

Why GAO Did This Study

Public health emergencies—the 2001 anthrax attacks, the 2009 H1N1 influenza pandemic, and others—have raised concerns about national vulnerability to threats from chemical, biological, radiological, and nuclear agents and new infectious diseases.

There are some medical countermeasures—drugs, vaccines, and medical devices such as diagnostics—available to prevent, diagnose, or mitigate the public health impact of these agents and diseases, and development continues. HHS leads federal efforts to develop and procure countermeasures through the interagency PHEMCE. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 mandated GAO to examine HHS's and PHEMCE's planning documents for medical countermeasure development and procurement needs and priorities.

This report examines the extent to which HHS developed timelines, milestones, and spending estimates for PHEMCE priorities. GAO reviewed relevant laws; analyzed HHS's 2012 PHEMCE Strategy and Implementation Plan, HHS's tools for tracking the implementation of PHEMCE activities, and data on countermeasure spending from fiscal years 2010 through 2013; and interviewed HHS officials.

What GAO Recommends

Although GAO is not making any new recommendations, based on prior work GAO is continuing to emphasize its 2011 recommendation that HHS make more specific anticipated spending information available to countermeasure developers. In its comments, HHS discussed its efforts to develop spending estimates.

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NATIONAL PREPAREDNESS

HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates

What GAO Found

The Department of Health and Human Services (HHS) has established timelines and milestones for the 72 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) priorities—33 activities, 25 threat-based approaches, and 14 capabilities—that HHS selected as key to fulfilling PHEMCE strategic goals. However, HHS has not made spending estimates for its medical countermeasure development or procurement priorities (priority countermeasures) publicly available. In the PHEMCE implementation plan, HHS has grouped the 72 PHEMCE priorities into three time frames for completion—near-term (fiscal years 2012 through 2014), midterm (fiscal years 2015 through 2017), and long-term (fiscal year 2018 and beyond). For 21 priority activities, 10 priority threat-based approaches, and 8 priority capabilities, HHS and PHEMCE have identified specific deliverables, each tied to a milestone or set of milestones that delineate the steps necessary to complete deliverables, and established more specific timelines for completion of deliverables and milestones. For example, HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) is to lead the development of medical countermeasure requirements, which outline countermeasure quantity, type, and desired characteristics. Deliverables are the threat-specific requirements, such as for antidotes for mustard gas and other blister agents. Milestones for mustard gas antidote requirements reflect the PHEMCE activities to develop the requirements and the necessary approvals; the milestones are tied to interim timelines and culminate in approval by the ASPR Assistant Secretary by September 2013. HHS has not established specific deliverables, milestones, or timelines for the remaining 12 priority activities, 15 priority threat-based approaches, and 6 priority capabilities other than their overall completion within the specified near- or midterm time frame. HHS monitors progress in completing deliverables and milestones for the priorities monthly, with PHEMCE partners meeting to discuss potential barriers to completing deliverables or meeting milestones and possible options to mitigate these barriers. As of September 2013 (the most recent information available), HHS reported that PHEMCE partners have completed 10 deliverables for the 72 priorities, resulting in completion of 5 priorities. GAO did not examine the status of the priorities that did not have specific deliverables, timelines, and milestones.

HHS has developed spending estimates for priority countermeasures for internal planning purposes but has not made them publicly available. In 2011, GAO recommended that HHS provide more specific anticipated spending information in an updated plan to assist with long-term planning. HHS's 2012 plan contains information on how countermeasures may be funded, such as through advanced development funds, but does not include estimates of how much PHEMCE may spend to develop specific countermeasures. HHS officials said they are hesitant to provide estimates because they do not want to create the expectation that estimates would reflect final contract amounts. However, consistent with our prior recommendation and Pandemic and All-Hazards Preparedness Reauthorization Act requirements, HHS plans to include spending estimates in the next iteration of the plan, anticipated in September 2014, but has not determined the nature and format of the estimates that would be included. Providing estimates would allow HHS's industry partners to suitably target research and development to fulfill countermeasure priorities, especially in tighter budget climates.