in the context of HHS's other efforts to address the opioid crisis.

Agency Comments

We provided a draft of this report to HHS, Labor, and Justice for comment. HHS and Labor provided technical comments, which we incorporated as appropriate. Justice told us that they did not have any comments.

²⁶This authority specifically applies to grants for assistance in transition from homelessness, grants for community mental health services, and grants for the prevention and treatment of substance abuse during a public health emergency.

²⁷As of July 2018, HHS officials reported that they have never used this authority during a public health emergency.

²⁸Telemedicine generally refers to the use of electronic information and telecommunications technologies to support long-distance health care through technologies such as videoconferencing.

²⁹As of July 2018, HHS officials told us that they have never used this authority during a public health emergency.

³⁰HHS officials reported that the Public Health Emergency Fund was last used in 1993 for the Hantavirus outbreak. The Public Health Emergency Fund, established in 1983, is available to the Secretary of HHS without fiscal year limitation to take appropriate action in response to a public health emergency. See Pub. L. No. 98-49, 97 Stat. 245 (1983).

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Secretary of Labor, the Attorney General, and appropriate congressional committees. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions concerning this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report were Will Simerl (Assistant Director), Natalie Herzog (Analyst-in-Charge), Amy Andresen, Kaitlin M. Farquharson, Laurie Pachter, and Carmen Rivera-Lowitt.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary Denigan-Macauley". The signature is written in black ink and is positioned above the typed name and title.

Mary Denigan-Macauley
Acting Director, Health Care

Enclosure(s) – 2

List of Requesters

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pension
United States Senate

The Honorable Tammy Baldwin
United States Senate

The Honorable Sherrod Brown
United States Senate

The Honorable Richard Blumenthal
United States Senate

The Honorable Cory A. Booker
United States Senate

The Honorable Robert P. Casey, Jr.
United States Senate

The Honorable Joe Donnelly
United States Senate

The Honorable Tammy Duckworth
United States Senate

The Honorable Dianne Feinstein
United States Senate

The Honorable Kirsten Gillibrand
United States Senate

The Honorable Margaret Wood Hassan
United States Senate

The Honorable Tim Kaine
United States Senate

The Honorable Edward J. Markey
United States Senate

The Honorable Bill Nelson
United States Senate

The Honorable Brian Schatz
United States Senate

The Honorable Jeanne Shaheen
United States Senate

The Honorable Debbie Stabenow
United States Senate

The Honorable Elizabeth Warren
United States Senate

The Honorable Sheldon Whitehouse
United States Senate

Enclosure I: Public Health Emergency Authorities

A public health emergency triggers the availability of certain authorities under federal law. These authorities may allow the federal government to increase support to and reduce administrative burdens on state and local governments and federal grantees affected by or responding to the public health emergency. We identified authorities that become available as a result of a public health emergency declaration under section 319 of the Public Health Service Act, as well as other authorities that become available when there is a public health emergency but do not require a declaration. Table 2 lists the public health emergency authorities; the source of the authority; a description of the authority; the reason an authority was not used during the public health emergency for the opioid crisis as of July 2018, according to Department of Health and Human Services and Department of Labor officials; and the last public health emergency declaration during which agency officials identified using the authority.

Table 2: List of Federal Public Health Emergency Authorities and Description of Their Use under the Opioid Crisis Public Health Declaration and Other Public Health Emergency Declarations

Authority	Description
Funding-related authorities	
Access to funds in the Public Health Emergency Fund	<ul style="list-style-type: none"> • Authority: Pub. L. No. 98-49 (1983) (codified as amended at 42 U.S.C. § 247d(a) and (b)) • Description: This provision allows the Secretary of Health and Human Services to take appropriate action to respond to a public health emergency, including by making grants, providing awards for expenses, entering into contracts, and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder. The Secretary may access the Public Health Emergency Fund to carry out these functions if the Secretary has declared a public health emergency. Appropriations made to the Public Health Emergency Fund are available to the Secretary without fiscal year limitation. Such funds may be used to supplement and not supplant other federal, state, and local public funds. • Reason not used for opioid public health emergency: Department of Health and Human Services (HHS) officials determined that other authorities could be used, rather than public health emergency authorities. HHS also provided evidence that the Public Health Emergency Fund currently contains approximately \$57,000. • Last use during a public health emergency: According to HHS officials, this authority was last used to respond to an outbreak of Hantavirus in 1993.
Supplies and services in lieu of award funds	<ul style="list-style-type: none"> • Authority: Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 110 (codified at 42 U.S.C. § 247d-7c) • Description: This provision allows the Secretary of HHS to provide supplies, equipment, services, and HHS personnel to help an award recipient, at the recipient's request, carry out the purposes of the award. The Secretary is required to reduce award payments by an amount equal to the value of the supplies, equipment, services, and personnel. • Reason not used for opioid public health emergency: HHS officials determined this authority is not applicable because it is dependent upon the use of the Public Health Emergency Fund. Specifically, this authority applies to awards under 42 U.S.C. §§ 247d through 247d-7b and 247d-7d. • Last use during a public health emergency: According to HHS officials, this authority has never been used for awards from the Public Health Emergency Fund.

Authority	Description
Waiver of certain Ryan White HIV/AIDS program requirements	<ul style="list-style-type: none"> • Authority: Ryan White HIV/AIDS Treatment Modernization Act of 2006, Pub. L. No. 109-415, § 501 (codified at 42 U.S.C. § 300ff-83) • Description: This provision allows the Secretary of HHS to waive requirements under Title XXVI of the Public Health Service Act, the Ryan White HIV/AIDS Program, to improve the health and safety of those receiving care under the Program and the general public in an area and during a period in which there exists: (1) a public health emergency declared by the Secretary under section 319 of the Public Health Service Act or (2) an emergency or disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act. The Secretary may not spend more than five percent of supplemental funds available under each of the Parts A and B to ensure access to care during a public health emergency. • Reason not used for opioid public health emergency: HHS officials reported that no eligible entities, such as states, requested the use of this authority. • Last use during a public health emergency: This authority was last used during the public health emergency declared for Hurricanes Irma and Maria in September 2017.
Access to National Dislocated Worker Grants	<ul style="list-style-type: none"> • Authority: Workforce Innovation and Opportunity Act, Pub. L. No. 113-128, § 170 (2014) (codified at 29 U.S.C. § 3225) • Description: This provision allows the Secretary of the Department of Labor (Labor) to award grants to eligible entities to provide employment and training assistance to workers in emergency or disaster areas and to those affected by major economic dislocations. Eligible entities may include states and entities capable of responding to the emergency, disaster, or dislocation. Eligible entities may apply for grants in the event of (1) an emergency or major disaster, as defined in the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or (2) an emergency or disaster of national significance that could result in a potentially large loss of employment, as declared by the chief official of a federal agency with jurisdiction over the federal response to the emergency or disaster. • Reason not used for opioid public health emergency: Labor officials reported that no eligible entities, such as states, requested the use of this authority. • Last use during a public health emergency: This authority was last used during the public health emergency declared for the Zika virus outbreak in August 2016.
Medication-related authorities	
Modifications to the practice of telemedicine	<ul style="list-style-type: none"> • Authority: Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, § 3 (codified at 21 U.S.C. § 802(54)(D)) • Description: The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 generally requires a health care practitioner to have conducted at least one in-person exam prior to prescribing a controlled substance. This provision allows the Secretary of HHS, with the concurrence of the Attorney General, to designate patients located in certain areas and controlled substances that are excepted from the in-person exam requirement during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act. • Reason not used for opioid public health emergency: HHS determined that other authorities could be used, rather than public health emergency authorities and HHS officials expressed concerns that use of authority could increase the risk of diversion of medications for improper use. • Last use during a public health emergency: According to HHS officials, this authority has never been used.

Authority	Description
Exemption from certain drug distribution supply chain requirements	<ul style="list-style-type: none"> • Authority: Drug Quality and Security Act, Pub. L. No. 113-54, § 202 (2013) (codified at 21 U.S.C. §§ 353(e)(4)(C), 360eee, and 360eee-1(a)(3)) • Description: The Drug Supply Chain Security Act, enacted as Title II of the Drug Quality and Security Act, generally establishes requirements for drug manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of prescription drugs through the supply chain. Upon a public health emergency declaration under section 319 of the Public Health Service Act, prescription drugs distributed for the public health emergency are excluded from the Act's product tracing and wholesale distribution requirements, including those pertaining to wholesale distribution. In addition, section 360eee-1(a)(3) requires the Secretary of HHS to establish, by guidance, a process for requesting a waiver from these and other requirements related to product tracing and wholesale distribution for emergency medical reasons, such as a public health emergency declaration under section 319 of the Public Health Service Act. • Reason not used for opioid public health emergency: HHS officials expressed concerns that use of authority could increase the risk of diversion of medications for improper use. • Last use during a public health emergency: According to HHS officials, certain Drug Quality and Security Act emergency authorities were last used during the public health emergency declared for Hurricane Maria in September 2017.
Adjustment of Medicare reimbursement for certain Part B drugs	<ul style="list-style-type: none"> • Authority: Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 303 (codified at 42 U.S.C. § 1395w-3a(e)) • Description: This provision allows the Secretary of HHS to pay the wholesale acquisition cost or other reasonable measure of price instead of the manufacturer's average sales price for a Medicare Part B-covered drug during a public health emergency declaration under section 319 of the Public Health Service Act. These drugs are typically administered under a physician's supervision and include injectable drugs, some oral cancer drugs, and drugs infused or inhaled through durable medical equipment. To exercise this authority, there must be a documented inability to access a drug or biological and a concomitant price increase that is not reflected in the manufacturer's average sales price for one or more quarters. • Reason not used for opioid public health emergency: HHS determined that the statutory requirements for an alternative payment methodology have not been met. • Last use during a public health emergency: According to HHS officials, this authority has never been used.
Research-related authorities	
Research related to public health emergencies ^a	<ul style="list-style-type: none"> • Authority: Health Research Extension Act of 1985, Pub. L. No. 99-158, § 2 (codified as amended at 42 U.S.C. § 289c) • Description: If the Secretary of HHS determines that a disease or disorder constitutes a public health emergency, this provision requires the Secretary of HHS, acting through the Director of NIH, to (1) expedite review by advisory councils and peer review groups of applications for grant research on the disease or disorder; (2) exercise authority to waive advertising requirements for contract proposals for research on the disease or disorder; and (3) disseminate information to health professionals and the public on the cause, prevention, and treatment of the disease or disorder that has been developed through this research. The Secretary may also provide administrative supplemental increases in existing grants and contracts to support new research relevant to the disease or disorder. • Reason not used for opioid public health emergency: Not applicable, because the authority was used. • Last use during a public health emergency: This authority was last used during the public health emergency declared for the opioid crisis in October 2017.

Authority	Description
Personnel related authorities	
Temporary reassignment of state and local personnel	<ul style="list-style-type: none"> • Authority: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, § 201 (codified at 42 U.S.C. § 247d(e)) • Description: This provision allows the Secretary of HHS to authorize the temporary reassignment of federally-funded state and local public health department or agency personnel funded under programs authorized under the Public Health Service Act, for purposes of addressing a public health emergency in a state or tribe. The reassignment must occur at the request of a state governor or tribal organization and may not exceed the period of a public health emergency declaration under section 319 of the Public Health Service Act. • Reason not used for opioid public health emergency: HHS officials reported that no eligible entities, such as states, requested the use of this authority. • Last use during a public health emergency: According to HHS officials, this authority has never been used.
Temporary (up to one year or the duration of the emergency) appointments of personnel	<ul style="list-style-type: none"> • Authority: 5 C.F.R. § 213.3102(i)(3) (2017) • Description: Under this authority, the Secretary of HHS is allowed to make temporary (up to one year or the duration of the emergency) appointments of personnel to positions that directly respond to a public health emergency when the urgency of filling positions prohibits examining applicants through the competitive process. • Reason not used for opioid public health emergency: HHS officials determined that other authorities could be used, rather than public health emergency authorities. • Last use during a public health emergency: This authority was last used during the public health emergency declared for Hurricanes Irma and Harvey in September 2017.
Activation of the National Disaster Medical System (NDMS) ^a	<ul style="list-style-type: none"> • Authority: Public Health Security and Bioterrorism Preparedness Response Act of 2002, Pub. L. No. 107-188, § 102 (codified as amended at 42 U.S.C. § 300hh-11(a)(3)) • Description: NDMS is a coordinated effort between federal, state, and private entities to respond to public health emergencies. This provision allows the Secretary of HHS to activate NDMS to provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency, whether or not a public health emergency declaration under section 319 of the Public Health Service Act has been made. HHS may also activate NDMS in a location that is at-risk of a public health emergency. • Reason not used for opioid public health emergency: HHS officials determined not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged. • Last use during a public health emergency: This authority was last used during the public health emergency declared for Hurricanes Irma and Maria in September 2017.
Deployment of the Volunteer Medical Reserve Corps ^a	<ul style="list-style-type: none"> • Authority: Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, § 303 (2006) (codified at 42 U.S.C. § 300hh-15(e)) • Description: The Secretary is required to build on state, local, and tribal programs to establish and maintain a Volunteer Medical Reserve Corps to provide an adequate supply of volunteers during a public health emergency. This provision allows the Secretary of HHS to activate and deploy willing members of the Volunteer Medical Reserve Corps to areas of need during a public health emergency, taking into consideration the public health and medical expertise required, with the concurrence of the state, local, or tribal officials from the area where the members reside. • Reason not used for opioid public health emergency: HHS officials determined not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged. • Last use during a public health emergency: HHS officials did not provide information on when this authority was last used.

Authority	Description
Deployment of Commissioned Corps Officers ^a	<ul style="list-style-type: none"> • Authority: Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, § 206(c)(1) (2006) (codified at 42 U.S.C. § 215(e)) • Description: This provision allows the Secretary of HHS to deploy any Commissioned Corps officer to an entity outside of HHS for service under the Secretary’s direction in response to an urgent or emergency public health care need. For purposes of this provision, an “urgent or emergency public health care need” includes a health care need arising as a result of (1) a national emergency declared by the President under the National Emergencies Act; (2) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; (3) a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; or (4) any emergency that, in the Secretary’s judgment, is appropriate for deployment. • Reason not used for opioid public health emergency: HHS officials determined not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged. • Last use during a public health emergency: This authority was last used during the public health emergency declared for Hurricanes Irma and Maria in September 2017.
Paperwork-related authorities	
Waiver of requirements under the Paperwork Reduction Act	<ul style="list-style-type: none"> • Authority: 21st Century Cures Act, Pub. L. No. 114-255, § 3087 (2016) (codified at 42 U.S.C. § 247d(f)) • Description: This provision allows the Secretary of HHS to waive requirements under the Paperwork Reduction Act for voluntary collection of information when necessary to prepare for and respond to a public health emergency. To exercise this authority, the Secretary must determine (1) that the criteria for a public health emergency have been met or that a disease or disorder is significantly likely to become a public health emergency; and (2) that the circumstances of the existing or potential emergency necessitate a waiver from requirements under the Paperwork Reduction Act. The period of the waiver may not exceed the period of the public health emergency. • Reason not used for opioid public health emergency: Not applicable, because the authority was used. • Last use during a public health emergency: This authority was last used during the public health emergency declared for the opioid crisis in October 2017.
Waiver of public notice process for Medicaid demonstrations under section 1115 of the Social Security Act	<ul style="list-style-type: none"> • Authority: 42 C.F.R. § 431.416(g) (2017) • Description: This provision allows the Centers for Medicare & Medicaid Services to waive federal and state public notice procedures to expedite a decision on a proposed Medicaid demonstration or demonstration extension request under section 1115(a) of the Social Security Act that addresses a public health emergency. This provision also allows the Secretary of HHS to exempt a state from the normal public notice process or required time constraints when the state demonstrates the existence of unforeseen circumstances resulting from a public health emergency that warrant such an exemption. • Reason not used for opioid public health emergency: Not applicable, because the authority was used. • Last use during a public health emergency: This authority was last used during the public health emergency declared for the opioid crisis in October 2017.

Authority	Description
Application extensions and waiver of requirements for block grant funding	<ul style="list-style-type: none"> • Authority: 21st Century Cures Act, Pub. L. No. 114-255, § 8003 (2016) (codified at 42 U.S.C. § 300x-67) • Description: This provision allows the Secretary of HHS to grant an application extension for or waive compliance with requirements for block grant funding or an allotment authorized under the Protection and Advocacy for Mentally Ill Individuals Act of 1986 during a public health emergency declaration under section 319 of the Public Health Service Act. This authority applies to grants for assistance in the transition from homelessness, grants for community mental health services, and grants for the prevention and treatment of substance abuse and may be exercised, on a state-by-state basis, as the circumstances of the emergency reasonably require. • Reason not used for opioid public health emergency: HHS officials determined not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged. • Last use during a public health emergency: According to HHS officials this authority has never been used.
Extensions or waiver of sanctions related to submission of data or reports required under laws administered by the Secretary of HHS	<ul style="list-style-type: none"> • Authority: Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 141 (codified at 42 U.S.C. § 247d(d)) • Description: This provision allows the Secretary of HHS to grant extensions or waive sanctions related to submission of data or reports required under laws administered by the Secretary of HHS. To exercise this authority, the Secretary must determine that individuals or public or private entities are unable to comply with deadlines for such data or reports due to a public health emergency declared under section 319 of the Public Health Service Act. The Secretary is also required to notify Congress and publish a Federal Register notice before or promptly after granting an extension or waiver. • Reason not used for opioid public health emergency: HHS officials determined not relevant to the opioid crisis; more appropriate to a short, time-limited public health issue or when infrastructure is damaged. • Last use during a public health emergency: According to HHS officials this authority has never been used.

Source: GAO analyses of information from Department of Health and Human Services, Department of Justice, and Department of Labor . | GAO-18-685R

^aThis authority may become available without a public health emergency declaration under section 319 of the Public Health Service Act.

Enclosure II: Federal Public Health Emergencies, June 2016 through July 2018

The Secretary of Health and Human Services may, under section 319 of the Public Health Service Act, declare a public health emergency if the Secretary determines, in consultation with other public health officials as may be necessary, that: (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. A public health emergency declaration is in effect until the Secretary declares the emergency no longer exists or 90 days after the declaration, whichever occurs first. The Secretary may renew the public health emergency declaration for subsequent 90-day periods for as long as the Secretary determines the public health emergency continues to exist. Federal public health emergencies declared since June 2016 are shown in table 3.

Table 3: Federal Public Health Emergencies Declared Since June 2016

Event	Emergencies declared
Wildfires	<ul style="list-style-type: none"> • October 15, 2017: Determination that a Public Health Emergency Exists in California • December 11, 2017: Determination that a Public Health Emergency Exists in California
Opioid Crisis	<ul style="list-style-type: none"> • October 26, 2017: Determination that a Public Health Emergency Exists Nationwide <ul style="list-style-type: none"> ○ January 19, 2018: Renewal of determination ○ April 20, 2018: Renewal of determination ○ July, 19, 2018: Renewal of determination
Hurricane Nate	<ul style="list-style-type: none"> • October 8, 2017: Determination that a Public Health Emergency Exists in Alabama • October 8, 2017: Determination that a Public Health Emergency Exists in Florida • October 8, 2017: Determination that a Public Health Emergency Exists in Louisiana • October 8, 2017: Determination that a Public Health Emergency Exists in Mississippi
Hurricane Maria	<ul style="list-style-type: none"> • September 19, 2017: Determination that a Public Health Emergency Exists in the Territory of the U.S. Virgin Islands and the Commonwealth of Puerto Rico <ul style="list-style-type: none"> ○ December 11, 2017: Renewal of determination ○ March 15, 2018: Renewal of determination for U.S. Virgin Islands ○ March 16, 2018: Renewal of determination for the Commonwealth of Puerto Rico ○ June 12, 2018: Renewal of determination for U.S. Virgin Islands
Hurricane Irma	<ul style="list-style-type: none"> • September 6, 2017: Determination that a Public Health Emergency Exists in the Commonwealth of Puerto Rico and the Territory of the U.S. Virgin Islands • September 7, 2017: Determination that a Public Health Emergency Exists in Florida • September 8, 2017: Determination that a Public Health Emergency Exists in Georgia • September 8, 2017: Determination that a Public Health Emergency Exists in South Carolina
Hurricane Harvey	<ul style="list-style-type: none"> • August 26, 2017: Determination that a Public Health Emergency Exists in Texas • August 28, 2017: Determination that a Public Health Emergency Exists in Louisiana
Zika Virus Outbreak	<ul style="list-style-type: none"> • August 12, 2016: Determination that a Public Health Emergency Exists in Puerto Rico <ul style="list-style-type: none"> ○ November 4, 2016: Renewal of determination ○ January 31, 2017: Renewal of determination ○ April 28, 2017: Renewal of determination

Source: GAO analyses of Department of Health and Human Services information. | GAO-18-685R

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