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PUBLIC HEALTH PREPAREDNESS

Critical Need to Address Deficiencies in HHS's Leadership and Coordination of Emergencies

Statement of Mary Denigan-Macauley, Director, Health Care

GAO-23-106829

GAO Highlights

Highlights of GAO-23-106829, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

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Why GAO Did This Study

HHS is responsible for leading and coordinating all matters related to federal public health and medical preparedness for, and response to, emergencies.

For over a decade, GAO has identified deficiencies at HHS that have hindered the nation's response to the COVID-19 pandemic and to a variety of past emergencies, including other infectious diseases. This includes the H1N1 influenza pandemic, Zika, and Ebola—and extreme weather events, such as hurricanes. This statement summarizes key findings from GAO's January 2022 addition of HHS's leadership and coordination of public health emergencies to its High-Risk List and related 2023 High-Risk report.

What GAO Recommends

Through GAO's body of work in this area, GAO has made 155 recommendations to HHS to improve its leadership and coordination of public health emergency preparedness and response efforts. As of April 2023, 91 of these recommendations remain unimplemented.

What GAO Found

GAO has found persistent deficiencies in the Department of Health and Human Services' (HHS) ability to lead and coordinate the nation's preparedness for, and response to, public health emergencies. Specifically, HHS has consistently fallen short in five areas of an effective national response (see figure).

Source: GAO analysis (data); GAO (icons). | GAO-23-106829

For example, GAO found that HHS has not

- developed clear roles and responsibilities, including exercising them;
- developed an interoperable network of systems for near real-time public health situational awareness, as required in statute since 2006;
- provided clear, consistent communication about disease outbreaks, including information about COVID-19 testing;
- been transparent when disseminating information during an emergency, such as the scientific reasoning for changes to the COVID-19 testing guidelines; and
- undertaken key workforce planning to meet its emergency planning and response mission and goals.

Sustained leadership and attention from the executive branch and Congress in this area is needed to ensure the systemic issues GAO has identified are sustainably addressed so that the U.S. is adequately prepared for future emergencies. A whole-of-nation multidisciplinary approach to preparedness and response is essential. HHS partnership and engagement with nonfederal entities, including state, local, tribal, and territorial governments, and the private sector are key elements of this approach. GAO will continue to monitor HHS's efforts in this area.

View GAO-23-106829. For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

Chair Guthrie, Ranking Member Eshoo, and Members of the Subcommittee:

I appreciate the opportunity to be here today to discuss the Department of Health and Human Services' (HHS) leadership and coordination of our nation's preparedness for, and response to, public health emergencies—including extreme weather events, infectious disease outbreaks, pandemics, and intentional acts. GAO added this topic to its High-Risk List in January 2022 based on a body of work that found persistent deficiencies for more than a decade in HHS's ability to perform its leadership role.[1] These deficiencies have hindered the nation's response to the COVID-19 pandemic and to a variety of past emergencies, including other infectious diseases—such as the H1N1 influenza pandemic, Zika, and Ebola—and extreme weather events, such as hurricanes. Improving HHS's leadership and coordination in this area will better prepare the nation for future emergencies and help mitigate their devastating public health and economic effects.

Addressing the deficiencies and related concerns we have raised—including improving the department's ability to respond to multiple concurrent events—is paramount as the nation faces new threats. As devastating as the COVID-19 pandemic has been, more frequent extreme weather events, new viruses, and bad actors who threaten to cause intentional harm loom, making the deficiencies we have identified particularly concerning. Not being sufficiently prepared for a public health emergency can also negatively affect the time and resources needed to achieve full recovery.

My statement today summarizes key findings from our work on HHS's leadership and coordination of emergency preparedness and response efforts. This statement is based on the work that led us to designate this area as High-Risk in January 2022, as well as our April 2023 High-Risk Report.[2] This statement also includes updates on the implementation status of agency recommendations that formed the basis of those reports.

[1]See *New High-Risk Designation: HHS and Public Health Emergencies* appendix in 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).

[2]See GAO-22-105291 and GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023).

We conducted our work in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Background

HHS is responsible for leading and coordinating all matters related to federal public health and medical preparedness for, and response to, emergencies, whether naturally occurring or intentional.[3] Preparing for and responding to nationally significant public health emergencies requires a whole-of-nation, multidisciplinary approach involving multiple federal agencies and coordination with nonfederal entities, including state, tribal, and territorial governments, and the private sector.

Within HHS, a variety of agencies are involved, including the following:

- The Administration for Strategic Preparedness and Response (ASPR) is to serve 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 to public health emergencies.[4]
- The Centers for Disease Control and Prevention (CDC) supports public health preparedness efforts to prevent, detect, and respond to new and emerging disease threats. For example, during infectious disease outbreaks, CDC conducts studies to learn about the link between infection and health outcomes, monitors and reports cases of infection, and provides guidance to travelers and health care providers, among other activities. Additionally, CDC typically develops a diagnostic test for an emerging pathogen when no diagnostic test has been approved, cleared, or authorized by the Food and Drug

[3]While HHS is the lead for the public health and medical response, the Federal Emergency Management Agency, an agency within the Department of Homeland Security, leads the overall federal response during emergencies and disasters.

[4]On July 22, 2022, HHS removed ASPR, which was formerly the Office of the Assistant Secretary for Preparedness and Response, from the Office of the Secretary and created a new operating division within the Department, known as the Administration for Strategic Preparedness and Response. According to HHS, the change will allow ASPR to mobilize a coordinated national response to future disasters and emergencies more effectively and efficiently.

Administration (FDA) and no adequate alternative is available, such as for H1N1 and Zika.

- FDA plays a critical role in protecting the U.S. from biological threats, including intentional acts and naturally occurring infectious diseases. For example, FDA is responsible for ensuring that medical countermeasures—including drugs, vaccines, diagnostic tests, and personal protective equipment—against these threats are safe and effective.[5] FDA may also issue emergency use authorizations to allow the temporary use of unapproved medical products to diagnose, prevent, or treat disease.[6]

HHS's Leadership and Coordination of Public Health Emergencies

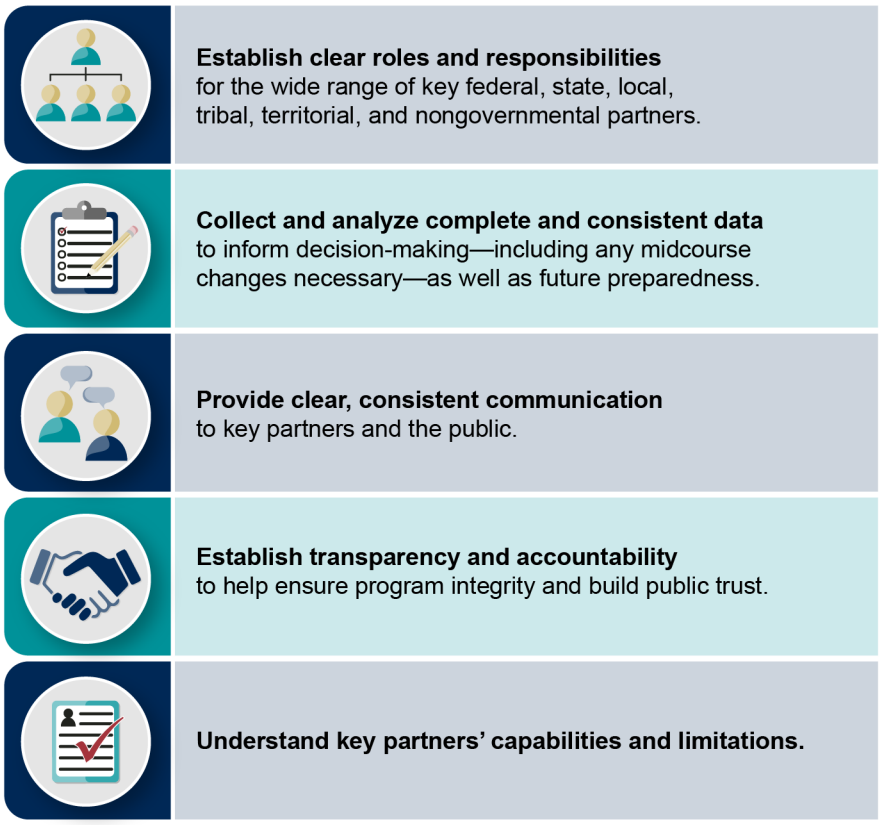
HHS must improve its leadership and coordination of public health emergencies to save lives, mitigate severe economic impacts, and prepare the nation to respond to multiple simultaneous threats. The Comptroller General of the U.S. has emphasized the importance of sustained attention to this area by the executive branch and Congress.

Over more than a decade, we have seen, and continue to see, HHS's efforts fall short in five key areas of an effective national response—shown in figure 1.

[5]Medical countermeasures are drugs, biologics, and devices used to diagnose, treat, prevent, or mitigate harm from any chemical, biological, radiological, or nuclear agent.

[6]The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products. Once such a declaration has been made, FDA may temporarily allow the use of an unapproved product through an emergency use authorization. For FDA to issue an emergency use authorization, it must be reasonable to believe that the product may be effective and that the known and potential benefits of the product outweigh the known and potential risks, among other statutory criteria. See 21 U.S.C. § 360bbb-3.

Figure 1: Five Key Areas of an Effective National Response



Source: GAO analysis (data); GAO (icons). | GAO-23-106829

We have evaluated HHS's actions in these five key areas and made several recommendations to strengthen these efforts. For example:

Clear roles and responsibilities. The unprecedented scale of the COVID-19 pandemic, and the whole-of-nation response required to address it, highlight the critical importance of clearly defining the roles and responsibilities for the wide range of federal departments and other key partners involved when preparing for pandemics and addressing unforeseen emergencies. For example, we reported that when HHS helped repatriate U.S. citizens from abroad and quarantine them domestically at the beginning of the COVID-19 pandemic to prevent the spread of the virus, significant confusion ensued.[7] As a result, HHS put

[7]GAO, *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, GAO-21-334 (Washington, D.C.: Apr. 19, 2021).

repatriates, its own personnel, and nearby communities at risk due to a lack of clarity as to which HHS agency was in charge, including which HHS agency was responsible for managing infection prevention.

In April 2021, we recommended that HHS agencies—ASPR, CDC, and the Administration for Children and Families—revise or develop new plans that clarify agency roles and responsibilities during a pandemic, and regularly exercise these plans with key partners. Regularly exercising preparedness plans with all response partners allows all involved parties to practice operationalizing the plans to help identify any gaps in procedures or barriers to plan implementation so that these can be addressed before an actual event occurs. HHS agreed with our recommendations, which have not been implemented as of April 2023.

Complete and consistent data. Data are also critical to inform the response to a public health emergency. However, the data HHS has relied on during the COVID-19 pandemic have been, and remain, incomplete and inconsistent, highlighting longstanding concerns in this area. Moreover, we reported in 2010, 2017, and again in 2022 that, although required by statute since 2006, HHS had made little progress in implementing a nationwide public health situational awareness capability through an interoperable network of systems to help ensure timely and complete collection of public health data to aid a response.[8] Under the existing process—which HHS has had to rely on during the COVID-19 pandemic—public health data are collected by thousands of different health departments and laboratories, as well as multiple federal agencies. In June 2022, we made 12 recommendations to HHS, including that it prioritize the development of an interoperable network of systems for near real-time public health situational awareness. HHS agreed with 10 and were reviewing two of the recommendations. As of April 2023, the recommendations have not been implemented.

Clear and consistent communication. In the midst of a public health emergency, clear and consistent communication—among all levels of government, with health care providers, and to the public—is paramount.

[8]GAO, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network*, GAO-22-104600 (Washington, D.C.: June 23, 2022); *Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377 (Washington, D.C.: Sept. 6, 2017); and *Public Health Information Technology: Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities*, GAO-11-99 (Washington, D.C.: Dec. 17, 2010).

Our work over the years has found that HHS has provided unclear and inconsistent communication during critical incidents. For example, this was problematic during the H1N1 response when we found that selected state officials reported being overwhelmed by the large volume of, and sometimes inconsistent, information received from HHS and the Department of Homeland Security.[9] Communication problems persisted during subsequent responses. For example, HHS had provided limited information to its response partners and the public regarding its COVID-19 testing strategies.[10] In January 2021, we made a recommendation for HHS to develop and make public testing strategies to ensure these entities were well informed. HHS partially concurred with this recommendation, expressing concern about producing a strategy while responding to a pandemic, among other things. However, we believe this is an important investment in resources that can be done without imposing unnecessary burden. As of April 2023, this recommendation remains unimplemented.

Transparency and accountability. When agencies need to quickly disseminate funding and information during public health emergencies, transparency and accountability are especially critical to help ensure program integrity and build public trust. However, we have found deficiencies in these areas both during and prior to the COVID-19 pandemic. For example, COVID-19 testing guidelines changed several times over the course of the pandemic with little scientific explanation of the rationale behind the changes, thereby confusing providers and public health stakeholder groups implementing the guidelines, and risking the erosion of trust in the federal government.[11] To help avoid confusion and mistrust, in November 2020, we recommended that CDC take action to clearly disclose to the public the rationale for guidance changes at the time changes are made. HHS agreed, and as of April 2023, this recommendation has not been implemented.

[9]GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C.: June 27, 2011).

[10]See *COVID-19 Testing* enclosure in GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, GAO-21-265 (Washington, D.C.: Jan. 28, 2021).

[11]See *COVID-19 Testing Guidance* enclosure in GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191 (Washington, D.C.: Nov. 30, 2020).

Key partners' capabilities and limitations. We reported in September 2019 that, in general, ASPR's resource response capacity—personnel and supplies—can support a response to two simultaneous events that occur in different areas in the continental U.S. for 30 days, according to officials.[12] Beyond that, ASPR relies on other response partners, but does not have a complete understanding of the capabilities and limitations of those partners, which creates a vulnerability. Furthermore, we have concerns that ASPR lacks the capability to fully execute its own responsibilities. In April 2022, we reported that ASPR had not undertaken key workforce planning steps to support the mission and goals of the new office it created to address medical product supply vulnerabilities highlighted during the pandemic.[13] Additionally, in June 2020, we reported that the extent to which ASPR aligned the size of its emergency responder workforce with the agency's strategic goals and objectives was limited, affecting ASPR's ability to ensure the size of the workforce could support its mission.[14]

This lack of planning was notable given that we had previously reported that during the 2017 hurricane season, ASPR experienced a shortage of these responders. This contributed to a reliance on the Department of Defense to provide essential public health and medical service functions. We have identified, and shared with HHS, key principles of strategic human capital planning, which include aligning the workforce with the agency's emergency planning and response mission and goals, and addressing gaps in the skills and competencies of staff.[15]

HHS leadership announced agency reforms in 2022 that could help address the concerns we have identified about their capabilities. Specifically, in July 2022, HHS announced that it had elevated ASPR to a stand-alone agency alongside other HHS agencies, such as CDC and

[12]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).

[13]See the *Public Health Industrial Base Expansion* enclosure in GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments*, GAO-22-105397 (Washington, D.C.: Apr. 27, 2022).

[14]GAO, *Public Health Preparedness: HHS Should Take Actions to Ensure It Has an Adequate Number of Effectively Trained Emergency Responders*, GAO-20-525 (Washington, D.C.: June 18, 2020).

[15]GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, GAO-04-39 (Washington, D.C.: Dec. 11, 2003).

FDA. According to an HHS statement, this change will ultimately allow ASPR to mobilize a coordinated national emergency response more effectively and efficiently. In August 2022, CDC announced programmatic, scientific, and operational improvements to better support the agency's public health response during emergencies and in normal operations. These agencies have taken some actions since their initial announcements, which we will continue to monitor. For example, in February 2023, ASPR announced a new organizational structure that, according to ASPR, accounts for the agency's expanded mission and new capabilities, among other considerations. We have shared key agency reform practices we identified in June 2018 with HHS officials as it implements these reforms.[16] These practices indicate that agencies can successfully change if they have clear goals, follow a process to develop proposed reforms, allocate implementation resources, and consider workforce needs during and after the reform.

In conclusion, the Secretary of Health and Human Services has an imperative, complex, and far-reaching role as the lead for the federal public health and medical response to public health emergencies. Numerous public health emergencies converging and occurring simultaneously can present significant challenges and tax already strained resources. As devastating as the COVID-19 pandemic and the concurrent fires and hurricanes have been, HHS, its partners, and Congress must be prepared for more frequent disasters and new viruses. Waiting to address the deficiencies we have identified is not an option—it is not possible to know precisely when the next threat will occur; only that it will come.

Improving HHS's leadership and coordination of public health emergencies will require sustained leadership and attention from the executive branch and Congress. It will also require effective and ongoing partnership and engagement with nonfederal entities, including state, local, tribal, and territorial governments, and the private sector as a part of a whole-of-nation multidisciplinary approach to preparedness and response.

We will continue to monitor HHS's efforts in this area. The 91 outstanding recommendations made in this area to HHS since fiscal year 2007 are a

[16]GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, GAO-18-427 (Washington, D.C.: June 13, 2018).

starting place.[17] To ensure the systemic issues we have identified are sustainably addressed, we will evaluate HHS's efforts against our five high-risk criteria: (1) leadership commitment to addressing risks; (2) capacity to resolve the risks; (3) development of a corrective action plan that defines the root cause, solutions, and corrective measures needed; (4) monitoring to validate the effectiveness and sustainability of corrective measures; and (5) demonstrated progress in the implementation of those measures. By taking actions in these areas, HHS will be better positioned to lead our nation through the next public health emergency, saving lives and lessening the negative impacts to our economy.

Chair Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions you may have.

GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Mary Denigan-Macauley 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 testimony. In addition to the contacts named above, key contributors to this statement were Deirdre G. Brown (Assistant Director), Kaitlin Farquharson, Sarah Resavy, and Cathleen Whitmore. Additional support was provided by Katherine L. Amoroso, William Hadley, Ariel Jona, and Roxanna Sun.

[17]Through our work on public health emergencies, from fiscal year 2007—when ASPR was created and designated the principal advisor to the Secretary of Health and Human Services on public health emergencies—through April 2023, we have made 155 recommendations to HHS related to its leadership and coordination of public health emergencies. While HHS has made progress toward addressing some of these recommendations, 91 remain unimplemented.

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