March 2014

NATIONAL PREPAREDNESS

HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect

GAO Highlights

Highlights of GAO-14-329, a report to congressional committees

Why GAO Did This Study

Public health emergencies, such as the 2001 anthrax attacks and the 2009 H1N1 influenza pandemic, raise concerns about the nation's vulnerability to threats from CBRN agents and new or reemerging infectious diseases, such as pandemic influenza. HHS is the federal agency primarily responsible for identifying medical countermeasures needed to address the potential health effects from exposure to CBRN agents and emerging infectious diseases. HHS conducted a review to assess how to better address these concerns. Its August 2010 review concluded that the advanced development and manufacture of CBRN medical countermeasures needed greater support. The review recommended that HHS develop centers to provide such support, in part by using flexible manufacturing technologies, such as disposable equipment, to aid in the development and rapid manufacture of products.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 requires GAO to examine HHS's flexible manufacturing initiatives and the activities these initiatives will support. This report addresses (1) how much funding HHS has awarded for flexible manufacturing activities for medical countermeasures, and (2) the extent to which these activities will support the development and production of CBRN medical countermeasures. To address these objectives, GAO examined HHS documents and interviewed HHS officials, contractors, and stakeholders. In comments on a draft of the report, HHS agreed with its findings and provided additional information.

View GAO-14-329. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

In fiscal years 2012 and 2013, the Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) awarded nearly $440 million in contracts to establish three Centers for Innovation in Advanced Development and Manufacturing (CIADM) and a network of facilities to provide packaging support for medical countermeasure distribution, known as the Fill Finish Manufacturing Network (FFMN). The contracts require the CIADMs to develop three activities to support flexible manufacturing for medical countermeasure development and production: the manufacture of pandemic influenza vaccines during an emergency; core services to support the development and production of chemical, biological, radiological, and nuclear (CBRN) medical countermeasures; and workforce training. During the contract base periods, each CIADM is to retrofit existing or build new facilities able to produce 50 million doses of pandemic influenza vaccine within 4 months of receipt of the influenza virus strain and to establish the capacity to provide core services, such as assisting countermeasure developers by manufacturing products to be used for clinical trials. The CIADMs are also required to develop workforce training programs, which are intended to increase expertise in CBRN medical countermeasure development. The CIADM base contracts are intended to retrofit or build facilities to stand ready to provide these three activities and maintain this readiness through annual contract option periods. Once the facilities are prepared to provide these activities, BARDA may place task orders for provision of CIADM vaccine surge capacity, core services, or training, and BARDA, through the task orders, would provide additional payments to obtain these services. The FFMN is to supplement CIADMs' pandemic influenza surge capacity, packaging up to 117 million doses of pandemic influenza vaccine in 12 weeks, if needed, and can also provide core services as CIADM subcontractors.

HHS's CIADM core services activities are designed to support the development and production of certain CBRN medical countermeasures, but it is too early to tell how effective this approach will be. BARDA's establishment of the CIADMs implements a recommendation from HHS's review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)—a federal interagency body that advises HHS on medical countermeasure priorities. The CIADMs are to support the development of biologics-based countermeasures only, which are products like vaccines that are derived from living sources such as cells, because BARDA considers these countermeasures to need the greatest support. BARDA has identified some of its current biologics-based countermeasure development contracts that could use core services' support and are priorities for PHEMCE. However, the CIADMs are still completing activities associated with their contract base period. Thus, BARDA has not issued any task orders for core services to date, but has created a CIADM steering committee and completed guidance to govern the task order process once the CIADMs are operational. Until the CIADM core services are used, it will be unclear how effectively they will support the development and production of CBRN medical countermeasures. Stakeholders we interviewed were uncertain about the demand for and availability of funding for core services. BARDA officials said that they anticipate having sufficient demand for the services and funding for task orders in fiscal years 2014 and 2015.