



May 2018

INFECTIOUS DISEASE THREATS

Funding and Performance of Key Preparedness and Capacity-Building Programs

GAO Highlights

Highlights of [GAO-18-362](#), a report to congressional committees.

Why GAO Did This Study

An infectious disease threat is unique because of the transmissibility of diseases and the mobility of human populations, among other reasons. Infectious disease threats in recent years—such as Zika and Ebola outbreaks—have heightened the United States’ attention to future potential threats, and raised questions about the nation’s preparedness and response capabilities.

A congressional report included a provision for GAO to report on the U.S. public health system’s current capacity to respond to infectious disease threats. This report describes (1) funding HHS has made available to awardees—states and other jurisdictions—through its key preparedness and capacity-building programs—ELC, HPP, and PHEP; and (2) these programs’ performance measurement data on the awardees’ infectious disease preparedness capacity.

To do this work, GAO analyzed HHS’s data on awards provided to awardees through the three key programs using annual and supplemental appropriations, and interviewed HHS officials and non-federal stakeholders about such funding. GAO identified non-federal stakeholders representing medical and public health associations, research centers, and others through a review of relevant literature, as well as prior GAO work. GAO also reviewed the most recently available data on awardee performance on 20 measures directly related to infectious disease preparedness collectively used by the three programs. GAO categorized these 20 measures into four preparedness capacity areas.

View [GAO-18-362](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov

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Funding and Performance of Key Preparedness and Capacity-Building Programs

What GAO Found

The Department of Health and Human Services (HHS) has three key preparedness and capacity-building programs—Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), the Hospital Preparedness Program (HPP), and Public Health Emergency Preparedness (PHEP). These three programs awarded about \$21.2 billion to states and other jurisdictions from 2002 through 2017 to carry out public health preparedness and response efforts, including those related to infectious diseases, natural disasters, or terrorist events. Of this amount, \$18.4 billion were awards funded from annual appropriations. The remaining was funded from supplemental appropriations to respond to specific infectious disease threats, including Zika, Ebola, and H1N1 pandemic influenza. HHS officials and non-federal stakeholders told GAO that supplemental appropriations were important for supporting necessary surges in capacity, but the timing of additional awards can limit response.

HHS’s Three Key Preparedness and Capacity-Building Programs: ELC, HPP, and PHEP

Program	Purpose of awards provided to states and other jurisdictions
Epidemiology and Laboratory Capacity for Infectious Diseases (ELC)	Supports epidemiologists, surveillance systems, and laboratory facilities to build state and local capacity to combat domestic infectious disease threats.
Hospital Preparedness Program (HPP)	Improves medical surge capacity by enhancing community and health system preparedness for various public health threats, including infectious disease threats.
Public Health Emergency Preparedness (PHEP)	Strengthens state and local public health departments’ ability to prepare for a variety of public health threats, including infectious disease threats.

Source: GAO summary of the Department of Health and Human Services’ (HHS) program information. | GAO-18-362

HHS’s three key preparedness and capacity-building programs measure performance in four areas that directly relate to infectious disease preparedness capacity—electronic lab reporting, epidemiology capacity, laboratory capacity, and responder protection. The majority of awardees (states and other jurisdictions) met targets for all nine measures in the responder protection area, which measures activities related to safety and coordination for responders. However, awardee performance in the other three areas was mixed.

- **Electronic lab reporting.** One of two measures was met in this area. This area relates to the sending of laboratory reports to public health agencies via electronic means (as opposed to traditional, paper reports).
- **Epidemiology capacity.** One of three measures was met in this area. This area relates to awardees’ ability to identify and respond to infectious disease outbreaks.
- **Laboratory capacity.** Five of six measures were met in this area. This area relates to both laboratory testing of certain pathogens, and communication between laboratories and other public entities.

HHS reviewed a copy of this report and provided technical comments, which GAO incorporated as appropriate.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
ELC	Epidemiology and Laboratory Capacity for Infectious Diseases
HHS	Department of Health and Human Services
HPP	Hospital Preparedness Program
NOFO	notice of funding opportunity
PHEF	Public Health Emergency Fund
PHEP	Public Health Emergency Preparedness

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May 24, 2018

The Honorable Roy Blunt
Chairman
The Honorable Patty Murray
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and
Related Agencies
Committee on Appropriations
United States Senate

The Honorable Tom Cole
Chairman
The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and
Related Agencies
Committee on Appropriations
House of Representatives

An infectious disease threat is unique because of the transmissibility of diseases, the universal susceptibility of the world’s population to pathogens that have not previously circulated, and the mobility of human populations. Infectious disease threats in recent years—such as Zika, Ebola, and H1N1 pandemic influenza—have heightened the United States’ attention to future potential infectious disease threats and raised questions about the nation’s preparedness and response capabilities. The Department of Health and Human Services (HHS) is the lead federal agency for public health and medical preparedness for, and response to, infectious disease threats. HHS provides funding to states, localities, territories, and freely associated states to aid capacity building and preparedness for infectious disease threats and other public health threats, such as natural disasters or terrorist events, through three key programs: (1) Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), (2) the Hospital Preparedness Program (HPP), and (3) Public Health Emergency Preparedness (PHEP). The Centers for Disease Control and Prevention (CDC) administers ELC and PHEP, while the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) administers HPP. These three key programs routinely

monitor select aspects of state and local preparedness capacity through certain performance measures.¹

State and local governments typically lead the domestic response to an infectious disease threat. If a threat is severe enough that state and local response capabilities—including those supported by ELC, HPP, and PHEP—are overwhelmed, state and local governments become reliant on additional support from the federal government. For example, during recent infectious disease threats, HHS received supplemental appropriations to respond to Zika in 2016, Ebola in 2014, and H1N1 pandemic influenza in 2009.² These recent threats have generated discussions about states' and other jurisdictions' preparedness and response capacity, as well as federal funding to support such capacity.

A Senate Report accompanying the 2017 Consolidated Appropriations Act included a provision for GAO to study the U.S. public health system's capacity to respond to infectious disease threats.³ This report describes

1. the funding that HHS has made available to awardees—states and other jurisdictions—through the three key programs that aid states' infectious disease preparedness capacity, and
2. these programs' performance measurement data on the awardees' infectious disease preparedness capacity.

To describe the funding that HHS has made available to awardees through the three key preparedness and capacity-building programs, we obtained data from ASPR and CDC on the amount of awards that the

¹Throughout this report, we use the term “preparedness capacity” to refer to preparedness activities, such as identifying and coordinating with partners involved in a response, as well as capacity-building activities that are critical to a response, such as laboratory services and public health surveillance.

²A supplemental appropriation is an act appropriating funds in addition to those already provided in an annual appropriation act. Supplemental appropriations provide additional budget authority usually in cases where the need for funds is considered too urgent to be postponed until enactment of the next regular annual appropriation bill. For Zika supplemental appropriations to HHS, see the Zika Response and Preparedness Act, Pub. L. No. 114-223, div. B tit. I, 130 Stat. 857, 901. For Ebola supplemental appropriations to HHS, see the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, div. G, tit. VI., 128 Stat. 2130, 2520. For H1N1 pandemic influenza supplemental appropriations to HHS see the Supplemental Appropriations Act, 2009, Pub. L. No. 111-32, tit. VIII, 123 Stat. 1859, 1884.

³See Pub. L. No. 115-31, § 4, 131 Stat. 135, 137; 163 Cong. Rec. H3949 (Daily ed. May 3, 2017); S. Rep. No. 114-274, at 80 (2016).

agencies made through ELC, HPP, and PHEP to states and other jurisdictions in the form of cooperative agreements from fiscal years 2002 through 2017.⁴ We analyzed these data to determine the amount of awards made by CDC (through ELC and PHEP) and ASPR (through HPP) with funding from annual appropriations, as well as awards made with funding from supplemental appropriations provided to respond to specific infectious disease threats. We assessed the reliability of the award data we obtained by comparing these data to data in published reports, such as agency budget justifications; following up with agency officials regarding any discrepancies in the data; and gathering information from agencies on the internal checks they use when maintaining their data. Based on these steps, we determined that the data were reliable for our reporting purposes. We also reviewed documentation and interviewed ASPR and CDC officials, as well as non-federal stakeholders, to gather information on how awards to states and other jurisdictions have aided responses to recent infectious disease threats (Zika, Ebola, and H1N1 pandemic influenza). We identified the non-federal stakeholders to interview by reviewing relevant literature on infectious disease preparedness and response funding, as well as our prior work.⁵ We selected and interviewed 10 non-federal stakeholders representing medical associations, public health associations, academic research centers, and organizations with emergency preparedness and response experience. The perspectives from non-federal stakeholders presented in our findings are those that the stakeholders generally agreed on, and when available, we present alternative stakeholder perspectives. While we attempted to gather similar information from all non-federal stakeholders, there were cases in which all stakeholders did not provide a perspective on each issue presented. The views of the 10 non-federal stakeholders are not generalizable beyond these stakeholders; however,

⁴For purposes of this report, we use the term “award,” which could also be referred to as an obligation—a definite commitment by a federal entity that creates a legal liability to make payments immediately or in the future. A cooperative agreement is a legal instrument used to provide financial support when substantial interaction is expected between a federal agency and a state, local government, or other recipient carrying out the funded activity.

⁵See, for example, GAO, *Emerging Infections Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, [GAO-17-445](#) (Washington, D.C.: May 23, 2017); *National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals*, [GAO-13-278](#) (Washington, D.C.: Mar. 22, 2013); and *Influenza Pandemic: Lessons Learned from the H1N1 Pandemic Should Be Incorporated into Future Planning*, [GAO-11-632](#) (Washington, D.C.: June 27, 2011).

they provide insights on how federal funding has aided the response to certain infectious disease threats.

To describe the three key programs' performance measurement data on awardees' infectious disease preparedness capacity, we obtained and reviewed data from ASPR and CDC on awardee performance. Specifically, we reviewed data for a total of 20 performance measures: 8 measures from ELC, 5 measures from HPP, and 7 measures from PHEP. For each measure, we reviewed the most recently available, agency-validated data (from 2015 to 2017, depending on the measure). The 20 measures we reviewed are a subset of measures used by the three programs that directly relate to infectious disease preparedness capacity. HPP and PHEP are programs that support "all-hazards" preparedness capacity, meaning they help states and other jurisdictions build capacities to respond to a range of public health threats, including, but not limited to, infectious diseases. Although many of the "all hazards" performance measures used by the programs could indirectly relate to infectious disease preparedness capacity, our review focused on those measures directly related to infectious disease preparedness capacity, as we determined through consultation with ASPR and CDC officials.⁶

Through our review of agency performance measure documentation and interviews with agency officials, we determined that the 20 performance measures fell into four areas of preparedness capacity: (1) electronic lab reporting, (2) epidemiology capacity, (3) laboratory capacity, and (4) responder protection. For our analysis, we grouped the performance measures into these four areas, with consultation from ASPR and CDC officials. In general, the majority of awardees reported data for each of the 20 measures in our review. Reasons for not reporting data included a measure not applying to the awardee or the awardee did not conduct an

⁶An example of a measure that indirectly relates to infectious disease preparedness capacity is the PHEP measure that asks if public health officials have procedures in place to manage volunteers supporting a public health or medical incident. Centers for Disease Control and Prevention, *Public Health Emergency Preparedness Cooperative Agreement Budget Period 1 Performance Measure Specifications and Implementation Guidance, July 1, 2017 – June 30, 2018* (Washington, D.C.).

exercise necessary to determine their performance on a measure.⁷ We calculated the percentage of awardees that achieved a performance target for each measure based on the number of awardees that reported data on the measure and to which the measure applied.

To assess the reliability of the performance measure data, we reviewed agency documentation, such as performance measure implementation guidance provided to awardees; interviewed knowledgeable ASPR and CDC officials about their data systems and data validation processes; and performed checks of the data for consistency and completeness. Based on these steps, we determined that the data for the 20 performance measures included in our review were sufficiently reliable for our reporting purposes. One limitation of performance measure data is that these data are self-reported by the awardees. ASPR and CDC officials conduct data checks to mitigate this limitation, such as looking for outliers in the data and conducting validation calls with awardees.

We conducted this performance audit from June 2017 to May 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.

Background

ELC, HPP, and PHEP are the three key HHS programs through which the department provides annual awards to states and other jurisdictions to aid capacity building and preparedness for public health threats, including infectious disease threats, natural disasters, or terrorist events. ELC was established in 1995 and currently has 64 awardees—all 50 states, 6

⁷A measure did not apply to an awardee when the measure referred to an entity, such as an Ebola treatment center, that did not exist within the awardee's jurisdiction. An Ebola treatment center is a hospital that is prepared to provide comprehensive care to people diagnosed with Ebola virus disease for the duration of a patient's illness, as designated by states and localities with CDC input. Awardees that were provided less funding, such as localities and U.S. territories, may not have been required to report data on certain measures, according to CDC officials.

localities, and 8 territories and freely associated states.⁸ HPP and PHEP were established in 2002 and currently have 62 awardees—all 50 states, 4 localities, and 8 territories and freely associated states.⁹ ASPR and CDC provide awards through the three programs using cooperative agreements.

ELC, HPP, and PHEP Goals and Activities

Federal support through ELC, HPP, and PHEP helps states and other jurisdictions build and strengthen their abilities to effectively respond to public health threats before they occur. While ELC primarily supports public health infectious disease prevention and control capacity, HPP and PHEP are programs that support “all-hazards” preparedness capacity, meaning they help build capacities to respond to a range of public health threats, including infectious diseases, natural disasters, or terrorist events. According to ASPR and CDC documentation, each program has a distinct goal:

- ELC’s goal is to support capacity building to combat domestic infectious disease threats. The program funds epidemiologists and activities that support surveillance systems, modernize laboratory facilities, and develop integrated information networks at local and state levels, among other disease detection and response activities. Two primary classes of ELC funding include (1) flexible, non-disease-specific funding (generally referred to as “cross-cutting” funding) to address high-priority needs related to epidemiology, laboratory, and health information systems; and (2) disease-specific, categorical funding that targets specific infectious diseases and other related public health threats, including antimicrobial-resistant bacteria, arboviral and tickborne diseases (e.g., Lyme, West Nile, Zika), foodborne disease and illnesses, healthcare-associated infections, influenza, and waterborne diseases.¹⁰

⁸ELC’s 64 awardees are the 50 states; 6 localities, which are Chicago, the District of Columbia, Houston, Los Angeles County, New York City, and Philadelphia; and 8 territories and freely associated states—American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands. See 42 U.S.C. § 247d-3a (authorizing awards made by ELC).

⁹HPP’s and PHEP’s 62 awardees are the same as the ELC awardees with the exception of 2 localities, Houston and Philadelphia. See 42 U.S.C. §§ 247d-3a, 247-3b (authorizing awards made by HPP and PHEP).

¹⁰Arbovirus, or arthropod-borne virus, refers to a virus that is transmitted via arthropods, such as mosquitoes and ticks. Other diseases in this category include chikungunya, dengue fever, Rocky Mountain spotted fever, and tularemia.

-
- HPP’s goal is to improve patient outcomes and medical surge capacity by enhancing community and health care system preparedness for health consequences of various public health threats, including infectious disease threats. The program funds the development of health care coalitions—networks of health care entities and response organizations that can provide medical services, resources, or support during a public health threat. Working through these coalitions, HPP funds activities such as establishing electronic coordination and situational awareness systems to track available hospital beds and other resources, engaging with other responders through interoperable communications systems, maintaining or enhancing medical caches to protect health care workers and patients during a response, and developing and improving preparedness plans through regional exercises.¹¹
 - PHEP’s goal is to develop effective public health emergency management and response programs nationwide. PHEP strengthens the capabilities of state, local, and territorial public health departments to prepare for, and respond to, evolving public health threats, including infectious disease threats. Activities funded include developing and exercising plans to receive, store, distribute, and dispense life-saving medicines and emergency medical supplies to the public during a response to a public health threat, and coordinating emergency operations activities during a public health response to limit the health effects of life-threatening emergencies. PHEP funding also supports building epidemiological surveillance systems and laboratory capability for detecting, testing, and identifying harmful pathogens and reporting results to CDC, and conducting drills and exercises to test response capabilities.

¹¹A medical cache is a storage of medical supplies and medications that can be deployed in an emergency.

Funding for ELC, HPP, and PHEP Awards

Awards to states and other jurisdictions through ELC, HPP, and PHEP are generally funded from annual appropriations.¹² Specifically,

- ELC awards are funded by annual appropriations to CDC, as well as amounts made available to the Prevention and Public Health Fund;¹³
- HPP awards are funded by annual appropriations to the Public Health and Social Services Emergency Fund;¹⁴ and
- PHEP awards are funded by annual appropriations to CDC.

In addition, ASPR and CDC have, at times, provided awards to states and other jurisdictions through these programs in response to specific infectious disease threats with funding from supplemental appropriations provided by Congress to HHS. Supplemental appropriations provide budget authority for government activities, in addition to funding provided in annual appropriations or continuing resolutions.¹⁵

ELC, HPP, and PHEP Performance Measures

ELC, HPP, and PHEP awardees must fulfill certain application, financial, and reporting requirements as part of the terms of the programs'

¹²When regular annual appropriations are not completed before the beginning of the fiscal year, funding may be provided by continuing resolutions for the full year, up to a specified date, or until regular appropriations are enacted. ELC awards are determined by a competitive technical and objective review process. HPP and PHEP annual awards are based on a formula that includes a base amount for each awardee plus population-based funding.

¹³Section 4002 of the Patient Protection and Affordable Care Act established the Prevention and Public Health Fund in 2010 to "provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public health care costs," and made appropriations to the fund for fiscal year 2010 and each year thereafter. Pub. L. No. 111-148, §§ 4002, 10401(b), 124 Stat. 119, 541, 974 (2010) (codified as amended at 42 U.S.C. § 300u-11). Since 2010, CDC has used Prevention and Public Health Fund resources to fund ELC awards for "cross-cutting" activities, as well as other public health programs and activities. For information on activities funded by Prevention and Public Health Fund in fiscal years 2010 and 2011, see GAO, *Prevention and Public Health Fund: Activities Funded in Fiscal Years 2010 and 2011*, [GAO-12-788](#) (Washington, D.C.: Sept. 13, 2012).

¹⁴The Public Health and Social Services Emergency Fund is an HHS budget account that funds authorized ASPR and other HHS office operations and activities to support the nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and manmade threats.

¹⁵Budget authority authorizes an agency to enter into financial obligations that will result in outlays of federal government funds.

cooperative agreements. As part of these reporting requirements, awardees are required to report on performance measures, which can number 35 or more across all three programs.¹⁶ For example, PHEP awardees must report on the percentage of volunteers that were deployed for an exercise or actual public health threat within a determined time frame, and HPP awardees are subject to several measures to assess the extent to which they have appropriate preparedness and response plans in place. Reporting on performance measures helps the agencies gauge awardees' progress on discrete activities related to preparedness capacity, as well as to determine where additional technical assistance and other resources to support awardees are needed. Further, agency officials stated that performance measures can have targets that are intended to continuously challenge awardees to meet high standards. The 20 performance measures included in this report (i.e., those that are directly related to infectious disease preparedness capacity) constitute a subset of the programs' measures. We reported in March 2013 that many other performance measures used by HPP and PHEP did not have targets and recommended that HHS develop targets for such measures.¹⁷ We also recommended that HPP and PHEP performance measures remain consistent over time. Since our 2013 report, PHEP's measures have generally remained consistent in recent years, but some of these measures lack targets. HPP implemented new measures for the 2017 to 2022 project period that are not consistent with those from prior years. As of February 2018, more than half of these new measures lacked targets. ASPR officials told us that they expect measures to change over time to allow HPP to adapt to evolving public health threats, and agency guidance notes that targets may be set at a later date after establishing awardees' baseline scores.

¹⁶See Centers for Disease Control and Prevention, *Public Health Emergency Preparedness Cooperative Agreement Budget Period 1 Performance Measure Specifications and Implementation Guidance, July 1, 2017–June 30, 2018* (Atlanta, Ga.); *Instructions for Preparing Annual Performance Report /Continuation Application: Epidemiology and Laboratory Capacity for Infectious Diseases, Funding Opportunity Announcement Number: CK14-140104PPHF17* (Atlanta, Ga.); and *Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement Performance Measures Guidance for Domestic Ebola Supplement, Project Period March 31, 2015 to March 30, 2018, Version 5* (Atlanta, Ga.: September 2017). See also Office of the Assistant Secretary for Preparedness and Response, *2017–2022 Hospital Preparedness Program Performance Measures Implementation Guidance* (Washington, D.C.); and *Hospital Preparedness Program Measure Manual: Implementation Guidance for Ebola Preparedness Measures* (Washington, D.C.: July 2015).

¹⁷See [GAO-13-278](#).

HHS Awarded \$21.2 Billion to States through Key Programs; Stakeholders Stated That Available Funding Assisted Capacity Surges, but They Also Cited Challenges

HHS's Three Key Programs Awarded \$21.2 Billion to States and Other Jurisdictions from Fiscal Years 2002 through 2017; Supplemental Awards Played a Large Role in Certain Years

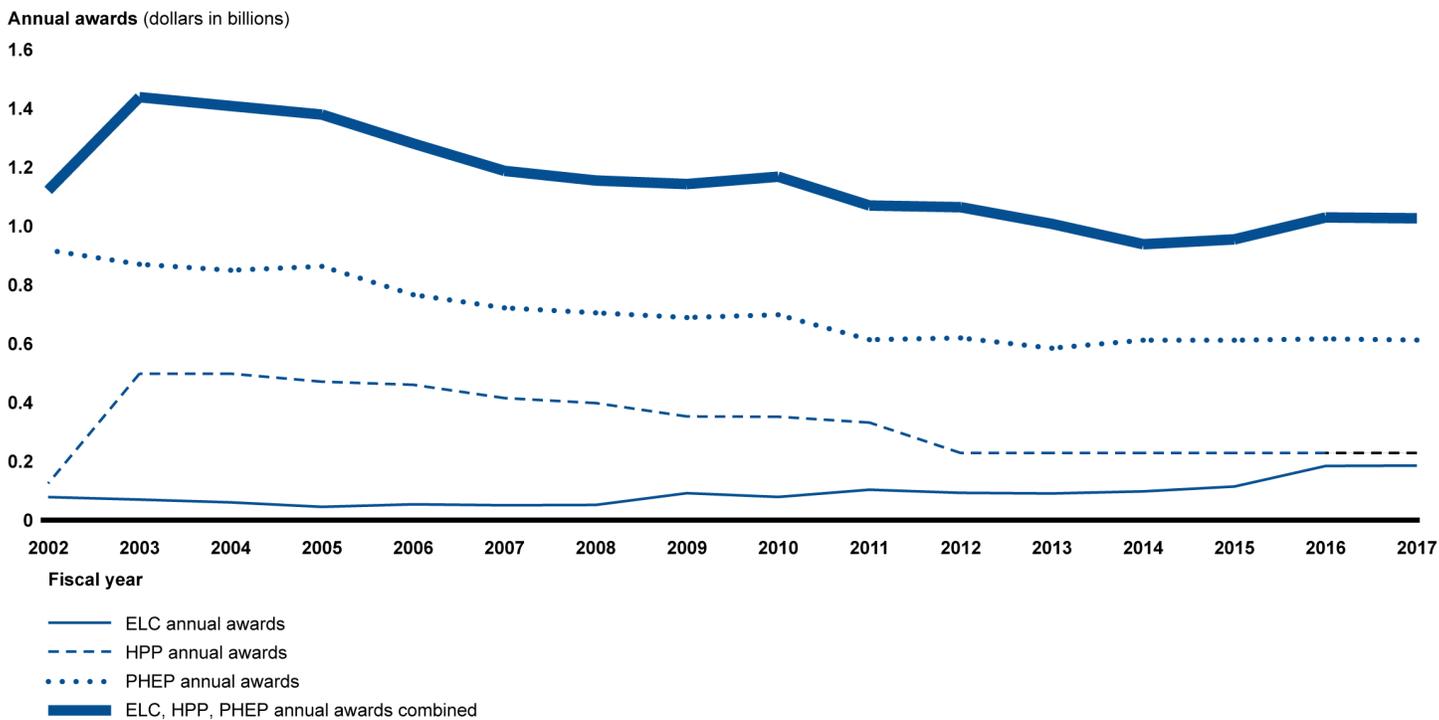
From fiscal years 2002 through 2017, a total of about \$21.2 billion was awarded by ASPR and CDC to states and other jurisdictions through ELC, HPP, and PHEP to carry out public health preparedness and response efforts, including those related to infectious diseases, natural disasters, or terrorist events.¹⁸ The vast majority of this amount—about 86 percent, or \$18.4 billion—was provided from annual appropriations. The amount of awards from annual appropriations was mostly made by CDC through PHEP, which totaled about \$11.4 billion over the time period. The amount of awards made by ASPR through HPP and by CDC through ELC totaled about \$5.6 billion and \$1.5 billion, respectively.

The combined amount of awards provided through the three programs' annual appropriations has generally decreased, from about \$1.4 billion in fiscal year 2003 (which was when the total awards were at the highest level) to about \$1.0 billion in fiscal year 2017, though funding trends between the three programs have varied over time. Specifically, the amount of awards provided through ELC from annual appropriations almost doubled, from about \$0.1 billion in fiscal year 2002 to about \$0.2 billion in fiscal year 2017. The amount of awards provided through HPP and PHEP from annual appropriations generally decreased, though the

¹⁸The nominal value of awards is presented in this report. Due to rounding, certain award amounts presented in this section may not sum to total award amounts reported.

amount of awards has remained relatively constant in recent years. Overall, from its high in fiscal year 2003 to fiscal year 2017, HPP award amounts decreased about 54 percent. PHEP award amounts decreased about 33 percent from its high in fiscal year 2002 to fiscal year 2017. (See fig. 1.)

Figure 1: Awards Provided to States and Other Jurisdictions through Three Key HHS Preparedness and Capacity-Building Programs, Annual Appropriations, Fiscal Years 2002-2017

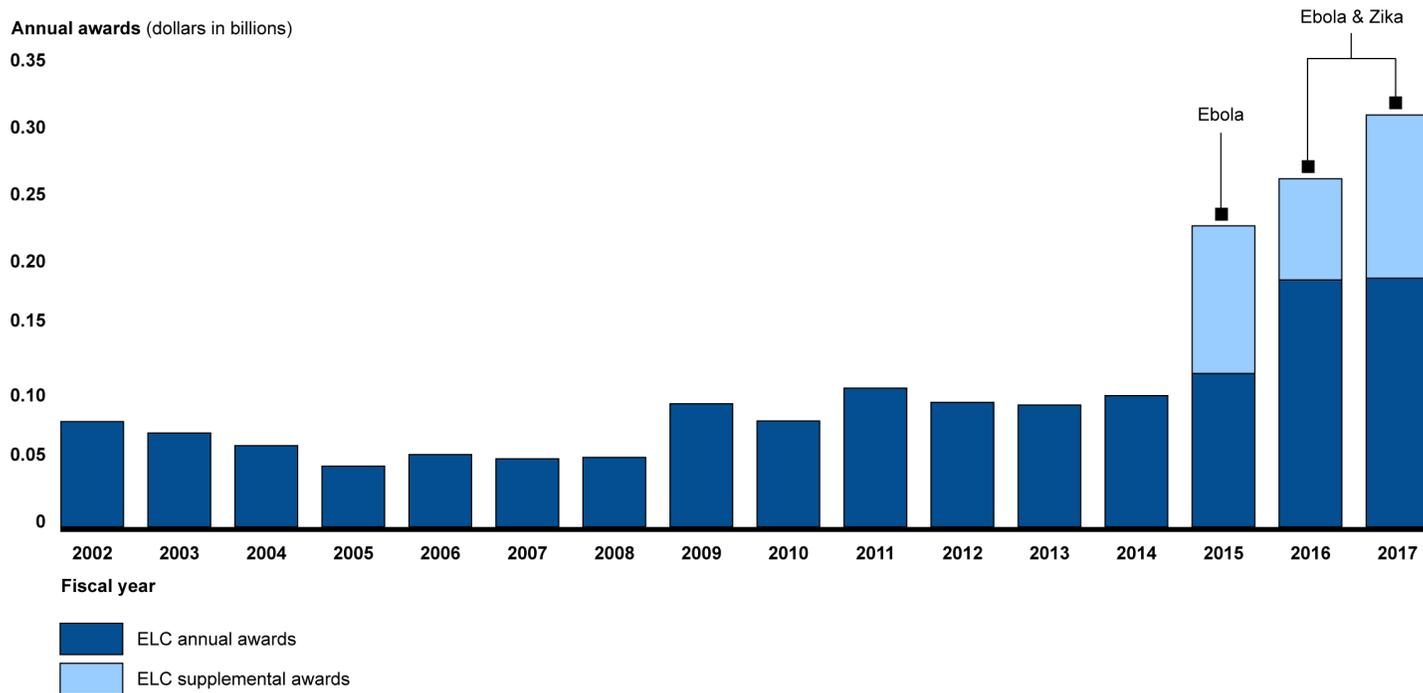


Source: GAO analysis of Office of the Assistant Secretary for Preparedness and Response and Centers for Disease Control and Prevention awards data. | GAO-18-362

Note: The Department of Health and Human Services (HHS) provides funding to states, localities, territories, and freely associated states to aid capacity building and preparedness for public health threats, including infectious disease threats, natural disasters, or terrorist events through three key programs: Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), the Hospital Preparedness Program (HPP), and Public Health Emergency Preparedness (PHEP). This figure includes data on annual awards to states and other jurisdictions provided through these three programs with funding from annual appropriations to address preparedness for public health threats that include, but are not limited to, infectious disease threats.

In addition, from fiscal years 2002 through 2017, a total of about \$2.9 billion in awards has been made through the three programs from supplemental appropriations, and these awards have been a large percentage of the total award amounts provided in certain years.¹⁹ For example, award amounts provided through ELC from supplemental appropriations in fiscal years 2015 through 2017 to respond to Ebola and Zika ranged between about 30 and 50 percent of the total award amounts during those years. (See fig. 2.)

Figure 2: Awards Provided through Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), Annual and Supplemental Appropriations, Fiscal Years 2002-2017



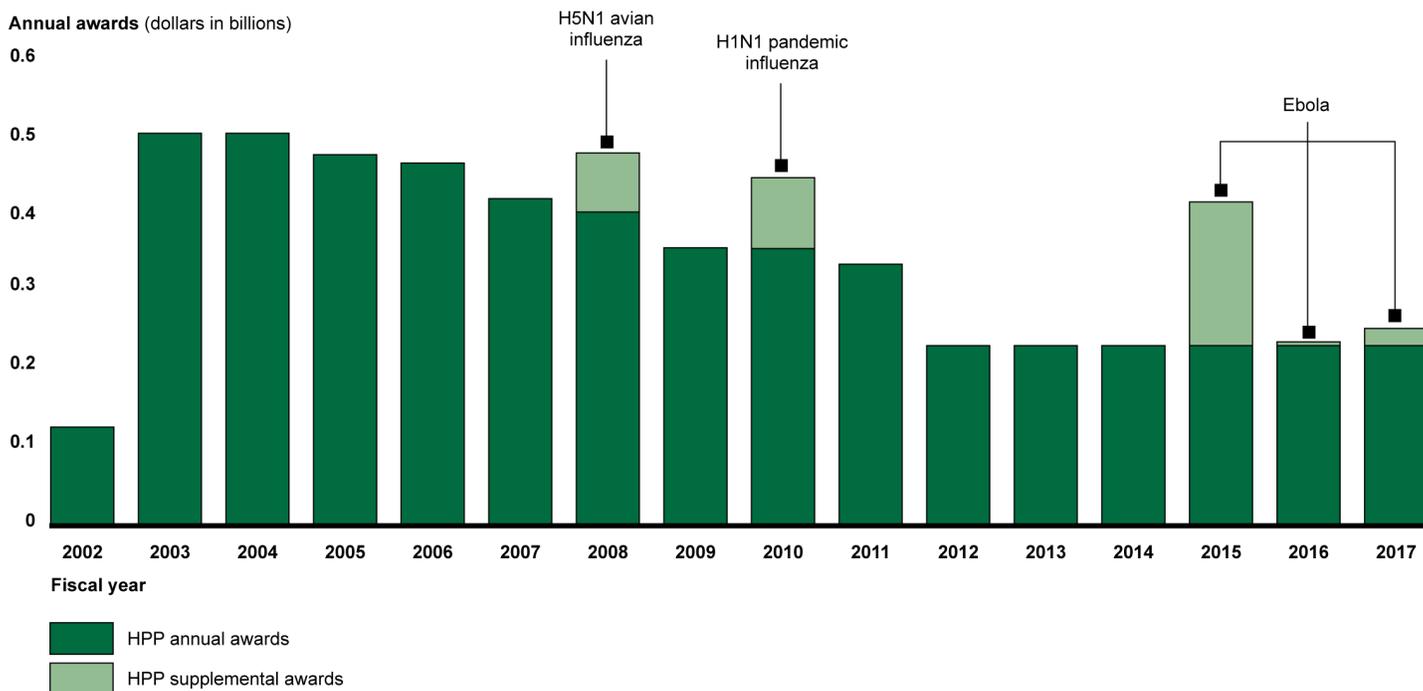
Source: GAO analysis of Centers for Disease Control and Prevention (CDC) awards data. | GAO-18-362

Note: Awards provided to respond to Zika in fiscal year 2016 were provided using funding that CDC reprogrammed away from other programs prior to supplemental appropriations being enacted. In this figure, these awards are included as awards provided from supplemental appropriations.

¹⁹This amount includes about \$0.3 billion through ELC, \$0.4 billion through HPP, and \$2.2 billion in awards through PHEP.

Similarly, in fiscal years 2015 through 2017, awards were provided through HPP from supplemental appropriations to respond to Ebola, and in fiscal year 2015 these awards made up a large percentage of awards provided through HPP. Specifically, these award amounts totaled approximately \$0.2 billion in 2015, which was about 44 percent of the total award amounts (about \$0.4 billion) provided through HPP in that year. (See fig. 3.)

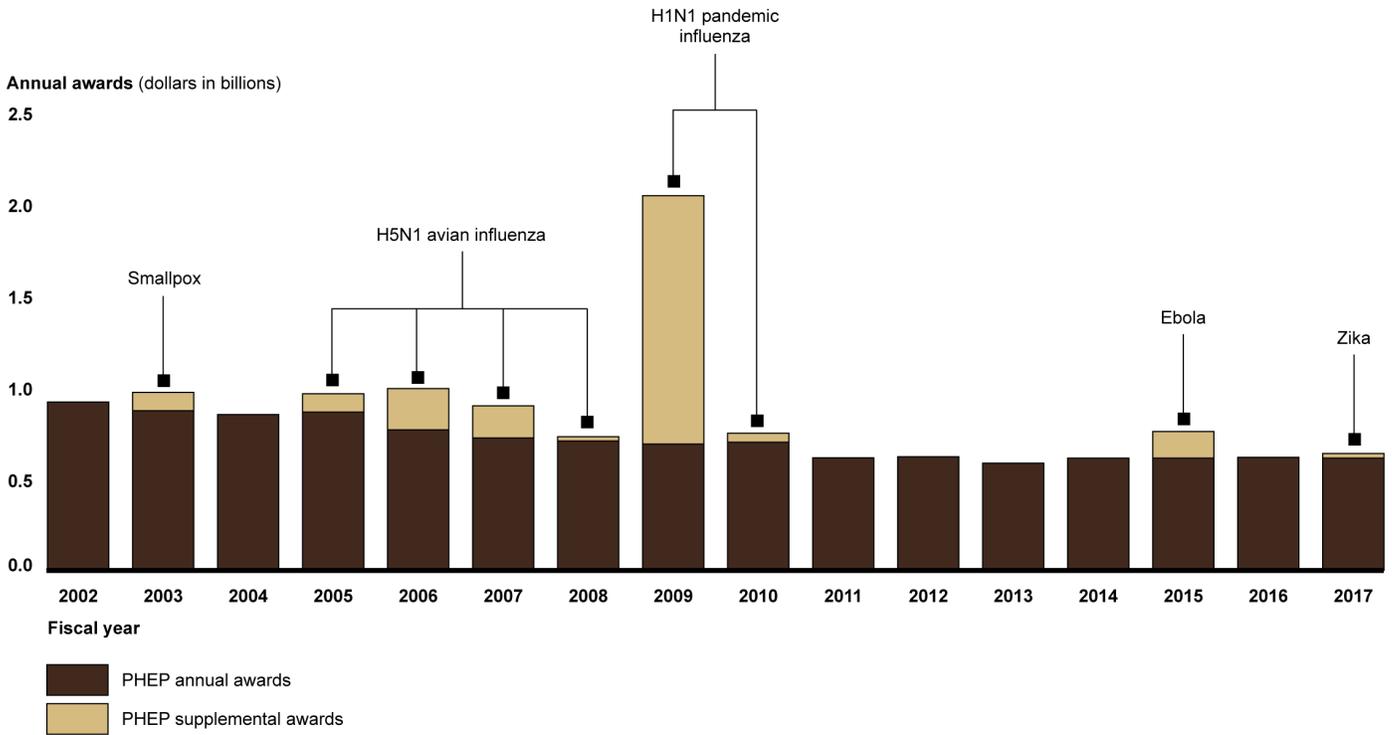
Figure 3: Awards Provided through the Hospital Preparedness Program (HPP), Annual and Supplemental Appropriations, Fiscal Years 2002-2017



Source: GAO analysis of Office of the Assistant Secretary for Preparedness and Response awards data. | GAO-18-362

Awards from supplemental appropriations were also provided through PHEP in certain years, including in fiscal years 2009 and 2010 to respond to H1N1 pandemic influenza. The fiscal year 2009 award amounts for H1N1 pandemic influenza totaled close to \$1.4 billion—66 percent of the total award amounts provided through PHEP in that year (about \$2 billion). (See fig. 4.)

Figure 4: Awards Provided through Public Health Emergency Preparedness (PHEP), Annual and Supplemental Appropriations, Fiscal Years 2002-2017



Source: GAO analysis of Centers for Disease Control and Prevention awards data. | GAO-18-362

Note: Awards provided to PHEP awardees from supplemental appropriations in fiscal years 2009 and 2010 to respond to H1N1 pandemic influenza were made through a separate granting mechanism—the Public Health Emergency Response Grant for H1N1 Influenza Pandemic. Awards provided to PHEP awardees from supplemental appropriations in fiscal year 2017 to respond to Zika were made through a separate granting mechanism—the Public Health Preparedness and Response Cooperative Agreement for All-Hazards Public Health Emergencies.

Stakeholders Reported That Available Funding Assisted Surges in Capacity during Recent Infectious Disease Threats; Timing of Awards Can Limit Preparedness and Response Activities

According to ASPR and CDC officials, as well as most non-federal stakeholders we interviewed, awards provided through HHS's three key preparedness and capacity-building programs with supplemental appropriations were important for allowing health care systems—which include state and local public health departments, laboratories, and hospitals—to make necessary surges in capacity or take other actions, such as creating plans and training staff, to respond to infectious disease threats.²⁰ For example, one stakeholder told us that during the Zika threat, awards provided through ELC from supplemental appropriations allowed public health laboratories to hire additional staff and purchase laboratory testing equipment needed to conduct the high volume of Zika tests. We previously reported that awards from supplemental appropriations helped states and local jurisdictions respond to the H1N1 pandemic influenza in 2009 and 2010.²¹ For example, we found that Vermont used its award to purchase lab equipment and hire 10 temporary employees to enter vaccination data into the state's vaccine registry. We also found that Nebraska used its award to contract with nurses to administer the H1N1 influenza vaccine at mass vaccination clinics. As another example, the Association of State and Territorial Health Officials reported that the awards from supplemental appropriations provided states with resources necessary to respond to the H1N1 pandemic influenza by providing funds to support increased public health workforce capacity in surveillance and immunization.²²

ASPR and CDC officials told us that awards provided through ELC, HPP, and PHEP are intended to establish and strengthen emergency preparedness and capacity building. Awards from annual appropriations may not fully support the need for surge capacity that states and other jurisdictions require in order to respond to an infectious disease threat, according to the officials. CDC officials said that the general decrease in PHEP awards from annual appropriations to state and local public health departments over time has limited state and local preparedness capacity.

²⁰A health care system's ability to "surge" is the ability to have the staff and resources in place to adequately care for increased numbers of affected individuals or individuals with unusual or highly specialized needs.

²¹See [GAO-11-632](#).

²²See Association of State and Territorial Health Officials, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic* (Arlington, Va.: June 2010), 25.

This, in turn, has increased the importance of awards from supplemental appropriations to respond to infectious disease threats. Agency officials cited a survey by the National Association of County and City Health Officials, which reported that there was a 12 percent rise in the number of local health departments that reported a decrease in their preparedness staff from 2015 levels to 2016 levels, with 34 percent reporting decreased levels in staff since 2015.²³

Although the awards from supplemental appropriations have allowed state and local public health departments, laboratories, and hospitals to surge during a threat, most non-federal stakeholders, as well as ASPR and CDC officials, said that the timing of these awards can result in challenges to carrying out preparedness and response activities during infectious disease threats. For example, two stakeholders said that state and local public health departments' routine activities or personnel hires can be delayed while resources are used to respond to an infectious disease threat. Two stakeholders also said that PHEP awardees were affected by CDC's reprogramming of a portion of the PHEP awards from annual appropriations away from awardees to fund Zika response activities prior to the availability of supplemental appropriations.²⁴ According to one of these stakeholders, the routine PHEP preparedness activities that awardees had planned were delayed or were not fully operational until the amounts of the reprogrammed awards were returned as new awards to the PHEP awardees. According to an April 2016 survey of PHEP awardees conducted by the National Association of County and City Health Officials and other organizations, about 72 percent of responding jurisdictions reported that ongoing preparedness program

²³In June 2016, the National Association of County and City Health Officials conducted a survey of 871 local health departments across the country. Data for the assessment were self-reported, and had a response rate of 53 percent (458 local health departments). National Association of County and City Health Officials, *The Public Health Emergency Preparedness Landscape: Findings from the 2016 Preparedness Profile Assessment* (Washington, D.C.: June 2017).

²⁴The term reprogramming refers to shifting funds within an appropriation or fund account to use them for purposes other than those contemplated at the time of appropriation. In February 2016, prior to supplemental appropriations being enacted, CDC reprogrammed \$44.25 million in annual appropriations away from PHEP awardees and used these funds for other activities to aid the Zika response. In September 2016, Zika supplemental funding was appropriated by the Zika Response and Preparedness Act. This funding allowed for the restoration of \$44 million back to PHEP so that the program could reinstate the remaining awards. According to CDC officials, the agency restored the remaining \$0.25 million from its operating budget so that the full amount of the funding—\$44.25 million—was eventually provided to the PHEP awardees.

areas (e.g., surveillance, epidemiological activities, and laboratory services) were likely to be affected by the reprogramming.²⁵

ASPR and CDC officials also told us that it can take up to 4 months to disseminate awards through the existing programs, once supplemental appropriations are enacted. ASPR and CDC officials said that although the process for administering funds through ELC, HPP, and PHEP is familiar to states and other jurisdictions, these cooperative agreement programs do not allow for rapid dissemination of funds, because the agencies must follow their cooperative agreement administrative requirements and protocols. For example, before awarding funds from supplemental appropriations, the agencies have to create and provide notice of funding opportunities (NOFO) that jurisdictions have to apply to and be approved for before funds can be disseminated. For example, CDC officials stated that the process to get awards from supplemental appropriations to ELC awardees took about 4 months for the Ebola response and about 3 months for Zika.

In October 2017, CDC issued a new NOFO that is intended to shorten the amount of time it takes the agency to disseminate funding to respond to public health threats. This NOFO establishes a list of awardees, with existing emergency preparedness and response capacity, that are pre-approved for funding by CDC when a public health threat occurs, including infectious disease threats. According to CDC officials, any CDC program, including ELC and PHEP, could use this funding mechanism. The NOFO requires that awardees have administrative structures and plans in place to receive funding, as well as plans to respond to a public health threat. According to CDC officials, awards could potentially be provided within 2 weeks to pre-approved awardees after supplemental appropriations are enacted, as opposed to months under the current cooperative agreement programs. According to officials, all of the 64 ELC and PHEP awardees have applied to the NOFO and have been deemed

²⁵The majority of jurisdictions also reported that vector control, contractual services, supplies, and staffing levels were likely to be affected. The survey was fielded between April 8, 2016, and April 15, 2016, to all 62 PHEP awardees. The survey was completed by representatives from 61 jurisdictions for a total response rate of 98.4 percent. National Association of County and City Health Officials, the Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, and the Association of Public Health Laboratories, *Impact of the Redirection of Public Health Emergency Preparedness (PHEP) Funding from State and Local Health Departments to Support National Zika Response* (Washington, D.C.: May 2016).

eligible.²⁶ As of February 2018, the agency had begun notifying these awardees that they are on CDC's pre-approved list for funding in the case of a future public health threat. The NOFO does not apply to ASPR programs, including HPP, and ASPR officials told us that the agency does not have plans to develop a similar opportunity for ASPR programs.²⁷

ASPR and CDC officials, as well as all non-federal stakeholders, also noted that a funding mechanism to fund rapid response activities when additional support is needed would be beneficial and could help address timing challenges. Such a mechanism could include the use of the existing Public Health Emergency Fund (PHEF) or a new emergency response fund specific to infectious disease.²⁸ The availability of any such fund for immediate use would be subject to available appropriations. According to CDC officials and most non-federal stakeholders we interviewed, such a mechanism could allow HHS to provide additional funds to state and other jurisdictions for a rapid response to infectious disease threats while the department waits for any supplemental appropriations to be enacted by Congress. While one non-federal stakeholder stated that PHEF, with available funding, could be a viable funding mechanism for funding infectious disease threats, the stakeholder

²⁶The NOFO was open to all 64 ELC and PHEP awardees, as well as five tribes, which CDC defines as federally or state recognized American Indian or Alaska Native tribal governments serving a population of at least 50,000 members. According to CDC officials, no tribes had applied to the NOFO. Agency officials told us that they were contacting the tribes to ensure they were aware of the opportunity. They also said that the application process for the NOFO will be reopened at a later date, and eligible tribes will have the opportunity to apply.

²⁷According to CDC and ASPR officials, the agencies are in the process of shifting the responsibility for HPP grants management—which includes administration of the HPP cooperative agreements—from CDC to ASPR. While ASPR has had programmatic management responsibility for HPP, CDC has had grants management responsibility for HPP (in addition to its programmatic management and grants management responsibilities for ELC and PHEP). Officials told us that this change will begin in July 2019, and that moving the HPP grants management to ASPR will allow more staff to oversee the HPP administrative process, which could aid the timeliness of awards provided from supplemental appropriations.

²⁸PHEF, established in 1983, is available to the Secretary of Health and Human Services to respond to a public health emergency, including infectious disease threats. See Pub. L. No. 98-49, 97 Stat. 245 (1983) (codified as amended at 42 U.S.C. § 247d). A Congressional Research Service report issued in 2009 indicated that the fund had not received an appropriation since Congress reauthorized it in 2000. Congressional Research Service, *Public Health and Medical Response to Disasters: Federal Authority and Funding*, RL33579 (Washington, D.C.: Apr. 29, 2009). According to HHS's 2016 budget justification estimates, PHEF has no balance.

cautioned against the use of such a fund without having clear definitions as to when it should be used. The stakeholder stated that there should be ongoing investments at all levels of government for preparedness and capacity-building activities, and that PHEF or another type of emergency fund should not be used to make-up for a lack in those investments. A few other stakeholders also commented that they would not want an emergency fund to be a substitute to providing ongoing funding to preparedness and capacity-building programs, such as ELC, HPP, and PHEP. (See app. I for six factors that the non-federal stakeholders said may be considered for an emergency response fund, whether using an existing fund like PHEF or creating a new fund.)

Majority of Awardees Met Targets for All Responder Protection Measures, but Performance Was Mixed Across Other Areas

The 20 performance measures we reviewed for HHS's three key preparedness and capacity-building programs (ELC, HPP, and PHEP) fell into four preparedness capacity areas: electronic lab reporting, epidemiology capacity, laboratory capacity, and responder protection.²⁹ The majority of awardees (states and other jurisdictions) that reported on performance measures in the responder protection area met all performance targets in this area. However, awardee performance in the other three preparedness capacity areas was mixed.

ELC had measures in each of the four preparedness capacity areas, while PHEP had measures in two areas, and HPP's performance measures fell into one of the four preparedness capacity areas. (See table 1.) The programs' performance measures are meant to demonstrate accountability and identify awardees' strengths, weaknesses, and areas for improvement on discrete activities related to preparedness capacity. According to CDC officials, the measures can include targets that are intended to challenge awardees to continuously meet high standards.

²⁹The 20 performance measures included in our review directly relate to infectious disease preparedness capacity. While the agencies have not categorized the performance measures, ASPR and CDC officials agreed with our categorization of the performance measures in the four areas.

Table 1: Performance Measures Used by HHS’s Three Key Preparedness and Capacity-Building Programs, by Preparedness Capacity Area

Program	Performance measure	Preparedness capacity area ^a			
		Electronic lab reporting	Epidemiology capacity	Laboratory capacity	Responder protection
ELC	Percentage of laboratory reports received electronically.	√	-	-	-
	Number of new electronic lab reporting feeds established.	√	-	-	-
	Investigated reported outbreaks.	-	√	-	-
	Laboratory test turnaround time completed within established time frame.	-	-	√	-
	Laboratories have designated a biosafety officer.	-	-	-	√
	Laboratories have conducted risk assessments and mitigated risks. ^b	-	-	-	√
	Laboratories have a biosafety plan in place that has been reviewed and communicated.	-	-	-	√
	Standard operating procedure in place to perform risk assessments for laboratories.	-	-	-	√
HPP	Ebola treatment centers can access personal protective equipment. ^c	-	-	-	√
	Assessment hospitals can access personal protective equipment. ^d	-	-	-	√
	Frontline facilities can receive information on personal protective equipment from their health care coalition. ^e	-	-	-	√
	Emergency medical services agencies that are required to participate in awardee’s concept of operations are engaged in the process of developing an operational plan for the state. ^f	-	-	-	√
	Health care coalitions that participate in an advisory group that makes recommendations on the prevention of health care-associated infections.	-	-	-	√
PHEP	Percentage of required disease reports received on time.	-	√	-	-
	Percentage of required disease reports for which initial control measures were initiated on time. ^g	-	√	-	-
	Completed emergency contact drill one on time. ^h	-	-	√	-
	Completed emergency contact drill two on time. ^h	-	-	√	-
	Proportion of laboratory response network-biological proficiency tests passed. ⁱ	-	-	√	-

Program	Performance measure	Preparedness capacity area ^a			
		Electronic lab reporting	Epidemiology capacity	Laboratory capacity	Responder protection
	Submitted subtyping results from E. coli samples to a national database. ^l	-	-	√	-
	Submitted subtyping results from Listeria monocytogenes samples to a national database. ^l	-	-	√	-
Total number of measures in each area		2	3	6	9

Legend: √= Performance measure included in preparedness capacity area. - = Performance measure not included in preparedness capacity area.

Source: GAO analysis of Office of the Assistance Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC) performance measurement information. | GAO-18-362

Note: The Department of Health and Human Services (HHS) provides funding to states, localities, territories, and freely associated states to aid capacity building and preparedness for public health threats, including infectious disease threats, natural disasters, or terrorist events, through three key programs: Epidemiology and Laboratory Capacity for Infectious Diseases (ELC), the Hospital Preparedness Program (HPP), and Public Health Emergency Preparedness (PHEP). This table shows the performance measures used in these key programs that are directly related to infectious disease preparedness capacity, as we determined through consultation with ASPR and CDC officials.

^aWe categorized the 20 performance measures in this table into four preparedness capacity areas. While the agencies have not categorized the performance measures, ASPR and CDC officials agreed with our categorization of the performance measures into these areas.

^bRisk assessments involve identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize exposure to those risks.

^cEbola treatment centers are hospitals that are prepared to provide comprehensive care to people diagnosed with Ebola virus disease for the duration of a patient's illness, as designated by states and localities with CDC input after conducting site visits.

^dEbola assessment hospitals are those that are prepared to receive and isolate a patient with potential Ebola virus disease, as designated by the state.

^eMost U.S. acute care facilities that are equipped for emergency care (such as hospital-based emergency departments, urgent care clinics, and critical access hospitals) are frontline facilities.

^fA concept of operations is an overview of the processes and steps for an effective system or operation, such as a response to an infectious disease outbreak.

^gInitial control measures vary by disease. Some examples of control measures include identification of potentially exposed individuals, investigation into the causes of an infectious disease threat after it is identified, and immunization.

^hDrill one is time to complete notification between CDC, on-call laboratorian, on-call epidemiologist, and then back to CDC; drill two is the reverse direction: time to complete notification between CDC, on-call epidemiologist, on-call laboratorian, and then back to CDC.

ⁱThe laboratory response network-biological is a group of state, local, and other public health laboratories that provides routine and specialized laboratory testing to quickly respond to public health threats.

^jSubtyping procedures can identify certain attributes of bacteria to distinguish between bacteria of the same species. Subtyping can be used to predict the severity and transmissibility of a certain strain of bacteria, such as E. coli or Listeria monocytogenes.

Of the 20 measures, we found that the majority of reporting awardees met the performance targets for 9 of the 9 measures in the responder protection area, 5 of the 6 measures in the laboratory capacity area, 1 of the 2 measures in the electronic lab reporting area, and 1 of the 3 measures in the epidemiology capacity area. These areas, and related awardee performance, are discussed in detail in the sections that follow.

Responder Protection

The responder protection performance measures apply to ELC’s and HPP’s Ebola awards from supplemental appropriations, and measure activities related to safety and coordination for laboratorians, hospital and emergency personnel, and other responders, including the coordination of these responders. The measures assess the extent to which awardees can safely respond in the event of a highly contagious infectious disease threat. Though these performance measures were designed specifically for Ebola, ASPR and CDC officials told us that these measures may also have some application to preparedness for other highly infectious diseases. For each of the four ELC measures in this area, the majority of ELC awardees met each target—the percentage of reporting awardees that met the target ranged from 77 to 97 percent. For each of the five HPP measures in this area, the majority of HPP awardees met each target—the percentage of reporting awardees that met the target ranged from 61 to 97 percent. (See table 2.)

Table 2: Awardee Performance on Responder Protection Performance Measures, by Program

Program	Performance measure	Target	Percent of reporting awardees that met target ^a
ELC	Laboratories have designated a biosafety officer.	Awardee reported “yes.”	97 percent (n = 61)
	Laboratories have conducted risk assessments and mitigated risks.	Awardee reported “yes.”	87 percent (n = 60)
	Laboratories have a biosafety plan in place that has been reviewed and communicated.	Awardee reported “yes.”	90 percent (n = 60)
	Standard operating procedure in place to perform risk assessments for laboratories.	Awardee reported “yes.”	77 percent (n = 60)
HPP	Ebola treatment centers can access personal protective equipment.	All Ebola treatment centers accessed within 10 minutes.	97 percent (n = 29)
	Assessment hospitals can access personal protective equipment.	All assessment hospitals accessed within 10 minutes.	94 percent (n = 49)

Program	Performance measure	Target	Percent of reporting awardees that met target ^a
	Frontline facilities can receive information on personal protective equipment from their health care coalition.	All frontline facilities received within 8 hours.	68 percent (n = 56)
	Emergency medical services agencies that are required to participate in awardee's concept of operations are engaged in the process of developing an operational plan for the state.	All required emergency medical services agencies engaged.	85 percent (n = 55)
	Health care coalitions that participate in an advisory group that makes recommendations on the prevention of health care-associated infections.	80 percent of health care coalitions participated.	61 percent (n = 57)

Source: GAO analysis of awardee performance measurement data provided by the Office of the Assistance Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC). | GAO-18-362

Note: Data are from October 1, 2016, through March 31, 2017, for Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) and from May 18, 2015, through May 17, 2016, for the Hospital Preparedness Program (HPP), according to ASPR and CDC officials. These are the most recent years for which validated data were available.

^aThe percentages in this column are based on the subsets of awardees that provided data and to which the measure applied, or (n). While almost all awardees reported data on eight of the nine measures, the exact number of awardees that provided data varied across measures. Some awardees did not report data for certain measures, because, for example, they did not conduct the exercise necessary to determine performance on a measure, or were not required to report on a measure, according to ASPR and CDC officials. For example, HPP's Ebola treatment center measure was not required of many awardees, because they did not have Ebola treatment centers within their jurisdictions.

According to CDC officials, the benefits of the ELC measures in this area include promoting a culture of safety within the awardee's jurisdiction, learning new technologies and procedures that could be used during a highly contagious infectious disease outbreak, and establishing written plans and procedures to train staff on how to respond to certain risks. These measures all asked for a "yes" or "no" response, and CDC's target was for awardees to submit a "yes" to each measure.

ASPR officials stated that the HPP measures in this area related to medical facilities' ability to quickly access personal protective equipment in the case of a potentially highly contagious infectious disease. The measures also assess coordination among various health care entities to help ensure that groups, such as emergency medical services and health care advisory groups, are involved in the planning for an infectious disease threat. The majority of awardees have already met targets for each of the five performance measures in this area, even though the targets set by ASPR are 5-year targets that do not need to be achieved until 2020. While ASPR has not yet established targets for awardees to aim for every year, officials stated they are planning to establish interim

targets for these performance measures in 2018, using data collected in 2016 and 2017 as a benchmark.

Laboratory Capacity

Laboratory capacity refers to both laboratory testing of certain pathogens and communication between laboratories and other public entities. ELC had one measure and PHEP had five measures in this area. Half of the reporting awardees (50 percent) met the target for ELC’s only measure in this area, while a large majority of PHEP awardees met the targets for each of the five PHEP measures in this area—the percentage of reporting awardees that met the target ranged from 75 to 100 percent. (See table 3.)

Table 3: Awardee Performance on Laboratory Capacity Performance Measures, by Program

Program	Performance measure	Target	Percent of reporting awardees that met target ^a
ELC	Laboratory test turnaround time completed within established time frame.	Varied between 2 and 65 days.	50 percent (n = 48)
PHEP	Completed emergency contact drill one on time.	Completed within 45 minutes.	96 percent (n = 51)
	Completed emergency contact drill two on time.	Completed within 45 minutes.	96 percent (n = 52)
	Proportion of laboratory response network-biological proficiency tests passed.	Failed no more than one proficiency test.	100 percent (n = 53)
	Submitted subtyping results from E. coli samples to a national database.	90 percent of samples within 4 working days.	90 percent (n = 52)
	Submitted subtyping results from Listeria monocytogenes samples to a national database.	90 percent of samples within 4 working days.	75 percent (n = 40)

Source: GAO analysis of awardee performance measurement data provided by the Centers for Disease Control and Prevention (CDC). | GAO-18-362

Note: Data are from calendar year 2015 for Epidemiology and Laboratory Capacity for Infectious Diseases (ELC); from July 1, 2016, through June 30, 2017, for Public Health Emergency Preparedness’s (PHEP) two emergency contact drill measures; and from July 1, 2014, through June 30, 2015, for PHEP’s other three measures, according to CDC officials. These were the most recent years for which validated data were available.

^aThe percentages in this column are based on the subset of awardees that provided data and to which the measure applied, or (n). While most awardees reported data for these measures, the exact number of awardees that provided data varied across measures. According to CDC officials, some awardees did not report data for certain measures, because, for example, they did not perform the necessary testing to determine performance on a measure, or were not required to report on a measure, as was the case for some localities and U.S. territories.

CDC officials stated that the ELC measure in this area—turnaround time for laboratory tests—allows awardees to choose diseases for which they would like to focus on to improve the timeliness of their laboratory testing. Targets for this measure were set by the awardee and varied from 2 to 62 days. Certain circumstances may make it more difficult for an awardee to meet the target, such as implementing complex laboratory procedures, according to CDC officials. Performance varied widely among awardees that missed the target; for example, several awardees missed their selected target by one or two days, while others missed the target by a week or more.

PHEP's two emergency contact drill measures in this area assess whether there is effective contact between on-call epidemiologists and laboratorians, which relates to how quickly they can respond during a public health threat, such as an infectious disease outbreak. The other three PHEP measures are important, because they ensure that laboratories have the capability to detect and report potentially deadly diseases. CDC established the targets for all five of these measures.

Electronic Lab Reporting

Electronic lab reporting involves sending clinical and laboratory reports to public health agencies via electronic means (as opposed to traditional paper reports). ELC had two measures in this area. The majority of reporting ELC awardees (58 percent) met the performance target for one of the two ELC performance measures in this area (establishing two or more electronic lab reporting feeds), while 16 percent met the target for the other measure (increasing the percentage of laboratory reports received electronically by at least 10 percentage points).³⁰ (See table 4.)

³⁰Electronic lab reporting feeds are direct data lines that electronically load laboratory results from a laboratory's data system to another data system, such as a public health department's data system.

Table 4: Awardee Performance on Electronic Lab Reporting Performance Measures

Program	Performance measure	Target	Percent of reporting awardees that met target ^a
ELC	Percentage of laboratory reports received electronically.	Increased at least 10 percentage points.	16 percent (n = 19)
	Number of new electronic lab reporting feeds established.	Two or more.	58 percent (n = 19)

Source: GAO analysis of awardee performance measurement data provided by the Centers for Disease Control and Prevention (CDC). | GAO-18-362

Note: Data are from calendar year 2016 for the two Epidemiology and Laboratory Capacity for Infectious Diseases' (ELC) measures in this area, according to CDC officials. These are the most recent years for which validated data were available.

^aThe percentages in this column are based on the subsets of awardees that provided data and to which the measure applied, or (n). The two measures in this table did not apply to the majority of awardees, because these measures were only required of awardees that did not receive at least 75 percent of their laboratory reports electronically.

According to CDC officials, using electronic lab reporting instead of paper reports results in timelier, more complete, and more accurate reports. ELC applies these measures to awardees that have not already reached the program threshold of reporting at least 75 percent of their laboratory reports electronically. CDC officials stated that the process of submitting reports via electronic lab reporting requires significant technical expertise and repeated communication between the laboratories, hospitals, and the state's public health department. CDC-established targets measure whether or not awardees are increasing their volume of reports received via electronic lab reporting each year. Awardees who have not met ELC's reporting threshold may struggle with electronic lab reporting for several reasons, such as difficulty hiring or maintaining skilled personnel to advance electronic lab reporting or implementing electronic reporting in low volume laboratories, according to CDC officials. The performance of the ELC awardees that did not meet the electronic lab reporting target varied widely. For example, over 20 percent of awardees submitted a smaller proportion of laboratory reports electronically in 2016 than they did in 2015, while other awardees came close to meeting the target (a 10 percent increase in electronic reports).

Epidemiology Capacity

Epidemiology capacity refers to identifying and responding to infectious disease outbreaks.³¹ ELC had one measure in this area, and PHEP had two. The majority of reporting ELC awardees (84 percent) met the established target for ELC’s measure; however, few PHEP awardees met the targets of the two PHEP measures in this area—the percentage of reporting awardees that met the target ranged from 10 to 12 percent. (See table 5.)

Table 5: Awardee Performance on Epidemiology Capacity Performance Measures, by Program

Program	Performance measure	Target	Percent of reporting awardees that met target ^a
ELC	Investigated reported outbreaks.	All reported outbreaks investigated.	84 percent (n = 61)
PHEP	Percentage of required disease reports received on time.	Disease reports received on time across all diseases. ^b	Across all six diseases combined: 10 percent (n = 52) ^c <ul style="list-style-type: none"> • Botulism: 63 percent • Tularemia: 50 percent • E. coli: 15 percent • Hepatitis A: 28 percent • Measles: 77 percent • Meningococcal: 30 percent
	Percentage of disease reports for which required initial control measures were initiated on time.	Initial control measures implemented on time across all diseases. ^b	Across all six diseases combined: 12 percent (n = 52) ^d <ul style="list-style-type: none"> • Botulism: 69 percent • Tularemia: 54 percent • E. coli: 17 percent • Hepatitis A: 36 percent • Measles: 77 percent • Meningococcal: 62 percent

Source: GAO analysis of awardee performance measurement data provided by the Centers for Disease Control and Prevention (CDC). | GAO-18-362

Note: Data are from calendar year 2015 for Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) and from July 1, 2015, through June 30, 2016, for Public Health Emergency Preparedness (PHEP), according to CDC officials. This is the most recent year for which validated data were available.

^aThe percentages in this column are based on the subsets of awardees that provided data and to which the measure applied, or (n). While almost all awardees reported data for these measures, the exact number of awardees that provided data varied across measures. Some awardees did not report

³¹CDC defines disease outbreak as the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area, or season. In some situations, a single case of disease may qualify as an outbreak. Awardees are also permitted to use their own definitions of what constitutes an outbreak when reporting performance measure data, according to CDC officials.

data for a measure, because, for example, the awardee was not required to report on a measure, as was the case for some localities and U.S. territories.

^bThis target is not indicated in CDC's performance measurement guidance to PHEP awardees. Rather, it is an expectation that CDC has for the awardees, according to CDC officials.

^cCDC officials stated that awardees determine their own reporting time frames for each of the six diseases that are required to be reported, and CDC expects each awardee to report all required diseases within those time frames. We have provided the percent of reporting awardees that met this expectation as it applies to all six diseases combined, as well as by each of the six diseases individually. Reporting time frames for what is considered "on time" vary by awardee but are from immediately to within 1 week, depending on the disease, according to CDC officials.

^dCDC officials stated that CDC determines the initial control measure time frames for each of the six diseases that are required to be reported, and CDC expects each awardee to implement all required initial control measures within those time frames. We have provided the percent of reporting awardees that met this expectation as it applies to all six diseases combined, as well as by each of the six diseases individually. The time frames for what is considered "on time" vary by disease and are from within 24 hours to 1 week, according to CDC officials.

ELC's measure in this area—the percent of total outbreaks investigated—is meant to assess the extent to which state public health agencies can effectively respond, prevent, and control infectious disease outbreaks. The measure indicates the proportion of outbreaks that were investigated by each awardee for reportable diseases compared to the total number of outbreaks, with the CDC-established target of investigating 100 percent of outbreaks, according to CDC officials.

The two PHEP measures in this area are key to being able to initiate timely investigations and limit the spread of disease. CDC officials stated that the nature of a disease may make it difficult for an awardee to meet the performance targets. For example, the source of foodborne diseases can be particularly difficult to track in order to implement control measures, especially when contamination may have originated outside of the United States. While few PHEP awardees met the targets for submitting all disease reports and implementing all initial control measures on time, awardee performance varied by disease. For example, among the awardees that had cases of disease, only 15 percent of disease reports were received on time and 17 percent of initial control measures were implemented on time for E. coli, but both targets were met 77 percent of the time for measles.

Agency Comments

We provided a draft of this report to the Secretary of Health and Human Services for 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, 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 crossem@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 II.



Marcia Crosse
Director, Health Care

Appendix I: Non-Federal Stakeholders' Views on Factors to Consider for an Emergency Response Fund

Ten non-federal stakeholders told us that a mechanism to fund rapid response to an infectious disease threat could be beneficial during infectious disease threats. Such a mechanism could include the use of the existing Public Health Emergency Fund or a new emergency response fund specific to infectious disease. The availability of any such fund for immediate use would be subject to available appropriations. Stakeholders reported six factors that may be considered for a new emergency response fund. The table below summarizes the information from stakeholders regarding the factors.

Table 6: Six Factors That May Be Considered for an Emergency Response Fund, According to Non-Federal Stakeholders

Factor	Stakeholder discussion
Who determines when to use an emergency fund	<p>Most of the non-federal stakeholders stated that it would be beneficial if the Secretary of Health and Human Services were authorized to determine when to use an emergency fund. Two stakeholders explained that it would be beneficial for the Secretary to make the determination, because the Department of Health and Human Services (HHS) is in charge of the public health response in the case of emergencies. Further, one of these stakeholders said that the Secretary can consult with, and benefit from, the technical and scientific knowledge of the Centers for Disease Control and Prevention (CDC) when making the decision. One stakeholder said that it would be beneficial for the use of such a fund to be determined by the CDC Director, because the agency has the expertise in dealing with public health threats. One stakeholder commented that a benefit of the existing Public Health Emergency Fund (PHEF) is that its use is determined by the Secretary of Health and Human Services.^a</p> <p>One non-federal stakeholder stated that it could be beneficial for use of the fund to be determined at the White House level because a cross-agency response is often required.</p>
What factors would trigger the use of an emergency fund	<p>A few non-federal stakeholders said that no one specific factor, or set of factors, could be used to determine when to trigger the use of an emergency fund. For example, one stakeholder provided the example that the factors for Zika and Ebola were very disparate, and both outbreaks started abroad with little mortality in the United States; however, according to the stakeholder, it would have been appropriate to use an emergency fund for both. Further, two other stakeholders commented that while factors such as morbidity and mortality rates are important, these rates might not be fully known before it is appropriate to take emergency action to stop an infectious disease threat. As a result of the varying factors, a few stakeholders commented it would be important to consult with subject matter experts—including the Secretary of Health and Human Services and other public health professionals, such as those within CDC—to determine if and when to trigger the use of an emergency fund.</p> <p>A few non-federal stakeholders also said that the capacity of the state and local response entities and whether their resources have been depleted are considerations for determining when to use an emergency fund. For example, two stakeholders told us that those with authority over a fund need to be in communication with the state and local public health departments, and use of an emergency fund could be considered when state and local capacities are overwhelmed.</p>
Methods to determine the amount of available funding	<p>While a few non-federal stakeholders supported the idea of maintaining a set amount in an emergency fund, there was no consensus on how that amount should be calculated. Two stakeholders liked the idea of using a formula that included data on past infectious disease response spending as a basis for determining the amount to maintain in an emergency fund, though two other stakeholders agreed that past events (and their costs) do not determine future events.</p> <p>A few non-federal stakeholders commented that it was important that any appropriations to an emergency fund supplement, but not supplant, regular annual appropriations that support preparedness and capacity-building programs. This is the case for funds appropriated to PHEF. 42 U.S.C. § 247d(c).</p>

**Appendix I: Non-Federal Stakeholders' Views
on Factors to Consider for an Emergency
Response Fund**

Factor	Stakeholder discussion
Activities to fund with an emergency fund	<p>A few non-federal stakeholders stressed that an emergency fund could be reserved for activities that need immediate action. For an infectious disease threat, a few non-federal stakeholders mentioned a variety of activities that could be funded with an emergency fund—including state and local public health laboratory operations and surveillance, risk communications, mass dispensing of medical countermeasures, and other activities—to provide additional surge capacity, some of which may be unpredictable.^b Because of the unpredictability of the next big infectious disease threat, a few stakeholders said that it would be beneficial for an emergency fund to be flexible in terms of the activities it is allowed to fund.</p> <p>A few non-federal stakeholders commented that it would be most beneficial for an emergency fund to be used for defined, short-term needs over long-term public health threats, such as the opioid epidemic. For example, one stakeholder stated that while PHEF could be used to support the initial response to any public health threat, it would not be beneficial for it to support any long-term or ongoing response efforts. Long-term public health threats, such as the opioid epidemic, could rapidly deplete the fund without making a difference in the threat itself, according to the stakeholder.</p>
Accountability for use of an emergency fund	<p>Most non-federal stakeholders generally agreed that it would be beneficial to have reporting requirements attached to an emergency fund, which include financial accountability measures, and a few of these stakeholders commented that such requirements are already in place for existing preparedness and capacity-building programs, as this is a part of good governance.^c</p> <p>A few non-federal stakeholders also said that requiring an after action report following the emergency would be beneficial.</p>
Whether an emergency fund would be specific to infectious disease threats	<p>One non-federal stakeholder told us that it would be beneficial to have a fund specific to infectious disease threats, while half of the non-federal stakeholders we interviewed did not agree with having an emergency fund limited to infectious disease threats. One of these stakeholders commented that an emergency fund is needed to surge quickly for any type of public health threat—including bioterrorism and radio-nuclear threats—and that often the same core resources are needed to respond to infectious disease threats, as well as these other types of threats.</p> <p>A few other stakeholders stated that there is not a consensus on how broad or narrow a fund should be. One of these stakeholders said that although there is not consensus, besides hurricanes, the last three big public health threats were infectious disease threats, so it would make sense to start with that type of event. A fund limited to infectious disease threats could be put in place, used, evaluated, and then analyzed over time to determine if it should be expanded to other public health threats.</p>

Source: GAO summary of information received from non-federal stakeholders interviewed. | GAO-18-362

^aPHEF, established in 1983, is available to the Secretary of Health and Human Services to respond to a public health emergency, including infectious disease threats. See Pub. L. No.98-49, 97 Stat. 245 (1983) (codified as amended at 42 U.S.C. § 247d). A Congressional Research Service report issued in 2009 indicated that the fund had not received an appropriation since Congress reauthorized it in 2000. Congressional Research Service, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, RL33579 (Washington, D.C.: Apr. 29, 2009). According to HHS's 2016 budget justification estimates, PHEF has no balance.

^bA health care system's ability to "surge" is the ability to have the staff and resources in place to adequately care for increased numbers of affected individuals or individuals with unusual or highly specialized needs.

^cWe previously reported on the application, financial, and reporting requirements that awardees must adhere to as part of the terms of the cooperative agreements of two programs that support preparedness capacity—the Hospital Preparedness Program and Public Health Emergency Preparedness. These include adhering to the HHS Office of Assistant Secretary for Preparedness and Response and CDC guidelines for the appropriate use of cooperative agreement funds, undergoing biennial financial audits of their cooperative agreement funds, and submitting midyear and end-of-year progress reports and periodic financial reports. For more detailed information, see GAO, *National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals*, GAO-13-278 (Washington, D.C.: Mar. 22, 2013).

Appendix II: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, Hernan Bozzolo (Assistant Director), Deirdre Gleeson Brown (Analyst-in-Charge), Alexander Cattran, and Jessica L. Preston made key contributions to this report. Also contributing were George Bogart, Muriel Brown, and Drew Long.

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