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# INFLUENZA PANDEMIC

Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential

Statement of Bernice Steinhardt Director, Strategic Issues





Highlights of GAO-09-760T, testimony before the Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration, Senate Committee on Homeland Security and Governmental Affairs

## Why GAO Did This Study

As the recent outbreak of the H1N1 (swine flu) virus underscores, an influenza pandemic remains a real threat to our nation and to the world. Over the past 3 years, GAO has conducted a body of work to help the nation better prepare for a possible pandemic. In a February 2009 report, GAO synthesized the results of this work, pointing out that while the previous administration had taken a number of actions to plan for a pandemic, including developing a national strategy and implementation plan, much more needs to be done, and many gaps in preparedness and planning still remain.

This statement is based on the February 2009 report which synthesized the results of 11 reports and two testimonies covering six thematic areas: (1) leadership, authority, and coordination; (2) detecting threats and managing risks; (3) planning, training, and exercising, (4) capacity to respond and recover; (5) information sharing and communication; and (6) performance and accountability.

### **What GAO Recommends**

The February 2009 report made no new recommendations. This statement discusses the status of GAO's prior recommendations on the nation's planning and preparedness for a pandemic.

View GAO-09-760T or key components. For more information, contact Bernice Steinhardt at (202) 512-6543 or steinhardtb@gao.gov.

## **INFLUENZA PANDEMIC**

# Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential

#### What GAO Found

- Leadership roles and responsibilities for an influenza pandemic need to be
  clarified, tested, and exercised, and existing coordination mechanisms, such
  as critical infrastructure coordinating councils, could be better utilized to
  address challenges in coordination between the federal, state, and local
  governments and the private sector in preparing for a pandemic.
- Efforts are underway to improve the surveillance and detection of pandemicrelated threats in humans and animals, but targeting assistance to countries at the greatest risk has been based on incomplete information, particularly from developing countries.
- Pandemic planning and exercising has occurred at the federal, state, and local government levels, but important planning gaps remain at all levels of government.
- Further actions are needed to address the capacity to respond to and recover from an influenza pandemic, which will require additional capacity in patient treatment space, and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines.
- Federal agencies have provided considerable guidance and pandemic-related information to state and local governments, but could augment their efforts with additional information on state border closures and other topics.
- Performance monitoring and accountability for pandemic preparedness needs strengthening. For example, the May 2006 National Strategy for Pandemic Influenza Implementation Plan does not establish priorities among its 324 action items and does not provide information on the financial resources needed to implement them.

The recent outbreak of the H1N1 influenza virus should serve as a powerful reminder that the threat of a pandemic influenza, which seemed to fade from public awareness in recent years, never really disappeared. While federal agencies have taken action on 13 of GAO's 23 recommendations, 10 of the recommendations that GAO has made over the past 3 years are still not fully implemented. With the possibility that the H1N1 virus could return in a more virulent form in a second wave in the fall or winter, the administration and federal agencies should turn their attention to filling in the planning and preparedness gaps GAO's work has pointed out.

#### Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss key themes from the body of work GAO has developed over the past several years to help the nation better prepare for, respond to, and recover from a possible influenza pandemic. An influenza pandemic remains a real threat to our nation and to the world, as we are witnessing during the current outbreak of the H1N1 (swine flu) virus. The previous administration took a number of actions to plan for a pandemic, including developing a national strategy and implementation plan. However, much more needs to be done, and many gaps in preparedness and planning still remain. At the same time, national priorities have been shifting as a global pandemic has yet to occur, and the nation's financial crisis and other national issues have become more immediate and pressing. Strengthening preparedness for large-scale public health emergencies, such as an influenza pandemic, is one of 13 urgent issues that we identified earlier this year as among those needing the immediate attention of the new administration and Congress.

In the past 3 years, GAO has issued 11 reports and two testimonies on influenza pandemic planning. We synthesized the results of this work in a February 2009 report, which I will discuss in more detail today. We have made 23 recommendations based on the findings from these reports and testimonies, thirteen of which have been acted upon by the responsible federal agencies. While the responsible federal agencies have generally agreed with our recommendations and some actions are underway to address them, 10 recommendations have not yet been fully implemented. While our February 2009 report made no new recommendations, we updated the status of recommendations that had not yet been implemented as of February 2009. Many of the recommendations that remain unimplemented have become even more pressing in light of the very real possibility of a more serious return of the H1N1 virus later this year. Lists of our open recommendations and related GAO products that

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<sup>&</sup>lt;sup>1</sup>GAO's 2009 Congressional and Presidential Transition Web site: http://www.gao.gov/transition\_2009.

<sup>&</sup>lt;sup>2</sup>We also have three pandemic-related reviews underway on the following topics: (1) plans to protect the federal workforce in a pandemic; (2) the status of implementing the *National Strategy for Pandemic Influenza Implementation Plan* (National Pandemic Implementation Plan); and (3) the effect of a pandemic on the telecommunications capacity needed to sustain critical financial market activities.

<sup>&</sup>lt;sup>3</sup>GAO, Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts, GAO-09-334 (Washington, D.C.: Feb. 26, 2009).

are referenced throughout this statement are located in attachments I and  $\scriptstyle\rm II$ 

In summary, my statement will address the following issues which were drawn from the key themes of GAO's pandemic work:

- Leadership roles and responsibilities for an influenza pandemic need
  to be clarified, tested, and exercised, and existing coordination
  mechanisms, such as critical infrastructure coordinating councils,
  could be better utilized to address challenges in coordination between
  the federal, state, and local governments and the private sector in
  preparing for a pandemic.
- Efforts are underway to improve the surveillance and detection of pandemic-related threats in humans and animals, but targeting assistance to countries at the greatest risk has been based on incomplete information, particularly from developing countries.
- Pandemic planning and exercising has occurred at the federal, state, and local government levels, but important planning gaps remain at all levels of government.
- Further actions are needed to address the capacity to respond to and recover from an influenza pandemic, which will require additional capacity in patient treatment space, and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines.
- Federal agencies have provided considerable guidance and pandemicrelated information to state and local governments, but could augment their efforts with additional information on state border closures and other topics.
- Performance monitoring and accountability for pandemic preparedness needs strengthening. For example, the May 2006 National Strategy for Pandemic Influenza Implementation Plan (National Pandemic Implementation Plan) does not establish priorities among its 324 action items and does not provide information on the financial resources needed to implement them.

This statement is largely based on our prior work, which was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient,

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appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Background

Given the consequences of a severe influenza pandemic, in 2006 GAO developed a strategy for our work that would help support Congress's decision making and oversight related to pandemic planning. Our strategy was built on a large body of work spanning two decades, including reviews of government responses to prior disasters such as Hurricanes Andrew and Katrina, the devastation caused by the 9/11 terror attacks, efforts to address the Year 2000 (Y2K) computer challenges, and assessments of public health capacities in the face of bioterrorism and emerging infectious diseases such as Severe Acute Respiratory Syndrome (SARS). The strategy was built around six key themes, as shown in figure 1. While all of these themes are interrelated, our earlier work underscored the importance of leadership, authority, and coordination, a theme that touches on all aspects of preparing for, responding to, and recovering from an influenza pandemic.

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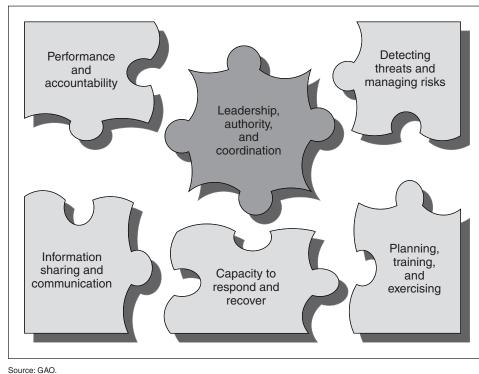


Figure 1: Key Themes of GAO's Pandemic Strategy

Source: GAO.

Influenza pandemic—caused by a novel strain of influenza virus for which there is little resistance and which therefore is highly transmissible among humans—continues to be a real and significant threat facing the United States and the world. Unlike incidents that are discretely bounded in space or time (e.g., most natural or man-made disasters), an influenza pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and pass through communities of all sizes across the nation and the world simultaneously. While the current H1N1 outbreak seems to have been relatively mild, the history of an influenza pandemic suggests it could return in a second wave this fall or winter in a more virulent form. While a pandemic will not directly damage physical infrastructure such as power lines or computer systems, it threatens the operation of critical systems by potentially removing the essential personnel needed to operate them from the workplace for weeks or months. In a severe pandemic, absences attributable to illnesses, the need to care for ill family members, and fear of infection may, according to the Centers for Disease Control and Prevention (CDC), reach a projected 40 percent during the peak weeks of a community outbreak, with lower rates of absence during the

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weeks before and after the peak.<sup>4</sup> In addition, an influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity.

The Homeland Security Council (HSC) took an active approach to this potential disaster by, among other things, issuing the National Strategy for Pandemic Influenza (National Pandemic Strategy) in November 2005, and the National Pandemic Implementation Plan in May 2006. The National Pandemic Strategy is intended to provide a high-level overview of the approach that the federal government will take to prepare for and respond to an influenza pandemic. It also provides expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities. The National Pandemic Implementation Plan is intended to lay out broad implementation requirements and responsibilities among the appropriate federal agencies and clearly define expectations for nonfederal entities. The plan contains 324 action items related to these requirements, responsibilities, and expectations, most of which were to be completed before or by May 2009. HSC publicly reported on the status of the action items that were to be completed by 6 months, 1 year, and 2 years in December 2006, July 2007, and October 2008, respectively. HSC indicated in its October 2008 progress report that 75 percent of the action items have been completed. At the request of the House Homeland Security Committee, we have ongoing work assessing the status of implementing this plan.

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<sup>&</sup>lt;sup>4</sup>GAO, Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy, GAO-07-781 (Washington, D.C.: Aug. 14, 2007).

<sup>&</sup>lt;sup>5</sup>On May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The HSC will be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as an influenza pandemic.

Leadership Roles and Responsibilities Need to Be Clarified and Tested, and Coordination Mechanisms Could Be Better Utilized

Federal government leadership roles and responsibilities for pandemic preparedness and response are evolving, and will require further testing before the relationships among the many federal leadership positions are well understood. Such clarity in leadership is even more crucial now, given the change in administration and the associated transition of senior federal officials. Most of these federal leadership roles involve shared responsibilities between the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS), and it is not clear how these would work in practice. According to the National Pandemic Strategy and Plan, the Secretary of HHS is to lead the federal medical response to a pandemic, and the Secretary of Homeland Security will lead the overall domestic incident management and federal coordination. In addition, under the Post-Katrina Emergency Management Reform Act of 2006, the Administrator of the Federal Emergency Management Agency (FEMA) was designated as the principal domestic emergency management advisor to the President, the HSC, and the Secretary of Homeland Security, adding further complexity to the leadership structure in the case of a pandemic. 6 To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary of Homeland Security predesignated a national Principal Federal Official (PFO) for influenza pandemic and established five pandemic regions each with a regional PFO and Federal Coordinating Officers (FCO) for influenza pandemic. PFOs are responsible for facilitating federal domestic incident planning and coordination, and FCOs are responsible for coordinating federal resources support in a presidentially-declared major disaster or emergency.

However, the relationship of these roles to each other as well as with other leadership roles in a pandemic is unclear. Moreover, as we testified in July 2007, state and local first responders were still uncertain about the need for both FCOs and PFOs and how they would work together in disaster response. Accordingly, we recommended in our August 2007 report on federal leadership roles and the National Pandemic Strategy that DHS and HHS develop rigorous testing, training, and exercises for influenza pandemic to ensure that federal leadership roles and responsibilities for a pandemic are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging

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<sup>&</sup>lt;sup>6</sup>Pub. L. No. 109-295, Title VI.

<sup>&</sup>lt;sup>7</sup>GAO, Homeland Security: Observations on DHS and FEMA Efforts to Prepare for and Respond to Major and Catastrophic Disasters and Address Related Recommendations and Legislation, GAO-07-1142T (Washington, D.C.: July 31, 2007).

challenges. In response to our recommendation, HHS and DHS officials stated in January 2009 that several influenza pandemic exercises had been conducted since November 2007 that involved both agencies and other federal officials, but it is unclear whether these exercises rigorously tested federal leadership roles in a pandemic.

In addition to concerns about clarifying federal roles and responsibilities for a pandemic and how shared leadership roles would work in practice, private sector officials told us that they are unclear about the respective roles and responsibilities of the federal and state governments during a pandemic emergency. The National Pandemic Implementation Plan states that in the event of an influenza pandemic, the distributed nature and sheer burden of the disease across the nation would mean that the federal government's support to any particular community is likely to be limited, with the primary response to a pandemic coming from states and local communities. Further, federal and private sector representatives we interviewed at the time of our October 2007 report identified several key challenges they face in coordinating federal and private sector efforts to protect the nation's critical infrastructure in the event of an influenza pandemic. 9 One of these was a lack of clarity about the roles and responsibilities of federal and state governments on issues such as state border closures and influenza pandemic vaccine distribution.

### Coordination Mechanisms

Mechanisms and networks for collaboration and coordination on pandemic preparedness between federal and state governments and the private sector exist, but they could be better utilized. In some instances, the federal and private sectors are working together through a set of coordinating councils, including sector-specific and cross-sector councils. To help protect the nation's critical infrastructure, DHS created these coordinating councils as the primary means of coordinating government and private sector efforts for industry sectors such as energy, food and

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<sup>&</sup>lt;sup>8</sup>GAO-07-781.

<sup>&</sup>lt;sup>9</sup>GAO, Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination, GAO-08-36 (Washington, D.C.: Oct. 31, 2007).

agriculture, telecommunications, transportation, and water. <sup>10</sup> Our October 2007 report found that DHS has used these critical infrastructure coordinating councils primarily to share pandemic information across sectors and government levels rather than to address many of the challenges identified by sector representatives, such as clarifying the roles and responsibilities between federal and state governments. <sup>11</sup> We recommended in the October 2007 report that DHS encourage the councils to consider and address the range of coordination challenges in a potential influenza pandemic between the public and private sectors for critical infrastructure. DHS concurred with our recommendation and DHS officials informed us at the time of our February 2009 report that the department was working on initiatives to address it, such as developing pandemic contingency plan guidance tailored to each of the critical infrastructure sectors, and holding a series of "webinars" with a number of the sectors.

Federal executive boards (FEB) bring together federal agency and community leaders in major metropolitan areas outside of Washington, D.C., to discuss issues of common interest, including an influenza pandemic. The Office of Personnel Management (OPM), which provides direction to the FEBs, and the FEBs have designated emergency preparedness, security, and safety as an FEB core function. The FEBs' emergency support role with its regional focus may make the boards a valuable asset in pandemic preparedness and response. As a natural outgrowth of their general civic activities and through activities such as hosting emergency preparedness training, some of the boards have established relationships with, for example, federal, state, and local governments; emergency management officials; first responders; and

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<sup>&</sup>lt;sup>10</sup>The 18 critical infrastructure and key resource sectors are: food and agriculture; banking and finance; chemical; commercial facilities; commercial nuclear reactors, materials, and water; dams; defense industrial base; drinking water and water treatment systems; emergency services; energy; governmental facilities; information technology; national monuments and icons; postal and shipping; public health and healthcare; telecommunications; transportation systems; and critical manufacturing. Critical infrastructure are systems and assets, whether physical or virtual, so vital to the United States that their incapacity or destruction would have a debilitating effect on national security, national economic security, and national public health or safety, or any combination of those matters. Key resources are publicly or privately controlled resources essential to minimal operations of the economy or government, including individual targets whose destruction would not endanger vital systems but could create a local disaster or profoundly damage the nation's morale or confidence.

<sup>&</sup>lt;sup>11</sup>GAO-08-36.

health officials in their communities. In a May 2007 report on the FEBs' ability to contribute to emergency operations, we found that many of the selected FEBs included in our review were building capacity for influenza pandemic response within their member agencies and community organizations by hosting influenza pandemic training and exercises. 12 We recommended that, since FEBs are well positioned within local communities to bring together federal agency and community leaders, the Director of OPM work with FEMA to formally define the FEBs' role in emergency planning and response. As a result of our recommendation, FEBs were included in the *National Response Framework* (NRF)<sup>13</sup> in January 2008 as one of the regional support structures that have the potential to contribute to development of situational awareness during an emergency. OPM and FEMA also signed a memorandum of understanding in August 2008 in which FEBs and FEMA agreed to work collaboratively in carrying out their respective roles in the promotion of the national emergency response system.

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<sup>&</sup>lt;sup>12</sup>GAO, The Federal Workforce: Additional Steps Needed to Take Advantage of Federal Executive Boards' Ability to Contribute to Emergency Operations, GAO-07-515 (Washington, D.C.: May 4, 2007).

<sup>&</sup>lt;sup>13</sup>Issued in January 2008 by the Department of Homeland Security (DHS) and effective in March 2008, the NRF is a guide to how the nation conducts all-hazards incident response and replaces the *National Response Plan*. It focuses on how the federal government is organized to support communities and states in catastrophic incidents. The NRF builds upon the National Incident Management System, which provides a national template for managing incidents.

Efforts Are Underway
to Improve the
Surveillance and
Detection of
Pandemic-Related
Threats in Humans
and Animals, but
Targeting Assistance
to Countries at the
Greatest Risk Has
Been Based on
Incomplete
Information

International disease surveillance and detection efforts serve as an early warning system that could prevent the spread of an influenza pandemic outbreak. The United States and its international partners are involved in efforts to improve pandemic surveillance, including diagnostic capabilities, so that outbreaks can be quickly detected. Yet, as reported in 2007, international capacity for surveillance has many weaknesses, particularly in developing countries. <sup>14</sup> As a result, assessments of the risks of the emergence of an influenza pandemic by U.S. agencies and international organizations, which were used to target assistance to countries at risk, were based on insufficiently detailed or incomplete information, limiting their value for comprehensive comparisons of risk levels by country.

Pandemic Planning and Exercising Has Occurred, but Planning Gaps Remain While the National Pandemic Strategy and National Pandemic Implementation Plan are important first steps in guiding national preparedness, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. In our August 2007 report on the National Pandemic Strategy and Implementation Plan, we found that while these documents are an important first step in guiding national preparedness, they do not fully address all six characteristics of an effective national strategy, as identified in our work. <sup>15</sup> The documents fully address only one of the six characteristics, by reflecting a clear description and understanding of problems to be addressed. Further, the

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<sup>&</sup>lt;sup>14</sup>GAO, Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic, GAO-08-92 (Washington, D.C.: Dec. 21, 2007).

<sup>&</sup>lt;sup>15</sup>The six characteristics of an effective national strategy include (1) purpose, scope, and methodology; (2) problem definition and risk assessment; (3) goals, subordinate objectives; activities, and performance measures; (4) resources, investments, and risk management; (5) organizational roles, responsibilities, and coordination; and (6) integration and implementation. GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

National Pandemic Strategy and Implementation Plan do not address one characteristic at all; they contain no discussion of what it will cost, where resources will be targeted to achieve the maximum benefits, and how benefits, risks, and costs will be balanced. Moreover, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints. Although the remaining four characteristics are partially addressed, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. For example, state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the National Pandemic Implementation Plan, even though it relies on these stakeholders' efforts. Stakeholder involvement during the planning process is important to ensure that the federal government's and nonfederal entities' responsibilities are clearly understood and agreed upon. Further, relationships and priorities among actions were not clearly described, performance measures were not always linked to results, and insufficient information was provided about how the documents are integrated with other response-related plans, such as the NRF. We recommended that HSC establish a process for updating the National Pandemic Implementation Plan and that the updated plan should address these and other gaps. HSC did not comment on our recommendation and has not indicated if it plans to implement it.

# State and Local Pandemic Planning

We reported in June 2008 that, according to CDC, all 50 states and the three localities that received federal pandemic funds have developed influenza pandemic plans and conducted pandemic exercises in accordance with federal funding guidance. A portion of the \$5.62 billion that Congress appropriated in supplemental funding to HHS for pandemic preparedness in 2006—\$600 million—was allocated for state and local planning and exercising. All of the 10 localities that we reviewed in depth had also developed plans and conducted exercises, and had incorporated lessons learned from pandemic exercises into their planning. <sup>16</sup> However, an HHS-led interagency assessment of states' plans found on average that

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<sup>&</sup>lt;sup>16</sup>We conducted site visits to the five most populous states—California, Florida, Illinois, New York, and Texas—for a number of reasons, including that these states constituted over one-third of the United States population, received over one-third of the total funding from HHS and DHS that could be used for planning and exercising efforts, and were likely entry points for individuals coming from another country given that the states either bordered Mexico or Canada or contained major ports, or both. Within each state, we also interviewed officials at 10 localities, which consisted of five urban areas and five rural counties.

states had "many major gaps" in their influenza pandemic plans in 16 of 22 priority areas, such as school closure policies and community containment, which are community-level interventions designed to reduce the transmission of a pandemic virus. The remaining six priority areas were rated as having "a few major gaps." Subsequently, HHS led another interagency assessment of state influenza pandemic plans and reported in January 2009 that although they had made important progress, most states still had major gaps in their pandemic plans. <sup>17</sup>

As we had reported in June 2008, HHS, in coordination with DHS and other federal agencies, had convened a series of regional workshops for states in five influenza pandemic regions across the country. Because these workshops could be a useful model for sharing information and building relationships, we recommended that HHS and DHS, in coordination with other federal agencies, convene additional meetings with states to address the gaps in the states' pandemic plans. As reported in February 2009, HHS and DHS generally concurred with our recommendation, but have not yet held these additional meetings. HHS and DHS indicated at the time of our February 2009 report that while no additional meetings had been planned, states will have to continuously update their pandemic plans and submit them for review.

We have also reported on the need for more guidance from the federal government to help states and localities in their planning. In June 2008, we reported that although the federal government has provided a variety of guidance, officials of the states and localities we reviewed told us that they would welcome additional guidance from the federal government in a number of areas, such as community containment, to help them to better plan and exercise for an influenza pandemic. Other state and local officials have identified similar concerns. According to the National Governors Association's (NGA) September 2008 issue brief on states' pandemic preparedness, states are concerned about a wide range of school-related issues, including when to close schools or dismiss students, how to maintain curriculum continuity during closures, and how to identify the appropriate time at which classes could resume. <sup>18</sup> NGA also reported that states generally have very little awareness of the status of disease

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<sup>&</sup>lt;sup>17</sup>DHS and HHS and other agencies, Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council (Washington, D.C.: Jan. 2009).

<sup>&</sup>lt;sup>18</sup>National Governors Association Center for Best Practices, *Issue Brief: Pandemic Preparedness in the States—An Assessment of Progress and Opportunity* (Sept. 2008).

outbreaks, either in real time or in near real time, to allow them to know precisely when to recommend a school closure or reopening in a particular area. NGA reported that states wanted more guidance in the following areas: (1) workforce policies for the health care, public safety, and private sectors; (2) schools; (3) situational awareness such as information on the arrival or departure of a disease in a particular state, county, or community; (4) public involvement; and (5) public-private sector engagement.

# Private Sector Pandemic Planning

The private sector has also been planning for an influenza pandemic, but many challenges remain. To better protect critical infrastructure, federal agencies and the private sector have worked together across a number of sectors to plan for a pandemic, including developing general pandemic preparedness guidance, such as checklists for continuity of business operations during a pandemic. However, federal and private sector representatives have acknowledged that sustaining preparedness and readiness efforts for an influenza pandemic is a major challenge, primarily because of the uncertainty associated with a pandemic, limited financial and human resources, and the need to balance pandemic preparedness with other, more immediate, priorities, such as responding to outbreaks of foodborne illnesses in the food sector and, now, the effects of the financial crisis.

In our March 2007 report on preparedness for an influenza pandemic in one of these critical infrastructure sectors—financial markets—we found that despite significant progress in preparing markets to withstand potential disease pandemics, securities and banking regulators could take additional steps to improve the readiness of the securities markets. <sup>19</sup> The seven organizations that we reviewed—which included exchanges, clearing organizations, and payment-system processors—were working on planning and preparation efforts to reduce the likelihood that a worldwide influenza pandemic would disrupt their critical operations. However, only one of the seven had completed a formal plan. To increase the likelihood that the securities markets will be able to function during a pandemic, we recommended that the Chairman, Federal Reserve; the Comptroller of the Currency; and the Chairman, Securities and Exchange Commission (SEC);

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<sup>&</sup>lt;sup>19</sup>GAO, Financial Market Preparedness: Significant Progress Has Been Made, but Pandemic Planning and Other Challenges Remain, GAO-07-399 (Washington, D.C.: Mar. 29, 2007).

consider taking additional actions to ensure that market participants adequately prepare for a pandemic outbreak. In response to our recommendation, the Federal Reserve and the Office of the Comptroller of the Currency, in conjunction with the Federal Financial Institutions Examination Council and the SEC, directed all banking organizations under their supervision to ensure that the pandemic plans the financial institutions have in place are adequate to maintain critical operations during a severe outbreak. SEC issued similar requirements to the major securities industry market organizations.

Further Actions Are Needed to Address the Capacity to Respond to and Recover from an Influenza Pandemic Improving the nation's response capability to catastrophic disasters, such as an influenza pandemic, is essential. Following a mass casualty event, health care systems would need the ability to adequately care for a large number of patients or patients with unusual or highly specialized medical needs. The ability of local or regional health care systems to deliver services could be compromised, at least in the short term, because the volume of patients would far exceed the available hospital beds, medical personnel, pharmaceuticals, equipment, and supplies. Further, in natural and man-made disasters, assistance from other states may be used to increase capacity, but in a pandemic, states would likely be reluctant to provide assistance to each other due to scarce resources and fears of infection.

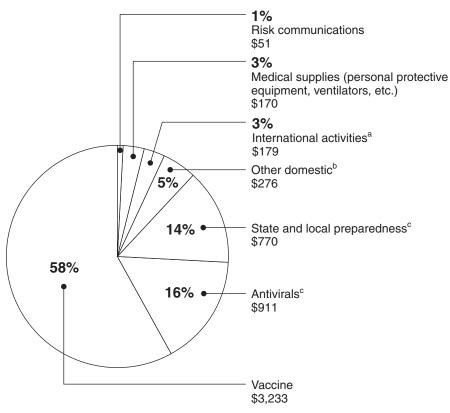
The \$5.62 billion that Congress provided in supplemental funding to HHS in 2006 was for, among other things, (1) monitoring disease spread to support rapid response, (2) developing vaccines and vaccine production capacity, (3) stockpiling antivirals and other countermeasures, (4) upgrading state and local capacity, and (5) upgrading laboratories and research at CDC. Figure 2 shows that the majority of this supplemental funding—about 77 percent—was allocated for developing antivirals and vaccines for a pandemic, and purchasing medical supplies. Also, a portion of the funding for state and local preparedness—\$170 million—was allocated for state antiviral purchases for their state stockpiles.<sup>20</sup>

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<sup>&</sup>lt;sup>20</sup>Supplemental funding for pandemic preparedness and response is provided in both the Senate- and House-passed versions of a 2009 supplemental appropriation currently under consideration. The Senate bill includes \$1.5 billion as requested by the administration and the House bill provides a total of \$2.05 billion.

Figure 2: HHS Influenza Pandemic Supplemental Appropriations, Fiscal Year 2006

#### **Dollars in millions**



Total \$5,590<sup>d</sup>

Source: GAO, HHS.

Notes: Data are from HHS, Pandemic Planning Update III: A Report from Secretary Michael O. Leavitt (Washington, D.C.: Nov. 13, 2006).

<sup>a</sup>International activities includes: international preparedness, surveillance, response, and research.

An outbreak will require additional capacity in many areas, including the procurement of additional patient treatment space and the acquisition and distribution of medical and other critical supplies, such as antivirals and

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<sup>&</sup>lt;sup>b</sup>Other domestic includes: surveillance, quarantine, lab capacity, and rapid tests.

<sup>°</sup>State and local preparedness includes funding for state subsidies of antiviral drugs.

<sup>&</sup>lt;sup>d</sup>This figure does not include \$30 million in supplemental funding that was transferred to the U.S. Agency for International Development.

vaccines for an influenza pandemic.<sup>21</sup> In a severe pandemic, the demand would exceed the available hospital bed capacity, which would be further challenged by the existing shortages of health care providers and their potential high rates of absenteeism. In addition, the availability of antivirals and vaccines could be inadequate to meet demand due to limited production, distribution, and administration capacity.

The federal government has provided some guidance and funding to help states plan for additional capacity. For example, the federal government provided guidance for states to use when preparing for medical surge and on prioritizing target groups for an influenza pandemic vaccine. Some state officials reported, however, that they had not begun work on altered standards of care guidelines, that is, for providing care while allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in mass casualty event, or had not completed drafting guidelines, because of the difficulty of addressing the medical, ethical, and legal issues involved. We recommended that HHS serve as a clearinghouse for sharing among the states altered standards of care guidelines developed by individual states or medical experts. HHS did not comment on the recommendation, and it has not indicated if it plans to implement it. 22 Further, in our June 2008 report on state and local planning and exercising efforts for an influenza pandemic, we found that state and local officials reported that they wanted federal influenza pandemic guidance on facilitating medical surge, which was also one of the areas that the HHS-led assessment rated as having "many major gaps" nationally among states' influenza pandemic plans. 23

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<sup>&</sup>lt;sup>21</sup>Antivirals can prevent or reduce the severity of a viral infection, such as influenza. Vaccines are used to stimulate the production of an immune system response to protect the body from disease.

<sup>&</sup>lt;sup>22</sup>GAO-08-668.

<sup>&</sup>lt;sup>23</sup>GAO-08-539.

Federal Agencies
Have Provided
Considerable
Guidance and
Pandemic-Related
Information, but
Could Augment Their
Efforts

The National Pandemic Implementation Plan emphasizes that government and public health officials must communicate clearly and continuously with the public throughout a pandemic. Accordingly, HHS, DHS, and other federal agencies have shared pandemic-related information in a number of ways, such as through Web sites, guidance, and state summits and meetings, and are using established networks, including coordinating councils for critical infrastructure protection, to share information about pandemic preparedness, response, and recovery. Federal agencies have established an influenza pandemic Web site (www.pandemicflu.gov) and disseminated pandemic preparedness checklists for workplaces, individuals and families, schools, health care and community organizations, and state and local governments.

However, state and local officials from all of the states and localities we interviewed wanted additional federal influenza pandemic guidance from the federal government on specific topics, such as implementing community interventions, fatality management, and facilitating medical surge. Although the federal government has issued some guidance, it may not have reached state and local officials or may not have addressed the particular concerns or circumstances of the state and local officials we interviewed. In addition, private sector officials have told us that they would like clarification about the respective roles and responsibilities of the federal and state governments during an influenza pandemic emergency, such as for state border closures and influenza pandemic vaccine distribution.

Performance
Monitoring and
Accountability For
Pandemic
Preparedness Needs
Strengthening

While the National Pandemic Strategy and Implementation Plan identify overarching goals and objectives for pandemic planning, the documents are not altogether clear on the roles, responsibilities, and requirements to carry out the plan. Some of the action items in the National Pandemic Implementation Plan, particularly those that are to be completed by state, local, and tribal governments or the private sector, do not identify an entity responsible for carrying out the action. Most of the plan's performance measures consist of actions to be completed, such as disseminating guidance, but the measures are not always clearly linked with intended results. This lack of clear linkages makes it difficult to ascertain whether progress has in fact been made toward achieving the national goals and objectives described in the National Pandemic Strategy and Implementation Plan. Without a clear linkage to anticipated results, these measures of activities do not give an indication of whether the purpose of the activity is achieved.

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In addition, as discussed earlier, the National Pandemic Implementation Plan does not establish priorities among its 324 action items, which becomes especially important as agencies and other parties strive to effectively manage scarce resources and ensure that the most important steps are accomplished. Moreover, the National Pandemic Strategy and Implementation Plan do not provide information on the financial resources needed to implement them, which is one of six characteristics of an effective national strategy that we have identified. As a result, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints.

## Concluding Observations

The recent outbreak of H1N1 influenza virus should serve as a powerful reminder that the threat of a pandemic influenza, which seemed to fade from public awareness in recent years, never really disappeared. While federal agencies have taken action on many of our recommendations, almost half the recommendations that we have made over the past 3 years are still not fully implemented. For one thing, it is essential, given the change in administration and the associated transition of senior federal officials, that the shared leadership roles that have been established between HHS and DHS along with other responsible federal officials, are tested in rigorous tests and exercises. Likewise, DHS should continue to work with other federal agencies and private sector members of the critical infrastructure coordinating councils to help address the challenges of coordination and clarify roles and responsibilities of federal and state governments. DHS and HHS should also, in coordination with other federal agencies, continue to work with states and local governments to help them address identified gaps in their pandemic planning. Moreover, the 3-year period covered by the National Pandemic Implementation Plan is now over and it will be important for HSC to establish a process for updating the National Pandemic Implementation Plan so that the updated plan can address the gaps we have identified, as well as lessons learned from the current H1N1 outbreak.

Pandemic influenzas, as I noted earlier, differ from other types of disasters in that they are not necessarily discrete events. While the current H1N1 outbreak seems to have been relatively mild, it could return in a second wave this fall or winter in a more virulent form. Given this risk, the administration and federal agencies should turn their attention to filling in some of the gaps our work has pointed out, while time is still on our side.

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Chairman Pryor, Senator Ensign, and Members of the Subcommittee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

## Contacts and Staff Acknowledgements

For further information regarding this statement, please contact Bernice Steinhardt, Director, Strategic Issues, at (202) 512-6543 or steinhardtb@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this testimony include Sarah Veale, Assistant Director; Maya Chakko; Melissa Kornblau; Susan Sato; Ellen Grady; Karin Fangman; and members of GAO's Pandemic Working Group.

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# Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions, GAO-08-671, September 30, 2008	The Secretary of HHS should expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and prepandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine.	In December 2008, HHS released final guidance on antiviral drug use during an influenza pandemic. HHS officials informed us that they are drafting the guidance on pre-pandemic influenza vaccination.
Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning, GAO-08-539, June 19, 2008	The Secretaries of HHS and Homeland Security should, in coordination with other federal agencies, convene additional meetings of the states in the five federal influenza pandemic regions to help them address identified gaps in their planning.	HHS and DHS officials indicated that while no additional meetings are planned at this time, states will have to continuously update their pandemic plans and submit them for review.
Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination, GAO-08-36, October 31, 2007	The Secretary of Homeland Security should work with sector-specific agencies and lead efforts to encourage the government and private sector members of the councils to consider and help address the challenges that will require coordination between the federal and private sectors involved with critical infrastructure and within the various sectors, in advance of, as well as during, a pandemic.	DHS officials informed us that the department is working on initiatives, such as developing pandemic contingency plan guidance tailored to each of the critical infrastructure sectors, and holding a series of webinars with a number of the sectors.
Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy, GAO-07-781, August 14, 2007  Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning, GAO-07-1257T, September 26, 2007	(1) The Secretaries of Homeland Security and HHS should work together to develop and conduct rigorous testing, training, and exercises for an influenza pandemic to ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges. Once the leadership roles have been clarified through testing, training, and exercising, the Secretaries of Homeland Security and HHS should ensure that these roles are clearly understood by state, local, and tribal governments; the private and nonprofit sectors; and the international community.	(1) HHS and DHS officials stated that several influenza pandemic exercises had been conducted since November 2007 that involved both agencies and other federal officials, but it is unclear whether these exercises rigorously tested federal leadership roles in a pandemic.

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Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
	(2) The Homeland Security Council (HSC) should establish a specific process and time frame for updating the National Pandemic Implementation Plan. The process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The National Pandemic Implementation Plan should also be improved by including the following information in the next update: (a) resources and investments needed to complete the action items and where they should be targeted, (b) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (c) clearer linkages with other strategies and plans, and (d) clearer descriptions of relationships or priorities among action items and greater use of outcome-focused performance measures.	(2) HSC did not comment on the recommendation and has not indicated if it plans to implement it.
Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response, GAO-07-652, June 11, 2007	(1) The Secretaries of Agriculture and Homeland Security should develop a memorandum of understanding that describes how the U.S. Department of Agriculture (USDA) and DHS will work together in the event of a declared presidential emergency or major disaster, or an Incident of National Significance, and test the effectiveness of this coordination during exercises.	(1) Both USDA and DHS officials told us that they have taken preliminary steps to develop additional clarity and better define their coordination roles. For example the two agencies meet regularly to discuss such coordination.
	(2) The Secretary of Agriculture should, in consultation with other federal agencies, states, and the poultry industry, identify the capabilities necessary to respond to a probable scenario or scenarios for an outbreak of highly pathogenic avian influenza. The Secretary of Agriculture should also use this information to develop a response plan that identifies the critical tasks for responding to the selected outbreak scenario and, for each task, identifies the responsible entities, the location of resources needed, time frames, and completion status. Finally, the Secretary of Agriculture should test these capabilities in ongoing exercises to identify gaps and ways to overcome those gaps.	(2) USDA officials told us that it has created a draft preparedness and response plan that identifies federal, state, and local actions, timelines, and responsibilities for responding to highly pathogenic avian influenza, but the plan has not been issued yet.

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Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
	(3) The Secretary of Agriculture should develop standard criteria for the components of state response plans for highly pathogenic avian influenza, enabling states to develop more complete plans and enabling USDA officials to more effectively review them.	(3) USDA told us that it has drafted large volumes of guidance documents that are available on a secure Web site. However, the guidance is still under review and it is not clear what standard criteria from these documents USDA officials and states should apply when developing and reviewing plans.
	(4) The Secretary of Agriculture should focus additional work with states on how to overcome potential problems associated with unresolved issues, such as the difficulty in locating backyard birds and disposing of carcasses and materials	(4) USDA officials have told us that the agency has developed online tools to help states make effective decisions about carcass disposal. In addition, USDA has created a secure Internet site that contains draft guidance for disease response, including highly pathogenic avian influenza, and it includes a discussion about many of the unresolved issues.
	(5) The Secretary of Agriculture should determine the amount of antiviral medication that USDA would need in order to protect animal health responders, given various highly pathogenic avian influenza scenarios. The Secretary of Agriculture should also determine how to obtain and provide supplies within 24 hours of an outbreak.	(5) USDA officials told us that the National Veterinary Stockpile now contains enough antiviral medication to protect 3,000 animal health responders for 40 days. However, USDA has yet to determine the number of individuals that would need medicine based on a calculation of those exposed to the virus under a specific scenario. Further, USDA officials told us that a contract for additional medication for the stockpile has not yet been secured, which would better ensure that medications are available in the event of an outbreak of highly pathogenic avian influenza.

Source: GAO.

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# **Attachment II: Related GAO Products**

Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions. GAO-08-671. Washington, D.C.: September 30, 2008.

Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning. GAO-08-539. Washington, D.C.: June 19, 2008.

Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources. GAO-08-668. Washington, D.C.: June 13, 2008.

Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic. GAO-08-92. Washington, D.C.: December 21, 2007.

Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination. GAO-08-36. Washington, D.C.: October 31, 2007.

Influenza Pandemic: Federal Executive Boards' Ability to Contribute to Pandemic Preparedness. GAO-07-1259T. Washington, D.C.: September 28, 2007.

Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning. GAO-07-1257T. Washington, D.C.: September 26, 2007.

Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy. GAO-07-781. Washington, D.C.: August 14, 2007.

Emergency Management Assistance Compact: Enhancing EMAC's Collaborative and Administrative Capacity Should Improve National Disaster Response. GAO-07-854. Washington, D.C.: June 29, 2007.

Influenza Pandemic: DOD Combatant Commands' Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation. GAO-07-696. Washington, D.C.: June 20, 2007.

Influenza Pandemic: Efforts to Forestall Onset Are Under Way; Identifying Countries at Greatest Risk Entails Challenges. GAO-07-604. Washington, D.C.: June 20, 2007.

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#### **Attachment II: Related GAO Products**

Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response. GAO-07-652. Washington, D.C.: June 11, 2007.

The Federal Workforce: Additional Steps Needed to Take Advantage of Federal Executive Boards' Ability to Contribute to Emergency Operations. GAO-07-515. Washington, D.C.: May 4, 2007.

Financial Market Preparedness: Significant Progress Has Been Made, but Pandemic Planning and Other Challenges Remain. GAO-07-399. Washington, D.C.: March 29, 2007.

Influenza Pandemic: DOD Has Taken Important Actions to Prepare, but Accountability, Funding, and Communications Need to be Clearer and Focused Departmentwide. GAO-06-1042. Washington, D.C.: September 21, 2006.

Catastrophic Disasters: Enhanced Leadership, Capabilities, and Accountability Controls Will Improve the Effectiveness of the Nation's Preparedness, Response, and Recovery System. GAO-06-618. Washington, D.C.: September 6, 2006.

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