INFLUENZA PANDEMIC

Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning

Statement of Bernice Steinhardt, Director Strategic Issues
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What GAO Found

The administration has taken an active approach to this potential disaster by, among other things, issuing a National Strategy for Pandemic Influenza (Strategy) in November 2005, and a National Strategy for Pandemic Influenza Implementation Plan (Plan) in May 2006. However, much more needs to be done to ensure that the Strategy and Plan are viable and can be effectively implemented in the event of an influenza pandemic.

Key federal leadership roles and responsibilities for preparing for and responding to a pandemic continue to evolve and will require further clarification and testing before the relationships of the many leadership positions are well understood. Most of these leadership roles involve shared responsibilities and it is unclear how they will work in practice. Because initial actions may help limit the spread of an influenza virus, the effective exercise of shared leadership roles and responsibilities could have substantial consequences. However, only one national, multi-sector pandemic-related exercise has been held, and that was prior to issuance of the Plan.

The Strategy and Plan do not fully address the characteristics of an effective national strategy and contain gaps that could hinder the ability of key stakeholders to effectively execute their responsibilities. Specifically, some of the gaps include:

- The Strategy and Plan do not address resources, investments, and risk management and consequently do not provide a picture of priorities or how adjustments might be made in view of limited resources.
- State and local jurisdictions were not directly involved in developing the Plan, even though they would be on the front lines in a pandemic.
- Relationships and priorities among action items are not always clear.
- Performance measures are focused on activities that are not always linked to results.
- The linkage of the Strategy and Plan with other key plans is unclear.
- The Plan does not contain a process for monitoring and reporting on progress.
- The Plan does not describe an overall framework for accountability and oversight and does not clarify how responsible officials would share leadership responsibilities.
- Procedures and time frames for updating and revising the Plan were not established.

These gaps can affect the usefulness of these planning documents for those with key roles to play. Also, the lack of mechanisms for future updates or progress assessments limit opportunities for congressional decision makers and the public to assess the extent of progress being made or to consider what areas or actions may be need additional attention. Although the Homeland Security Council (HSC) publicly reported on the status of action items in December 2006 and July 2007, it is unclear when the next report will be issued or how much information will be released.
Mr. Chairman and Members of the Subcommittee:

I am pleased to appear here today to discuss the federal government’s efforts to prepare for and respond to a possible influenza pandemic. An influenza pandemic is a real and significant threat facing the United States and the world. Although the timing and severity of the next pandemic is unpredictable, there is widespread agreement that a pandemic will occur at some point. Unlike incidents that are discretely bounded in space or time (such as a storm or a terrorist attack), a pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and could pass through communities of all sizes across the nation and the world simultaneously.

Today, I will discuss (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic, (2) our assessment of the National Strategy for a Pandemic Influenza (Strategy) and the Implementation Plan for the National Strategy for a Pandemic Influenza (Plan), and (3) opportunities to increase the clarity of federal leadership roles and responsibilities and improve pandemic planning.

This statement is based on our August 14, 2007, report, requested by the Ranking Member, Senate Budget Committee; the Chairman and Ranking Member, House Committee on Oversight and Government Reform; and the Chairman, House Committee on Homeland Security.¹ Our objectives in that report were to address the extent to which (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic are clearly defined and documented and (2) the Strategy and the Plan address the characteristics of an effective national strategy; we conducted our work in accordance with generally accepted government auditing standards. We analyzed relevant documents, interviewed cognizant federal officials, and assessed the Strategy and Plan to determine the extent to which they jointly addressed the six desirable characteristics of an effective national strategy that we developed and used in previous work.²


While national strategies necessarily vary in content, the six characteristics we identified apply to all such planning documents and can help ensure that they are effective management tools.

In summary, although the administration has taken an active approach to this potential disaster by developing a Strategy and Plan, and has undertaken a number of other efforts, much more needs to be done to ensure that the Plan is more viable and can be effectively implemented in the event of an influenza pandemic.

- Key federal leadership roles and responsibilities for preparing for and responding to a pandemic continue to evolve and will require further clarification and testing before the relationships of the many leadership positions are well understood. Most of these leadership roles involve shared responsibilities, and it is not clear how these would work in practice. Because initial actions may help limit the spread of an influenza virus, the effective exercise of shared leadership roles and responsibilities could have substantial consequences. However, only one national, multisector pandemic-related exercise has been held, and that was prior to issuance of the Plan.

- The Strategy and Plan do not fully address the characteristics of an effective national strategy and contain gaps that could hinder the ability of key stakeholders to effectively execute their responsibilities. In addition to the fact that the Strategy and Plan do not clarify how responsible officials will share leadership responsibilities, they do not include a description of the resources required to implement the Plan, and consequently do not provide a picture of priorities or how adjustments might be made in view of resource constraints. Additionally, state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the Plan, and the linkage of the Strategy and Plan with other key plans is unclear.

The gaps in the Strategy and Plan are particularly troubling because they can affect the usefulness of these planning documents for those with key roles to play and, with no mechanisms for future updates or progress assessments, limit opportunities for congressional decision makers and the public to assess the extent of progress being made or to consider what areas or actions may need additional attention.

We made two recommendations in our August 2007 report to address these concerns.
We recommended that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza 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 Health and Human Services should ensure that these roles and responsibilities are clearly understood by nonfederal partners.

Our report also recommended that the Homeland Security Council (HSC) establish a specific process and time frame for updating the Plan. This process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The next update of the Plan could be improved by addressing the gaps we identified. The Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) concurred with the first recommendation. The HSC did not comment on the draft report or our recommendation.

Background

To address the potential threat of an influenza pandemic, the President and his HSC issued two planning documents. The Strategy was issued in November 2005 and 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 articulates expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities.

The Plan was issued in May 2006 and is intended to lay out broad implementation requirements and responsibilities among the appropriate federal agencies and clearly define expectations for nonfederal entities. The Plan includes 324 action items related to these requirements, responsibilities, and expectations and most of them are to be completed before or by May 2009. It is intended to support the broad framework and goals articulated in the Strategy by outlining specific steps that federal departments and agencies should take to achieve these goals. It also describes expectations regarding preparedness and response efforts of state and local governments, tribal entities, the private sector, global partners, and individuals. The Plan’s chapters cover categories of actions that are intended to address major considerations raised by a pandemic, including protecting human and animal health; transportation and borders; and international, security, and institutional considerations.
Federal Leadership Roles Are Unclear, Evolving, and Untested

Several federal leadership roles involve shared responsibilities for preparing for and responding to an influenza pandemic, including the Secretaries of Health and Human Services and Homeland Security, the Administrator of the Federal Emergency Management Agency (FEMA), a national Principal Federal Official (PFO), and regional PFOs and Federal Coordinating Officers (FCO). Many of these leadership roles and responsibilities have not been tested under pandemic scenarios, leaving unclear how all of these new and developing relationships would work.

Federal Leadership Roles and Responsibilities Are Unclear and Evolving

The Strategy and Plan do not clarify the specific leadership roles and responsibilities for a pandemic. Instead, they restate the existing leadership roles and responsibilities, particularly for the Secretaries of Homeland Security and Health and Human Services, prescribed in the National Response Plan (NRP)—an all-hazards plan for emergencies ranging from hurricanes to wildfires to terrorist attacks. However, the leadership roles and responsibilities prescribed under the NRP need to operate somewhat differently because of the characteristics of a pandemic that distinguish it from other emergency incidents. For example, because a pandemic influenza is likely to occur in successive waves, planning has to consider how to sustain response mechanisms for several months to over a year—issues that are not clearly addressed in the Plan.

In addition, the distributed nature of a pandemic, as well as the sheer burden of disease across the nation, means that the support states, localities, and tribal entities can expect from the federal government would be limited in comparison to the aid it mobilizes for geographically and temporarily bounded disasters like earthquakes and hurricanes. Consequently, legal authorities, roles and responsibilities, and lines of authority at all levels of government must be clearly defined, effectively communicated, and well understood to facilitate rapid and effective decision making. This is also important for public and private sector organizations and international partners so everyone can better understand what is expected of them before and during a pandemic.

The Strategy and Plan state that the Secretary of Health and Human Services is responsible for leading the medical response in a pandemic, while the Secretary of Homeland Security is responsible for overall domestic incident management and federal coordination. However, since a pandemic extends well beyond health and medical boundaries, to include sustaining critical infrastructure, private sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations, it is not clear when, in a pandemic, the Secretary
of Health and Human Services would be in the lead and when the Secretary of Homeland Security would lead.

A pandemic could threaten our critical infrastructure, such as the capability to deliver electricity or food, by removing essential personnel from the workplace for weeks or months. The extent to which this would be considered a medical response with the Secretary of Health and Human Services in the lead, or when it would be under the Secretary of Homeland Security’s leadership as part of his/her responsibility for ensuring that critical infrastructure is protected, is unclear. According to HHS officials we interviewed, resolving this ambiguity will depend on several factors, including how the outbreak occurs and the severity of the pandemic. Although DHS and HHS officials emphasize that they are working together on a frequent basis, these roles and responsibilities have not been thoroughly tested and exercised.

Moreover, under the Post-Katrina Emergency Management Reform Act of 2006 (referred to as the Post-Katrina Reform Act in this testimony), the FEMA Administrator was designated 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. The act also gives the Administrator responsibility for carrying out a national exercise program to test and evaluate national preparedness for responding to all-hazards, including an influenza pandemic.

Other evolving federal leadership roles include those of PFOs and FCOs. To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary of Homeland Security predesignated a national PFO and established five pandemic regions each with a regional PFO and FCO. 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.

U.S. Coast Guard and FEMA officials we met with recognized that planning for and responding to a pandemic would require different operational leadership roles and responsibilities than for most other

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3Pub. L. No. 109-295, Title VI.
emergencies. For example, a FEMA official said that given the number of people who would be involved in responding to a pandemic, collaboration between HHS, DHS, and FEMA would need to be greater than for any other past emergencies. Officials are starting to build on these relationships. For example, some of the federal officials with leadership roles for an influenza pandemic met during the week of March 19, 2007, to continue to identify issues and begin developing solutions. One of the participants told us that although additional coordination meetings are needed, it may be challenging since there is no dedicated funding for the staff working on pandemic issues to participate in these and other related meetings.

It is also unclear whether the newly established national and regional positions for a pandemic will further clarify leadership roles in light of existing and newly emerging plans and issues. For example, in 2006, DHS made revisions to the NRP and released a Supplement to the Catastrophic Incident Annex—both designed to further clarify federal roles and responsibilities and relationships among federal, state, and local governments and responders. However, we reported in February 2007 that these revisions had not been tested and there was little information available on the extent to which these and other actions DHS was taking to improve readiness were operational.\footnote{GAO, \textit{Homeland Security: Management and Programmatic Challenges Facing the Department of Homeland Security}, GAO-07-398T (Washington, D.C.: Feb. 6, 2007).}

We also reported in May 2007 that FEMA has predesignated five teams of FCOs and PFOs in the Gulf Coast and eastern seaboard states at risk of hurricanes. However, there is still some question among state and local first responders about the need for both positions and how they will work together in disaster response.\footnote{GAO, \textit{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-07-835T (Washington, D.C.: May 15, 2007).}

More recently, DHS reviewed the NRP and its supplemental documents. One of the issues this review intended to address was clarifying roles and responsibilities of key structures, positions, and levels of government, including the role of the PFO and that position’s current lack of operational authority over the FCO during an emergency. On September 10, 2007, DHS released a draft National Response Framework to replace the NRP, for public comment. Comments on the framework are due October 11, 2007, and comments on the supplemental documents, such as...
revised Emergency Support Function specifications, are due by November 9, 2007.

Exercising and Testing of Plans Is Crucial in Ensuring Capacity

Disaster planning, including for a pandemic influenza, needs to be tested and refined with a rigorous and robust exercise program to expose weaknesses in plans and allow planners to refine them. Exercises—particularly for the type and magnitude of emergency incidents such as a severe influenza pandemic for which there is little actual experience—are essential for developing skills and identifying what works well and what needs further improvement. Our prior work examining the preparation for and response to Hurricane Katrina highlighted the importance of realistic exercises to test and refine assumptions, capabilities, and operational procedures, and build upon strengths.6

While pandemic influenza scenarios have been used to exercise specific response elements, such as the distribution of stockpiled medications at specific locations or jurisdictions, no national exercises have tested the new federal leadership structure for pandemic influenza.7 The only national multisector pandemic exercise to date was a tabletop simulation conducted by members of the cabinet in December 2005. This tabletop exercise was prior to the release of the Plan in May 2006, the establishment of a national PFO and regional PFO and FCO positions for a pandemic, and enactment of the Post-Katrina Reform Act.

Gaps in the National Strategy and Plan Limit Their Usefulness

Our work found that the Strategy and Plan do not address all of the characteristics of an effective national strategy as identified in our prior work. While national strategies necessarily vary in content, the six characteristics we identified apply to all such planning documents and can help ensure that they are effective management tools. Gaps and deficiencies in these documents are particularly troubling in that a pandemic represents a complex challenge that will require the full understanding and collaboration of a multitude of entities and individuals. The extent to which these documents, that are to provide an overall framework to ensure preparedness and response to a pandemic influenza,


fail to adequately address key areas could have critical impact on whether the public and key stakeholders have a clear understanding and can effectively execute their roles and responsibilities.

Specifically, we found that the documents fully address only one of the six characteristics of an effective national strategy—problem definition and risk assessment—because they identified the potential problems associated with a pandemic as well as potential threats, challenges, and vulnerabilities. The Strategy and Plan did not address one characteristic—resources, investments, and risk management—because they did not discuss the financial resources and investments needed to implement the actions called for and therefore, do not provide a picture of priorities or how adjustments might be made in view of resource constraints. They partially addressed the four remaining characteristics, as shown in table 1.

<table>
<thead>
<tr>
<th>Desirable characteristic</th>
<th>Addresses</th>
<th>Partially addresses</th>
<th>Does not address</th>
</tr>
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<tr>
<td>Clear purpose, scope, and methodology</td>
<td>X</td>
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<tr>
<td>Problem definition and risk assessment</td>
<td>X</td>
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<td>Goals, subordinate objectives, activities, and performance measures</td>
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<td>Resources, investments, and risk management</td>
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<td>Organizational roles, responsibilities, and coordination</td>
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<td>Integration and implementation</td>
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Source: GAO analysis of the National Strategy for Pandemic Influenza and Implementation Plan for the National Strategy for Pandemic Influenza.

More specifically, the following are highlights of some of the gaps in the Strategy and Plan.

- *The Strategy and Plan do not address resources, investments, and risk management.* Developing and sustaining the capabilities stipulated in the Plan would require the effective use of federal, state, and local funds. Given that funding needs may not be readily addressed through existing mechanisms and could stress existing government and private resources, it is critical for the Plan to lay out funding requirements. For example, one of the primary objectives of domestic vaccine production capacity is for manufacturers to produce
enough vaccine for the entire U.S. population within 6 months. However, the Plan states that production capacity would depend on the availability of future appropriations. Despite the fact that the production of enough vaccine for the population would be critical if a pandemic were to occur, the Plan does not provide even a rough estimate of how much the vaccine could cost for consideration in future appropriations.

- State and local jurisdictions were not directly involved in developing the Strategy and Plan. Neither the Strategy nor Plan described the involvement of key stakeholders, such as state, local, and tribal entities, in their development, even though these stakeholders would be on the front lines in a pandemic and the Plan identifies actions they should complete. Officials told us that state, local, and tribal entities were not directly involved in reviewing and commenting on the Plan, but the drafters of the Plan were generally aware of their concerns.

- Relationships and priorities among action items are not always clear. While some action items depend on other action items, these linkages are not always apparent in the Plan. An HHS official who helped draft the Plan acknowledged that while an effort was made to ensure linkages among action items, there may be gaps in the linkages among interdependent action items within and across the Plan’s chapters that focused on such issues as human health, animal health, and transportation and borders considerations.

In addition, we found that the 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.

- Performance measures are focused on activities that are not always linked to results. Most of the Plan’s performance measures are focused on activities such as disseminating guidance, but the measures are not always clearly linked with intended results. This lack of linkages to outcomes and results makes it difficult to ascertain whether progress has in fact been made toward achieving the national goals and objectives described in the Strategy and Plan.

- The linkage of the Strategy and Plan with other key plans is unclear. Although the Strategy states that it is consistent with the National Security Strategy and the National Strategy for Homeland Security, it does not state how it is consistent or describe the relationships with
these two strategies. In addition, the Plan does not specifically address how the Strategy, Plan, or other related pandemic plans should be integrated with the goals, objectives, and activities of the national initiatives already in place, such as the interim National Preparedness Goal.

Further, the Strategy and Plan do not provide sufficient detail about how the Strategy, action items in the Plan, and a proposed set of agency plans are to be integrated with other national strategies and frameworks. For example, the Plan contains 39 action items that are response related (i.e., specific actions are to be taken within a prescribed number of hours or days after an outbreak). However, these action items are interspersed among the 324 action items, and the Plan does not describe the linkages of these response-related action items with the NRP or other response related plans.

- **The Plan does not contain a process for monitoring and reporting on progress.** While most of the action items have deadlines for completion, ranging from 3 months to 3 years, the Plan does not identify a process to monitor and report on the progress of the action items nor does it include a schedule for reporting progress. According to agency officials, the HSC is monitoring executive branch agencies' efforts to complete the action items. However, there is no specific documentation describing this process or institutionalizing it. This is important since some of the action items are not expected to be completed during this administration. Also, a similar monitoring process for those actions items for which nonfederal entities have the lead responsibility does not appear to exist. Additionally, there is no explicit timeline for the HSC to report on the overall progress and thus, when progress is reported is left to the HSC’s discretion.

- **The Plan does not describe an overall framework for accountability and oversight.** While the plan contains broad information on roles and responsibilities and describes coordination mechanisms for responding to a pandemic, it does not, as noted earlier, clarify how responsible officials would share leadership responsibilities. In addition, it does not describe an overall accountability and oversight framework. Agency officials told us that they had identified individuals to act as overall coordinators to monitor the action items for which their agencies have lead responsibility and provide periodic progress reports to the HSC. However, we could not identify a similar oversight mechanism for the action items that fall to state and local governments or the private sector. This is a concern since some action items,
particularly those that are to be completed by state, local, and tribal governments or the private sector, do not identify an entity accountable for carrying out the action.

• Procedures and time frames for updating and revising the Plan were not established. The Plan does not describe a mechanism for updating it to reflect policy decisions, such as clarifications in leadership roles and responsibilities and other lessons learned from exercises, or to incorporate other needed changes. Although the Plan was developed as initial guidance and was intended to be updated and expanded over time, officials in several agencies told us that specific processes or time frames for updating and revising it have not been established.

Opportunities Exist To Clarify Federal Leadership Roles and Improve Pandemic Planning

A pandemic poses some unique challenges and would be unlike other emergencies given the likelihood of its duration and geographic coverage. Initial actions may help limit the spread of an influenza virus, reflecting the importance of a swift and effective response. Therefore, the effective exercise of shared leadership roles and implementation of pandemic plans could have substantial consequences, both in the short and long term.

Since no national pandemic exercises of federal leadership roles and responsibilities have been conducted since the release of the Plan in May 2006, and key leadership roles continue to evolve, rigorous testing, training, and exercising is needed. Exercises test whether leadership roles and responsibilities, as well as procedures and processes, are clear and well-understood by key stakeholders. Additionally, they help identify weaknesses and allow for corrective action to be taken before an actual emergency occurs. Consequently, in our August 2007 report, we recommended that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza 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 Health and Human Services should ensure that these roles and responsibilities are clearly understood by state, local, and tribal governments; the private and nonprofit sectors; and the international community. DHS and HHS concurred with the recommendation, and DHS stated that it is taking action on many of the shortfalls identified in the report.
The Strategy and Plan are important because they broadly describe the federal government’s approach and planned actions to prepare for and respond to a pandemic and also set expectations for states and communities, the private sector, and global partners. The extent to which the Strategy and Plan fail to adequately address key areas could have a critical impact on whether key stakeholders and the public have a clear understanding of their roles and responsibilities. However, gaps in the Strategy and Plan limit their usefulness as a management tool for ensuring accountability and achieving results. The plan is silent on when information will be reported or when it will be updated. Although the HSC publicly reported on the status of action items in December 2006 and July 2007, it is unclear when the next report will be issued or how much information will be released. This lack of transparency makes it difficult to inform a national dialogue on the progress made to date or what further steps are needed. It also inhibits congressional oversight of strategies, funding priorities, and critical efforts to enhance the nation’s level of preparedness.

Therefore, in our August 2007 report we recommended that the HSC establish a specific process and time frame for updating the Plan. We stated that this process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. Further, we stated that the Plan could be improved by including the following information in the next update: (1) resources and investments needed to complete the action items and where they should be targeted, (2) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (3) clearer linkages with other strategies and plans, and (4) clearer descriptions of relationships or priorities among actions items and greater use of outcome-focused performance measures. The HSC did not comment on the draft report.

Mr. Chairman and Members of the Subcommittee, this completes my statement. I would be pleased to respond to any questions that you might have.

Contacts and Acknowledgments

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