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PUBLIC HEALTH INFORMATION TECHNOLOGY

Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities





Highlights of GAO-11-99, a report to congressional committees

Why GAO Did This Study

A catastrophic public health event could threaten our national security and cause hundreds of thousands of casualties. Recognizing the need for efficient sharing of real-time information to help prevent devastating consequences of public health emergencies, Congress included in the Pandemic and All-Hazards Preparedness Act in December 2006 a mandate for the Secretary of the Department of Health and Human Services (HHS), in collaboration with state, local, and tribal public health officials, to develop and deliver to Congress a strategic plan for the establishment and evaluation of an electronic nationwide public health situational awareness capability.

Pursuant to requirements of the act, GAO reviewed HHS's plans for and status of efforts to implement these capabilities, described collaborative efforts to establish a network, and determined grants authorized by the act and awarded to public health entities. GAO assessed relevant strategic planning documents and interviewed HHS officials and public health stakeholders.

What GAO Recommends

GAO is recommending that HHS develop and implement a strategic plan to guide and integrate efforts to establish electronic situational awareness capabilities. In written comments on a draft of the report, HHS neither agreed nor disagreed with GAO's recommendation, but stated that a complete strategy would be developed.

View GAO-11-99 or key components. For more information, contact Valerie C. Melvin at (202) 512-6304 or melvinv@gao.gov.

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What GAO Found

HHS did not develop and deliver to congressional committees a strategic plan that demonstrated the steps to be taken toward the establishment and evaluation of an electronic public health situational awareness network, as required by PAHPA. While multiple offices within HHS have developed related strategies that could contribute to a comprehensive strategic plan for an electronic public health information network to enhance situational awareness, these strategies were not developed for this purpose. Instead, the offices developed the strategies to address their specific goals, objectives, and priorities and to meet requirements of executive and statutory authorities that mandated the development of strategies for nationwide health information exchange, coordinated biosurveillance, and health security. However, HHS has not defined a comprehensive strategic plan that identifies goals, objectives, activities, and priorities and that integrates related strategies to achieve the unified electronic nationwide situational awareness capability required by PAHPA.

The department has developed and implemented information technology systems intended to enable electronic information sharing to support early detection of and response to public health emergencies; however, these systems were not developed as part of a comprehensive, coordinated strategic plan as required by PAHPA. Instead, they were developed to support ongoing public health activities over the past decade, such as disease and syndromic surveillance. Without the guidance and direction that would be provided by an overall strategic plan that defines requirements for establishing and evaluating the capabilities of existing and planned information systems, HHS cannot be assured that its resources are being effectively used to develop and implement systems that are able to collect, analyze, and share the information needed to fulfill requirements for an electronic nationwide public health situational awareness capability.

HHS has engaged in collaborative efforts to improve information technology capabilities to share situational awareness information. For example, HHS has collaborated with public and private health care partners to establish standards, services, and policies that support the electronic exchange of interoperable health care and public health data to support electronic sharing of information for biosurveillance purposes. The department has also awarded funds through cooperative agreement programs to state and local public health entities intended to improve capabilities to detect public health emergencies and to identify emergency response resources.

Although the act authorized the use of funds for the award of grants to states to establish statewide or regional public health situational awareness systems, to date, Congress has not appropriated funds pursuant to the authorization.

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Abbreviations

ASPR	Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
eLEXNET	Electronic Laboratory Exchange Network
EWIDS	Early Warning Infectious Disease Surveillance
FDA	Food and Drug Administration
HAvBED	Hospital Available Beds for Emergencies and
	Disasters
HHS	Department of Health and Human Services
NEDSS	National Electronic Disease Surveillance System
NHIN	Nationwide Health Information Network
ONC	Office of the National Coordinator for Health
	Information Technology
PAHPA	Pandemic and All-Hazards Preparedness Act

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United States Government Accountability Office Washington, DC 20548

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Congressional Committees

A catastrophic public health event—such as a widespread disease outbreak—could threaten our national security, weaken our economy, cause hundreds of thousands of casualties, and damage public morale and confidence. Recent events, such as the Deepwater Horizon drilling rig explosion and the H1N1 influenza outbreak, draw attention to the need for public health officials to have access to real-time information about emerging threats to enhance their awareness of situations and enable them to make responsible and timely decisions.

Public health situational awareness is the knowledge of key components needed to prepare for and respond to disease outbreaks and other public health emergencies. These components include, but are not limited to, health-related events, critical response resources, medical care capacity, environmental threats, public awareness, and preparedness status across the many public health jurisdictions in the country. Creating and maintaining situational awareness involves an active, continuous, and timely data-oriented loop that enhances public health officials' ability to make decisions that lead to successful mitigation of emerging threats, better use of resources in preparing for and responding to emergencies, and better health outcomes for the population. The use of information technology to collect and share this information electronically among public health entities can aid in creating the situational awareness needed to enable early detection of and effective response to emerging events.

The Pandemic and All-Hazards Preparedness Act (PAHPA)¹ of 2006 mandated actions by the Secretary of the Department of Health and Human Services (HHS) for improvements in public health emergency preparedness and response. Within this act, Congress recognized the need for efficient sharing of real-time information to help prevent potentially devastating consequences that could result from public health emergencies. To address this need, PAHPA required the Secretary of HHS, in collaboration with state, local, and tribal public health officials, to develop an overall strategic plan for and undertake the establishment of a near real-time electronic nationwide public health situational awareness

¹Pub. L. No. 109-417 (Dec. 19, 2006).

capability through an interoperable network of systems. The systems are to collect, store, and analyze public health data and share the information needed to enhance early detection of and rapid response to potential catastrophic infectious disease outbreaks and other public health emergencies originating domestically or abroad. The act established within HHS the position of the Assistant Secretary for Preparedness and Response to, among other things, serve as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response for public health emergencies.²

PAHPA also required us to evaluate and report on activities conducted by HHS to implement such a network. Accordingly, we studied HHS's efforts to meet the requirements of PAHPA. As agreed with your offices, our specific objectives were to (1) determine HHS's plans for and status of implementing the network; (2) describe HHS's efforts to collaborate with state, local, and tribal public health officials to achieve a nationwide situational awareness capability; and (3) determine how HHS uses grants authorized by PAHPA to enhance states' ability to establish coordinated public health situational awareness systems.

To accomplish the objectives, we reviewed relevant program documentation and interviewed appropriate agency officials. Specifically, to determine HHS's plans for implementing a nationwide situational awareness network, we assessed the requirements defined by PAHPA and identified strategic planning documents and status reports of relevant public health information technology initiatives. We evaluated these documents to determine whether they met criteria established by PAHPA and effective strategic planning practices. To determine HHS's status in implementing the network, we discussed with agency officials key information technology initiatives that addressed elements of an electronic situational awareness capability defined by the act. To describe efforts to collaborate with state, local, and tribal public health officials, we collected and reviewed documents and artifacts from stakeholder collaborations, such as minutes from meetings between HHS and public health stakeholders, materials used to solicit input from conference attendees, and presentations on the results of information technology initiatives funded through cooperative agreements between HHS and regional, state, and local public health entities. We also interviewed agency officials and stakeholders identified through research of public health information

²42 U.S.C. §300hh-10(b)(1).

	technology programs and from our previous work on the use of information technology to support public health emergency preparedness and response. To determine the use of grants for establishing coordinated public health situational awareness systems, we held discussions with department officials about the award of grant funds authorized by PAHPA Section 202.		
	We conducted this performance audit at the headquarters of HHS in Washington, D.C., and its agencies—the Food and Drug Administration and the Indian Health Service, both in Washington, D.C., and the Centers for Disease Control and Prevention in Atlanta, Georgia—from November 2009 through December 2010 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. Detailed information about our objectives, scope, and methodology can be found in appendix I.		
Background	Responsibilities for detecting and responding to public health emergencies are dispersed among federal, state, and local public health entities throughout the country. As such, it is important that these entities share information about emerging events, such as disease outbreaks or environmental hazards, to enable decision making by public health officials as they prepare for and respond to emergencies. The use of information technology can enable the many public health officials involved in emergency preparedness and response to more efficiently share information on a near real-time basis.		
Roles of Federal, State, and Local Public Health Officials in Detecting and Responding to Emergencies	Public health functions in the United States—such as disease detection, vaccinations, clinical lab testing, and emergency preparedness and response—are conducted by public health officials from 59 state and territorial health departments; more than 3,000 county, city, and tribal health departments; more than 180,000 public and private clinical laboratories; and multiple federal agencies, including the Department of Homeland Security (DHS) and HHS's Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).		
	Initial detection of and response to a public health emergency is generally a local responsibility that could involve multiple jurisdictions in a region,		

with states providing additional support when needed. Since clinicians at the local level are most likely to be the first ones to detect an incident, they and local public health officials are expected to report incidents or symptoms of diseases to the state health department and other designated parties. States provide supporting personnel, financial resources, laboratory capacity, and other assistance to local responders when needed. When an incident occurs that exceeds or is anticipated to exceed state, local, or tribal resources, state governors may request the federal government to provide resources to assist the state in its response efforts. For incidents involving primarily federal jurisdiction or authorities (e.g., on a military base, federal facility, or federal lands), federal departments or agencies may be the first responders and first line of defense in coordinating activities with state, local, and tribal partners. The federal government also maintains working relationships with private health care entities, such as hospitals and clinical laboratories, and nongovernment organizations, such as the Red Cross.

Because of the many participants involved, the identification and management of public health emergencies calls for effective communication and collaboration across all levels of government and the public health community, and for sharing information to create and maintain the situational awareness essential to effectively prepare for, respond to, and manage public health emergencies. However, sharing information across public health jurisdictions can be challenging because of the need for rapid and comprehensive distribution of alerts and information to public health workers across multiple jurisdictions and organizations, while at the same time respecting the autonomous authority of each agency to control the flow of information within its jurisdiction of responsibility and among its workforce. The ability to share information electronically is further challenged by the wide variety of public health

entities' technological capabilities and implementation of nonstandard systems and software that are unable to exchange and share data.

Figure 1 provides a simplified view of the roles of local, state, and federal entities in public health emergencies.





Note: Figure continued on next page.



Source: GAO based on research of HHS and other data.

^aHealth care providers can also contact state entities directly.

HHS, primarily through the activities of CDC, collects health data from state and local health departments and analyzes the data using information technology to detect biological events, such as disease outbreaks.³ In addition, FDA conducts surveillance of food-borne illnesses and adverse drug events. When an event is detected, states may provide HHS regional emergency coordinators access to state, local, and tribal data within their jurisdictions.

HHS serves as the federal focal point for coordinating response support for public health and medical services, which is 1 of 15 emergency support functions defined by DHS's Federal Emergency Management Agency.⁴ The department coordinates national emergency response efforts for public health emergencies primarily through the Secretary's Operations Center, which is a 24-hour-a-day, 7-day-a-week emergency operations center that collects and analyzes data from other federal emergency centers, such as CDC's and FDA's emergency operations centers. The Secretary's Operations Center shares information with other federal agencies that have responsibility for public health and other emergency support functions, such as DHS and the Departments of Agriculture and Transportation; the World Health Organization; and state and local entities through HHS's Regional Emergency Coordinators. The regional coordinators maintain daily contact with public health entities in their designated regions and communicate regularly by telephone and e-mail.

Figure 2 presents a simplified illustration of the relationships and information sharing among the Secretary's Operations Center and its partners in emergency response.

³Health data collected by public health entities for purposes of syndromic and disease surveillance are generally "deidentified"—i.e., aggregated statistical data is stripped of individual identifiers. Under the Health Insurance Portability and Accountability Act Privacy Rule, these deidentified data, unless reidentified, are not individually identifiable health information and, as such, the data are not covered by the protections for that information defined by the rule (45 C.F.R. §§ 164.502(d), 164.512, 164.514).

⁴The Federal Emergency Management Agency coordinates response support from across federal government and nongovernment organizations by calling up, as needed, 1 or more of 15 emergency support functions. Each of these functions has a lead coordinator and primary and support agencies. The mission of the emergency support functions and respective coordinators and agencies is to provide the greatest possible access to capabilities of the federal government irrespective of the agency having those capabilities. The emergency support functions also assist in functional areas including transportation, communications, public works and engineering, firefighting, mass care, housing, human services, public health and medical services, search and rescue, agriculture, natural resources, and energy.





Use of Information Technology in Supporting Situational Awareness

Information technology plays an essential role in providing data needed by public health entities to enhance situational awareness of emergencies and potential emergencies. For more than a decade, federal, state, and local public health organizations, private companies, and academic institutions have been developing systems for collecting and analyzing electronic surveillance data from sources such as hospital emergency departments, clinical laboratories, and pharmacies. These systems support emergency preparedness by providing near real-time information needed to detect disease outbreaks and other public health emergencies. For example, electronic biosurveillance⁵ systems collect and provide data such as lab test results and complaints from emergency department patients to public health officials. These surveillance techniques are employed not only to

Source: GAO presentation of HHS information.

⁵Biosurveillance is a concept that emerged in response to increased concern about biological threats from infectious diseases and bioterrorism. Biosurveillance contributes to situational awareness for a response that gives decision makers and the public accurate information about how to prevent, manage, or mitigate the potentially catastrophic consequences of an event. A subset of biosurveillance, syndromic surveillance is a technique that uses health-related data to identify patterns of disease symptoms prior to the diagnosis of a specific disease. Effective use of this technique can provide information that enhances situational awareness and enables early detection of a disease outbreak.

detect initial signs of emerging threats but also to track the spread of syndromes, diseases, and other biological events throughout the duration of public health emergencies. Additionally, geographic information systems and mapping tools that support emergency response to events are useful to public health officials, as these tools provide visual and quantitative data such as maps of available hospital facilities and bed capacity, the location of electrical grids, and regional population information during a disease outbreak or other public health emergency.

Recent domestic public health events provide examples of HHS's use of information systems and tools in preparation for and response to emerging public health events. During the Deepwater Horizon oil spill in 2010, CDC, in coordination with state and local health departments, conducted surveillance for related health effects across the five states bordering the Gulf of Mexico. As part of this effort, CDC used BioSense, a syndromic surveillance system, and the National Poison Data System to maintain a situational awareness of more than 20 health conditions related to the eyes, skin, and respiratory, cardiovascular, gastrointestinal, and neurological systems in states affected by the spill. Further, the Secretary's Operations Center at HHS employed geographic information systems and Internet-based mapping tools to track the spread of the oil and manage response efforts during this event.

Information technology also played a role in providing situational awareness for the early detection of influenza-like illnesses during the 2009-2010 H1N1 influenza outbreak. During this outbreak, CDC, in partnership with the Public Health Informatics Institute⁶ and the International Society for Disease Surveillance,⁷ used another surveillance system called Distribute to collect, analyze, and share surveillance information from local emergency departments' surveillance systems throughout the affected areas and across multiple public health jurisdictions. Additionally, during the public health emergency that occurred as a result of the earthquake in Haiti, CDC used Internet-based

HHS's Use of Information Systems to Prepare For and Respond to Public Health Events

⁶The Public Health Informatics Institute, located in Decatur, Georgia, is a program of the Task Force for Global Health, a nonprofit organization. The institute brings together public health professionals to facilitate their understanding of information needs and to define solutions for their informatics challenges.

⁷The International Society of Disease Surveillance is a nonprofit professional society founded in 2005 and is administratively supported by Tufts Health Care Institute located in Boston, Massachusetts. The mission of the society is to improve population health by advancing the field of disease surveillance.

mapping tools to identify available medical facilities and open transportation routes for delivering medical supplies.

State, Local, and Federal Tribal Public Health Entities' Use of Information Technology to Share Information State, local, and tribal public health entities have implemented and used information systems and tools for more than a decade to help personnel conduct jurisdictional syndromic and disease surveillance, public health reporting, and emergency response operations. Many of these systems were developed locally or were acquired from commercial, government, or academic sources.⁸ Additionally, public health personnel with the Indian Health Service track syndromes and diseases of tribal populations using the service's medical facilities by extracting, aggregating, and analyzing medical data from its electronic health records system. The Indian Health Service demonstrated this capability during the 2009 H1N1 outbreak.

HHS Regional Emergency Coordinators with whom we spoke described the use of information technology by state and local entities to support event detection and emergency response operations in their jurisdiction. They described variations in the use of these systems and in state and local health entities' information technology infrastructures and capabilities to collect, transmit, and receive electronic data.⁹ The regional coordinators stated that some local health departments lack the resources and technology to develop and implement electronic data collection and analysis systems, or to electronically share information with HHS. On the other hand, they described some states, such as New York and New Jersey, which have implemented robust public health surveillance and reporting systems and sophisticated tools for supporting emergency response.

While some state and local public health officials are able to view in near real-time the graphs and charts produced by CDC's biosurveillance systems, such as BioSense and Distribute, they are not currently able to view information that the HHS emergency operations centers produce in near real-time. According to HHS officials, the department is not able to

⁸In an earlier report, we described syndromic surveillance systems in use by hospitals and state and local health departments throughout the country, including locally developed systems and systems available from the Department of Defense and the University of Pittsburgh. See GAO, *Health Information Technology: More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program*, GAO-09-100 (Washington, D.C.: Nov. 20, 2008).

⁹The emergency coordinators' descriptions were consistent with findings of our earlier study, GAO-09-100.

	share much of the information across all public health jurisdictions in part because of data ownership and governance issues, but they are working towards making the data that are shareable more easily accessible to state and local entities. Additionally, according to HHS officials and public health stakeholders with whom we spoke, electronic data collection, analysis, and sharing capabilities of many state and local public health departments are limited by challenges such as lack of infrastructure, funding, and personnel resources. HHS officials further stated that, even in cases where state and local public health entities have implemented information systems that support response operations, data and interoperability standards have not been defined to allow electronic transmission from state and local systems into the Secretary's Operations Center's systems and tools used during response operations; as a result, public health officials experience lost time and increased workloads associated with the need to duplicate data entry efforts.
PAHPA's Requirements for Electronic Public Health Situational Awareness Capabilities	In December 2006, PAHPA established within HHS the Office of the Assistant Secretary for Preparedness and Response (ASPR). Among other things, the act required the Assistant Secretary to serve as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response for public health emergencies, and to coordinate with state, local, and tribal public health officials to ensure effective integration of federal public health and medical assets during public health emergencies. Records from a November 2007 PAHPA stakeholders' meeting conducted by officials from ASPR, the Office of the National Coordinator for Health Information Technology (ONC), and CDC highlighted requirements for HHS to establish a near real-time electronic nationwide public health situational awareness capability in accordance with Section 202 of the act. (Table 1 summarizes the requirements of the act.) PAHPA authorized the use of grants for purposes of meeting this

mandate through fiscal year 2011 (i.e., September 30, 2011).¹⁰ To date, no appropriations have been made pursuant to the authorization.

Requirement	Description
Strategic plan	• Submit a strategic plan that demonstrates the steps the Secretary will undertake to develop, implement, and evaluate the network no later than 180 days after December 19, 2006 (i.e., June 16, 2007).
Electronic situational awareness network	• Establish by December 19, 2008, in collaboration with state, tribal, and local health officials, a near real-time electronic nationwide public health situational awareness network of systems to share data and information to enhance early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad.
	• The network is to include data transmitted in a standardized format from state, local, and tribal public health entities, including:
	public health laboratories;
	federal health agencies;
	 zoonotic disease monitoring systems;
	 public and private sector health care entities, hospitals, pharmacies, poison control centers, and clinical labs to the extent practicable and provided that such data are voluntarily provided simultaneously to HHS and to state, local, and tribal public health agencies; and
	 other sources as the Secretary deems appropriate.
	• The Secretary was further required to use interoperability standards determined through a joint public and private sector process and to define minimal data elements for the network.
Collaborative efforts	 Collaborate with state, local, and tribal public health officials to establish the network; integrate and build on existing capabilities to ensure simultaneous sharing of data from the network with state, local, and tribal public health agencies; and develop procedures and standards for the collection, analysis, and interpretation of data collected and reported to the network.

Table 1: Summary of Requirements Defined by PAHPA Section 202

¹⁰HHS officials noted that statutory authorities and directives other than those provided by PAHPA identify roles and responsibilities of other federal agencies, such as DHS and the Departments of Transportation and Agriculture, that also support public health situational awareness. However, these statutes are related primarily to biosurveillance activities, which do not meet the broader definition of situational awareness established by HHS. Further, the mandate for HHS to establish electronic network capabilities for enhanced situational awareness is unique to PAHPA. We describe relevant laws and directives in our June 2010 report, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010).

Requirement	Description
Grants	 The Secretary was authorized, but not required, to award grants to states or consortia of states to establish or operate a coordinated statewide or regional public health situational awareness system.
	 Any state or consortium of states that received an award was required to establish, enhance, or operate a coordinated public health situational awareness system for both regional and statewide early detection of, response to, and management of public health emergencies.

Source: GAO analysis of PAHPA Section 202.

Our Previous Studies Highlighted the Need for Coordination and Definition of National Strategic Plans for Biosurveillance and Public Health Information Technology Capabilities

Prior to the enactment of PAHPA, we issued reports on the need for HHS to develop strategies and plans for coordinating public health information technology initiatives among federal, state, and local public health entities. In these reports, we noted a need for definitions of data and interoperability standards to better enable the analysis of data and the sharing of information needed to support public health emergency preparedness and response. For example, in 2003, we studied federal agencies' efforts to develop and implement information technology to support public health emergency preparedness and response.¹¹ We noted that information technology could more effectively facilitate emergency response if standards were defined and implemented to allow systems to be interoperable. We also noted that an underlying challenge for establishing and implementing such standards is the lack of an overall strategy guiding information technology initiatives. We recommended that the Secretary of HHS, in coordination with other key stakeholders—such as the Secretaries of Defense, Homeland Security, and Veterans Affairsestablish a national information technology strategy for public health preparedness and response. HHS, through activities initiated by ONC, has activities underway to implement this recommendation to define interoperability standards and address other concerns, such as privacy, as part of its efforts to advance the nationwide implementation of health care information technology.

Also, in a June 2005 report,¹² we described the reported progress of federal agencies on major public health information technology initiatives

¹¹GAO, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Abilities to Respond to Public Health Emergencies*, GAO-03-139 (Washington, D.C.: May 30, 2003).

¹²GAO, Information Technology: Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure, GAO-05-308 (Washington, D.C.: June 10, 2005).

including one broad initiative at CDC-the Public Health Information Network—that is intended to provide the nation with integrated public health information systems to support activities such as disease detection, tracking, outbreak management, and exchange of laboratory information. As a result of our study, we recommended that the Secretary of HHS ensure that the federal initiatives were (1) aligned with the national health information technology strategy, the federal health architecture, and other ongoing public health information technology initiatives, and (2) coordinated with state and local public health initiatives and ensure federal actions to encourage the development, adoption, and implementation of health care data and communication standards across the health care industry to address interoperability challenges associated with the exchange of public health information. The department addressed our recommendations by including public health strategies within its overall strategy for nationwide health information technology, including state and local entities, in initiatives to improve the exchange of clinical and public health data, and awarding a contract for harmonization of standards across the public and private health care sectors.

Further, in 2004 as part of our reporting related to homeland security, we identified a set of desirable characteristics for effective strategies to aid the entities responsible in further developing and implementing seven national strategies related to homeland security and combating terrorism.¹³ Among the characteristics we identified were: (1) goals, objectives, activities, and priorities; (2) performance measures; (3) costs and benefits; (4) identification of resources; and (5) integration of related strategies.

In November 2008, we reported on our study of CDC's BioSense program. We found that state and local public health entities with whom we spoke considered costs and benefits of electronic syndromic surveillance systems difficult to track since syndromic surveillance activities are only one component of a wide range of emergency response activities, including identifying available hospital beds. Additionally, we reported that CDC had not identified annual and long-term cost and time line estimates and performance measures for implementation of its redesigned BioSense program.¹⁴ We recommended that the Director of CDC develop

¹³GAO, Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

¹⁴GAO-09-100.

reliable cost and time line estimates for implementing the BioSense program, and, with stakeholder input, develop outcome-based performance measures. HHS welcomed the recommendations discussed in our report and has taken steps to implement them. Specifically, CDC has initiated activities to define reliable cost and time line estimates and has worked with a panel of state and local stakeholders to define performance measures that are focused on the intended results of the program. However, as of December 2010 the recommendations had not yet been fully addressed.

In a related report issued in December 2009,¹⁵ we noted that DHS's National Biosurveillance Integration Center was not fully equipped to carry out its mission because it lacked key resources—such as data and personnel—from its partner agencies. We recommended that the Director of the center finalize a strategy for more effectively collaborating with current and potential members of the center's National Biosurveillance Information System by (1) clearly defining the center's mission and purpose, along with the value of National Biosurveillance Information System membership for each agency; (2) addressing challenges to sharing data and personnel, including clearly and properly defining roles and responsibilities in accordance with the unique skills and assets of each agency; and (3) developing and achieving buy-in for joint strategies, procedures, and policies for working across agency boundaries. We also recommended that the Director establish and use performance measures to monitor and evaluate the effectiveness of collaboration with current and potential National Biosurveillance Information System partners. DHS generally concurred with our findings and recommendations and stated that the National Biosurveillance Information Center would work to develop a collaboration strategy to clarify the mission, roles, and responsibilities of all National Biosurveillance Information System partners.

Most recently, we reported that, while national biodefense strategies have been developed to address biological threats such as pandemic influenza, there is neither a comprehensive national strategy nor a focal point with the authority and resources to guide the effort to develop a national biosurveillance capability. We also reported that limited information is available to develop a reliable assessment of the costs and benefits of a

¹⁵GAO, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

	national biosurveillance capability. In our June 2010 report, ¹⁶ we recommended that the Homeland Security Council direct the National Security Staff to, in coordination with relevant federal agencies, (1) establish the appropriate leadership mechanism to provide a focal point with authority and accountability for developing a national biosurveillance capability and (2) charge this focal point with the responsibility for developing, in conjunction with relevant federal agencies, a national biosurveillance strategy. Officials from HHS, DHS, and the Departments of Agriculture and Defense stated that having a focal point would help coordinate federal efforts to develop a national biosurveillance capability. In particular, DHS noted that it is important to develop a strategy that encompasses all biological domains.
HHS Has Not Defined a Strategic Plan or Fully Established a Network as Required by PAHPA, but Has Developed Related	PAHPA mandated that the Secretary of HHS develop and submit to the appropriate committees of Congress by June 16, 2007, a strategic plan that described the steps the department would take to develop, implement, and evaluate an electronic network of interoperable systems for the simultaneous sharing of information needed to enhance situational awareness at the federal, state, local, and tribal levels of public health. The act required the department to establish such a network by December 19, 2008.
Strategies and Systems	HHS did not develop and submit to congressional committees the strategic plan required by PAHPA, although it has developed related strategies that could contribute to a comprehensive strategic plan for an electronic public health information network to enhance situational awareness. These related strategies were developed by different offices within HHS—such as ONC, CDC, and ASPR—to address goals, objectives, and priorities established by their offices ¹⁷ and to meet specific requirements of executive and statutory authorities for the development of strategies for nationwide health information exchange coordinated biosurveillance and

nationwide health information exchange, coordinated biosurveillance, and health security. However, HHS has not defined a comprehensive strategic plan that identifies goals, objectives, activities, priorities, and performance measures, and that integrates related strategies to achieve the unified

¹⁶GAO-10-645.

¹⁷According to HHS, the *National Biosurveillance Strategy for Human Health* reflects goals, objectives, and priorities established through a CDC-led collaboration with federal, state, local, and other health partners to reflect both CDC's and its partners' needs.

electronic nationwide situational awareness capability required by PAHPA.

	Additionally, the department has developed and implemented information technology systems intended to enable electronic information sharing to support early detection of and response to public health emergencies. However, these systems were not developed as part of a comprehensive, coordinated strategic plan as required by PAHPA. Instead, they were developed to support ongoing public health activities over the past decade, such as disease and syndromic surveillance. Without the guidance and direction that would be provided by an overall strategic plan that defines requirements for establishing and evaluating the capabilities of existing and planned information systems, the department cannot be assured that its resources are being used to develop and implement systems that are able to collect, analyze, and share the information needed to fulfill requirements for an electronic nationwide public health situational awareness capability.
HHS Has Not Developed a Strategic Plan for Establishing an Electronic Network to Support Nationwide Public Health Situational Awareness	PAHPA required HHS to develop a strategic plan that demonstrated steps the department would take to develop and implement an electronic network for public health situational awareness. The act further stated that the plan was to define steps for evaluating network capabilities. It also established criteria for evaluating the extent to which the network met requirements of the act, such as the integration of data from various sources and the implementation of interoperability standards.
	HHS did not develop and deliver to congressional committees a strategic plan as required by PAHPA. HHS officials stated that when PAHPA was enacted in December 2006, the Assistant Secretary for Preparedness and Response and the Director of CDC interpreted the PAHPA language describing situational awareness to mean the knowledge obtained from biosurveillance activities. These officials stated that, as a result of this understanding, a policy decision was made by ASPR and CDC in early 2007 that CDC would serve as the lead for PAHPA-related biosurveillance activities and that a nationwide biosurveillance strategy that was expected to be developed by CDC would satisfy the PAHPA strategic plan requirement. However, CDC did not develop and HHS did not deliver such a plan to congressional committees, as required by PAHPA.
	Although a comprehensive strategic plan for an electronic situational awareness network of systems has not yet been developed, CDC, ASPR, and ONC have individually taken steps to define strategies that identify certain objectives, goals, priorities, and activities related to the

development of electronic networks and systems intended to support event detection and emergency response. For example:

- In June 2008, ONC released the ONC-Coordinated Federal Health IT • Strategic Plan,¹⁸ which defines strategies, objectives, goals, and measures for the implementation of the Nationwide Health Information Network (NHIN), an HHS initiative intended to define standards, policies, and procedures for enabling the secure exchange of interoperable health care and public health information over the Internet. In addition to establishing goals and objectives for the exchange of clinical health information, this strategy also defines population health-oriented goals. For example, the Federal Health IT Strategic Plan identifies an objective and supporting strategies for enabling the secure exchange of interoperable health information for population health purposes, including public health emergency preparedness and response. However, this strategy was developed to coordinate federal health information technology initiatives focused on sharing electronic health data collected from health care providers (e.g., hospitals and physicians) and was not intended to address the exchange of data between public health entities.
- In December 2008, CDC's Biosurveillance Coordination unit released the initial version of the *National Biosurveillance Strategy for Human Health*, ¹⁹ which defines goals to support integrated biosurveillance information as a priority. The strategy states that health information exchange, enabled by the NHIN, is a foundation for a nationwide exchange of biosurveillance data. It also emphasizes the need for data and interoperability standards to enable systems to share information across jurisdictions, disciplines, and domains related to human health, such as veterinary, environmental, food, and agricultural. Version 2.0 of the strategy, which was released in February 2010, defines an activity that is intended to identify and compile a registry of existing biosurveillance systems in use by federal, state, and local public health entities. While this

¹⁸ONC, *ONC-Coordinated Federal Health IT Strategic Plan 2008-2012* (Washington, D.C., June 2008). ONC's health information technology strategy was developed and maintained to meet requirements of an April 2004 Presidential Executive Order (E.O. 13335). According to HHS officials, ONC is revising the 2008 plan and expects to publish the revision by the end of 2010.

¹⁹HHS, CDC, Office of Public Health Preparedness and Response, Biosurveillance Coordination Unit, *National Biosurveillance Strategy for Human Health*, *Version 1.0* (Atlanta, Ga., December 2008). This strategy was developed to meet requirements of the Homeland Security Presidential Directive 21, Public Health and Medical Preparedness, which was issued in October 2007.

strategy addresses the need for improved electronic exchange of biosurveillance data to enhance public health emergency preparedness and response capabilities of federal, state, and local public health entities, it does not address another key component of situational awareness—i.e., the knowledge of resources available for emergency response operations.

In December 2009, HHS published the National Health Security Strategy and a companion implementation plan to meet another PAHPA requirement.²⁰ In this strategy, the department defined situational awareness more broadly than the knowledge provided by biosurveillance activities to include, among other things, knowledge of operational resources needed to respond to public health emergencies. According to HHS officials with ASPR, the health security strategy represents current HHS policy defining situational awareness, which is consistent with PAHPA. This strategy includes an objective to "ensure situational awareness" and emphasizes the need to improve the efficiency, accuracy, interoperability, and usability of information systems to enhance situational awareness. However, the strategy does not identify goals, objectives, or priorities for developing and implementing a network of information systems for situational awareness, nor does it identify steps for evaluating such a network. According to ASPR officials, the implementation plan for the health security strategy is being revised. They stated that they expect a new version will be released in 2011.

As HHS broadened the scope and definition of public health situational awareness to encompass knowledge of emerging events and emergency response resources, the department did not develop an overall strategic plan for the establishment and evaluation of an electronic nationwide public health situational awareness network that addressed this scope. Until HHS develops a strategic plan that identifies goals, objectives, activities, and priorities that integrate related strategies to achieve the unified electronic nationwide situational awareness capability required by PAHPA, the department will not be able to provide the guidance needed to help ensure that the various offices across HHS coordinate their strategic planning efforts to meet the PAHPA mandate.

²⁰HHS, *National Health Security Strategy of the United States of America* and *Interim Implementation Guide for the National Health Security Strategy of the United States of America* (Washington, D.C., December 2009). This strategy was developed to meet other requirements of PAHPA, such as for HHS to identify processes for achieving the preparedness goals described in the act, evaluate the progress made by federal, state, local, and tribal entities toward levels of preparedness established by the act, and include a national strategy for establishing an effective and prepared public health workforce.

HHS Has Taken Steps to Implement Systems and Tools that Support Event Detection and Emergency Response, but They Do Not Fully Address Objectives of PAHPA PAHPA describes data and other technical requirements for establishing and evaluating a public health situational awareness network that was to be completed by December 19, 2008. Specifically, the act required HHS to build on existing systems to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems. The act identified the sources of data to be collected, analyzed, and shared among the systems, such as state, local, and tribal public health entities; federal health agencies; zoonotic disease monitoring systems;²¹ poison control centers; and clinical laboratories. The act further required HHS to use interoperability standards determined through a joint public and private sector process and to define minimal data elements for the network of systems. The electronic capability described by PAHPA was to support simultaneous sharing of data among federal, state, local, and tribal public health entities.

CDC, ASPR, and ONC officials described more than 25 ongoing information technology initiatives that, in their view, contribute to the department's efforts to enable electronic information sharing to support situational awareness for early event detection and emergency response. Some of them address certain criteria for systems defined by the PAHPA mandate, such as requirements for data sources, interoperability standards, and minimal data elements for an electronic public health situational awareness network. Among the ongoing initiatives, the officials described the following:

• HHS officials identified key information technology systems and tools that support early event detection through the analysis of electronic data collected from sources specified by PAHPA. Biosurveillance systems, such as BioSense and Distribute, collect, analyze, and share data from sources such as state and local public health departments, public health laboratories, and health care facilities. These systems are intended to enhance public health entities' ability to detect disease outbreaks and other public health emergencies by enabling simultaneous sharing of information produced by the systems. In addition, officials with the FDA stated that they use a Web-based system called the Electronic Laboratory Exchange Network (eLEXNET) to collect, analyze, and share electronic food safety laboratory data among federal, state, and local agencies to help detect potential for outbreaks of foodborne illnesses.

²¹Diseases transmitted between people and animals are called zoonotic diseases. Examples of zoonotic diseases include mad cow disease, West Nile virus, and H1N1 influenza.

- ONC officials described initiatives to define interoperability standards and identify minimal data elements for the electronic exchange of biosurveillance information through electronic health records. CDC, through the Public Health Information Network initiative, identified interoperability standards and developed messaging software that allow public health entities to securely send and receive encrypted public health information, including disease and syndromic surveillance data, over the Internet.
- HHS emergency response officials who operate and manage the Secretary's Operations Center identified systems and tools that are crucial to the department's ability to support response operations in public health emergencies, such as MedMap, a system that allows users to identify the status of a health event and future areas of concern. ASPR developed and maintains the *Information Management Plan*, which is intended to define the data needed, along with methods and processes for collecting and managing information, to support situational awareness and decision making during emergency response to public health events.

See table 2 in appendix II for additional details about the key event detection and emergency response information systems identified by HHS officials.

While the systems that HHS officials described collect and analyze data from many of the sources required by PAHPA and while HHS has recently taken some steps to define data elements and standards to support sharing of biosurveillance information throughout the public health community, these activities were initiated to collect, analyze, and share data to support specific public health functions, such as biosurveillance and hospital capacity planning. Department officials stated that HHS does not view a situational awareness network or system as being one comprehensive system, but rather an integrated collection of systems and networks. These officials further stated that the information systems and networks they described comprise a network that makes up an electronic situational awareness capability.

Nonetheless, while these systems and tools enhance the nation's ability to detect and respond to public health emergencies, they were developed and implemented without the guidance and direction that would be provided by an overall strategic plan that defines requirements for establishing and evaluating the capabilities of existing and planned information systems. Lacking such a plan, HHS cannot be assured that its resources are being used to develop and implement systems that are able to collect, analyze,

	and share the information needed to fulfill requirements for an electronic nationwide public health situational awareness capability.
HHS Has Taken Steps to Collaborate with State and Local Entities	PAHPA required the Secretary of HHS to collaborate with state, local, and tribal public health officials in establishing an electronic information- sharing network which builds on existing capabilities to ensure simultaneous sharing of data with state, local, and tribal public health agencies. The act required collaborative efforts to develop procedures and standards for the collection, analysis, and interpretation of data collected and reported to the network.
	Department officials have engaged in certain collaborative efforts with stakeholders to define components of an electronic information-sharing network. Additionally, the department has awarded funds through cooperative agreement programs to engage state and local public health officials in collaborative efforts to improve information sharing for enhanced situational awareness.
ONC, CDC, and ASPR Have Engaged in Collaborations with Public Health Partners to Define Information Technology Standards and Data Requirements	Since its establishment in 2004, ONC has engaged in collaborations with public and private health care partners to establish standards, services, and policies that support the electronic exchange of interoperable health care and public health data as part of the NHIN initiative. Through these collaborative efforts, the office defined minimal data elements that must be included in electronic health records to support electronic sharing of information for biosurveillance purposes, along with interoperability standards to enable sharing of electronic health and public health information. ²² Additionally, HHS's requirements for demonstrating meaningful use of electronic health records by providers include the ability to report syndromic surveillance data to state and local public health entities. ²³ CDC officials stated that they are working with ONC and

²²The data elements and standards established to date were defined by the Health Information Technology Standards Panel and the American Health Information Community, which are committees made up of representatives from the public and private health sectors, established by ONC to support NHIN initiatives.

²³Within the American Recovery and Reinvestment Act of 2009, the Health Information Technology for Economic and Clinical Health Act authorized incentive payments to Medicare and Medicaid providers that meaningfully use electronic health records in their practices. 42 U.S.C. §§ 1395w-4(o), 1395ww(n), 1396b(t). To demonstrate "meaningful use" providers must meet specific criteria defined by HHS in three phases. Phase I requirements were finalized in July 2010 and phase II requirements are planned to be announced in 2012.

other public health stakeholders, including the International Society for Disease Surveillance, to define data requirements for situational awareness as part of future meaningful use criteria.

CDC officials have also taken steps to improve collaborative efforts with public health stakeholders in biosurveillance and other public health information technology initiatives. For example, they contracted with state and regional health information exchanges to integrate and build on the exchanges' existing capabilities to collect and share data using the BioSense system. Additionally, through a partnership with other public and private entities (the International Society for Disease Surveillance and the Public Health Informatics Institute), the agency created a data format, the Geocoded Interoperable Population Summary Exchange, to facilitate the electronic exchange of syndromic surveillance data among public health entities using the Distribute system.²⁴ In September 2010, as part of ongoing efforts initiated during the H1N1 outbreak response, CDC officials established a community forum on its BioSense Redesign Collaboration Web site to obtain input from and provide updated information to public health surveillance stakeholders regarding the ongoing redesign of the BioSense program, including the area of situational awareness.²⁵ Public health stakeholders, such as the Council of State and Territorial Epidemiologists and the Public Health Informatics Institute, agreed that CDC has improved efforts to collaborate on information technology initiatives to support early event detection.

ASPR officials stated that they work with state and local public health emergency response partners to develop information collection plans for the Secretary's Operations Center. These plans identify the data elements needed to assess potential threats (such as the spread of disease outbreaks or natural disasters), the source of each data element, and mechanisms for sharing data between the Secretary's Operations Center and other public health entities to enhance situational awareness. For example, the information collection plan for response to the spread of

²⁵The BioSense Redesign Collaboration Web site address is https://sites.google.com/site/biosenseredesign/

²⁴This format included the minimal data elements for conducting biosurveillance defined by ONC and its partners—the Health Information Technology Standards Panel and the America Health Information Community, which are public-private partnerships established by HHS to provide consultation and technical support to ONC as it defines specifications for the NHIN. AHIC has been replaced by other committees formed by the Health Information Technology for Economic and Clinical Health Act.

influenza-like illness identifies information requirements for measuring the impact of the illness, such as school absenteeism or closure, and for identifying the capacity to meet needs during medical surges, such as availability of ventilators or pharmaceuticals.

HHS Has Established Cooperative Agreement Programs Intended to Improve State and Local Public Health Entities' Information Systems

Under authorities other than PAHPA, HHS initiated additional activities to collaborate with public health stakeholders through cooperative agreement programs intended to support the development and implementation of information systems to collect, analyze, and share data for enhanced situational awareness. For example, according to HHS, the Public Health Emergency Preparedness Cooperative Agreement program, the Regional Surveillance Collaboratives program, and the Hospital Preparedness Program were designed to, among other things, award funds to regional, state, and local public health entities for implementation of information systems to improve syndromic surveillance and emergency response operations.²⁶

- The Public Health Emergency Preparedness program awards funds to state and local public health jurisdictions. Awardees are required to use the funds for, among other things, improving capabilities to prepare for and respond to bioterrorism, outbreaks of infectious diseases, and other public health threats and emergencies. North Carolina public health officials stated that they used funds from this program to enhance the capabilities of an existing Web-based syndromic surveillance system called NC DETECT, which collects poison control and school absenteeism data and data describing patients' complaints from all the state's hospital emergency departments. The system was enhanced to transmit these data to CDC's BioSense system.
- The Regional Surveillance Collaboratives program awards funds to states and consortia of states to promote collaboration, planning, and use of standards to allow for effective surveillance and exchange of data using existing technologies. The collaboratives are intended to bring together resources from multiple jurisdictions to enhance overall public health

²⁶The Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6305, defines the cooperative agreement as similar to a grant in that a thing of value is transferred to a recipient to carry out a public purpose. However, a cooperative agreement is used whenever substantial federal involvement with the recipient during performance is anticipated. The difference between grants and cooperative agreements is the degree of federal programmatic involvement rather than the type of administrative requirements imposed.

surveillance and situational awareness. According to officials with the Missouri Regional Collaborative, as a result of the funds and support provided through this program, Missouri and Kansas built on their existing technologies to implement features that enabled them to share syndromic surveillance data. They also stated that they used these funds to integrate state surveillance data into Johns Hopkins University's surveillance system and into CDC's BioSense system.

- The Hospital Preparedness Program funds activities of states, territories, and localities intended to improve preparedness planning for disease outbreaks and other public health emergencies. Program guidance for fiscal year 2010 states that funds are to be used by awardees to, among other things:
 - enhance or maintain the ability of health care systems to adequately prepare for increased numbers of patients in the event of a public health emergency;
 - engage with other responders through interoperable communication systems;
 - track bed and resource availability through electronic systems;
 - develop systems to facilitate the use of volunteers in local, territorial, and federal emergency response;²⁷ and
 - coordinate regional emergency response exercises.

More than 30 state and local public health entities reported that they have implemented, refined, or maintained National Hospital Available Beds for Emergencies and Disasters (HAvBED) capabilities using funds from this program. In one case, a county health department revised HAvBED reporting schedules from four times a month to daily in order to meet reporting needs during the H1N1 outbreak.

²⁷According to ASPR, development of systems within the Emergency System for Advance Registration of Volunteer Health Professionals network is funded through the program. The purpose of the program is to establish a single national interoperable network of statebased programs to effectively facilitate the use of volunteers in local, territorial, and federal emergency responses. All awardees under the Hospital Preparedness Program are required to meet and maintain all Emergency System for Advance Registration of Volunteer Health Professionals electronic system, operational, evaluation, and reporting compliance requirements.

	Cooperative agreement awardees with whom we spoke stated that the funds available through these programs have supported their ability to enhance nationwide public health situational awareness by improving the capabilities of existing information systems that support public health officials' collection, analysis, and sharing of information. According to a public health official participating in CDC's Regional Collaborative with Missouri and Kansas, funds awarded through the program facilitated the implementation of technologies that met the unique needs of states that were at different levels of technical capacity. Additionally, public health officials from North Carolina indicated that funds provided by the Public Health Emergency Preparedness Cooperative Agreement contributed to the implementation of technologies that provide statewide early event detection and timely public health surveillance information to public health officials and hospital users. More detailed information about these and other key cooperative agreements administered by ASPR and CDC can be found in appendix III.
HHS Has Not Awarded Grants to States for Improved Information Systems to Enhance	PAHPA states that the Secretary of HHS may award grants to states or consortia of states to enhance their ability to establish or operate public health situational awareness systems for regional or statewide early detection of, response to, and management of public health emergencies. The act authorized the use of funds for this purpose through September 30, 2011. To date, Congress has not appropriated funds pursuant to the
Nationwide Situational Awareness	authorization. HHS officials with ASPR stated that if funds are appropriated for grant awards under the mandate, they will administer them.
Conclusions	HHS did not develop and deliver to congressional committees the situational awareness strategic plan required by PAHPA. While ONC, CDC and ASPR have developed other related strategies and information systems intended to address the need for improvements in health information exchange and information technology to support early event detection and emergency response operations, the department has not yet developed and implemented a strategic plan for the development, implementation, and evaluation of an electronic public health situational awareness network as required by PAHPA. Without such a plan, HHS has not established overall goals, objectives, priorities, and activities to guide and integrate related efforts, nor has it defined steps and performance

	measures for evaluating the effectiveness of existing and ongoing information technology initiatives toward establishing an information- sharing network of interoperable systems.
	HHS's current efforts to revise its related strategies provide an opportunity for the department to define and implement a comprehensive strategic plan that integrates the goals, objectives, and priorities for electronic health information exchange, biosurveillance capabilities, and national health security into an overall strategic plan for electronic situational awareness capabilities. This strategic plan would also define steps and performance measures for evaluating the outcomes of the department's various efforts related to electronic public health situational awareness capabilities. Until HHS develops and implements such a strategic plan, the department cannot ensure that its efforts to develop and implement systems that support public health emergency preparedness and response fulfill the PAHPA mandate and meet goals and objectives for enhanced nationwide public health situational awareness through electronic information-sharing systems.
Recommendation for Executive Action	To address the requirements of PAHPA, we recommend that the Secretary of HHS direct the Assistant Secretary for Preparedness and Response to immediately lead efforts, in collaboration with other federal, state, local, and tribal public health officials, to develop and implement an overall strategic plan for establishing and evaluating an electronic network of systems that meets the information-sharing requirements for enhanced nationwide public health situational awareness defined by the act. The strategy should
•	define specific goals, objectives, priorities, and activities for establishing the network;
•	identify steps and performance measures for evaluating capabilities of existing and planned information systems to establish the network; and
•	integrate elements of related strategies to achieve unified electronic public health situational awareness capabilities defined by PAHPA.

Agency Comments and Our Evaluation	HHS's Assistant Secretary for Legislation provided written comments on a draft of this report. In the comments, the department neither agreed nor disagreed with our recommendations. HHS described strategies and existing resources it has utilized to support improvements for situational awareness at the state, local, tribal, and territorial levels. Further, the department believed that its efforts are consistent with direction provided in the Pandemic and All-Hazards Preparedness Act. Nonetheless, HHS stated that a complete strategy for health and public health situational awareness will be developed and incorporated into the Biennial Implementation Plan for the National Health Security Strategy which will identify actions to be accomplished in the next 2 years. The department added that it intends to release this first biennial plan in early 2011. As discussed in our report, developing a strategic plan that integrates the goals, objectives, and priorities of related strategies will be essential to ensuring success of the department's efforts to support and enhance nationwide public health situational awareness.
	 We are sending copies of this report to the Secretary of HHS and interested congressional committees. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov. If you have any questions on matters discussed in this report, please contact me at (202) 512-6304 or at melvinv@gao.gov. Contact points for our offices of Congressional Relations and Public Affairs may be found on the last page of this report. Other contacts and key contributors to this report are listed in appendix V.
	Valerie C. Melnin Valerie C. Melvin

Director, Information Management and Human Capital Issues

List of Congressional Committees

The Honorable Tom Harkin Chairman Committee on Health, Education, Labor, and Pensions United States Senate The Honorable Michael B. Enzi Ranking Member Committee on Health, Education, Labor, and Pensions United States Senate The Honorable Joseph I. Lieberman Chairman Committee on Homeland Security and Governmental Affairs United States Senate

The Honorable Susan M. Collins Ranking Member Committee on Homeland Security and Governmental Affairs United States Senate

The Honorable Henry A. Waxman Chairman Committee on Energy and Commerce House of Representatives

The Honorable Joe Barton Ranking Member Committee on Energy and Commerce House of Representatives

The Honorable Edolphus Towns Chairman Committee on Oversight and Government Reform House of Representatives

The Honorable Darrell Issa Ranking Member Committee on Oversight and Government Reform House of Representatives

Appendix I: Objectives, Scope, and Methodology

The objectives of our review were to (1) determine the Department of Health and Human Services' (HHS) plans for and status of implementing an electronic nationwide public health situational awareness network; (2) describe HHS's efforts to collaborate with state, local, and tribal public health officials to achieve a nationwide situational awareness capability; and (3) determine how HHS uses grants authorized by the Pandemic and All-Hazards Preparedness Act (PAHPA), Section 202, to enhance states' ability to establish coordinated public health situational awareness systems.

To determine HHS's plans for and status of the establishment of an electronic network to enhance nationwide public health situational awareness, we reviewed Section 202 of PAHPA to identify requirements for an electronic situational awareness network as defined by the act. We collected and analyzed agency documentation regarding program planning and management activities, such as strategic and information management plans, and descriptions of current uses and outcomes of systems and tools used by the department to collect, analyze, and share information to enhance nationwide, state, and local public health situational awareness. We reviewed strategic planning documents related to the implementation of information technology to enhance public health situational awareness including the Centers for Disease Control and Prevention's (CDC) 2010 National Biosurveillance Strategy for Human Health; the Office of the National Coordinator for Health Information Technology's (ONC) ONCcoordinated Federal Health IT Strategic Plan, 2008-2012; HHS's Assistant Secretary for Preparedness and Response's (ASPR) 2009 National Health Security Strategy and Interim Implementation Guide; and ASPR's 2007 Information Management Plan.

In addition, we identified key information systems used by HHS to support early event detection and emergency response operations by reviewing HHS planning documents and prior GAO reports and by having discussions with officials from ASPR, ONC, the Food and Drug Administration, the Indian Health Service, and CDC's Office of Surveillance, Epidemiology, and Laboratory Services, Emergency Operation's Center, and the Center for Global Health. We also visited HHS's Secretary's Operations Center and CDC's Emergency Operations Center to discuss and observe the use of key systems and tools that support detection of and response to public health emergencies. Within CDC's Office of Surveillance, Epidemiology, and Laboratory Services, we held more detailed discussions with officials in the Public Health Informatics and Technology Program Office and Biosurveillance Coordination regarding the status of and plans for information technology initiatives to support early detection of disease outbreaks and other public health emergencies, including the definition and implementation of data and interoperability standards within such a network. To supplement this information, we attended presentations on the status of and plans for CDC's biosurveillance initiatives, such as the BioSense and Distribute systems. From the information we gathered, we developed a table of HHS's key information technology initiatives intended to enhance early detection of and response to public health emergencies.

To describe HHS's efforts to collaborate with state, local, and tribal public health officials, we reviewed Section 202, Title II, of PAHPA to determine requirements for HHS to collaborate with stakeholders on the establishment of an electronic situational awareness capability. We collected and analyzed documentation including cooperative agreements between HHS and state and local partners, and artifacts from stakeholders' participation at conferences related to nationwide biosurveillance activities. We discussed with officials from the Food and Drug Administration, CDC, and ASPR, including officials involved with HHS's Secretary's Operation Center and CDC's Emergency Operations Center, their efforts to collaborate with public health officials. To supplement our discussions with HHS officials, we met with representatives from four public health organizations to obtain their views on the department's efforts to collaborate on implementation of information systems for event detection and emergency and on the department's efforts to establish an electronic network for sharing information to enhance public health situational awareness. Specifically, we held discussions with officials from the National Association of City and County Health Officials, Association of State and Territorial Health Organizations, Council of State and Territorial Epidemiologists, and Public Health Informatics Institute. We selected these organizations through research of public health information technology programs and from our previous work on the use of information technology to support public health emergency preparedness and response. In addition, we interviewed representatives of the National Association of State Chief Information Officers who are involved in state public health information technology initiatives. We also interviewed state and local public health officials participating in CDC's demonstration projects with health information exchanges in New York, Washington state, and Indiana, and in other regional collaborative efforts with South Carolina, Missouri, Kansas, the University of Pittsburgh, and John Hopkins University. To describe further the extent to which HHS collaborates with the tribal community, we interviewed public health and information technology officials with the Indian Health Service.

To determine the extent to which HHS provided funds through grants authorized by PAHPA to enhance states' ability to establish coordinated public health situational awareness systems, we held discussions with HHS officials. These officials stated that no grants had been established or awarded under authorization of the act. For each of the objectives, we assessed the reliability of the data we analyzed by reviewing existing documentation related to the data sources and interviewing knowledgeable agency officials about the data we used. We found the data sufficiently reliable for the purposes of this review.

We conducted this performance audit from November 2009 through December 2010 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.

Appendix II: HHS's Key Information Technology Initiatives

Table 2 describes key information technology initiatives to develop and implement systems intended to enhance capabilities to detect and respond to disease outbreaks and other public health emergencies.

Table 2: Key HHS Information Technology Systems Used to Enhance Situational Awareness

Dollars in thousands Description Users **Data providers** CDC systems BioSense National program to improve Public health staff at state 640 acute-care hospitals; capabilities for early event and local health departments, 1,300 Department of Status: system is operational and is detection, monitoring, and real-CDC program staff, CDC's Defense and Department of undergoing revision to collect data time situational awareness **Emergency Operations** Veterans Affairs hospitals from existing automated surveillance through access to specific Center, International Society and health care facilities; 2 systems operated by state and local health care data from for Disease Surveillance, large national commercial health departments rather than from VA's Office of Public Health participating organizations. laboratories; and a national hospitals. CDC officials expect revised and Environmental Hazards. retail pharmacy database program plans to be in place by late and VA's Infectious Disease representing 27,000 retail 2011. Program Office pharmacies (as of FY 2009 costs: \$27,656 September 2010) Note: This only includes the program funds for BioSense. Distribute A collaborative surveillance CDC, state, and local public 41 local or state public activity that aggregates health officials health departments (as of Status: system is operational information from hospital September 2010) FY 2009 costs: \$1,480 emergency department syndromic surveillance systems operated by state and local health departments and merges those data with other existing surveillance systems to enhance situational awareness of geographic and age-specific patterns of influenza-like illness. CDC, local, state, and A nationwide system serving as **Health Alert Network** State public health officials a platform for the distribution of from 50 states, 3 large city federal health authorities Status: system is operational health departments, 3 county health alerts, dissemination of access and share disease FY 2009 costs: \$341 prevention guidelines and other health departments, 8 reports, response plans, information, distance learning, territories, the District of and CDC diagnostic and national disease surveillance, Columbia, and multiple health treatment guidelines and electronic laboratory organizations and major reporting, as well as for CDC's hospital networks bioterrorism and related initiatives to strengthen preparedness at the local and state levels.

Dollars in thousands			
	Description	Users	Data providers
Epidemic Information Exchange Status: system is operational FY 2009 costs: \$2,008	A system for the secure exchange of epidemiologic data, including provisional or secure- but-not-classified information regarding outbreaks and other emergent public health events, among public health officials at the local, state, and federal levels.	Approximately 5,000public health officials, including CDC epidemiologists and program staff, state and territorial health officers, state and territorial epidemiologists, and other state and local officials	CDC epidemiologists, state epidemiologists, poison control center directors, local health officers, and other public health professionals
Laboratory Response Network Status: system is operational FY 2009 costs: \$7,594	An integrated network of 165 public health and clinical laboratories that provide laboratory diagnostics and have a disseminated testing capability for public health preparedness and response.	State and local public health officials	165 public health and clinical laboratories
National Electronic Disease Surveillance System Base System Status: system is operational FY 2009 costs: \$4,022 Note: Not an actual "surveillance system," it is a secure Internet-based infrastructure for public health surveillance data exchange.	An integrated electronic disease surveillance system application that includes the capability to receive standards-based electronic records. The system provides public health jurisdictions with a reference implementation of National Electronic Disease Surveillance System/National Notifiable Diseases Surveillance System policy and standards consistent with the Nationwide Health Information Network and CDC's Public Health Information Network.	16 state health departments	State and local health departments and providers
National Notifiable Diseases Surveillance System Status: system is operational FY 2009 costs: \$1,800	A system that enables CDC to collect and publish data concerning nationally notifiable diseases.	State and local public health officials and CDC officials	Public health officials in 50 states, 5 territories, the District of Columbia, and New York City
Border Infectious Disease Surveillance Project Status: system is operational FY 2009 costs: \$728	An early warning and active syndromic illness and disease monitoring network operating in the U.SMexico border region that targets approximately 12 million people.	State and local public health epidemiologists at the U.S Mexico border	Data are contributed by local, state, and federal public health officials from the United States and Mexico
National Molecular Subtyping Network for Foodborne Disease Surveillance Status: system is operational FY 2009 costs: \$4,400	An early warning system for outbreaks of food-borne diseases.	State public health laboratories in all 50 states as well as other city, county, agricultural, and federal food safety laboratories	Public health labs

Dollars in thousands			
	Description	Users	Data providers
Outbreak Management System Status: system is operational FY 2009 costs: \$419	A system that enables rapid, coordinated detection and response to multistate outbreaks of food-borne illness to promote more comprehensive outbreak surveillance.	CDC, Food and Drug Administration (FDA), and Department of Agriculture public health and food safety officials and state and local health departments	Local, state and federal officials with responsibility for investigating and reporting food-borne, waterborne, and other enteric diseases outbreaks
Arboviral Surveillance System Status: system is operational FY 2009 costs: \$12,700	An Internet-based national arboviral surveillance system developed by state health departments and CDC in 2000 to assist states in tracking West Nile and other mosquito-borne viruses.	State and local public health officials and CDC officials, with distribution to the general public via CDC's Web site	Public health departments in all states and three local districts (New York City, Washington D.C., and Puerto Rico)
National Poison Data System Status: system is operational FY 2009 costs: \$2,000	A database that holds more than 50 million poison exposure case records.	Information from the National Poison Data System is available to the general public	General public via case phone calls into poison centers across the country
National Toxic Substance Incidents Program Status: system is operational FY 2009 costs: \$495	National database of toxic substance incidents. Currently seven states contribute data to the system. Activities include national database, surveillance, and response teams.	CDC, state, and local public health officials, other federal agencies	State health departments and affiliated agencies
Indian Health Service System			
Resource and Patient Management System Status: system is operational FY 2009 costs: not available	An automated system for managing clinical and administrative information in health care facilities that serves as a mechanism to provide near real-time health and public health data to the tribal community. A specific use of the overall system is to aggregate data for national public health surveillance for influenza and other reportable conditions in tribal areas.	Indian Health System federal and tribal hospitals, health centers and stations, and urban Indian health projects	Indian Health Service federal sites, through tribally contracted and operated health programs, and urban Indian health projects
FDA Systems			
Electronic Laboratory Exchange Network Status: system is operational FY 2009 costs: \$1,097	A Web-based system for real- time sharing of food safety laboratory data among federal, state, and local agencies.	1,800 users including 203 participating labs	Public health and agricultural food safety officials

Dollars in thousands				
	Description	Users	Data providers	
Emergency Operations Network Incident Management System Status: system is operational FY 2009 costs: \$2,046	The central hub for exchanging and relaying all incident-related information within the FDA. The Emergency Operations Network Incident Management System includes the central data repository for reports to the Reportable Food Registry, where industry is required to submit notification when there is a reasonable probability their human or animal food product could cause illness or injury.	FDA	Systems such as the Electronic Laboratory Exchange Network and the Epidemic Electronic Exchange, FDA laboratories, and investigators and external agencies	
International Food Safety	A system that monitors potential international food safety-related	177 member states and the Food and Drug Administration	Member states	
Status: system is operational	events in addition to receiving	r ood and Drug Administration		
FY 2009 costs: funding provided by the World Health Organization	Information through International Food Safety Authorities Network emergency contact points.			
National Consumer Complaint	A system used to collect and	Consumer complaint coordinators at FDA headquarters and regional	Consumers of FDA- regulated products	
Status: system is operational	consumers about FDA-			
FY 2009 costs: not available	regulated products.	offices		
MedWatch	A system that provides	General public, healthcare	Healthcare professionals	
Status: system is operational	important and timely clinical information about safety issues	professionals, and consumers	and consumers	
FY 2009 costs: not available	involving medical products, including prescription and over- the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products.			
ASPR Systems				
Hospital Available Beds for Emergencies and Disasters	A Web system that provides a centralized, national view of bed	HHS Secretary's Operation Center and CDC's	Civilian, Department of Defense, and Department	
Status: system is operational.	availability for supporting a	Emergency Operation Center	of Veterans Affairs hospitals, mental health institutions, and nursing homes	
FY 2009 costs: \$12,000	emergency, disaster, or disaster training event.	as well as public health responders		
WebEOC	A commercial off-the-shelf	HHS Secretary's Operation	HHS's federal, state, and	
Status: system is operational FY 2009 costs: \$15.4	crisis information management system.	Operations Center and the FDA Emergency Operations Center	Geospatial Information System data	

Dollars in thousands			
	Description	Users	Data providers
MedMap Status: system is operational FY 2009 costs: \$499.7	MedMap is a Web-based application that allows the user to become aware of the current status of a health event from the field and identify future areas of concern or gaps.	HHS Secretary's Operation Center Federal health responders, including HHS's regional emergency coordinators	Emergency Support Function-8 partners, the U.S. Census Bureau, commercial health and medical data repositories, and open source news pushes (free and commercial)
Geospatial Information System Status: system is operational FY 2009 costs: \$110.7	Computer hardware, software, geographic data, and processes designed to capture, store, update, manipulate, analyze, and display all forms of geographically referenced data.	HHS Secretary's Operation Center, Federal and state health departments, and FDA Emergency Operations Center	Geospatial Information System technology— Environmental Systems Research Institute geographical information systems software
Electronic Medical Record Status: system is operational FY 2009 costs: \$1,877	A disaster response system that supports operational decision making with near real-time injury and illness data and supports patient care documentation and the exchange of that information over the Nationwide Health Information Network.	HHS Secretary's Operation Center and hospital, doctors, and clinics	Hospitals, doctors, and clinics
The Joint Patient Assessment and Tracking System Status: system is operational FY 2009 costs: \$283	A system that provides a means of tracking patients as they move through the National Disaster Medical System.	HHS Secretary's Operation Center and HHS staff, contractors, and other authorized users	HHS; Departments of Defense, Veterans Affairs, and Homeland Security; and 72 federal coordination centers

Source: HHS officials.

Appendix III: HHS's Key Cooperative Agreement Programs

Table 3 describes key cooperative agreement programs identified by HHS that provide funds for collaborations between HHS and state and local public health entities to support development of information systems to enhance public health situational awareness.

Table 3: Key HHS Cooperative Agreement Programs Funding Enhanced State and Local Public Health Situational Awareness through Information Technology Systems

Program and funding mechanism	Approximate total amount awarded	Description	Awardees [®]
CDC-administered programs			
Early Warning Infectious Disease Surveillance (EWIDS) ^b Funding authorized through CDC <i>Public</i> <i>Health Emergency Preparedness</i> <i>Cooperative Agreement Program</i> , Announcement AA154 from 2003-2009. In fiscal year 2010, EWIDS funding was issued by ASPR to CDC under authorization from the Consolidated Appropriations Act 2010 (P. L. 111-117), through an Intra-Departmental Delegation of Authority rather than the CDC Public Health Emergency Preparedness authorization	\$38.7 million	HHS created the EWIDS program in fiscal year 2003. The U.S. Border States EWIDS program exclusively focuses on building the capacity of public health systems of all 20 U.S. border states, including Alaska. The purpose of the program is to provide cross-border early warning of infectious diseases by enhancing surveillance capabilities and prompt sharing of findings of concern among U.S. states, Mexican states, and Canadian provinces along local and tribal jurisdictions adjacent to or straddling the U.S. international boundary to the north and south.	20 states
The Public Health Emergency Preparedness Cooperative Agreement Funding authorized through CDC Public Health Emergency Preparedness Cooperative Agreement Program, Announcement AA154	7 billion	Congress authorized funding for the Public Health Emergency Preparedness Cooperative Agreement in 2002 to support all- hazards preparedness nationwide. The program provides funds to support development and maintenance of critical public health preparedness and response capacities and capabilities, including implementation of interoperable systems consistent with Public Health Information Network standards.	62 states, territories, and localities

Program and funding mechanism	Approximate total amount awarded	Description	Awardees ^ª
Epidemiology and Laboratory Capacity for Infectious Diseases—NEDSS Funding authorized through CDC Epidemiology and Laboratory Capacity for Infectious Diseases Program under Announcements CDC-RFA-CI04-040; CI07- 701 and CI07-702	102.1 million	This program was originated in 2001 to promote the use of data and information system standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state, and local levels. NEDSS is a major component of the Public Health Information Network. This broad initiative is designed to detect outbreaks rapidly and to monitor the health of the nation, facilitate the electronic transfer of appropriate information from clinical information systems in the health care system to public health departments, reduce provider burden in the provision of information, and enhance both the timeliness and quality of information provided.	50 states, 5 localities, and 1 territory
Epidemiology and Laboratory Capacity for Infectious Diseases—BioSense Funding authorized through CDC Epidemiology and Laboratory Capacity for Infectious Diseases Program under Announcements CDC-RFA-CI04-040	462,000	This program was started in 2010 to support early event detection and timely public health surveillance using a variety of secondary data sources, such as hospital emergency departments.	North Carolina
Epidemiology and Laboratory Capacity for Infectious Diseases—Infrastructure and Interoperability Support for Public Health Laboratories Funding authorized by the American Recovery and Reinvestment Act through Epidemiology and Laboratory Capacity for Infectious Diseases Program under Announcements CDC-RFA-CI10- 1007ARRA10	5 million	This program began in 2010 to enhance and advance infrastructure and interoperability support for public health laboratories to satisfy Stage 1 meaningful use criteria for reporting to public health agencies.	8 states and 2 localities

Program and funding mechanism	Approximate total amount awarded	Description	Awardees [®]
Epidemiology and Laboratory Capacity for Infectious Diseases—Building and Strengthening Epidemiology, Laboratory, and Health Information Systems Capacity in State and Local Health Departments Funding authorized by the Patient Protection and Affordable Care Act through Epidemiology and Laboratory Capacity for Infectious Diseases Program under Announcement CDC-RFA-C110-1012	22.74 million total (including \$9.1 million for health information systems and \$13.56 million for epidemiology and laboratory capacity, which includes \$2.65 million of BioSense funding)	This program began in 2010 to invest in public health's capacity to participate in modern health information exchange through support of Laboratory Information Management Systems, electronic laboratory-based reporting; supporting public health capacity to participate in "meaningful use" of electronic health records. While the Epidemiology and Laboratory Capacity for Infectious Diseases has supported NEDSS activities over the years, the laboratory Patient Protection and Affordable Care Act funding is more clearly focused on an important area for health reform— public health's participation in meaningful use as electronic health records evolve.	49 states and 5 localities
CDC Regional Surveillance Collaboratives Program Funded through Announcement-CDC RFS HK08-802	1 million	The CDC Regional Surveillance Collaboratives program started in June 2008. The program provides funds to demonstrate and evaluate earlier detection of potential outbreaks and enhanced situational awareness by exchanging cross- jurisdiction summary data from existing surveillance systems.	Missouri Department of Health and Senior Services, Johns Hopkins University, South Carolina Department of Health and Environmental Control, and the University of Pittsburgh
ASPR-administered program			_
Hospital Preparedness Program Funded through a Continuation Cooperative Agreement and the Consolidated Appropriations Act in fiscal year 2010 Announcement-HHS-2009-ASPR-SA-0901	3.6 billion	I he program has provided all-hazard preparedness funding to 62 awardees since fiscal year 2002 to increase the capacities and capabilities of health care systems, including the Hospital Available Beds for Emergencies and Disasters system; to improve surge capacity; and enhance community and hospital preparedness for public health emergencies and mass casualty events.	62 states, territories, and localities

Source: HHS officials.

^aAll awardees received funds in 2009, with the exception of awardees for the Epidemiology and Laboratory Capacity programs that originated in 2010.

^bEWIDS is a joint collaboration between HHS-ASPR and CDC's Office of Public Health and Preparedness Response. CDC manages the programmatic distribution and implementation of EWIDS funds through a supplement to Public Health Emergency Preparedness cooperative agreements with the states. ASPR leads policy development for border and trans-border activities and program management with partner countries in Canada and Mexico.

Appendix IV: Comments from the Department of Health and Human Services

	ENT OF HEALTH & HUMAN SERVICES	OFFICE OF THE SECRETARY
Avera 2		Assistant Secretary for Legislation Washington, DC 20201
	DEC 1 4 2010,	
Valerie C. Melvin Director, Information M Human Capital Issues J.S. Government Accou 441 G Street N.W. Washington, DC 20548 Dear Ms. Melvin:	anagement and intability Office	ility Office's (GAO) report entitled:
Public Health Informat	ion Technology: Additional Strategi	c Planning Needed to Guide HHS's ilities" (GAO-11-99)
The Department appreci	ates the opportunity to review this c	orrespondence before its publication.
	Sincerely.	
	Jim R. Esquea Assistant Secre	tary for Legislation
Attachment		





Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact	Valerie C. Melvin, (202) 512-6304 or melvinv@gao.gov
Staff Acknowledgments	In addition to the contact named above, Teresa F. Tucker (assistant director), Michael A. Alexander, Tonia B. Brown, Neil J. Doherty, Nancy Glover, Franklin D. Jackson, Lee A. McCracken, Dana R. Pon, and Adam Vodraska made key contributions to this report.

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