

Report to Congressional Committees

August 2023

PUBLIC HEALTH PREPAREDNESS

HHS Reserve Funding for Emergencies

Accessible Version

GAO Highlights

Highlights of GAO-23-106102, a report to congressional committees

August 2023

PUBLIC HEALTH PREPAREDNESS

HHS Reserve Funding for Emergencies

Why GAO Did This Study

Public health can be at significant risk during emergencies, like a pandemic or hurricane. State and local governments typically lead the domestic response to a public health emergency. However, if their capabilities are overwhelmed, HHS may provide additional support. To respond immediately to such emergencies, HHS has two reserve funds designed to hold funding over multiple fiscal years, for use as needed

The Pandemic and All-Hazards
Preparedness and Advancing
Innovation Act of 2019 included a
provision for GAO to review the Public
Health Emergency Fund. This report
describes: (1) the available resources
and specific purposes for which HHS's
reserve funds have been used; and (2)
HHS officials' perspectives on the
challenges obtaining funding to
respond to immediate needs of public
health threats or emergencies, and
how the reserve funds have helped
address these challenges.

To conduct this work, GAO reviewed documentation and interviewed current and former agency officials about their use of the funds, any challenges they faced, and any funding characteristics that helped address challenges. To identify challenges, GAO asked HHS officials about their experiences during four selected public health emergencies that were infectious diseases or extreme weather events during the past 20 years—H1N1 influenza, Zika, Hurricane Maria, and mpox.

View GAO-23-106102. For more information, contact Mary Denigan-Macauley at (202) 512-7114 or DeniganMacauleyM@gao.gov

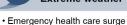
What GAO Found

The Department of Health and Human Services (HHS) can use a variety of funding options to help address a public health emergency or threat. For example, HHS may use annual or supplemental appropriations that were made for specific agency programs and activities. HHS also has two reserve funds to address immediate needs that arise in the first days or weeks of an emergency.

The **Public Health Emergency Fund**, established in 1983, is a reserve fund to help HHS agencies, such as the Administration for Strategic Preparedness and Response and the Centers for Disease Control and Prevention (CDC), to rapidly respond to any kind of public health emergency or threat. Such threats include extreme weather; diseases; radiological or nuclear incidents; or acts of terrorism. However, the fund has not received appropriations or been used in over 25 years.

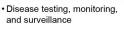
Examples of Possible Immediate Needs during Public Health Emergencies





- Water safety surveillance
- Health care facility evacuation
- Care for vulnerable patients

Infectious diseases



- Public outreach and education
- Development and distribution of vaccines



Radiological or nuclear incidents

- Environmental testing and hazard assessment
- Radiation countermeasures
- Treatment for injuries and illness

Source: GAO analysis of Department of Health and Human Services information; GAO (icons). | GAO-23-106102

The Infectious Diseases Rapid Response Reserve Fund, established in 2018, is another reserve fund to allow CDC to rapidly respond to infectious disease threats. This fund received \$800 million in appropriations from 2019 through 2023, including \$600 million in 2020 after the beginning of the COVID-19 pandemic. From fiscal year 2020 through May 2023, CDC used \$211 million from the fund for activities such as diagnostic testing and airport screening to help control the spread and severity of three infectious diseases: COVID-19, Ebola, and mpox (formerly known as monkeypox).

HHS officials described challenges funding immediate needs during selected public health emergencies. For example, prior to the infectious disease fund, HHS officials said it took time to identify and secure funding to address the immediate needs of the Zika outbreak in 2016. They were ultimately able to identify some funds from another program to use for the Zika response.

HHS officials said that the Infectious Diseases Rapid Response Reserve Fund has helped to address some of these challenges, specifically for CDC. In particular they said that having readily available, flexible, and consistently replenished funding has helped CDC respond quickly to emerging infectious disease threats before they worsen. However, HHS officials said they continue to face challenges addressing immediate needs, for example noting that the fund is available only for infectious diseases and not for other public health threats.

__ United States Government Accountability Office

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	ASPR	Administration for Strategic Preparedness and Response				
	CDC	Centers for Disease Control and Prevention				
	Ebola FEMA	Ebola virus disease				
	hantavirus	Federal Emergency Management Agency hantavirus pulmonary syndrome				

HHS Infectious Diseases Reserve Fund Stafford Act

Department of Health and Human Services Infectious Diseases Rapid Response Reserve Fund

Robert T. Stafford Disaster Relief and Emergency Assistance Act

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August 15, 2023

The Honorable Bernard Sanders
Chair
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers Chair The Honorable Frank Pallone, Jr. Ranking Member Committee on Energy and Commerce House of Representatives

Infectious diseases, hurricanes, tornadoes, floods, and wildfires have all threatened public health and safety in recent years, and required a rapid response to save lives. As the COVID-19 pandemic illustrated, the United States faces an ongoing risk from these threats. Future public health risks include, for example, new disease outbreaks; extreme weather events; radiological, or nuclear incidents; or acts of terrorism.

We have previously reported on the importance of preparing for, and urgently responding to, public health threats, and on the need for significant improvements in how the federal government supports state and local governments during such times. The Department of Health and Human Services (HHS) takes the lead in the federal public health and medical response to these threats, and the Secretary of Health and Human Services may declare when these threats become public health emergencies. As we have reported, not being sufficiently prepared for a public health threat or emergency can also negatively affect the time and resources needed to achieve full recovery. Based on the results of this

¹A public health threat is an event, disease, or disorder with significant potential to become a public health emergency.

past work, we named HHS's leadership and coordination of public health emergencies as a high risk issue in January 2022.²

Immediate needs such as disease testing or a surge in injury treatment may arise during the first days or weeks following a public health threat or emergency. To respond to these needs, HHS may use a variety of funding sources. These include two reserve funds—the Public Health Emergency Fund and the Infectious Diseases Rapid Response Reserve Fund (Infectious Diseases Reserve Fund)—that are designed to hold funding over multiple fiscal years so that HHS can use them as needed.³

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 included a provision for GAO to review the Public Health Emergency Fund, including the resources available in the fund, and the fund's uses.⁴ In this report, we describe:

- 1. the available resources in and specific purposes for which HHS's reserve funds have been used;
- 2. HHS officials' perspectives on the challenges obtaining funding to respond to immediate needs of public health emergencies, and how the reserve funds have helped address these challenges.

To describe the available resources and the specific purposes for which HHS's reserve funds have been used, we reviewed laws authorizing and appropriating funds to the Public Health Emergency Fund and the Infectious Diseases Reserve Fund. We also reviewed agency documentation on the amount of funds appropriated to and obligated from these reserve funds.

We assessed the reliability of these funding data by comparing them with other available sources of information and discussing them with agency officials. Based on this assessment, we determined that these data were sufficiently reliable for the purposes of this engagement. We interviewed current and former officials from HHS's Administration for Strategic Preparedness and Response (ASPR) and Centers for Disease Control

²See GAO, COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies, GAO-22-105291 (Washington, D.C.: Jan. 27, 2022).

³Federal agencies generally receive annual appropriations that can only be obligated for a specific fiscal year. Certain appropriations, including some reserve funds, remain available for obligation for an indefinite period of time.

⁴Pub. L. No. 116-22, § 206, 133 Stat. 905, 926 (codified at 42 U.S.C. § 247d(b)(5)).

and Prevention (CDC) about the specific activities for which they used the funds, among other things. Former ASPR and CDC officials we interviewed had experience with public health emergencies that occurred since 2009. We interviewed current officials from HHS's Office of the Assistant Secretary for Financial Resources, which provides advice and guidance within the department on financial management. We also interviewed officials from the Federal Emergency Management Agency (FEMA)—within the Department of Homeland Security—the federal agency with primary responsibility for coordinating the federal response to and recovery from emergencies or major disasters declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). FEMA also oversees the Disaster Relief Fund, which is available for such recovery and response efforts.

To describe HHS officials' perspectives on challenges funding immediate response needs of selected public health emergencies, and how the reserve funds have helped address these challenges, we selected four of the 40 public health emergencies declared from August 2005 through November 2022: H1N1 influenza (2009), Zika (2016), Hurricane Maria (2017), and mpox (previously known as monkeypox) (2022).⁵ We selected these four public health emergencies to include various types of emergencies, such as those resulting from infectious diseases and extreme weather.⁶ We reviewed documentation about actions HHS agencies took to address each emergency, and any funding challenges. We also interviewed current and former agency officials from ASPR and CDC about their experiences obtaining funding to address immediate needs, any challenges they faced addressing immediate needs, and their views about how the reserve funds have helped address these challenges.

We conducted this performance audit from June 2022 to August 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

⁵We initially selected a fifth public health emergency, the 2020 California wildfires. However, we did not include information on this public health emergency in this report because CDC and ASPR officials said their agencies did not have a significant role in addressing it.

⁶We did not include the COVID-19 pandemic in our selection of public health emergencies because we have previously issued numerous reports on funding for COVID-19 response activities, including funding challenges. See

https://www.gao.gov/coronavirus-oversight-all-covid-19-reports and the Related GAO Products page at the end of this report. However, we include the COVID-19 pandemic in this report when discussing use of the Infectious Diseases Reserve Fund.

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.

Background

Public Health Emergencies

State and local governments typically lead the domestic response to a public health threat or emergency. However, if a threat is severe enough that state and local capabilities are overwhelmed, state and local governments may seek support from the federal government. Under section 319 of the Public Health Service Act, the Secretary of Health and Human Services 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 otherwise exists, including significant outbreaks of infectious disease or bioterrorist attacks.

A declaration of a public health emergency triggers the availability of certain authorities under federal law that may allow the federal government to increase support to and reduce administrative burdens on state and local governments affected by the public health emergency.⁷

Immediate Needs during Public Health Emergencies

Immediate needs during the first days or weeks following a public health threat or emergency can vary; for example particular needs may depend on whether the emergency results from extreme weather such as a hurricane or flood; an infectious disease; or a radiological or nuclear incident. Figure 1 illustrates examples of possible immediate needs during different types of public health emergencies.

⁷For example, upon request by a state governor or tribal organization, the Secretary of Health and Human Services may authorize the temporary reassignment of federally funded state and local public health department personnel funded in whole or in part through programs authorized under the Public Health Service Act to address the immediate needs of a public health emergency in a state or tribe. 42 U.S.C. § 247d(e).

Figure 1: Examples of Possible Immediate Needs during Public Health Emergencies



Extreme weather

- · Emergency health care surge
- Treatment for patients on electricity-dependent medical devices
- · Water safety surveillance
- · Health care facility evacuation
- Medical care, behavioral health care, and medications for vulnerable patients



Infectious disease

- Disease testing, monitoring, and surveillance
- · Screening and quarantine
- · Public outreach and education
- Vaccine development and distribution
- Development of disease tests and treatments



Radiological or nuclear incident

- Environmental testing and hazard assessment
- Assessment and treatment of radiation-related illness and injury
- · Radiation countermeasures
- Treatment for blast-related injuries, burns, and respiratory irritation

Source: GAO analysis of Department of Health and Human Services information; GAO (icons). I GAO-23-106102

Federal Public Health Agencies

HHS leads the federal government's public health and medical response to emergencies and disasters. Within HHS, ASPR is the lead agency for medical and public health emergency preparedness and response, policy coordination, and strategic direction. ASPR also serves as the principal advisor to the Secretary of Health and Human Services on all matters related to federal public health and medical preparedness and response. In addition, it maintains a stockpile of resources, including supplies important for responding to different types of public health emergencies. Another agency within HHS, CDC, also has a lead role in addressing public health emergency preparedness and response, including detecting and responding to new and emerging disease threats. CDC also maintains expertise in addressing public health needs resulting from natural disasters and severe weather, radiation and chemical

⁸Specifically, HHS is required to lead all federal public health and medical responses to public health emergencies and incidents covered by the National Response Framework. 42 U.S.C. § 300hh(a). The National Response Framework establishes an all-hazards response structure to coordinate federal resources during emergencies and disasters and is divided into 14 emergency support functions, which are functional areas that are most frequently needed during a national response.

HHS is the lead agency for Emergency Support Function #8: Public Health and Medical Services Response. See

https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response.

emergencies, and bioterrorism. In addition to CDC and ASPR, HHS's Office of the Assistant Secretary for Financial Resources provides advice and guidance to the Secretary of Health and Human Services on financial management, including funding for public health emergencies.

HHS Reserve Funds for Public Health Emergencies

The Public Health Emergency Fund was established in 1983 and is available to HHS and its agencies when the Secretary declares a public health emergency, or when the Secretary determines there is a significant potential for a public health emergency. The purpose of the fund is to allow the Secretary to "rapidly respond to the immediate needs" resulting from such emergencies or potential emergencies, and authorized uses include facilitating coordination among entities affected by a public health threat or emergency, facilitating advanced research and development of countermeasures, strengthening bio-surveillance capabilities, and carrying out other activities determined to be appropriate.

The Infectious Diseases Reserve Fund was established in 2018 to provide CDC with funds to "prevent, prepare for, or respond to an infectious disease emergency." Similar to the Public Health Emergency Fund, the Infectious Diseases Reserve Fund may be used when the Secretary declares an infectious disease emergency to be a public health emergency, or if the Secretary determines there is a significant potential for the infectious disease emergency to imminently occur and to affect national security or the health and security of U.S. citizens.

Public Health Emergencies and FEMA's Disaster Relief Fund

In some cases, circumstances giving rise to a public health emergency declaration may also lead to a presidential declaration of an emergency or major disaster under the Stafford Act. The Disaster Relief Fund—administered by FEMA—may be used to address certain public health and medical needs for Stafford Act emergencies and major disasters through a mission assignment to HHS and other agencies. For example,

⁹Pub. L. No. 98-49, 97 Stat. 245 (1983) (codified as amended at 42 U.S.C. § 247d(b)).

¹⁰Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 231, 132 Stat. 2981, 3095 (2018) (codified at 42 U.S.C. § 247d-4a).

for Hurricane Maria, FEMA tasked HHS with a mission assignment to provide emergency medical and public health services in multiple localities in Puerto Rico.

One of HHS's Two Reserve Funds Available for Public Health Emergencies Has Received Funding and Been Used to Respond to Disease Threats in Recent Years

Appropriations for Reserve Funds

The balance in the Infectious Diseases Reserve Fund—\$560.5 million as of May 31, 2023—has remained relatively consistent since 2020, and is available to respond to current and future disease threats. The fund first received appropriations in fiscal year 2019, and had received a cumulative total of \$800 million in appropriations as of May 31, 2023. The majority of these appropriations—\$600 million—were made in 2020 after the beginning of the COVID-19 pandemic through the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 and the CARES Act. The remaining amounts were added through annual appropriations that ranged between \$10 million and \$85 million. In addition, HHS's congressional budget justification for fiscal year 2024 includes a request for \$35 million for the Infectious Diseases Reserve Fund. (See Table 1.)

¹¹Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, div. A, tit. III, 134 Stat. 146, 148 (\$300 million); CARES Act, Pub. L. No. 116-136, div. B, tit. VIII, 134 Stat. 554-55 (2020) (\$300 million).

Table 1: Appropriations, Obligations, and End-of-Year Balances for the Infectious Diseases Rapid Response Reserve Fund by Fiscal Year, 2019 to 2023

Dollars in millions

Category	Federal Fiscal Year					
	2019	2020	2021	2022	(2023) ^c	
Appropriations	50.0	685.0	10.0	20.0	35.0	
Annual	50.0	85.0	10.0	20.0	35.0	
Supplemental	0	600.0	0	0	0	
Obligations ^a	0	104.4	17.8	10.7	77.9	
COVID-19	0	104.4	0	0	0	
Ebola virus disease	0	0	17.8	4.7	6.8	
Мрох	0	0	0	6.0	71.1	
Other adjustments ^b	0	-30.0	.6	.2	.6	
Cumulative Unobligated Balance at End of Year ^{c,d}	50.0	600.6	593.4	602.9	560.5	

Source: Appropriations acts and Centers for Disease Control and Prevention information. | GAO-23-106102

blincludes an authorized transfer of \$30 million in fiscal year 2020 and recoveries of prior year balances in fiscal years 2021 through 2023. See Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, Pub. L. No. 116-59, § 138, 133 Stat. 1093, 1101 (2019) and Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019, Pub. L. No. 116-69, § 101(4), 133 Stat. 1134, 1135 (2019).

 $^{\rm c}$ Appropriations, obligations, and balance information for fiscal year 2023 reflect partial year data through May 31, 2023.

^dNumbers may not total due to rounding.

In addition to the Infectious Diseases Reserve Fund, HHS has access to the Public Health Emergency Fund. According to HHS officials, the fund had a balance of about \$57,000 as of June 2023. It received appropriations in 1987 and 1993, and has not received appropriations in recent years. HHS's congressional budget justification for fiscal year 2024 includes a request for \$50 million for the Public Health Emergency Fund.

^aIncludes prior budget year upward adjustments.

¹²Supplemental Appropriations Act, 1987, Pub. L. No. 100-71, tit. I, 101 Stat. 391, 420; Supplemental Appropriations Act of 1993, Pub. L. No. 103-50, ch. V, 107 Stat. 241, 253. Legislation has been introduced in recent years to appropriate funds to the Public Health Emergency Fund, but appropriations have not been enacted. For example, H.R.7614, introduced during the 116th Congress, would have appropriated \$5 billion to the fund. In addition, S. 2467, introduced during the 117th Congress, would have amended section 319 of the Public Health Service Act to provide for appropriations to the Public Health Emergency Fund upon the declaration of a public health emergency arising from an infectious disease outbreak, a bioterrorist attack, or a disaster.

Uses of Reserve Funds

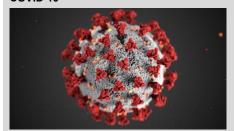
The Infectious Diseases Reserve Fund has been used by CDC for three different disease threats since the fund was established in 2018: COVID-19 starting in 2020, Ebola virus disease (Ebola) starting in 2021, and mpox starting in 2022.¹³

- To use the fund in each of these cases, officials told us that they
 considered the scale, scope, and nature of the disease and whether it
 posed an imminent threat to public health and security.
- To help preserve funding for future threats, officials also said they
 considered the availability of other resources, and generally used the
 fund when other funding options were not available.
- In each case, officials said that they identified specific response activities expected to have the largest effects in controlling the spread or severity of the disease.

HHS officials described specific response activities supported by the fund for each of the three disease threats.

¹³The Infectious Diseases Reserve Fund was not available for disease threats before 2018, such as Zika and H1N1 influenza.

COVID-19



COVID-19 is a disease caused by the virus SARS-CoV-2. It spreads when an infected person breathes out droplets and very small particles that contain the virus. It can be very contagious and spreads quickly. COVID-19 most often causes respiratory symptoms that can feel much like a cold, the flu, or pneumonia. Most people with COVID-19 have mild symptoms, but some people become severely ill.

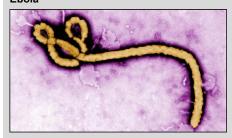
COVID-19 was first identified in Wuhan, China, late in 2019. In the first 6 weeks of 2020, it had spread to 20 other countries. On January 30, 2020, the World Health Organization declared that the outbreak constituted a public health emergency of international concern. The Secretary of Health and Human Services declared COVID-19 a public health emergency in the United States on January 31, 2020, and the President declared a national emergency under the National Emergencies Act and a nationwide emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) on March 13, 2020. The President also approved major disaster declarations under the Stafford Act for all 50 states, the District of Columbia, five territories, and certain Tribes. As of June 5, 2023, the Centers for Disease Control and Prevention (CDC) reported a cumulative total of 1.1 million deaths due to COVID-19 in the United States. (GAO reports related to the COVID-19 pandemic are available on GAO's website at https://www.gao.gov/coronavirus.)

Source: World Health Organization, GAO, and CDC (information); Alissa Eckert, Dan Higgins (image). | GAO-23-106102

COVID-19. On January 22, 2020—while COVID-19 was emerging as a threat to the United States—the Secretary of Health and Human Services determined that COVID-19 had the potential to imminently become an infectious disease emergency. This determination allowed for CDC's use of the Infectious Diseases Reserve Fund to respond to the threat. At the time, diagnostic testing, vaccines, and therapeutics were not yet widely available. HHS officials told us that COVID-19 cases were increasing internationally, and that CDC's prior experience with other novel coronaviruses indicated the need for extensive public health actions to mitigate risk.

CDC documentation shows that the agency used the Infectious Diseases Reserve Fund to support rapid response activities including airport screening and quarantine of persons exposed to confirmed cases; enhanced laboratory capacity for testing, including purchase of equipment and supplies, shipping, and support to states; and CDC's related operational needs, such as travel and overtime. CDC also used these funds for prevention and education efforts about home isolation and quarantine after exposure to infected people. In total, CDC obligated \$104.4 million from the fund for COVID-19-related response activities, as of May 2023.

Ebola



Ebola virus disease (Ebola) is an acute, serious illness that is often fatal if untreated. Symptoms of infection include fever, muscle pain, abdominal pain, and vomiting. Scientists think Ebola is initially introduced into human populations through contact with the blood and bodily fluids of infected animals. It can be spread through contact with a person who is sick with or has died from Ebola.

Ebola viruses were first identified in 1976 in what is now the Democratic Republic of the Congo. Since then, they have emerged periodically. In 2014-2016 an outbreak spread to multiple countries, including the United States. The Centers for Disease Control and Prevention (CDC) has supported activities to respond to outbreaks, including in 2021 in the Democratic Republic of the Congo and the Republic of Guinea.

Source: CDC (information); Frederick A. Murphy (image). | GAO-23-106102

Ebola. In February 2021, CDC determined that outbreaks of Ebola in the Democratic Republic of the Congo and the Republic of Guinea had significant potential to adversely affect the national security and health of U.S. citizens if not contained in a timely manner, and the Secretary of Health and Human Services authorized use of the Infectious Diseases Reserve Fund. CDC has reported that controlling Ebola outbreaks is particularly important because Ebola can spread very rapidly and is often deadly. According to CDC, during these outbreaks local health officials in these countries were also responding to concurrent epidemics of COVID-19, measles, yellow fever, and polio, increasing the need for assistance to prevent the spread of Ebola.

CDC documentation shows that the agency used the Infectious Diseases Reserve Fund to support Congolese and Guinean health authorities' surveillance and contact tracing activities, laboratory operations, infection prevention and control, border and travel surveillance, vaccination programs, and Ebola survivor programs. The fund also supported international arrival passenger screening and quarantine at multiple U.S. airports. ¹⁴ In addition, CDC used the fund in September 2022 to address an Ebola outbreak in Uganda. In total, CDC obligated \$29.3 million from the fund for Ebola-related response activities as of May 2023.

¹⁴According to HHS officials, airports were chosen based on the percentage of air passengers from affected countries arriving in the United States.

Mpox (previously known as Monkeypox)



Mpox is transmitted through close personal contact, contaminated materials, and animals. Symptoms include fever, malaise, headache, and rash. Previously, mpox was typically transmitted from animals to humans with limited human-to-human spread. However, in 2022, an outbreak of mpox occurred with significant person-to-person spread. This outbreak spread to the United States, and on August 4, 2022, the Secretary of Health and Human Services declared a public health emergency.

As of July 19, 2023, the Centers for Disease Control and Prevention (CDC) reported 30,611 cases of mpox in the United States since the outbreak early in 2022 and 45 deaths. CDC reported 88,549 cases worldwide for this period.

Source: CDC and Congressional Research Service (information); Anna/stock.adobe.com (image). | GAO-23-106102

Mpox. HHS officials said that on June 17, 2022, the Secretary of Health and Human Services approved CDC's use of the Infectious Diseases Reserve Fund to respond to the mpox outbreak, determining that the outbreak had the potential to imminently become an infectious disease emergency. Officials said there were increasing numbers of confirmed cases in the United States in May 2022, including for individuals without any travel history to countries where mpox was endemic. Based on U.S. and international trends and epidemiology data, CDC expected to see a continued rise in cases. Further, officials said that at the time, vaccine supplies were very limited, and there were no data on the efficacy of the available vaccine for this outbreak or for available treatments.

According to CDC officials and agency documentation, CDC used the Infectious Diseases Reserve Fund in July 2022 for a range of response activities, including testing, surveillance, investigation of disease cases and clusters, education and outreach, and monitoring for antiviral resistance. Subsequently, in December 2022 and January 2023, CDC provided funding to affected jurisdictions to provide support, including for vaccine-related needs. In total, CDC had obligated \$77.1 million from the fund for mpox activities, as of May 2023.

Hantavirus



Hantavirus pulmonary syndrome (hantavirus) is a severe and sometimes fatal respiratory disease, primarily related to rodent infestations. Early symptoms—which may develop between 1 and 8 weeks after exposure—include fatigue, fever, and muscle aches; and sometimes headaches and abdominal pain. Late symptoms include shortness of breath and coughing, and this respiratory distress may lead to death.

Hantavirus disease surveillance in the United States began in 1993 during an outbreak of severe respiratory illness in the Four Corners region—the area where Arizona, Colorado, New Mexico, and Utah meet. As of the end of 2021, 850 cases of hantavirus infection had been reported in the United States, 94 percent of them occurring west of the Mississippi River. More than one-third of the cases resulted in death.

Source: Centers for Disease Control and Prevention (information); Bernd Wolter/stock.adobe.com (image). GAO-23-106102

The Public Health Emergency Fund was last used to respond to a 1993 outbreak of hantavirus pulmonary syndrome (hantavirus). As noted earlier in this report, the purpose of the Public Health Emergency Fund is to allow HHS to rapidly respond to immediate needs of public health emergencies, such as facilitating development of countermeasures and strengthening surveillance capabilities. However, current and former agency officials told us that the balance in this fund—about \$57,000 as of June 2023—was not enough to be useful in addressing immediate needs resulting from public health emergencies, based on their recent experience.

HHS Officials Identified Challenges Obtaining Funding to Respond to Selected Public Health Emergencies and Characteristics of Existing Reserve Funding That Helped

Officials Identified Challenges Obtaining Funding for Immediate Needs in a Timely Manner

We interviewed current and former HHS officials about challenges they faced in obtaining funding to address immediate needs in the days or weeks following four selected public health emergencies: H1N1 influenza (2009), Zika (2016), Hurricane Maria (2017), and mpox (2022). These challenges fall into five categories.

Identifying and securing funding can be time- and resource-intensive. HHS officials noted that the process of identifying funding can take time and can slow their response to immediate needs. HHS officials told us that they review a range of options to identify funding for immediate response activities, depending on the type of public health emergency. These options may include: (1) using annual appropriations that were made for specific agency programs and activities; (2) using HHS reserve funds for emergency activities; (3) requesting reimbursement from FEMA's Disaster Relief Fund, for declared Stafford Act emergencies or major disasters; and (4) using or requesting

supplemental appropriations, which may be enacted to address specific circumstances that occur outside the annual appropriations process.¹⁵

For the 2016 Zika outbreak, before the Infectious Diseases Reserve Fund was established, officials told us that ASPR was able to identify some funds appropriated for the Ebola response that the agency reprogrammed for Zika vaccine development and technologies to protect the blood supply. However, they noted that it took time to ensure that using the funds for these activities was consistent with the purpose for which the funds were originally appropriated. Officials also needed time to assess the effects of using funds the agency had planned to use for existing activities to instead respond to immediate needs.





Zika virus is primarily transmitted through mosquito bites and causes symptoms that include fever, rash, headache, and joint and muscle pain, though many infected individuals do not have symptoms or only experience mild symptoms. In pregnant women, this

¹⁵Existing annual appropriations may include funds for a program that is related to the immediate needs resulting from the particular public health emergency, funds that have been reprogrammed, or funds that have been transferred from another program. An agency transfers funds when it shifts all or part of the budget authority in one appropriation account to another. Agencies may transfer funds only as authorized by law. An agency reprograms funds when it shifts funds within an appropriation account for purposes other than those contemplated at the time of the appropriation. Unlike transfers, agencies may reprogram funds without specific statutory authority, though reprogramming often involves some kind of notification to Congress.

¹⁶See Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, div. G, tit. VI, 128 Stat. 2130, 2521 (2014).

¹⁷Under the purpose statute, appropriated funds are available only for the purposes authorized by Congress. 31 U.S.C. § 1301(a). However, agencies generally may shift funds within an appropriation account to use them for purposes other than those contemplated at the time of the appropriation, also known as reprogramming.

infection has been linked to adverse pregnancy and birth outcomes. The virus can also cause nervous system illnesses in infected adults.

The first recognized case of locally acquired Zika transmission in the Americas appeared in Brazil in May 2015. The first reported confirmed case in the United States occurred on December 31, 2015, and the Secretary of Health and Human Services declared a public health emergency on August 12, 2016. In 2016, the peak year of infections, 41,680 cases were reported in the United States, primarily in Puerto Rico. (See GAO-19-356 and GAO-18-389 for more information on the Zika virus.)

Source: Administration for Strategic Preparedness and Response and Centers for Disease Control and Prevention (information); Johnstocker/stock.adobe.com (image). | GAO-23-106102 CDC officials also stated that they identified a need to develop Zika prevention communication materials specifically for at-risk pregnant women in Puerto Rico, but were delayed in addressing this need when they were unable to identify federal funding to use for this purpose. Officials told us CDC and ASPR were eventually able to obtain private donations through the CDC Foundation for this purpose.¹⁸

HHS officials said the process of identifying and securing the funds requires substantial staff time and effort. In particular, they said the process has required staff to develop funding strategies and requests for additional funding while concurrently conducting response activities and assessing immediate and longer-term response needs. Officials also said that when requesting supplemental appropriations, agency staff must prepare a supplemental request package, and obtain multiple levels of approval within the department and the Office of Management and Budget, before submitting the request to Congress. Officials told us that the process can take 2 to 3 months, depending on the public health emergency.

Immediate needs may vary widely, and some are difficult to predict. HHS officials told us immediate needs may vary widely depending on the scope, scale, and nature of the public health emergency, and by community characteristics such as the strength of the area's existing health system and available resources. They said these variations limit agencies' ability to plan for potential uses of annual appropriations in advance of a public health emergency, because appropriations are made for specific programs and purposes and may not be sufficiently flexible to address unexpected needs.

For example, officials stated that development of vaccines or other medical countermeasures may be an important immediate need for some infectious disease threats or emergencies, but not for others. To illustrate, officials told us that COVID-19 vaccine development was an immediate need in early 2020 because there were no existing COVID-19 vaccines, and because significant additional time would be required for vaccine testing and approval. On the other hand, when mpox became a public health threat in 2022, vaccines for mpox (that could also be used for

¹⁸The CDC Foundation is a private nonprofit corporation established under the Public Health Service Act to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for the promotion of public health. See 42 U.S.C. § 280e-11.

smallpox) had already been developed. Therefore, for mpox, vaccine procurement and distribution were important immediate needs.

Hurricane Maria



Hurricane Maria made landfall in Puerto Rico on September 20, 2017, as a category 4 hurricane, which has wind speeds between 131 and 155 miles per hour. The Secretary of Health and Human Services declared a public health emergency on September 19, 2017, and the President declared a major disaster on September 20, 2017.

Heavy flooding and high winds led to catastrophic damage to Puerto Rico's power grid—leaving 3.7 million of the island's residents without electricity—as well as severe damage to the water, communications, transportation, and health care infrastructure. The majority of the power grid was down for nearly two months. See GAO-21-297, GAO-19-592, and GAO-19-486, and GAO-18-472 for more information about Hurricane Maria.

Sources: Administration for Strategic Preparedness and Response, Federal Emergency Management Agency, and GAO Reports (information); Sasa Kadrijevic/stock.adobe.com (image). | GAO-23-106102 According to HHS officials, immediate needs may also be hard to predict, and therefore challenging for HHS to plan for. As a result, HHS officials told us they assess the needs for each public health emergency as it unfolds so they can identify appropriate mitigation and response activities. For example, officials said that while ASPR anticipated the need for emergency and trauma care after Hurricane Maria in 2017, it had not anticipated the immediate need for primary and chronic care, such as dialysis. According to officials, this need resulted because of the large scale of hurricane damage and the inability of affected populations to travel to hospitals to receive care. ¹⁹ See figure 2 for examples of immediate needs resulting from the selected public health emergencies.

¹⁹See GAO, *Disaster Response: HHS Should Address Deficiencies Highlighted by Recent Hurricanes in the U.S. Virgin Islands and Puerto Rico, GAO-19-592* (Washington, D.C.: Sept. 20, 2019).

Figure 2: Immediate Needs Reported by HHS Officials Resulting From Selected Public Health Emergencies



H1N1 Influenza - April 2009

- Vaccine development and production
- · Increased surveillance through increased lab capacity and re-tooling of labs
- · Supplies for administering vaccines, including syringes and gloves
- Public communication and educational materials on hygiene practices and school closure guidance



Zika - August 2016

- Vaccine development
- Tests to ensure the safety of the collected blood supply
- · Diagnostics to identify infection history for pregnant women
- · Focus group research with pregnant residents on birth defect risk communication
- Translation of written and visual communications, and interpretation services



Hurricane Maria - September 2017

- Pre-positioning of disaster medical assistance teams and caches of supplies
- · Assessment of health care facilities
- · Tetanus and flu vaccination
- Primary health care, including pediatrics, and chronic health care services (e.g., dialysis)



Mpox - August 2022

- · Vaccine ordering, inspection, and shipment from Europe
- · Development of a digital vaccine ordering and distribution system
- Communication and outreach on the need for early notification and intervention
- · Training on vaccine administration protocols

Source: GAO analysis of interviews with officials of the Department of Health and Human Services (data); Sherry Young/Johnstocker/Sasa Kadrijevic/Anna/stock.adobe.com (images). | GAO-23-106102

Note: The dates in this figure indicate the month and year during which the Secretary of Health and Human Services declared a public health emergency under section 319 of the Public Health Service Act.

Redirecting funds may be subject to limitations and may affect other programs. Agencies generally may shift funds within an appropriation account to use them for purposes other than those contemplated at the time of the appropriation, also known as reprogramming. Additionally, if authorized by law, agencies may also have authority to transfer funds from one account to another. Reprogramming and transfers of appropriations typically involve notification to congressional committees and may be subject to limitations. For example, for fiscal year 2023, HHS is authorized to transfer up to 1 percent of any discretionary

appropriations, if doing so does not (1) increase any appropriation by more than 3 percent or (2) create any new program or fund any project or program not provided for in the annual appropriations act.²⁰ HHS officials said that they generally plan at the outset of the fiscal year to use the available transfer authority for HHS programs, and that they rarely use the transfer authority to provide funding for immediate needs during public health emergencies. HHS's congressional budget justification for fiscal year 2024 includes a proposal to expand HHS's transfer authority such that the Public Health and Social Services Emergency Fund appropriation could be increased by up to 10 percent instead of 3 percent.²¹ According to the budget justification, this change would provide the department with additional flexibility to transfer more resources to the public health and medical response during a public health emergency.

Even though HHS may have authority to reprogram or transfer funds for certain programs and activities to fund immediate needs, officials said that doing so can negatively affect other programs and activities. For example, officials said that \$472 million used to purchase more than 1.5 million vials of mpox vaccine came from funds allocated to two ASPR programs, Project BioShield and another program to develop radiological and nuclear medical countermeasures. Officials said that these programs would need additional future funding to maintain their effectiveness. HHS's congressional budget justification for fiscal year 2024 includes a proposal to partially restore funding that was used for mpox to Project BioShield and to other programs for countermeasures development and procurement.

Funding for some immediate needs may be insufficient or restricted. HHS officials told us they are not always able to identify a sufficient amount of funding from existing programs and activities. Funds from

²⁰Additionally, 15 days prior to transferring funds, HHS must notify the Committees on Appropriations of the House and Senate. See Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. H, tit. II, § 205, 136 Stat. 4459, 4879 (2022).

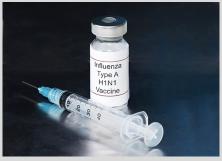
²¹The Public Health and Social Services Emergency Fund is an HHS account that supports HHS's efforts to improve the nation's preparedness against naturally occurring and man-made health threats and threats to the ability of HHS to carry out such missions.

²²The purpose of Project BioShield is to accelerate the research, development, purchase, and availability of effective medical countermeasures against chemical, biological, radiological, and nuclear threats. In fiscal year 2022, appropriations for Project BioShield were \$780 million. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, tit. II, 136 Stat. 49, 465. According to HHS, the radiological and nuclear portfolio in the Public Health Emergency Medical Countermeasures Enterprise Multiyear Budget for fiscal years 2022-2026 is \$509 million.

these sources may be unavailable or limited; for example annual appropriations may have already been spent or obligated for other programs and activities. Officials also noted that funds planned for response activities may be limited toward the end of the fiscal year because of increased numbers and severity of emergencies or disasters. For example, HHS's emPOWER program provides information to help first responders quickly locate medically vulnerable individuals before, during, and after threats and emergencies, so their care is not disrupted. ASPR officials said that the program helps, for example, those who rely on life-maintaining, electricity-dependent medical equipment, such as oxygen machines, and essential health care services, such as dialysis. According to officials, due to the frequency and severity of hurricanes, extreme heat, wildfires, and other power outages, the program faces the risk of not having sufficient resources to respond to emergencies at the end of the fiscal year.

HHS officials also noted that reserve funding may be restricted to certain types of threats or emergencies. The Infectious Diseases Reserve Fund, for example, is available for infectious diseases but cannot be used for other types of public health emergencies that may be caused by extreme weather or by chemical, radiological, or nuclear incidents.

H1N1



H1N1 influenza is a viral respiratory illness transmitted via respiratory droplets among people in close contact. In 2009, a new strain called H1N1pdm09 emerged, with different characteristics from circulating H1N1 viruses. This virus caused significant illnesses, hospitalizations, and deaths, particularly among children and young adults, as well as pregnant women. The Secretary of Health and Human Services declared a public health emergency in the United States on April 26, 2009.

The Centers for Disease Control and Prevention (CDC) estimated 60.8 million cases in the United States from April 12, 2009, to April 10, 2010, 274,304 hospitalizations, and 12,469 deaths. The H1N1 virus that caused that pandemic is now a regular human flu virus and continues to circulate seasonally worldwide. (See GAO-11-632 and GAO-09-760T for more information about H1N1 influenza pandemic.)

Source: CDC (information); Sherry Young/stock.adobe.com (image). | GAO-23-106102

Supplemental funding may not be available in time to meet immediate needs. HHS officials reported that supplemental appropriations have been essential for responding to public health emergencies, but they also said that these funds may not be available to address immediate needs in the days or weeks following a threat or emergency. HHS received supplemental funding to respond to two of our selected public health emergencies—Zika and H1N1 influenza. The time between the request for supplemental funding and its enactment was 7 months for Zika, and 2 months for H1N1.²³ We have previously reported that HHS was able to identify funding to support its Zika response prior to

On February 22, 2016, the administration requested more than \$1.89 billion in supplemental funding for the Zika response. The Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act, enacted on September 29, 2009, provided a total of \$933 million to HHS agencies for the Zika response. Pub. L. No. 114-223, div. B, tit. I, 130 Stat. 857 (2016).

²³On April 30, 2009, the administration requested \$1.5 billion in supplemental funding from Congress for the H1N1 influenza response. A second request for an additional \$2 billion was sent on June 2, 2009. The Supplemental Appropriations Act, 2009, enacted on June 24, 2009, provided \$1.85 billion to HHS for the H1N1 response and another \$5.8 billion to prepare for and respond to an influenza pandemic. See Pub. L. No. 111-32, tit. VIII, 123 Stat. 1860, 1884-85. See also Department of Health and Human Services, *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness*, (Washington, D.C.:June 15, 2012).

the enactment of supplemental funding.²⁴ HHS officials we spoke to said that even though they were able to identify such funding, their efforts to develop Zika vaccines, diagnostics, and technologies to reduce pathogens in the blood supply were delayed until supplemental funding became available. We have previously reported that the timing of supplemental appropriations can result in challenges to carrying out preparedness and response activities for infectious disease threats.²⁵

Recent Reserve Funding Has Facilitated Federal Response to Public Health Emergencies, According to HHS Officials

When discussing funding to address the immediate needs of a public health threat or emergency, current and former HHS officials noted characteristics of reserve funds that helped address funding challenges. These included being readily available, flexible, and consistently replenished.²⁶

Readily Available. Officials told us that having readily available access to reserve funding from the Infectious Diseases Reserve Fund—before a public health threat becomes an emergency—has helped CDC respond more quickly to infectious disease threats. For example, according to officials, the rapid availability of funding from the Infectious Diseases Reserve Fund allowed a faster response for the Ebola outbreak, compared to their experiences for previous infectious disease threats, such as Zika, which occurred before the fund existed. In particular, officials credited the actions supported by the Infectious Diseases Reserve Fund with helping to contain the Ebola outbreak, and preventing it from developing into a larger outbreak that would require a more extensive response. Officials also told us that readily available reserve funding helped them to address challenges associated with unexpected immediate needs—since they may vary widely and are difficult to predict. In addition, officials said readily available reserve funding could provide similar benefits for future emergencies that are not related to infectious

²⁴See GAO: *Zika Supplemental Funding: Status of HHS Agencies' Obligations, Disbursements, and the Activities Funded,* GAO-18-389 (May 14, 2018: Washington, D.C.)

²⁵See GAO: *Infectious Disease Threats: Funding and Performance of Key Preparedness and Capacity-Building Programs*, GAO-18-362 (May 24, 2018: Washington, D.C.)

²⁶GAO-18-362 includes a summary of non-federal stakeholders' views on factors to consider for an emergency response fund (Appendix I).

diseases (such as extreme weather events or chemical, radiological, or nuclear incidents) for example, by facilitating the rapid deployment of risk communication and medical countermeasures to help contain the effects of these events.

Flexible. HHS officials emphasized the importance of flexible reserve funding given the unpredictable nature of immediate response needs. They said that the most flexible reserve funds are not limited to any particular type of public health emergency, can be used for a range of purposes or immediate needs, and can be used across fiscal years. Officials explained that some existing funds are flexible in some of these ways; for example, the Infectious Diseases Reserve Fund and Disaster Relief Fund can be used for a range of needs across multiple fiscal years, so they are useful in challenging situations, such as when needs change quickly, or at the end of a fiscal year when annual appropriations may be limited. However, as noted above, the Infectious Diseases Reserve Fund is limited to infectious diseases, and the Disaster Relief Fund is limited to presidentially declared emergencies and major disasters under the Stafford Act.

According to HHS officials, the flexibility of reserve funds can be accompanied by accountability measures to help ensure that agencies use reserve funding appropriately. For example, for the Infectious Diseases Reserve Fund, CDC is required to notify the House and Senate appropriations committees before using the fund and must provide detailed spend plans no later than 15 days after notification. These plans must be updated and submitted to the committees every 90 days until funds have been fully expended.

Consistently Replenished. HHS officials stated that consistent replenishment of reserve funding helps to address challenges related to uncertainty about whether funding may be sufficient for future needs, allowing agency officials to move quickly to address immediate needs. They cited the Infectious Diseases Reserve Fund as an example of a fund that has been regularly replenished. In contrast, they cited the Public Health Emergency Fund as an example of a fund that has not been replenished in recent years, so it has not been available to address immediate needs of public health emergencies.

Officials' views on reserve funds that are readily available, flexible, and consistently replenished highlight the ways in which reserve funding can help HHS respond quickly and effectively to new public health threats. They said use of reserve funding helps to reduce risks to public health

and safety, and helps decrease the scale of the response that would otherwise be needed. In particular, officials stated that reserve funding with these characteristics is especially valuable for a rapid response to emerging threats, before they become emergencies, and to more unpredictable public health emergencies. HHS officials pointed out ways that HHS's reserve funds exhibit some of these characteristics, while also noting that one fund is limited to infectious diseases and the other has not been replenished in recent years.

Agency Comments

We provided a draft of this report to HHS and the Department of Homeland Security for review and comment. HHS provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Homeland Security, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about 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 are listed in appendix I.

Denigar-Ma

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Appendix I: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, Will Simerl (Assistant Director), Mary Giffin (Analyst-in-Charge), Martha Elbaum Williamson, and Brian Schmidt-Meyer made key contributions to this report. Sam Amrhein, Aditi Archer, Kaitlin Farquharson, Eric Peterson, and Roxanna Sun also made important contributions.

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