

September 2008

INFLUENZA PANDEMIC

HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions





Highlights of [GAO-08-671](#), a report to congressional requesters

Why GAO Did This Study

The emergence of the H5N1 avian influenza virus (also known as “bird flu”) has raised concerns that it or another virus might mutate into a virulent strain that could lead to an influenza pandemic. Experts predict that a severe pandemic could overwhelm the nation’s health care system, requiring the rationing of limited resources. GAO was asked to provide information on the progress of the Department of Health and Human Services’s (HHS) plans for responding to a pandemic, including analyzing how HHS plans to (1) use pharmaceutical interventions to treat infected individuals and protect the critical workforce and (2) use nonpharmaceutical interventions to slow the spread of disease. To conduct this work, GAO reviewed government documents and scientific literature, and interviewed HHS officials, state and local public health officials, and subject-matter experts on pandemic response.

What GAO Recommends

GAO recommends that HHS expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and pre-pandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine. In comments on a draft of this report, HHS described additional actions it has taken and plans to take relating to GAO’s recommendation, including releasing for public comment in the near future proposed guidance on pre-pandemic vaccine allocation.

To view the full product, including the scope and methodology, click on [GAO-08-671](#). For more information, contact Marcia Crosse at (202) 512-7114 or CrosseM@gao.gov.

INFLUENZA PANDEMIC

HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions

What GAO Found

HHS plans to make existing federal stockpiles of pharmaceutical interventions available for distribution once a pandemic begins. These interventions would include antivirals, which are drugs to prevent or reduce the severity of infection, and pre-pandemic vaccines, which are vaccines produced prior to a pandemic and developed from influenza strains that have the potential to cause a pandemic. HHS has established a national goal of stockpiling 75 million treatment courses of antivirals in the Strategic National Stockpile and in jurisdictional stockpiles. According to HHS, these public sector stockpiles are intended to be used primarily for the treatment of individuals sick with influenza. HHS intends to oversee the distribution and administration of pre-pandemic vaccine to individuals identified as members of the critical workforce. Members of the critical workforce—estimated to be about 20 million—include workers in sectors that are considered necessary to keep society functioning, such as health care and law enforcement personnel. HHS’s strategy for using pre-pandemic vaccine is to keep society functioning until a pandemic vaccine—a vaccine specific to the pandemic-causing strain—becomes widely available. HHS anticipates that initial batches of a pandemic vaccine may not be available until 20 to 23 weeks after the start of the pandemic. As batches of the pandemic vaccine become available, HHS plans for state and local jurisdictions to provide it to members of targeted groups based on factors such as occupation and age, instead of making it available to the general public. HHS faces challenges implementing its strategy for using pharmaceutical interventions during a pandemic, including the lack of vaccine manufacturing capacity in the United States. HHS is currently making large investments to expand domestic vaccine manufacturing capacity. In 2008, HHS released guidance on prioritizing target groups for pandemic vaccine and draft guidance on antiviral use during a pandemic. HHS has not yet released draft guidance for public comment on prioritizing target groups for pre-pandemic vaccine.

HHS will rely on state and local jurisdictions to utilize nonpharmaceutical interventions, such as isolation of sick individuals and voluntary home quarantine of those exposed to the pandemic strain. To assist state and local jurisdictions with implementing nonpharmaceutical interventions, HHS has developed guidance that describes the department’s “community mitigation framework.” The framework involves the early initiation of multiple nonpharmaceutical interventions, each of which is expected to be partially effective and to be maintained consistently throughout a pandemic. HHS faces difficulties, including helping jurisdictions develop ways to ensure community compliance. HHS is investing in several initiatives to increase the nation’s knowledge about the general use and effectiveness of nonpharmaceutical interventions. The findings from this research will be used to update existing guidance.

Contents

Letter		1
	Results in Brief	6
	Background	9
	HHS Plans to Make Federal Stockpiles of Pharmaceuticals Accessible to State and Local Jurisdictions, but Faces Challenges with Implementation	19
	HHS Efforts to Improve Surge Capacity of Health Care Providers Will Be Challenged during a Pandemic	30
	HHS Has Provided Guidance to Help State and Local Jurisdictions Overcome Difficulties with Implementing Nonpharmaceutical Interventions	37
	HHS Is Developing Messages and Procedures for Communicating to the Public during a Pandemic but Challenges Remain	42
	Conclusions	48
	Recommendation for Executive Action	49
	Agency Comments and Our Evaluation	49
Appendix I	Summaries of Select Federal Documents Relevant for Preparing for and Responding to Influenza Pandemic	52
Appendix II	HHS Activities for Acquiring Pharmaceutical Interventions for an Influenza Pandemic within the United States	57
Appendix III	Comments from the Department of Health and Human Services	63
Appendix IV	GAO Contact and Staff Acknowledgments	68
Related GAO Products		69

Tables

Table 1: Comparison of Pharmaceutical Interventions for a Pandemic	10
Table 2: Some Types of Nonpharmaceutical Interventions and Their Definitions	16
Table 3: HHS Target Groups for Pandemic Vaccination for a Severe Pandemic	24
Table 4: Example of an HHS Message Map	45
Table 5: Response Elements Needed for Preparing for and Responding to an Influenza Pandemic and Examples of Priority Activities for Each Response Element	54
Table 6: HHS Goals for Amounts of Pharmaceutical Interventions to Be Stockpiled Nationally	57
Table 7: Approximate Number of Treatment Courses of Antivirals in the Strategic National Stockpile as of May 2008	58
Table 8: HHS Efforts to Acquire Pre-Pandemic Vaccine as of August 2007	59
Table 9: HHS Efforts in Establishing Domestic Infrastructure for Vaccine Manufacturing as of June 2007	60
Table 10: HHS Progress on Vaccine Development Projects	61

Figures

Figure 1: Potential Effect of Nonpharmaceutical Interventions on a Pandemic Outbreak	17
Figure 2: Pandemic Vaccine Production Timeline	27

Abbreviations

CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
EMAC	Emergency Management Assistance Compact
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
ICU	intensive care unit
mcg.	Microgram
PAHPA	Pandemic and All-Hazards Preparedness Act
SARS	severe acute respiratory syndrome
Stafford Act	Robert T. Stafford Disaster Relief and Emergency Assistance Act
SNS	Strategic National Stockpile

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office
Washington, DC 20548

September 30, 2008

The Honorable Edward M. Kennedy
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor,
and Pensions
United States Senate

The Honorable Bennie G. Thompson
Chairman
Committee on Homeland Security
House of Representatives

The emergence of the H5N1 avian influenza virus (also known as “bird flu”) has raised concerns that it or another influenza virus might mutate into a novel and virulent strain that could lead to a human influenza pandemic¹ that would pose a grave threat to global public health. Pandemics occur when an influenza strain to which humans have little or no immunity begins to cause serious illness and spreads easily from person to person. In the United States alone, at least 675,000 people died during the 1918-19 pandemic, the deadliest pandemic in the twentieth century. The Department of Health and Human Services (HHS) has estimated that a pandemic similar to the severe 1918-19 pandemic would sicken 90 million people in the United States (30 percent of the population), of whom nearly 10 million would require hospitalization and almost 2 million would die.² Given that as of 2005 there were approximately 950,000 staffed hospital beds³ in the United States, HHS’s

¹In this report, the term “pandemic” will refer to a human influenza pandemic.

²Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Washington, D.C.: November 2005). HHS also estimated that 1,485,000 people would require care in an intensive care unit (ICU) and 742,500 people would require mechanical ventilation.

³The term “staffed bed” means that there are health care staffs available to attend to a patient occupying the bed.

estimates indicate that the effects of a severe pandemic would far exceed the capacity of U.S. hospitals.⁴

HHS has made substantial progress in its preparedness for pandemic influenza. For example, since 2000, we had been urging HHS to complete its pandemic plan.⁵ HHS released the *HHS Pandemic Influenza Plan* in November 2005. (See app. I for summaries of select federal pandemic documents.) We recently reported that HHS has improved its influenza surveillance and diagnostic testing capabilities.⁶ Prompted by concerns regarding H5N1, HHS and its international partner organizations have increased efforts to enhance animal and human surveillance systems overseas. Additionally, in February 2006, the Food and Drug Administration (FDA)—an agency within HHS—approved a diagnostic test developed by the Centers for Disease Control and Prevention (CDC)—another agency within HHS—that recognizes H5 influenza viruses within 4 hours of testing; it previously would have taken 2 to 3 days.

Despite this progress, a severe pandemic would pose formidable challenges to the federal government's efforts to minimize damage to the public's health and the nation's economy. The single most important pharmaceutical intervention during a pandemic—a pandemic vaccine that is well-matched to the pandemic-causing strain—will not be available in large quantities in the initial stages of a pandemic. Other pharmaceutical interventions,⁷ such as antivirals⁸ and pre-pandemic vaccines (possibly less effective vaccines produced prior to the pandemic and based on strains experts believe may cause a pandemic) are also expected to be in limited

⁴HHS estimates show that the effects of even a moderate pandemic would exceed the capacity of U.S. hospitals, with 865,000 people requiring hospitalization, 128,750 people requiring care in an ICU, 64,875 people requiring mechanical ventilation, and 209,000 deaths.

⁵GAO, *Influenza Pandemic: Plan Needed for Federal and State Response*, [GAO-01-4](#) (Washington, D.C.: Oct. 27, 2000), 27 and GAO, *Influenza Pandemic: Challenges Remain in Preparedness*, [GAO-05-760T](#) (Washington, D.C.: May 26, 2005), 17.

⁶GAO, *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), 30-32, 36.

⁷HHS refers to pharmaceutical interventions as medical countermeasures.

⁸Antivirals are drugs designed to prevent or reduce the severity of a viral infection, such as influenza. Vaccines are drugs used to stimulate the response of the human immune system to help protect the body from disease.

supply and unavailable to the population at large.⁹ In addition, although the ability to quickly increase the number of health care providers, called surge capacity, will be vital for treating the potentially large numbers of infected individuals, efforts to do so must overcome existing shortages of health care workers in the United States.¹⁰ Similarly, because they are rarely used on a large scale, the effectiveness of large-scale implementation of nonpharmaceutical interventions, including closing schools and voluntary home quarantine, is uncertain. In addition, throughout the initial stages of a pandemic, crucial information—such as when and where to access medical care, and how to reduce the chances of infection—will need to be communicated to the public in a way that does not incite panic.

Given these obstacles and the possible risk that the best-made plans may still be ineffective in a severe pandemic, the federal government is taking steps to prepare the nation for a potential pandemic in hopes of lessening its overall impact. The *National Response Framework* charges the Secretary of the Department of Homeland Security (DHS) with responsibility for overall management and federal coordination of domestic incidents when needed,¹¹ the Federal Emergency Management Agency (FEMA) Administrator with responsibility as principal advisor to the President regarding emergency management, and the Secretary of HHS with responsibility for public health and medical response.¹² On November 2, 2005, the Secretary of HHS released the *HHS Pandemic Influenza Plan*,

⁹For more detailed information on the use of antivirals and vaccines in a pandemic, see [GAO-08-92](#), 4.

¹⁰Surge capacity may also include the ability to acquire other resources such as hospital beds, pharmaceuticals, and equipment, and to allocate scarce resources and provide care outside of the normal health care delivery system and infrastructure. For the purpose of this report, we refer to surge capacity in the context of the ability to increase the number of health care providers.

¹¹Federal assistance can be provided to state, local, and tribal jurisdictions through mechanisms and authorities that do not require coordination of federal response activities and can be provided without a Presidential declaration of a major disaster or emergency. For example, federal assistance can be provided through the National Search and Rescue Plan and the Maritime Security Plan.

¹²Department of Homeland Security, *National Response Framework* (Washington, D.C.: 2008). The *National Response Framework* replaced the *National Response Plan* in March 2008. See app. I for details regarding the genesis of the plan.

which provides HHS's plans for responding to a pandemic.¹³ The document also provides pandemic response guidance to officials in state and local jurisdictions¹⁴ and to health care facility officials. Since then, HHS has released five updates regarding the department's preparedness efforts and has released its *Pandemic Influenza Implementation Plan*. Despite these efforts, influenza and public health preparedness experts have raised concerns about the adequacy of HHS's plans and guidance to state and local officials and to health care facility officials.

Because of your interest in pandemic preparedness, we are providing information on the progress of HHS's plans and its guidance to state and local officials, and to health care facility officials, for responding to a pandemic outbreak. The focus of our work is on 4 key components taken from 5 of the 11 response elements critical for preparedness as described in the *HHS Pandemic Influenza Plan* (see table 5 in app. I for a list of all the response elements). Three components that we examined—pharmaceutical interventions (vaccines and antivirals), surge capacity of health care providers, and public communications—have repeatedly been found to need improvement by GAO and outside experts. In prior work, we reported on potential problems with pharmaceutical interventions during a pandemic, including vaccine shortages and the need for identifying target groups in advance.¹⁵ Health care provider shortages, including nurses and physicians, have been reported for many years by

¹³This is only part of the federal government's planning efforts for responding to a pandemic. The President of the United States released two documents for a broader response: (1) the *National Strategy for Pandemic Influenza*, which provides a framework for future planning efforts for how the country will prepare for, detect, and respond to a pandemic and (2) the *National Strategy for Pandemic Influenza Implementation Plan*, which further clarifies the roles and responsibilities of governmental and non-governmental entities and provides preparedness guidance for all segments of society. See app. I for general descriptions of these documents.

¹⁴For this report, we use the term "state and local jurisdictions" to refer to state, local, territorial, and tribal areas. For the allocation of pharmaceutical interventions during a pandemic, "state and local jurisdictions" refers to state, local, and territorial areas. Tribal populations are included in states' populations. HHS uses the term "Project Areas" when discussing the allocation of antivirals and points of distribution when discussing pre-pandemic and pandemic vaccines.

¹⁵See [GAO-08-92](#), 4; GAO, *Influenza Pandemic: Applying Lessons Learned from the 2004-05 Influenza Vaccine Shortage*, [GAO-06-221T](#) (Washington, D.C.: Nov. 4, 2005), 2, 10; GAO, *Influenza Pandemic: Challenges in Preparedness and Response*, [GAO-05-863T](#) (Washington, D.C.: June 30, 2005), 6-9, 11-12; and GAO, *Influenza Pandemic: Challenges Remain in Preparedness*, [GAO-05-760T](#) (Washington, D.C.: May 26, 2005), 12-15. For additional information, see *Related GAO Products* at the end of this report.

GAO.¹⁶ We reported that during the anthrax incidents of 2001, the media and the general public looked to CDC as the source for health-related information. However, CDC was not always able to successfully convey the information that it had.¹⁷ We also reported on the significance of communicating clearly on response efforts during a pandemic.¹⁸ The fourth component we focus on in our work—guidance for nonpharmaceutical interventions—is based on limited scientific evidence.

Specifically, for this report we analyzed how HHS plans to (1) use pharmaceutical interventions for treatment of infected individuals and to protect the critical workforce, (2) improve surge capacity of health care providers, (3) prepare state and local authorities to use nonpharmaceutical interventions for slowing the spread of disease, and (4) prepare to communicate with the public during a pandemic.

To determine how HHS plans to implement the four key components, we reviewed government documents related to a pandemic response. (See app. I for a description of each document.) In addition, to learn more about the elements needed for an effective public health emergency response, we reviewed related reports issued by GAO and HHS agencies, independent studies (including those from the Institute of Medicine, Congressional Research Service, and World Health Organization), and peer-reviewed journals. We interviewed officials from HHS offices, including the Office of the Assistant Secretary for Preparedness and Response, Office of the Assistant Secretary for Public Affairs, CDC, National Vaccine Program Office, National Institutes of Health, Agency for Healthcare Research and Quality, Health Resources and Services Administration, and FDA to learn more about their planning efforts. In addition, we interviewed state and local public health officials and members of the National Association of County and City Health Officials

¹⁶See [GAO-05-863T](#), 13; [GAO-05-760T](#), 16-17; GAO, *Infectious Diseases: Gaps Remain in Surveillance Capabilities of State and Local Agencies*, [GAO-03-1176T](#) (Washington, D.C.: Sept. 24, 2003), 9-10; GAO, *Bioterrorism: Preparedness Varied across State and Local Jurisdictions*, [GAO-03-373](#) (Washington, D.C.: Apr. 7, 2003), 17-18, 21-22; GAO, *Nursing Workforce: Emerging Nurse Shortages Due to Multiple Factors*, [GAO-01-944](#) (Washington, D.C.: July 10, 2001), 6-12; and GAO, *Nursing Workforce: Recruitment and Retention of Nurses and Nurse Aides Is a Growing Concern*, [GAO-01-750T](#) (Washington, D.C.: May 17, 2001), 4-14.

¹⁷GAO, *Bioterrorism: Public Health Response to Anthrax Incidents of 2001*, [GAO-04-152](#) (Washington, D.C.: Oct. 15, 2003), 24.

¹⁸[GAO-05-863T](#), 9-11.

and the Association of State and Territorial Health Officials. We also interviewed officials from the American Hospital Association, American Medical Association, American Society For Microbiology, Council of State and Territorial Epidemiologists, Infectious Diseases Society of America, and Association of Public Health Laboratories. We also interviewed subject-matter experts to get their perspectives on HHS's planning efforts. We participated in relevant public meetings on pandemic preparedness, such as those sponsored by the Institute of Medicine, to gain knowledge of new scientific evidence on the effectiveness of planning efforts.

U.S. pandemic preparedness work is an ongoing process. The data in this report were last updated on August 2008. However, changes have continued to occur since completion of our data collection, and this report may not reflect all these changes. We conducted our work from April 2006 through September 2008 in accordance with generally accepted government auditing standards.

Results in Brief

Once a pandemic begins, HHS plans to make accessible to state and local jurisdictions federal stockpiles of antivirals and pre-pandemic vaccine until a pandemic vaccine becomes widely available. HHS has established a national goal of stockpiling 75 million treatment courses of antivirals in public-sector stockpiles—meaning those in the Strategic National Stockpile (SNS) and in jurisdictional stockpiles. HHS expects state and local jurisdictions to distribute antivirals received from the SNS as well as from stockpiles maintained by the jurisdictions. According to HHS, these public-sector stockpiles are intended to be used primarily for the treatment of sick individuals. HHS intends to oversee the distribution and administration of federally owned pre-pandemic vaccine to individuals identified as members of the critical workforce. Members of the critical workforce—estimated to be about 20 million—include workers in sectors that are considered necessary to keep society functioning, such as health care and law enforcement personnel. HHS's strategy for using pre-pandemic vaccine is to keep society functioning until a pandemic vaccine becomes widely available. However, HHS anticipates that initial batches of a pandemic vaccine may not be available for as long as 20 to 23 weeks after the start of the pandemic. HHS recommends that as batches of pandemic vaccine become available, state and local jurisdictions provide it to members of targeted groups based on factors such as occupation and age, instead of making the vaccine available to the general public. HHS faces challenges implementing its strategy for using pharmaceutical interventions during a pandemic, including the lack of vaccine-manufacturing capacity in the United States. HHS is currently making

large investments in domestic vaccine manufacturing capacity. Additionally, we and others have reported since 2000 how problems can arise if potential target groups are not established in advance. In 2008, HHS released guidance on prioritizing target groups for pandemic vaccine and draft guidance on antiviral use during a pandemic. HHS has not yet released draft guidance for public comment on prioritizing target groups for pre-pandemic vaccine.

HHS has initiated efforts to improve the surge capacity of health care providers, but these efforts will be challenged during a severe pandemic because of the widespread nature of such an event, the existing shortages of health care providers, and the potential high absentee rate of providers. HHS is encouraging health care facilities to be capable of increasing the number of health care providers in the event of a pandemic through efforts such as using medical and nursing students to treat patients directly and cross training health care personnel. In addition, HHS's plans include using a national database to enable state and local officials to quickly identify licensed volunteers. However, there are concerns about the use of untrained health care personnel. Given the uncertain effectiveness of efforts to increase surge capacity, HHS has developed guidance to assist health care facilities in planning for altered standards of care; 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 events. For example, the HHS guidance recommends that, rather than treat all patients equally, health care facilities determine how to identify and treat the subset of patients who have a critical need for treatment and are likely to survive.

HHS will rely on state and local jurisdictions to utilize nonpharmaceutical interventions, such as isolation of sick individuals and voluntary home quarantine of those exposed to the pandemic-causing strain. To assist state and local jurisdictions with implementing nonpharmaceutical interventions, HHS has developed guidance that describes the department's "community mitigation framework." This framework is based upon a targeted, layered strategy involving the direct application of multiple nonpharmaceutical interventions, each of which is partially effective, initiated early and maintained consistently throughout a pandemic. However, HHS faces difficulties in helping state and local jurisdictions overcome implementation challenges, such as developing ways to help jurisdictions ensure community compliance. HHS is also investing in several initiatives to increase the nation's knowledge about the general use and effectiveness of nonpharmaceutical interventions. The findings from this research will be used to update existing guidance.

HHS has made progress in establishing roles, responsibilities, and procedures for communicating with the general public during a pandemic. For example, HHS's Office of the Assistant Secretary for Public Affairs has responsibility for coordinating the public health and medical communications effort aimed at the general public. In addition, HHS has undertaken activities to better understand public perceptions and knowledge of pandemics, developed pandemic educational materials to communicate messages to the general public before and during a pandemic, and identified ways to disseminate these materials. Nevertheless, communications during a pandemic will be challenging, as a pandemic will create an immediate, intense, and sustained demand for information from the general public. HHS plans to communicate with the general public about sensitive and technical issues, which may include why a vaccine is not readily available to the population at large and why a pandemic may require allocating scarce health care resources in a way that saves the largest number of lives. The public may become confused if they receive inconsistent information from other sources, as HHS will not be able to ensure that messages delivered to the general public by non-HHS entities are consistent with HHS messages.

Although HHS has made progress in identifying issues that need to be addressed, significant challenges remain, many of which are beyond HHS's control or cannot be quickly addressed, such as the length of time it will take to develop a pandemic vaccine. However, among the important activities within HHS's control that HHS could address before a pandemic is finalizing the guidance on how limited pharmaceutical interventions should be used during a pandemic. Therefore, we are recommending that the Secretary of HHS expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and pre-pandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine.

In comments on a draft of this report, HHS described actions it has taken and plans to take relating to our recommendation. HHS also provided clarifications and additional details about its pandemic preparedness activities, which we incorporated where appropriate.

Background

Pandemics occur when an influenza virus mutates into a novel strain that is highly transmissible among humans, leading to outbreaks worldwide. Because there is little or no pre-existing immunity in the population, the strain is highly pathogenic, thus causing disease among those who become infected. Infected individuals may be capable of transmitting the virus strain for 1 to 2 days before developing symptoms. Pandemics arise periodically but unpredictably and can cause successive waves of disease lasting for up to 3 years.

In recent years, the H5N1 strain and other strains of the influenza virus have emerged or re-emerged. Experts are concerned because of similarities between the H5N1 strain and the H1N1 strain, which caused the 1918-19 pandemic. For example, research suggests that both the H5N1 and H1N1 strains prompt an over-reaction of the inflammatory response in humans, causing rapid and severe damage to the lungs. Although the H5N1 strain has not been easily transmitted among humans, influenza experts believe that H5N1 or another new influenza strain may eventually mutate to become highly transmissible.

Pharmaceutical Interventions during a Pandemic

Pharmaceutical interventions available during a pandemic include vaccines and antivirals. Pharmaceutical interventions are the primary methods used to prevent the spread of disease as well as to reduce morbidity and mortality caused by the influenza virus. See table 1.

Table 1: Comparison of Pharmaceutical Interventions for a Pandemic

Pharmaceutical interventions	How it works	Time frame for development	When it is expected to be available	Dosage	Known potential benefits	Known potential weaknesses
Antivirals	Disrupts viral infection of cells, such as the ability to bind to human cells or be released from an infected cell	Before a pandemic	Before and during a pandemic	Varies, depending on the type of antiviral used and age of patient	<ul style="list-style-type: none"> • May be used as a form of prophylaxis or treatment • May be made and stockpiled in advance of a pandemic 	<ul style="list-style-type: none"> • Virus can develop resistance • Must be taken within 48 hours of developing symptoms for maximum effectiveness^a
Pre-pandemic vaccine	Stimulates a human immune response	Before a pandemic	Early in a pandemic	Research on one type of vaccine suggests 2 doses of 90 micrograms (mcg.) ^b	<ul style="list-style-type: none"> • May prevent severe illness and death • May be made and stockpiled in advance 	<ul style="list-style-type: none"> • May or may not be well-matched to the pandemic-causing strain
Pandemic vaccine	Stimulates a human immune response	During a pandemic	HHS estimates that initial doses will not be available until 20 to 23 weeks after the start of the pandemic	Unknown until actual pandemic-causing strain emerges	<ul style="list-style-type: none"> • Will help prevent infection or serious illness because the vaccine will be well-matched to the pandemic-causing strain 	<ul style="list-style-type: none"> • Cannot be developed in advance • Will take months to develop

Source: GAO analysis of HHS documents and journal articles.

^aEffectiveness estimate is based on antiviral use during seasonal influenza outbreaks.

^bThis dosing is based on the vaccine developed from an H5N1 strain and was approved by FDA for use in humans in the United States in April 2007.

Vaccination is the primary method for preventing infection with the influenza virus. Vaccines reduce the severity of disease or provide immunity by causing the body to produce protective antibodies to fight off

a particular virus strain.¹⁹ In order for a vaccine to be most effective, it needs to be well-matched to a particular strain of the influenza virus so that the antibodies formed in response to the vaccine protect against that strain. However, existing strains of the influenza virus can mutate into new strains; in part, this is why a new vaccine is created each year for the upcoming influenza season. Much of what is known about the anticipated effectiveness of a pandemic vaccine is based on evidence from the annual seasonal vaccine.

During a pandemic, it may be necessary to use a vaccine that was developed prior to a pandemic and therefore may not be well-matched to the pandemic-causing strain. This vaccine, called a pre-pandemic vaccine, is developed using an influenza strain that experts believe is likely to cause the next pandemic.²⁰ Research exploring the use of a pre-pandemic vaccine based on strains of the H5N1 virus suggests that it may provide some protection against serious illness and death.²¹ In contrast, a pandemic vaccine would be developed against an identified pandemic-causing strain and would likely provide better protection against the pandemic strain.

¹⁹An antibody is a molecule produced by the immune system that helps fight infections. The ability of influenza vaccine to protect a person depends on the age and health status of the person getting the vaccine and the similarity or “match” between the virus strain(s) in the vaccine and those in circulation. For example, when the seasonal influenza vaccine and circulating virus strains are well-matched, the vaccine will prevent illness in approximately 70 percent to 90 percent of healthy adults under the age of 65. The protection drops to about 30 percent to 40 percent for the elderly. Vaccine effectiveness can also be lower for individuals with medical conditions such as compromised immune systems.

²⁰Experts believe that a strain of the H5N1 influenza virus is the most likely candidate to cause a pandemic; thus, pre-pandemic vaccines currently under development are based on this virus. However, experts remain concerned that other influenza viruses—such as the H2N2, H7N7, and H9N2—have the potential to cause a pandemic.

²¹See, for example, Robert G. Webster and Elena A. Govorkova, “H5N1 Influenza—Continuing Evolution and Spread,” *New England Journal of Medicine*, vol. 355, no. 21 (2006) 2174-77 and Aleksandr S. Lipatov, Richard J. Webby, Elena A. Govorkova, Scott Krauss, and Robert G. Webster, “Efficacy of H5 Influenza Vaccines Produced by Reverse Genetics in a Lethal Mouse Model,” *Journal of Infectious Diseases*, vol. 191 (2005), 1216-20.

It is likely that seasonal influenza vaccine manufacturers will produce the vaccine used during a pandemic.²² However, for the 2007-08 influenza season, only five vaccine manufacturers were licensed to produce seasonal influenza vaccine for the United States²³ and only one manufacturer produced its vaccine from start to finish in facilities within U.S. borders.²⁴ We also recently reported that experts are concerned that countries without domestic manufacturing capacity will not have access to vaccine in the event of a pandemic if the countries with manufacturing capacity prohibit the export of pandemic vaccine until their own needs are met.²⁵

Antivirals can reduce symptoms and help prevent the spread of influenza by suppressing the growth of the influenza virus.²⁶ Unlike the immune response triggered by a vaccine, antivirals target the virus itself. For example, some antivirals interfere with the virus's ability to attach to cells, thereby preventing infection of human cells. Antivirals also differ from vaccines in that they do not need to be reformulated to match a specific influenza strain in order to be effective. In addition, antivirals can be manufactured and stockpiled in advance, making them potentially available at the beginning of a pandemic. HHS currently maintains a stockpile of antivirals in the SNS.²⁷

²²We previously reported that seasonal vaccine manufacturers for the U.S. market have agreed in principle to switch to production of pandemic vaccine should the need arise and compensation and indemnification be provided. Our prior work noted, therefore, that it would probably be unnecessary for the federal government to nationalize vaccine production, although a senior HHS official indicated that the federal government has the authority to do so if circumstances warrant it. [GAO-05-863T](#), 5.

²³The five vaccine manufacturers were GlaxoSmithKline plc (which includes its subsidiary ID Biomedical Corporation of Quebec), MedImmune Vaccines, Inc., Novartis Vaccines and Diagnostics Limited, sanofi pasteur, Inc. (the policy of this company is to spell its name without capital letters), and CSL Limited.

²⁴This manufacturer is sanofi pasteur, Inc. in Swiftwater, Pa., and it produces a vaccine that is injected into muscle. The injectable vaccine represents the large majority of influenza vaccine administered in this country. Throughout this report, vaccine refers to the injectable form.

²⁵[GAO-08-92](#), 26.

²⁶The amount of antiviral administered is measured in treatment courses. One treatment course is the number of doses of the antiviral needed to treat one person.

²⁷The SNS is a federal repository of pharmaceuticals and medical supplies that can be delivered to the site of a bioterrorist attack or other event.

However, as we have previously reported, there are limitations associated with relying on antivirals during a pandemic.²⁸ For example, the effectiveness of antivirals during seasonal influenza has been limited if they are used more than 48 hours after the onset of symptoms in an infected individual. For prophylactic use against seasonal influenza in healthy individuals, antivirals may not be as effective if they are not taken throughout the entire time an outbreak is present in a community. Some influenza strains have become resistant to the antivirals currently approved for prevention and treatment, and thus, the antivirals may not always be effective in preventing disease.²⁹ In addition, antivirals, like vaccines, take several months to produce, and the lead time needed to scale up production capacity may make it difficult to meet any large-scale, unanticipated demand immediately. As we recently reported, current antiviral production capacity is inadequate to meet expected demand during a pandemic.³⁰ Further, antivirals can be expensive to stockpile and difficult to administer, depending on the form in which they are given. For example, Tamiflu is given as a capsule or liquid and is relatively easy to administer, whereas, Relenza, is more difficult to administer because it is a powder that must be inhaled using a special device.

Since 2000, we and others have reported that federal, state, and local officials need to have information on target groups that have priority for receiving pharmaceutical interventions to know how, where, and to whom to distribute the interventions. We reported that having established target groups is particularly crucial in times of limited supply, such as during a

²⁸See *Related GAO Products* at the end of this report.

²⁹Two classes of antivirals are currently approved by the FDA for prevention and treatment of influenza. The first, older class is called adamantanes, which includes two drugs called amantadine and rimantadine. This class of antivirals has been affected by the emergence of drug-resistant influenza viruses. Antiviral resistance is the result of viruses changing in ways that reduce or eliminate the effectiveness of antiviral agents to prevent or treat infections. The second class of antivirals is called neuraminidase inhibitors. This relatively newer class of antivirals includes two drugs—oseltamivir (Tamiflu) and zanamivir (Relenza)—and are associated with fewer side-effects than the older class of antivirals. However, concerns regarding Tamiflu and Relenza have recently increased. In 2006, FDA announced a change to the prescribing information for Tamiflu to include a precaution about neuropsychiatric events. The revision is based on postmarketing reports of self-injury and delirium with the use of Tamiflu primarily in pediatric patients with influenza. In 2007, FDA's Pediatric Advisory Committee recommended stronger warning labels for both Tamiflu and Relenza because of reports of neuropsychiatric problems in children and teens.

³⁰[GAO-08-92](#), 23.

pandemic, when a lack of specific guidance makes it difficult for federal, state, and local officials to plan. For example, in a prior report, we noted that health officials in one state did not know exactly how many individuals were considered a priority for receiving a vaccine.³¹ In that case we found that it took state officials nearly a month to compile data on high-risk individuals, to decide how many doses of vaccine were needed in local areas, and to receive and ship vaccine to counties. State and local officials rely on federal guidance when making decisions on which groups should be targeted first for vaccination. For example, in a prior report on the 2004-05 influenza season, when the United States lost approximately half of its seasonal vaccine supply because of manufacturing difficulties, we found that CDC quickly revised its recommendations on who should be prioritized for vaccine.³² CDC's changes decreased the targeted population from approximately 188 million to 98 million. State and local officials we spoke with for this report told us that they quickly adopted CDC's revised recommendations.

Surge Capacity of Health Care Providers

Since the terrorist attacks on September 11, 2001, public health departments and hospitals have been considered vital elements of emergency preparedness and response efforts. Surge capacity in public health departments and hospitals will be critical to pandemic response given the large number of people expected to require medical care. During a pandemic, hospitals will need to provide care for influenza patients as well as continue providing care for other patients.

A pandemic will put a severe strain on the health care system, which already is easily overwhelmed by seasonal influenza outbreaks. Seasonal influenza results in more than 200,000 hospital admissions and 36,000 deaths in the United States every year, and hospitals were stretched to capacity in some past seasonal influenza outbreaks. A severe pandemic would overwhelm hospitals in the United States. For example, using HHS's planning assumptions, authors of one study estimated that influenza

³¹ [GAO-05-863T](#), 8.

³² [GAO-05-984](#), 11-12.

patients would need the equivalent of 191 percent of available staffed non-ICU beds and 461 percent of available staffed ICU beds.³³

A pandemic would occur in the context of existing health care provider shortages. Shortages of health care providers, including physicians and nurses, have been reported for many years by GAO and others.³⁴ For example, the Association of American Medical Colleges recently released a report summarizing studies issued by 15 states between 2000 and 2007 regarding physician shortages in the United States.³⁵ That report found that many of these states reported shortages of physicians in specialties such as primary care, cardiology, and endocrinology. Similarly, a recent survey of chief executive officers by the American Hospital Association found that as of December 2006, hospitals across the country reported having an estimated 116,000 registered nurse vacancies.³⁶ That survey also found that nearly half of emergency departments are operating at or above capacity.³⁷

Partly in response to these workforce shortages, Congress passed the Pandemic and All-Hazards Preparedness Act (PAHPA) in December 2006.³⁸ Among other things, the law requires the Secretary of HHS by 2009 to identify strategies to recruit, retain, and protect the public health workforce from workplace exposures during public health emergencies, which would include pandemics.³⁹ In addition, PAHPA established the Office of the Assistant Secretary for Preparedness and Response to

³³See Eric Toner and Richard Waldhorn, "What hospitals should do to prepare for an influenza pandemic," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 4, no. 4 (2006).

³⁴See [GAO-05-863T](#), 13; [GAO-05-760T](#), 16-17; [GAO-03-1176T](#), 9-10; [GAO-03-373](#), 17-18, 21-22; [GAO-01-944](#), 6-12; and [GAO-01-750T](#), 4-14. Also, Trust for America's Health, *Ready or Not? Protecting the Public's Health From Diseases, Disasters, and Bioterrorism* (Washington, D.C.: 2006); and American Hospital Association, *Taking the Pulse: The State of America's Hospitals* (Washington, D.C.: 2005).

³⁵Association of American Medical Colleges, *Recent Studies and Reports on Physician Shortages in the U.S.* (Washington, D.C.: 2007).

³⁶To identify nursing shortages as of December 2006, the American Hospital Association sent a survey to approximately 5,000 community hospital chief executive officers in late February 2007 and collected data through March 2007. The association received 840 responses for a response rate of approximately 17 percent.

³⁷Hospital capacity is the number of staffed beds.

³⁸Pub. L. No. 109-417, 120 Stat. 2831 (2006).

³⁹Pub. L. No. 109-417, § 103, 120 Stat. 2836.

coordinate activities between HHS and other federal departments, agencies, and offices and state and local officials responsible for emergency preparedness.⁴⁰

Nonpharmaceutical Interventions

Nonpharmaceutical interventions are measures used to reduce the impact of a communitywide infectious disease outbreak without the use of pharmaceuticals. Examples of nonpharmaceutical interventions include isolation, quarantine, social distancing, and infection control (see table 2).

Table 2: Some Types of Nonpharmaceutical Interventions and Their Definitions

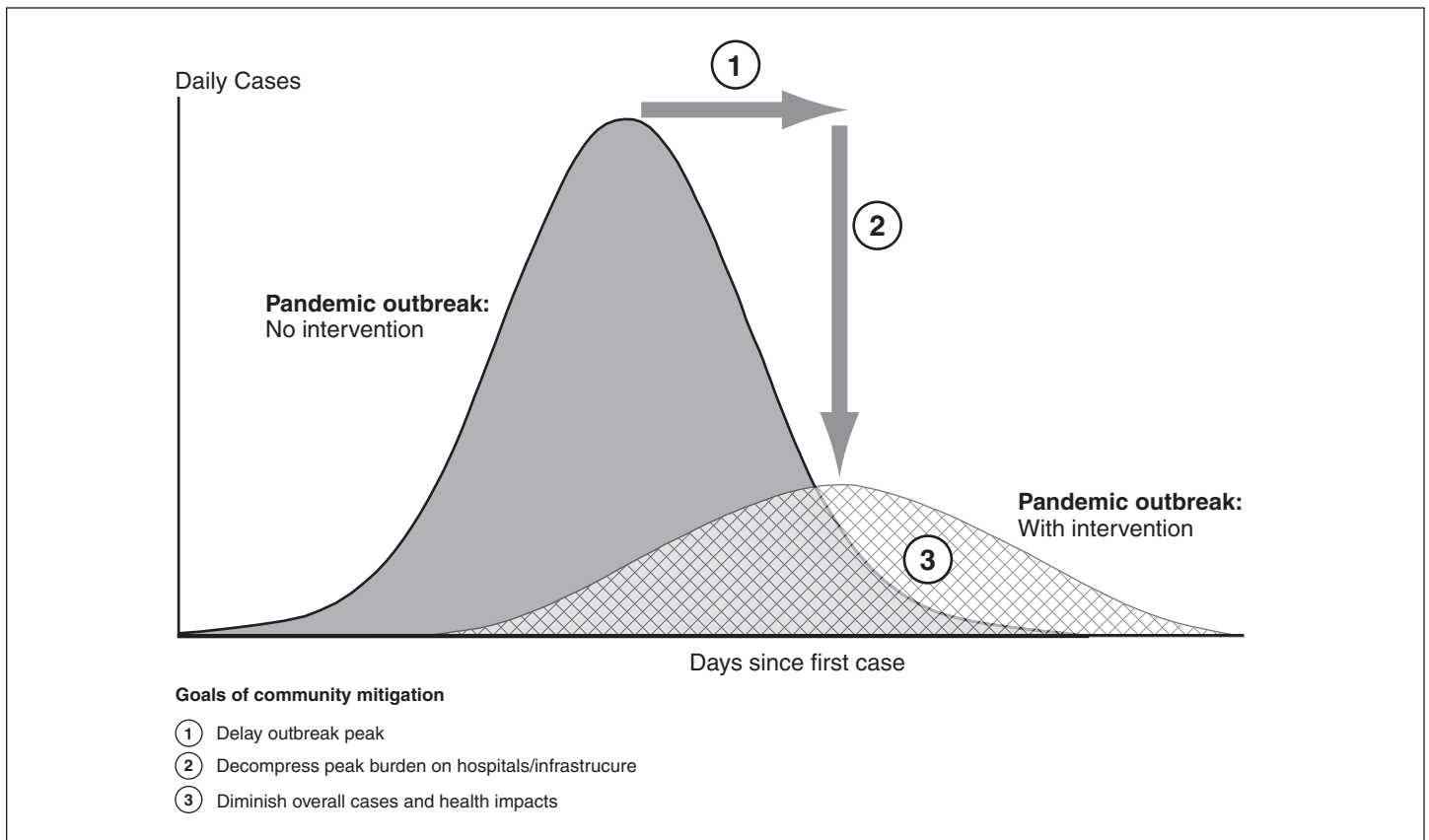
Type of Nonpharmaceutical Intervention	Definition
Isolation	The separation or restriction of movement of individuals ill with an infectious disease to prevent transmission to others.
Quarantine	The separation or restriction of movement of individuals exposed to an infectious disease, but not yet ill, who may become infectious to others.
Social distancing	Measures taken to decrease the frequency of contact among people, such as school closures.
Infection control	Hygiene measures to reduce the risk of transmission from infected individuals to uninfected individuals, including hand washing, cough etiquette, and disinfection.

Source: CDC.

Slowing the spread of disease during a pandemic will be particularly important given anticipated shortages of pharmaceutical interventions and the expectation that a severe pandemic will overwhelm the health care system. Experts have suggested that nonpharmaceutical interventions can help the health care system by reducing the anticipated influx of patients by limiting the rate of disease transmission (see fig. 1).

⁴⁰Pub. L. No. 109-417, § 101, 120 Stat. 2833.

Figure 1: Potential Effect of Nonpharmaceutical Interventions on a Pandemic Outbreak



Source: HHS, *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States - Early, Targeted Layered Use of Nonpharmaceutical Interventions*, Atlanta, Ga., 2007.

In the past, nonpharmaceutical interventions have been used in some cases to successfully slow the spread of infectious disease outbreaks. For example, during the 1918-19 pandemic, local public health officials relied on nonpharmaceutical interventions—including rules forbidding overcrowding in streetcars and bans on public gatherings—to slow the spread of disease. More recently, during the global outbreak of severe acute respiratory syndrome (SARS) in 2003, nonpharmaceutical interventions were also implemented to slow the spread of disease. For example, we reported that nonpharmaceutical interventions, such as

closing two hospitals to new admissions, appeared to be useful in Canada's management of the SARS outbreak.⁴¹

Communication with the Public

Public health emergencies such as the SARS outbreak in 2003 and the anthrax incidents in 2001 have demonstrated that communication with the public about a public health emergency by federal officials is a critical component of national preparedness. In July 2003, we reported that effective communication between health care providers and the public reinforced the need to adhere to infectious disease control measures and that rapid and frequent communications regarding SARS helped slow its spread.⁴² In addition, in October 2003, we reported that the media and the public looked to CDC as the source for health-related information during the anthrax incidents, but that CDC was not always able to successfully convey the information that it had.⁴³

As with the SARS outbreak and anthrax incidents, a pandemic will generate immediate, intense, and sustained demand for information. The public will want information quickly about the risks and status of the pandemic, what they can do to stay healthy, what is being done by the government to protect them, and where to go for medical services. Very technical points and sensitive political issues will need to be explained to the general public. If accurate and consistent information is not available and disseminated in a timely and efficient manner, rumors, myths, and misinformation may lead to unnecessary public anxiety and could result in mistrust of, and noncompliance with, the public health and medical measures that are recommended to save lives.

⁴¹GAO, *SARS Outbreak: Improvements to Public Health Capacity Are Needed for Responding to Bioterrorism and Emerging Infectious Diseases*, [GAO-03-769T](#) (Washington, D.C.: May 7, 2003), 4.

⁴²[GAO-03-1058T](#), 15-16.

⁴³[GAO-04-152](#), 24.

HHS Plans to Make Federal Stockpiles of Pharmaceuticals Accessible to State and Local Jurisdictions, but Faces Challenges with Implementation

Once a pandemic begins, HHS plans to make accessible to state and local jurisdictions⁴⁴ federal stockpiles of antivirals and pre-pandemic vaccine until a pandemic vaccine becomes widely available. According to HHS, public-sector stockpiles of antivirals are intended to be used primarily for the treatment of sick individuals. HHS intends to oversee the distribution and administration of federally owned pre-pandemic vaccine to individuals identified as members of the critical workforce; that is, workers in sectors that are necessary for society to continue functioning. HHS also plans to provide jurisdictions with doses of the pandemic vaccine as they become available. HHS recommends that state and local jurisdictions follow its list of targeted groups in administering the pandemic vaccine. However, HHS faces challenges with implementing its strategy for using pharmaceutical interventions, such as the lack of vaccine manufacturing capacity within U.S. borders and the length of time experts anticipate will be needed to manufacture a pandemic vaccine. Additionally, we and others have reported since 2000 how problems can arise if potential target groups are not established in advance. In 2008, HHS released guidance on prioritizing target groups for pandemic vaccine and draft guidance on antiviral use during a pandemic. HHS has not yet released draft guidance for public comment on prioritizing target groups for pre-pandemic vaccine.

HHS Plans to Distribute Antivirals from the SNS to Jurisdictions and Is Relying on Additional Stockpiles to Supplement These Drugs

Until a pandemic vaccine becomes widely available, one part of HHS's strategy for using pharmaceutical interventions involves distributing antivirals in the SNS to state and local jurisdictions. HHS has established a national goal of stockpiling 75 million treatment courses of antivirals in public-sector stockpiles—meaning those in the SNS and in jurisdictional stockpiles.⁴⁵ As of May 2008, HHS had stockpiled 44 million courses of antivirals for treatment in the SNS and is subsidizing the purchase of 31 million treatment courses by state and local jurisdictions for storage in

⁴⁴For the allocation of pharmaceutical interventions during a pandemic, "state and local jurisdictions" refers to state, local, and territorial areas. Tribal populations are included in states' populations.

⁴⁵In the draft guidance released for public comment in June 2008, HHS proposed increasing the national goal to 79 million.

their own stockpiles.⁴⁶ As of May 2008, state and local jurisdictions had collectively stockpiled nearly 22 million treatment courses of antivirals.⁴⁷

Of the federally stockpiled antivirals, HHS has reserved 6 million courses for containment of an initial outbreak.⁴⁸ For example, these 6 million courses may be used to respond to initial outbreaks abroad and parts of the United States experiencing the earliest cases. Officials told us that after the department distributes these initial 6 million courses of antivirals, it plans to deliver the remaining antivirals in the SNS to all jurisdictions simultaneously for treatment of individuals sick with influenza. According to HHS's guidance, state and local jurisdictions will receive their allotments of antivirals on a per-capita basis and should prepare to receive their share of antivirals when a pandemic begins, either in the United States or overseas. According to HHS officials, the decision to release antivirals from the SNS will be made by the Secretary of HHS in conjunction with the Director of CDC. HHS officials estimate that it will take between 7 days and 1 month for all antivirals to be distributed to jurisdictions. HHS officials also told us that they have conducted several exercises to test HHS's plan to distribute antivirals to these jurisdictions during a pandemic. Antivirals from the SNS will be delivered to one location within each jurisdiction. According to HHS officials, state and local jurisdictions will distribute both the SNS antivirals and antivirals stored in their own stockpiles throughout their respective areas using pandemic-specific distribution plans.

⁴⁶HHS has allocated \$170 million to subsidize state and local jurisdictions in purchasing up to 31 million treatment courses of antivirals at 25 percent off the federal contract price. According to HHS officials, there is no current need for additional federal funding to be allocated towards this subsidy program.

⁴⁷Of this nearly 22 million, almost 21 million treatment courses were purchased by state and local jurisdictions using the federal government subsidy of 25 percent. Separately, jurisdictions have purchased about 879,000 additional treatment courses without the use of the federal subsidy but under the contracts governing the program. Approximately 121,000 treatment courses of antivirals have been purchased on the open market, that is, separately from the governing contracts.

⁴⁸These 6 million courses are included in addition to the 44 million treatment courses already purchased by HHS for storage in the SNS, for a total of 50 million courses of antivirals. The containment strategy is based on studies suggesting that efforts centered on using antivirals to prevent infection as well as to treat cases might contain a pandemic at the site of the outbreak or at least slow its spread.

HHS officials told us that the stockpiles of antivirals owned by state and local jurisdictions will provide the jurisdictions with more immediate access to the drugs during the initial stages of a pandemic. Because these stockpiles will be entirely under each jurisdiction's control, officials there may choose to use some of these antivirals as prophylaxis—as proposed in HHS's draft guidance on antiviral use during a pandemic—in an attempt to slow the spread of the pandemic by providing them to healthy individuals who have been exposed to the pandemic-causing strain. However, to ensure that stockpiles are not rapidly depleted, HHS currently recommends that jurisdictions use antivirals only for treatment. HHS also advises jurisdictions to begin deploying their respective antiviral stockpiles immediately when a pandemic has been confirmed.

In June 2008, HHS released draft guidance for the use of antivirals during a pandemic in the *Federal Register* for public comment. The draft guidance is consistent with HHS's previous recommendation that public-sector stockpiles be used primarily for treatment of individuals sick with influenza. In its draft guidance, HHS also acknowledged that more antivirals will be needed than will be available in public-sector stockpiles particularly if antivirals are used for prophylaxis. HHS proposes in its draft guidance that the private sector stockpile 110 million additional courses. HHS also suggests that antivirals in the private-sector stockpile be targeted for prophylactic use for health care and emergency services personnel, and in some circumstances, for persons with compromised immune systems as well as those living in group settings.⁴⁹ The purchasing, allocation, and distribution of private-sector stockpiles would be the responsibility of the owner of those stockpiles.

⁴⁹HHS also released a second draft guidance that includes advice for employers, other than health care providers and emergency services personnel, to help employers determine if antivirals would be useful in their plans to protect critical operations and personnel. The guidance does not recommend that all employers use antivirals. Rather, it recommends that maintaining critical infrastructure and operations should be strongly considered in deciding how to allocate antivirals for prophylactic use. Additionally, the guidance does not recommend all employers use antivirals because other measures, such as nonpharmaceutical measures, may be implemented instead.

HHS Intends to Make Available Federally Owned Pre-Pandemic Vaccine to Protect the Critical Workforce

HHS's strategy also involves releasing federally owned pre-pandemic vaccine to specific locations in state and local jurisdictions for administration when it has been determined that sustained transmission of the pandemic virus has occurred. HHS intends to oversee distribution and administration of pre-pandemic to members of the critical workforce identified by a federal interagency group—the National Infrastructure Advisory Council. Workers considered critical consist of those necessary to maintain national or homeland security, economic survival, and the public health and welfare. These employees include emergency service providers, such as law enforcement, banking and financing personnel, and health care providers. The National Infrastructure Advisory Council estimates that the critical workforce includes about 20 million people.⁵⁰ HHS has a goal of stockpiling enough pre-pandemic vaccine to cover this group.⁵¹ As of May 2008, HHS had purchased and stockpiled enough pre-pandemic vaccine for about 13 million people.⁵² HHS's strategy for using pre-pandemic vaccine is to keep society functioning until a pandemic vaccine becomes widely available.

State and local jurisdictions will receive allotments of pre-pandemic vaccine on a per-capita basis. According to HHS officials, stockpiles of pre-pandemic vaccine will be released for simultaneous distribution to

⁵⁰In May 2006, the Secretaries of HHS and DHS tasked the National Infrastructure Advisory Council with, among other things, providing recommendations regarding the prioritization and distribution of pharmaceutical interventions to the critical workforce. According to this Council's report, the number of the most essential critical-infrastructure workers is approximately 12 million. See National Infrastructure Advisory Council, *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group: Final Report and Recommendations by the Council*, (Washington, D.C.: Jan. 16, 2007). According to HHS, the 20 million people in the critical workforce include the 12 million identified by the National Infrastructure Advisory Council as the most critical as well as other essential personnel such as military personnel, including the National Guard and critical government workers, such as border protection personnel.

⁵¹The Office of Biomedical Advanced Research and Development Authority within HHS manages contracts for the manufacturing and stockpiling of pre-pandemic vaccine. See app. II for more information on these contracts.

⁵²Each individual would require two doses of vaccine, according to the dosing instructions for the pre-pandemic vaccine developed from an H5N1 strain and approved by FDA for use in humans in the United States. Thus, in order to vaccinate 13 million people, HHS has stockpiled 26 million doses of vaccine. HHS has also awarded contracts to vaccine manufacturers for the development of pre-pandemic vaccines containing adjuvants—substances that may be added to a vaccine to increase the body's immune response, thereby necessitating a lower dose of vaccine. According to HHS officials, if FDA approves the use of adjuvants in these vaccines and adjuvants were obtained, there would be enough pre-pandemic vaccine in the current stockpile for more than 75 million people.

selected sites in each jurisdiction. Currently, each vaccine manufacturer stores the doses of pre-pandemic vaccine that it produces. According to HHS, each manufacturer is assigned to supply this vaccine to certain jurisdictions using its established distribution channels. HHS officials also told us that they have a longer-term plan to distribute vaccine using a single distributor, based on CDC's Vaccine Management Business Improvement Project.⁵³ According to HHS officials, this centralized distribution system would be incorporated with its existing Vaccine Ordering and Distribution System, which allows for federal tracking of vaccine distribution. HHS anticipates having a centralized distribution system in place around 2010. HHS officials told us that utilizing this type of system would be beneficial during the early stages of a pandemic, when it is expected that maintaining central control of and securing vaccine will be a high priority.

HHS Plans to Distribute Pandemic Vaccine As It Becomes Available for Vaccination of Target Groups

HHS plans to provide pandemic vaccine as it becomes available to state and local jurisdictions for use among target groups. HHS has developed guidance for the prioritization system for administration of the pandemic vaccine. HHS has divided the entire U.S. population into four broad categories—homeland and national security, health care and community support services, critical infrastructure, and the general population. Within each category, groups are clustered into five tiers that correspond to the vaccination priority—or target group—for that specific category. (See table 3 for target groups for a severe pandemic.) These targeted groups were derived through consideration of four vaccination program objectives: (1) protecting those who are essential to the pandemic response and provide care for persons who are ill; (2) protecting those who maintain essential community services; (3) protecting children; and (4) protecting workers who are at greater risk of infection because of their job. In its guidance, HHS also proposed that not all targeted groups be vaccinated in every pandemic, depending on the severity of the pandemic.⁵⁴ For a less severe pandemic, for example, individuals in tiers 2

⁵³The Vaccine Management Business Improvement Project is a collaborative effort between HHS, state and local immunization program managers, and the private sector to improve vaccine management processes at the federal, state, and local levels. Goals of the project include simplifying processes for the ordering, distribution, and management of vaccines to enhance response to public health emergencies, such as vaccine shortages.

⁵⁴HHS created the Pandemic Severity Index to aid in determining the severity of a pandemic. This index is primarily based on case-fatality ratios. CDC defines case-fatality ratio as the proportion of deaths among clinically-ill persons.

and 3 in the category of critical infrastructure would not be targeted for vaccination.⁵⁵ HHS also noted that the guidance will need to be reassessed periodically before a pandemic occurs to consider factors such as changes in vaccine production capacity. During a pandemic, guidance will also be modified based on additional factors that will not be known until a pandemic occurs, including the characteristics of pandemic illness.

Table 3: HHS Target Groups for Pandemic Vaccination for a Severe Pandemic

Tier	Homeland and national security	Health care and community support services	Critical infrastructure	General population
Tier 1	<ul style="list-style-type: none"> • Deployed and mission critical personnel 	<ul style="list-style-type: none"> • Public health personnel • Inpatient health care providers • Outpatient and home health care providers • Health care providers in long-term care facilities 	<ul style="list-style-type: none"> • Emergency services sector personnel (Emergency Medical Services, law enforcement, and fire services) • Manufacturers of pandemic vaccine and antivirals 	<ul style="list-style-type: none"> • Pregnant women • Infants and toddlers, 6 to 35 months old
Tier 2	<ul style="list-style-type: none"> • Essential support and sustainment personnel • Intelligence services • Border protection personnel • National Guard personnel • Other domestic national security personnel 	<ul style="list-style-type: none"> • Community support services and emergency management • Pharmacists • Mortuary services personnel 	<ul style="list-style-type: none"> • Communications/information technology, electricity, nuclear, oil and gas, and water sector personnel • Financial clearing and settlement personnel • Critical operational and regulatory government personnel 	<ul style="list-style-type: none"> • Household contacts of infants under 6 months old • Children 3 to 18 years old with high-risk conditions
Tier 3	<ul style="list-style-type: none"> • Other active duty and essential support 	<ul style="list-style-type: none"> • Other important health care personnel 	<ul style="list-style-type: none"> • Banking and finance, chemical, food and agriculture, pharmaceutical, postal and shipping, and transportation sector personnel • Other critical government personnel 	<ul style="list-style-type: none"> • Children 3 to 18 years old without high-risk
Tier 4	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Persons 19 to 64 years old with high-risk condition • Persons over 65 years old
Tier 5	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Not Applicable 	<ul style="list-style-type: none"> • Healthy adults, 19 to 64 years old

Source: HHS and DHS.

Note: Table was developed from *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*, Washington, D.C., 2008.

⁵⁵However, these individuals would be targeted under the category of general population for this scenario.

HHS officials told us that should a pandemic occur in the near future, pandemic vaccine will likely be distributed from vaccine manufacturers directly to state and local jurisdictions using the same distribution systems the manufacturers regularly use for seasonal influenza vaccine.⁵⁶ As with pre-pandemic vaccine, HHS anticipates that eventually multiple manufacturers will produce pandemic vaccine. However, it anticipates utilizing a single, centralized distributor. HHS expects to have a centralized distribution system in place around 2010.

HHS Faces Challenges with Implementing Its Strategy for Using Pharmaceutical Interventions

HHS faces three challenges with implementing its strategy for using pharmaceutical interventions during a pandemic. The first challenge is associated with uncertainties about the effectiveness and clinical outcomes of the pharmaceutical interventions. For example, the uncertainty concerning which influenza strain will cause the next pandemic raises the possibility that the pre-pandemic vaccine currently being developed will not offer protection against the pandemic strain. Also, because the actual pandemic-causing strain has not yet surfaced, researchers can only estimate what amount of vaccine will actually be needed to stimulate a sufficient human immune response. Similarly, the appropriate dosage of antivirals or the exact length of the treatment course needed to make them effective will not be known until the actual pandemic-causing strain emerges. Further, the ability of influenza viruses to develop resistance to antivirals also raises questions about their effectiveness. In 2005, a group of global experts on antivirals noted that studies have suggested that different strains of the H5N1 avian influenza virus have developed resistance to different antivirals.⁵⁷

⁵⁶HHS has exercised this distribution plan for pandemic vaccine several times. Also, HHS officials told us that manufacturers will provide the syringes and needles needed for administration when the pandemic vaccine is distributed.

⁵⁷For example, the H5N1 viral strains in circulation in Thailand, Vietnam, and Cambodia are resistant to the older class of antivirals, adamantanes, which includes amantadine and rimantadine. In contrast, the H5N1 virus strain that emerged in 2004 has shown in a few cases to have some resistance to oseltamivir (Tamiflu), one of the relatively newer classes of antivirals. However, all strains of H5N1 currently are susceptible to zanamivir (Relenza). Frederick Hayden, Alexander Klimov, Masato Tashiro, Alan Hay, Arnold Monto, Jennifer McKimm-Breschkin, Catherine Macken, Alan Hampson, Robert G. Webster, Michèle Amyard, and Maria Zambon, "Neuraminidase Inhibitor Susceptibility Network position statement: antiviral resistance in influenza A/H5N1 viruses," *Antiviral Therapy*, vol. 10 (2005), 873-77.

There is also the potential for adverse outcomes that may result from large-scale administration of a newly developed vaccine, such as what occurred during the “swine flu” outbreak of 1976. The government’s success in vaccinating large numbers of the public with the swine flu vaccine was negated by the development of Guillain-Barré syndrome among hundreds of immunized individuals, leading to several deaths.⁵⁸ This adverse event only became apparent when the vaccine had been administered to large numbers of people.⁵⁹

A second challenge concerns difficulties with the production of pharmaceutical interventions, particularly vaccines. The United States lacks vaccine manufacturing capacity; for example, we found that for the 2007-08 influenza season only one influenza vaccine manufacturer had its production processes entirely within U.S. borders. Additionally, in 2007 we found that the lack of U.S. vaccine manufacturing capacity is cause for concern among experts because it is possible that countries without domestic manufacturing capacity will not have access to vaccine in the event of a pandemic if the countries with domestic manufacturing capacity prohibit the export of the pandemic vaccine until their own needs are met.⁶⁰

According to HHS, exacerbating the lack of manufacturing capacity is the length of time experts anticipate will be needed to manufacture a pandemic vaccine. HHS estimates that it may take as long as 20 to 23 weeks after the start of the pandemic for the first doses of pandemic

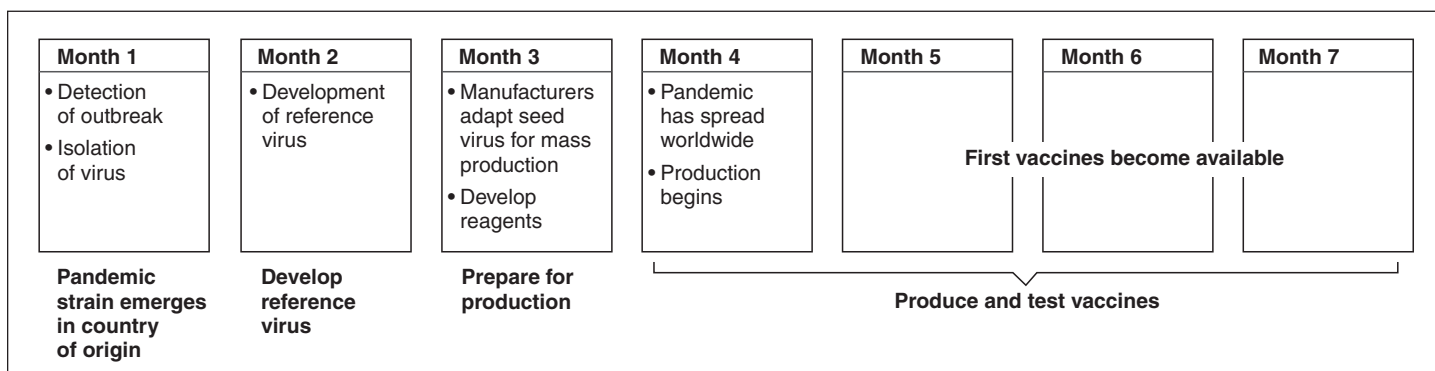
⁵⁸ Guillain-Barré syndrome is a disorder in which the body’s immune system attacks part of the peripheral nervous system. Symptoms include varying degrees of weakness or tingling sensations in the legs, which in many cases spreads to the arms and upper body.

⁵⁹ Elissa A. Laitin and Elise M. Pelletier, *Drugs and Devices Information Line*, “The Influenza A/New Jersey (Swine Flu) Vaccine and Guillain-Barré Syndrome: The Arguments for a Causal Association,” (1997): p. 1-11 and David J. Sencer and J. Donald Millar, *Emerging Infectious Diseases*, “Reflections on the 1976 Swine Flu Vaccination Program,” vol. 12, no. 1 (2006), 29-33.

⁶⁰ [GAO-08-92](#), 26.

vaccine to become available.⁶¹ Figure 2 shows how pharmaceutical manufacturers would proceed to develop and produce pandemic vaccine as well as when initial batches of vaccine are likely to become available.

Figure 2: Pandemic Vaccine Production Timeline



Source: GAO analysis of HHS, International Federation of Pharmaceutical Manufacturers & Associations, and World Health Organization data.

In response to this lack of manufacturing capacity, HHS has established the long-term goal of domestically producing enough pandemic vaccine for 300 million people within 6 months of having a reference strain of the pandemic virus. HHS expects to reach this level of manufacturing capacity around 2010.⁶² The department is currently making large investments in domestic vaccine manufacturing capacity for this purpose. (See app. II for a description of these investments.) HHS is doing this in part by supporting vaccine research with contracts that require manufacturers to

⁶¹The time required to produce vaccine depends, in part, on the satisfactory growth and yield of the virus in chicken eggs, the number of doses required to build immunity, and access to raw materials. Other factors that affect timing of vaccine production include testing by FDA and manufacturers to determine vaccine strength and the development of a reagent for such testing. A reagent is a substance used in a chemical reaction to detect, measure, examine, or produce other substances. Reagents are used to determine the purity and strength of influenza vaccine and must be developed each year for the specific new annual influenza vaccine.

⁶²In order to provide enough pandemic vaccine for 300 million people, HHS has established a goal of producing 600 million doses to provide two doses per person. The 2010-2011 time frame is based on vaccine production without adjuvants. According to HHS officials, if adjuvants were to be used, lowering the amount of vaccine needed to promote an immune response, HHS could reach its production goal in 2008 or 2009.

establish vaccine-producing facilities within U.S. borders.⁶³ Through these contracts, one U.S. facility has expanded its manufacturing capacity and is expected to double its existing capacity by 2009 and triple its capacity by 2011. A second facility was recently established in the United States and is expected to manufacture a licensed product in 2010. HHS officials told us there had also been progress in expanding domestic manufacturing capacity for antivirals.

The third challenge HHS faces involves difficulties in stockpiling and distributing pharmaceutical interventions. The high costs of purchasing and storing antivirals calls into question HHS's plan to rely on state and local jurisdictions to acquire and store their own stockpiles of antivirals. For example, officials from one state we spoke with told us that the state was facing financial difficulty in determining how it will purchase its share of antivirals and in identifying and paying for adequate storage space. HHS officials have acknowledged that the cost of purchasing antivirals is high, but have also noted that the contract price HHS has negotiated for state and local jurisdictions is better than the retail price. No federal funding has been made available to aid state and local jurisdictions in building and maintaining storage capacity. In addition, should a pandemic occur in the near future, HHS plans to utilize multiple distributors for pre-pandemic and pandemic vaccines, allowing manufacturers to use existing processes with which they are familiar. However, HHS acknowledged that this process also has multiple weaknesses. For example, the current distribution plan requires extensive coordination between HHS and multiple manufacturers and distributors. It also requires that states and local jurisdictions manage vaccine shipments from multiple sources, which may complicate receipt and storage activities. In response, HHS is planning to centralize its distribution system through a single distributor.

⁶³HHS's investments in research have also resulted in FDA-approved products. In April 2007, FDA approved the first influenza vaccine based on an H5N1 strain for human use in the United States.

HHS Has Made Progress on Revising Guidance for Target Groups for Use of Pandemic Vaccine, but Has Not Finalized Guidance for Using Pre-Pandemic Vaccine and Antivirals

HHS has made progress on revising its 2005 guidance to state and local jurisdictions for identifying target groups for the use of pandemic vaccine, but has not finalized guidance for using antivirals and pre-pandemic vaccine. Since 2000, GAO and others have reported on the importance of having pre-established target groups for pharmaceutical interventions to avoid problems deciding who should receive these interventions. In addition, during times of shortage, state and local public health officials look to the federal government for guidance, including when making decisions on which groups should be targeted for prioritization. For example, during the seasonal influenza vaccine shortage of 2004-05, state and local officials immediately adopted the revised guidance on who should be targeted for vaccination as recommended by CDC.⁶⁴ State and local public health officials and others have stressed that federal guidance on target groups is needed to aid in their pandemic planning efforts.

HHS first published target groups for pandemic vaccine and antivirals in the *HHS Pandemic Influenza Plan* in November 2005.⁶⁵ These initial groups were identified to support a goal of reducing morbidity and mortality among those at greatest risk for developing complications from influenza, such as the elderly. Since the publication of the *HHS Pandemic Influenza Plan*, there has been wide recognition that other factors should be considered, such as protecting those critical workers needed to keep society functioning, including health care and law enforcement personnel. In addition, recent expansion in the production of antivirals has increased the amount available. Thus, HHS, in consultation with other federal agencies, was tasked by the *National Strategy for Pandemic Influenza Implementation Plan* and the *HHS Pandemic Influenza Implementation Plan* to revise the groups outlined in the *HHS Pandemic Influenza Plan*.⁶⁶ In July 2008, HHS released guidance on prioritizing target groups for pandemic vaccine. HHS released draft guidance for public comment in the *Federal Register* on how antivirals may be used during a pandemic in June 2008.

⁶⁴ [GAO-05-984](#), 11-12.

⁶⁵ Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Washington, D.C.: Nov. 2005).

⁶⁶ Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* (Washington, D.C.: May 3, 2006) and Department of Health and Human Services, *Pandemic Influenza Implementation Plan* (Washington, D.C.: Nov. 2006).

However, HHS has not yet released draft guidance identifying target groups for pre-pandemic vaccine. HHS officials told us they are working on draft guidance for pre-pandemic vaccine in collaboration with other federal agencies, such as DHS. According to officials, target groups for pre-pandemic vaccine are likely to resemble those for pandemic vaccine, but with more of a focus on the critical workforce rather than on the general population. HHS officials said a tiered structure, such as that used for the pandemic vaccine, would only be needed if a pandemic occurs before HHS has reached its goal of stockpiling enough doses for 20 million people.⁶⁷

HHS Efforts to Improve Surge Capacity of Health Care Providers Will Be Challenged during a Pandemic

HHS has initiated efforts to improve the surge capacity of health care providers, but these efforts will be challenged during a severe pandemic. Surge capacity of health care providers will be hindered by existing shortages of health care providers and by the potentially high absentee rates of providers during a pandemic. Inadequate staffing of health care facilities will be likely, and the ability to deliver health care consistent with established standards of care may be compromised.⁶⁸ HHS's efforts include plans to supplement the number of health care providers with medical and nursing students. Given the uncertain effectiveness of efforts to increase surge capacity, HHS has developed guidance to assist health care facilities in planning for altered standards of care; 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 events, such as pandemics.

⁶⁷ According to HHS, if adjuvants are approved for use in pre-pandemic vaccine, it could in turn alter the prioritization and increase the population groups included in receiving pre-pandemic vaccine.

⁶⁸ A standard of care is the diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance. It is how similarly qualified health care providers would manage the patient's care under the same or similar circumstances.

Surge Capacity during a
Pandemic Will Be
Hindered by the
Potentially High Absentee
Rate of Health Care
Workers

In a severe pandemic, existing health-care provider shortages would worsen as health care providers become infected through exposure to infected patients or reach exhaustion because of longer working hours. The federal government assumes absenteeism among all workers, including health care providers, could be as high as 40 percent.⁶⁹ During the 2003 SARS outbreak (a disease that has a high mortality rate and poses a high risk for health care workers similar to a pandemic), health care workers accounted for more than 20 percent of the infected cases. During the epidemics in Toronto and Hong Kong, 51 percent and between 28 percent and 50 percent, respectively, of health care providers who treated SARS patients became infected with the SARS virus.⁷⁰

Studies have shown that during extreme public health emergencies, such as a pandemic, some health care workers may be unable or unwilling to report to work.⁷¹ For example, a survey of public health department workers, including communicable disease staff, nurses, and physicians, at three public health departments in Maryland found that approximately 46 percent would be likely not to report to work during a pandemic outbreak.⁷² Similarly, in a survey of hospital personnel, including doctors and nurses, only half responded that they would be willing to report to work during a pandemic. Those who said they may be unlikely to report to work cited fear of contracting an illness as the reason.⁷³ These potential

⁶⁹Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* (Washington, D.C., 2006), 13.

⁷⁰Henry Masur, Ezekiel Emanuel, and H. Clifford Lane, "Severe Acute Respiratory Syndrome: Providing Care in the Face of Uncertainty," *Journal of the American Medical Association*, vol. 289, no. 21 (2003): 2861-2863.

⁷¹Charlene Irvin, Lauren Cindrich, William Patterson, Angela Ledbetter, and Anthony Southall, "Hospital Personnel Response during a Hypothetical Influenza Pandemic: Will They Come to Work?" *Academic Emergency Medicine*, vol. 14, no. 5, suppl.1 (2007): S13; K. Qureshi, R.R.M. Gershon, M.F. Sherman, T. Straub, E. Gebbie, M. McCollum, M.J. Erwin, and S.S. Morse, "Health Care Workers' Ability and Willingness to Report to Duty During Catastrophic Disasters," *Journal of Urban Health*, vol. 82, no. 3 (2005), 378-388; Kristine A. Qureshi, Jacqueline A. Merrill, Robyn R. M. Gershon, and Ayxa Calero-Breckheimer, "Emergency Preparedness Training for Public Health Nurses: a Pilot Study," *Journal of Urban Health*, vol. 79, no. 3 (2002), 413-416; and Yaron Shapira, Baruch Marganitt, Ilan Roziner, Tzipora Shochet, Yael Bar, and Joshua Shemer, "Willingness of Staff to Report to Their Hospital Duties Following an Unconventional Missile Attack: A State-Wide Survey," *Israel Journal of Medical Sciences*, vol. 27 (1991), 704-711.

⁷²Ran D. Balicer, Saad B. Omer, Daniel J. Barnett, and George S. Everly, Jr., "Local Public Health Workers' Perceptions Toward Responding to an Influenza Pandemic," *BioMedCentral Public Health*, vol. 6, no. 99 (2006), 3.

⁷³Irvin, Cindrich, Patterson, Ledbetter, and Southall, S13.

workforce shortages during a pandemic will affect care for all patients, not just those with influenza.

HHS's Efforts to Improve Surge Capacity during a Pandemic Will Face Challenges

HHS has initiated many efforts to increase the number of health care workers during a public health emergency by supplementing the workforce with federal response teams and by encouraging mutual aid between states. However, HHS faces challenges in improving surge capacity during a severe pandemic because of the widespread effects of a pandemic and the existing shortages of health care providers.

HHS's Plans for Surge Capacity of Health Care Providers during a Pandemic

HHS has planned four types of efforts to improve surge capacity during a pandemic. First, the *HHS Pandemic Influenza Plan* recommends that health care facilities use personnel available locally to increase the number of health care providers during emergencies. These recommendations include using trainees (such as medical and nursing students), patients' family members, and retired health care providers to provide support for essential patient care at times of severe staffing shortages. The plan recommends that hospital clinical administrators take on patient care responsibilities and that facilities recruit health care providers from other medical settings, such as medical offices and day surgery centers, to assist with patient care in the hospital setting. Additionally, the plan recommends that health care providers be cross-trained to provide support for essential patient care at times of severe staffing shortages. To assist with this effort, HHS's Agency for Healthcare Research and Quality has developed a video to help train health care workers who are not respiratory care specialists to provide basic respiratory care and ventilator management to adult patients during mass casualty events. In addition, the *HHS Pandemic Influenza Plan* recommends deployment of federal medical responders, such as members of the National Disaster Medical System, during the early stages of a pandemic to supplement the number of health care providers.

Second, the *HHS Pandemic Influenza Plan* encourages state and territory officials to use the Emergency System for Advance Registration of Volunteer Health Professionals program, which enables state and territory officials to quickly identify licensed volunteer professionals to work in areas with shortages. This program is state-based systems that provide advanced registration and the credentialing information of clinicians needed to augment health care facilities during a declared emergency. The program enables the sharing of pre-registered health care professionals across state lines. According to HHS, as of February 2008, 40 state and territorial jurisdictions had begun to implement the program; all states and

territories are required to have this program fully operational by August 2008.

Third, HHS has advised state officials to incorporate the Emergency Management Assistance Compact (EMAC) in their plans as another vehicle for obtaining medical assistance during a pandemic. Once a governor declares a state of emergency, a state can request that EMAC address its need for resources, such as health care providers. EMAC personnel will find states that have health care providers who can be deployed across state lines. EMAC was established in 1996 and is administered by the National Emergency Management Association. All 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands have enacted legislation providing authority to join EMAC.

Fourth, HHS encourages state and local officials to use other mechanisms to expand surge capacity of health care providers for providing care to less severely ill patients during a pandemic. These mechanisms would encourage home care of less severely ill patients and include “telehealth” (also known as “telemedicine”), which allows health care providers in hospitals to care for and monitor patients at home with the use of electronic information and telecommunications technologies; and call centers (similar to nurse advice lines), which will allow patients at home to contact health care providers in hospitals in order to obtain medical advice regarding home care.

Challenges to Efforts to Increase Surge Capacity during the Initial Outbreak of a Pandemic

HHS faces several challenges in its efforts to increase surge capacity of health care providers during a pandemic. There are concerns that the use of untrained personnel may reduce the capacity of trained health care providers to deliver needed care. For example, officials from one professional association told us that using such individuals would require training and supervision, which would actually increase the workload of the health care facilities’ staff. They also told us that cross-training personnel to provide support for essential patient care during a mass casualty event may be infeasible because health care providers will be busy caring for patients in their own areas of expertise. Cross-training of health care providers needs to be done in advance, but this may be infeasible because it would take providers away from their daily patient-care responsibilities, and this may be difficult to do given current workforce shortages.

Furthermore, health care providers from other areas may not be available for deployment in a severe pandemic. Members of response teams, such as those of the National Disaster Medical System, already have full-time jobs

in health care. Therefore, these teams would not necessarily add to the nation's overall number of health care providers who would be available to treat influenza patients. We were told by HHS and FEMA officials that the National Disaster Medical System response teams will not likely be deployed during a pandemic outbreak because of the widespread nature of a pandemic and the need for those responders in their own regions. Similarly, while the EMACs make it easier for health care providers to work in states other than those in which they are licensed, given the widespread nature of pandemics, health care providers likely will be needed in their own home regions.⁷⁴

HHS Has Issued Guidance Regarding Implementation of Altered Standards of Care to Be Used If There Is Inadequate Staffing of Health Care Facilities

During a severe pandemic, inadequate staffing of health care facilities will be likely despite efforts to improve surge capacity. Thus, the ability to deliver health care consistent with established standards of care for all patients may be compromised.⁷⁵ HHS officials told us they believe that decisions on the allocation of scarce resources—such as equipment, supplies and personnel—are best made at the local level.⁷⁶ Therefore, the *HHS Pandemic Influenza Implementation Plan* recommends that health care facilities plan ahead for providing altered standards of care;⁷⁷ that is, for providing care while allocating scarce resources in a way that saves the largest number of lives in mass casualty events.⁷⁸ With altered standards of care, instead of treating the sickest or most injured patients first, health care providers would identify and treat patients who have a critical need

⁷⁴GAO, *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), 32.

⁷⁵Established standards of care are the allocation of appropriate health and medical resources to improve the health status or save the lives of all patients under normal conditions.

⁷⁶GAO recently reviewed emergency preparedness planning documents for 20 states and found that only 7 of the 20 states had adopted or were drafting altered standards of care for specific medical issues. See GAO, *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), 21-22.

⁷⁷Altered standards of care are also referred to as "standards of care appropriate to the situation."

⁷⁸Altered standards of care can be thought of in terms of triage, which refers to the process of sorting victims according to their need for treatment and the resources available. Triage is often done in emergency rooms, disasters, and wars when limited medical resources must be allocated to maximize the number of survivors.

for treatment and would be likely to survive. Complicating conditions, such as an underlying chronic disease that may impact an individual's ability to survive, would be considered in the decision-making process. Resources being used by current patients, such as those recovering from surgery, would also become part of the overall resource allocation decisions and might be re-allocated to patients with a more critical need for treatment and a higher likelihood to survive. Altered standards of care would be implemented on a temporary basis. Once the event wanes and more resources become available, provision of health care would return to established standards of care used in normal situations.

HHS has issued two guidance documents, *Altered Standards of Care in Mass Casualty Events* and *Mass Medical Care with Scarce Resources: A Community Planning Guide*, to assist health care facilities to plan for providing altered standards of care.⁷⁹ *Altered Standards of Care in Mass Casualty Events* provides health care facilities guiding principles for developing altered standards of care. Additionally, it includes a discussion of the authority to activate the use of altered standards of care and the associated legal and regulatory issues, including the possible need for liability protection for health care providers and facilities.⁸⁰ *Mass Medical Care with Scarce Resources* expands on the *Altered Standards of Care in Mass Casualty Events* report. It provides a discussion of the circumstances that communities would face as a result of a mass casualty event, approaches and strategies that could be used to provide the most appropriate standards of care possible under the circumstances, examples of tools and resources available to help state and local officials in their planning process, ethical considerations in planning for a mass casualty event, and a pandemic case study.

⁷⁹Health Systems Research Inc., *Altered Standards of Care in Mass Casualty Events*, a special report prepared at the request of the Department of Health and Human Services, the Agency for Healthcare Research and Quality (Rockville, Md.: 2005) and Health Systems Research Inc., *Mass Medical Care with Scarce Resources: A Community Planning Guide*, a special report prepared at the request of the Department of Health and Human Services, the Agency for Healthcare Research and Quality (Rockville, Md.: 2007).

⁸⁰The uncertainty of emergency situations, the need for altered standards of care, and the unpredictability of injuries during emergencies may raise liability fears and may deter health care providers and facilities from participating. Therefore, laws and regulations governing the delivery of health care under normal conditions may need to be modified or enhanced to address a mass casualty event.

Long-Term Efforts to Increase the Number and Enhance the Preparedness Level of Health Care Providers

PAHPA calls for HHS's Assistant Secretary for Preparedness and Response to lead and coordinate HHS emergency preparedness and response activities.⁸¹ Accordingly, the Assistant Secretary is engaged in efforts to increase the number and enhance the preparedness level of health care providers for public health emergencies. As part of this effort, HHS officials told us that they have begun to examine issues related to recruitment, retention, and protection of the public health workforce with the goal of identifying strategies to overcome workforce shortages. In addition, to encourage health professionals to enter employment in a state or local public health agency, PAHPA authorizes HHS to award grants to states to assist in operating public health workforce loan repayment programs for individuals who serve in health professional shortage areas or in areas at high risk of a public health emergency.⁸²

PAHPA also authorized HHS to develop Centers of Public Health Preparedness at accredited schools of public health.⁸³ HHS intends that these centers will help to train and educate health professionals to prepare for and respond to public health emergencies, including a pandemic. As part of this effort, CDC will develop core emergency preparedness and response curriculums, identify performance goals, and develop health systems research projects. HHS has already incorporated standardized benchmarks and performance measures into existing grant programs.⁸⁴

⁸¹Pub. L. No. 109-417, § 102, 120 Stat. 2833.

⁸²Pub. L. No. 109-417, § 203, 120 Stat. 2849.

⁸³Pub. L. No. 109-417, § 304, 120 Stat. 2860.

⁸⁴See Department of Health and Human Services, *Pandemic and All-Hazards Preparedness Act Progress Report* (Washington, D.C.: Nov. 2007), 11.

HHS Has Provided Guidance to Help State and Local Jurisdictions Overcome Difficulties with Implementing Nonpharmaceutical Interventions

HHS will rely on state and local jurisdictions to utilize nonpharmaceutical interventions to help slow the spread of disease and to lessen the burden on the nation's health care system until a pandemic vaccine is widely available. HHS has developed guidance and is investing in research on the general use and effectiveness of nonpharmaceutical interventions, thereby helping jurisdictions make more informed decisions. According to HHS, the findings from this research will be used to update existing guidance. However, HHS faces difficulties in helping state and local jurisdictions overcome implementation challenges, such as identifying steps for ensuring community compliance.

HHS Will Rely on State and Local Jurisdictions to Utilize Nonpharmaceutical Interventions to Help Slow the Spread of Disease

The authority to implement nonpharmaceutical interventions—such as decisions on school closures—to slow the spread of disease and lessen the burden on the nation's health care system until a pandemic vaccine is available rests with state and local jurisdictions. To assist state and local authorities with their current planning efforts for using nonpharmaceutical interventions, HHS published a guidance document in February 2007—the *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions*.⁸⁵ HHS officials told us that the recommendations in the guidance are for pre-pandemic contingency planning and are intended to provide state and local jurisdictions with a conceptual framework to guide their planning. In this guidance, HHS introduces its “community mitigation framework” that is based upon a targeted, layered strategy involving the direct application of multiple, partially-effective nonpharmaceutical interventions, initiated early and maintained consistently throughout a pandemic. Specifically, HHS's guidance describes four interventions: (1) isolation (either at home or in a health care setting) and treatment (as appropriate) with antivirals of all individuals with confirmed or probable infections; (2) voluntary home quarantine of members of households exposed to the disease and consideration of combining this intervention with antivirals, provided sufficient amounts are available and can readily be distributed; (3) school closures (including public and private schools as well as colleges and universities) accompanied by closures of other public settings

⁸⁵Department of Health and Human Services, *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions* (Washington, D.C.: February 2007).

(e.g., shopping malls and movie theaters) to prevent out-of-school social contacts; and (4) adult social distancing to reduce contact among adults in the community and workplace.

HHS officials and other experts have acknowledged the significance of implementing certain nonpharmaceutical interventions in order to maximize the available public health benefit while minimizing adverse secondary effects of the interventions. Thus, HHS recommends that state and local jurisdictions consider the severity of the pandemic when making decisions about how to respond to the outbreak. For example, for a less severe pandemic, HHS recommends voluntary home isolation of sick individuals, but generally does not recommend measures that may be more burdensome, such as voluntary quarantine of exposed household members, school closures, and adult social distancing. HHS recommends that state and local jurisdictions implement those additional measures and others in a more severe pandemic.

Department officials and experts have also stressed the importance of balancing the need to intervene early enough for nonpharmaceutical measures to be effective, while at the same time not causing unnecessary hardship by implementing them too early. HHS and other federal agencies released guidance in March 2008—the *Federal Guidance to Assist States in Improving State-Level Pandemic Influenza Operating Plans*⁸⁶—that included information to assist state and local jurisdictions in determining when to implement certain nonpharmaceutical interventions. For example, this guidance recommends implementing voluntary quarantine and administering antivirals to individuals exposed to the pandemic virus when a case of novel influenza is detected in an area, including before sustained human-to-human transmission has been established.

Once a pandemic is underway, HHS anticipates providing technical assistance to state and local jurisdictions on the implementation of nonpharmaceutical interventions. This technical assistance would include assessing the specific epidemiological characteristics of the pandemic, such as how the pandemic-causing strain is transmitted, and consulting with state and local jurisdictions on the effectiveness of the nonpharmaceutical interventions that had been implemented. Because it is not possible to accurately predict the severity of a pandemic, HHS officials

⁸⁶U.S. government, *Federal Guidance to Assist States in Improving State-Level Pandemic Influenza Operating Plans* (Washington, D.C.: Mar. 11, 2008).

HHS's Guidance on
Nonpharmaceutical
Interventions Is Based on
Inconclusive Scientific
Evidence

told us the recommendations in the guidance may change significantly during an actual pandemic, based on data HHS gathered from providing technical assistance as well as from data from initial outbreak investigations or from routine surveillance systems.

HHS officials acknowledge that the recommendations in its guidance are not specific because the scientific evidence on the use and effectiveness of nonpharmaceutical interventions is limited, and therefore inconclusive. The research to date using mathematical modeling and analysis of historical data of past pandemics suggests that utilizing multiple nonpharmaceutical interventions simultaneously and early in a pandemic may aid in slowing disease transmission.⁸⁷ For example, historical studies of the 1918-19 pandemic describe how some cities reduced death rates by successfully implementing multiple nonpharmaceutical interventions, including social distancing, mandated mask wearing, and case isolation.⁸⁸ However, because of incomplete historical records, researchers are not able to determine precisely, where, when, and for how long these interventions were implemented.

HHS has supported several research initiatives to establish a stronger evidence base concerning the implementation and effectiveness of nonpharmaceutical interventions, thereby helping jurisdictions to make more informed decisions. For example, in October 2006, HHS awarded \$5.2 million to support eight research projects on topics ranging from the role hand hygiene can play in reducing disease transmission to examining

⁸⁷Martin C. J. Bootsma and Neil M. Ferguson, "The effect of public health measures on the 1918 influenza pandemic in U.S. cities," *Proceedings of the National Academy of Sciences of the United States of America*, vol. 104, no. 18 (2007), 7588-93; Richard J. Hatchett, Carter E. Mecher, and Marc Lipsitch, "Public health interventions and epidemic intensity during the 1918 influenza pandemic," *Proceedings of the National Academy of Sciences of the United States of America*, (2007), 1-6; Michael J. Haber, David K. Shay, Xiaohong M. Davis, Rajan Patel, Xiaoping Jin, Eric Weintraub, Evan Orenstein, and William W. Thompson, "Effectiveness of Interventions to Reduce Contact Rates during a Simulated Influenza Pandemic," *Emerging Infectious Diseases*, vol. 13, no. 4 (2007), 581-89; Howard Markel, Alexandra M. Stern, J. Alexander Navarro, Joseph R. Michalsen, Arnold S. Monto, and Cleto DiGiovanni, Jr, "Nonpharmaceutical Influenza Mitigation Strategies, US Communities 1918-1920 Pandemic," *Emerging Infectious Diseases*, vol. 12, no. 12 (2006), 1961-64; Robert J. Glass, Laura M. Glass, Walter E. Beyeler, and H. Jason Min, "Targeted Social Distancing Design for Pandemic Influenza," *Emerging Infectious Diseases*, vol. 12, no. 11 (2006): 1671-81; and Joseph T. Wu, Steven Riley, Christophe Fraser, and Gabriel M. Leung, "Reducing the Impact of the Next Influenza Pandemic Using Household-Based Public Health Interventions," *Public Library of Science*, vol. 3, no. 9 (2006), 1-9.

⁸⁸Bootsma and Ferguson, 7588 and Hatchett, Mecher, and Lipsitch, 1.

upper respiratory infections in families. According to HHS, the findings from this research will be used to update existing guidance. HHS and other experts have stressed the need for additional research to, for example, better inform the assumptions used in mathematical models.⁸⁹ HHS listed other key areas for further research in its guidance, such as understanding fundamental questions regarding influenza transmission and the potential psychosocial effects of certain nonpharmaceutical interventions, such as prolonged voluntary home quarantine and social distancing.

HHS Faces Difficulties in Assisting State and Local Jurisdictions to Overcome Implementation Challenges

HHS faces difficulties in helping state and local jurisdictions implement nonpharmaceutical interventions. First, as HHS acknowledged in its guidance, there is the potential for state and local jurisdictions to implement these interventions in an uncoordinated, untimely, and inconsistent manner, thereby dramatically reducing their effectiveness. For example, if one jurisdiction implements a voluntary quarantine of sick individuals and a neighboring jurisdiction does not, the overall movement of sick individuals in the area may not be sufficiently reduced. HHS hopes that state and local jurisdictions will follow its guidance and act in concert, but HHS cannot compel jurisdictions to do so.

Second, HHS faces the challenge of helping state and local jurisdictions identify specific thresholds for implementing and ending nonpharmaceutical interventions, such as at what point to close schools. The *Federal Guidance to Assist States in Improving State-Level Pandemic Influenza Operating Plans* provides general guidance to state and local jurisdictions on when to consider beginning to implement nonpharmaceutical interventions. However, this guidance does not provide details on when to implement specific interventions. For example, the guidance recommends state and local officials begin to consider closing schools when transmission of a pandemic virus occurs, but does

⁸⁹ A report by the Institute of Medicine identified major limitations with the current use of mathematical models, particularly with the uncertainty associated with many of the assumptions made by researchers regarding key parameters, such as the transmissibility of the virus, the effectiveness of social distancing interventions, and compliance with these interventions. For example, results from a model with the assumption that most viral transmission occurs among children in schools will differ from a similar model with the assumption that most transmission occurs among household contacts. Committee on Modeling Community Containment for Pandemic Influenza Board on Population Health and Public Health Practice, Institute of Medicine of the National Academies, "Modeling Community Containment for Pandemic Influenza, A Letter Report." (Washington, D.C.: 2006).

not identify a specific absentee rate at which officials should take action. Experts have noted that determining specific triggers is difficult, partly because the data currently available are imperfect and sparse, requiring decision-makers to make assumptions regarding the transmission rate of the pandemic-causing strain as well as the effects of other community behaviors during the pandemic. In addition, state and local officials generally do not have the capabilities to collect the data that federal authorities will need to develop specific triggers during an actual pandemic. For example, one local official noted that one method of determining specific community triggers would be to use prevalence rates, which measure the percentage of the population infected with disease. However, state and local areas do not have surveillance systems capable of providing this level of detail in real-time.

Third, HHS faces the challenge of helping state and local jurisdictions convince residents to comply with its requests regarding nonpharmaceutical interventions. This task is especially difficult because restrictions on public activities to combat a pandemic may need to be in place for several months. During the 1918-19 pandemic, nonpharmaceutical interventions were implemented for 2 to 8 weeks. However, researchers have suggested that such interventions would need to be implemented for a longer period for a future pandemic in order to prevent another increase in transmission after the interventions are discontinued.⁹⁰ In the 1918-19 pandemic, nonpharmaceutical interventions were lifted. In some cases, the public became fatigued with the interventions, leading to public opposition and noncompliance when authorities found it necessary to reimpose the restrictions.

A fourth challenge HHS faces is that these restrictions may have negative impacts on the nation's economy and on the financial well-being of individual households. For example, nonpharmaceutical interventions may exacerbate worker absenteeism as parents stay home to care for their children when schools are closed. This could eventually result in disruptions in the provision of essential services, such as law enforcement. Similarly, lengthy nonpharmaceutical interventions could financially strain individuals and families. For example, while an HHS-sponsored study on public perceptions regarding a pandemic found a generally high willingness to comply with public health recommendations, it also found a decrease in reported ability to comply with recommended measures when

⁹⁰Hatchett, Mecher, and Lipsitch, 5, and Bootsma and Ferguson, 7592.

financial constraints were considered.⁹¹ Thus, 57 percent of respondents said they would have problems complying with recommended measures because of financial difficulties if they had to be out of work for 1 month, with 76 percent reporting problems if they had to miss 3 months.

A fifth challenge for HHS is the lack of trust by U.S. citizens of federal government public health authorities. A recent study found that only 40 percent of the U.S. population would trust federal government public health authorities as a source for accurate information.⁹² The authors of this study assert that this lack of trust may have been exacerbated by the public's negative perceptions of the government's response to Hurricane Katrina in 2005 and that the U.S. population may now be less willing to cooperate with some public health requirements in the future, including isolation of sick individuals.

HHS Is Developing Messages and Procedures for Communicating to the Public during a Pandemic but Challenges Remain

HHS has made progress by establishing roles, responsibilities, and procedures for communicating messages to the general public during a pandemic. HHS has also developed pandemic educational materials to communicate messages to the general public before and during a pandemic and has identified ways to disseminate these materials. In addition, HHS has engaged the general public on pandemic issues to better understand public perceptions and knowledge. Nonetheless, communicating sensitive and complex issues to the general public during a pandemic will be challenging.

Roles, Responsibilities, and Procedures Have Been Established for How HHS Plans to Communicate with the General Public about a Pandemic

HHS has assigned roles and responsibilities, and developed procedures, for how HHS plans to communicate with the general public about a pandemic. Under the *National Response Framework*, HHS is the lead federal agency for public health and medical services, and as such, HHS is the federal agency responsible for communicating with the general public about the public health and medical aspects of a pandemic before and during an outbreak. In addition, the *HHS Pandemic Influenza Plan*

⁹¹R.J. Blendon, L.M. Koonin, J.M. Benson, M.S. Cetron, W.E. Pollard, E.W. Mitchell, et. al, "Public response to community mitigation measures for pandemic influenza, *Emerging Infectious Diseases*, vol. 14 (2008): 778-786.

⁹²Robert J. Blendon, Catherine M. DesRoches, Martin S. Cetron, John M. Benson, Theodore Meinhardt, and William Pollard, "Attitudes Toward the Use of Quarantine In a Public Health Emergency in Four Countries," *Health Affairs*, vol. 25 (2006): W22.

identified activities that should be undertaken to prepare HHS to communicate with the general public before and during a pandemic.

In November 2006, HHS completed the *U.S. Department of Health and Human Services Pandemic Influenza Communications Plan* which lays out detailed roles, responsibilities, and procedures to guide HHS communications with the general public.⁹³ For example, this plan assigned HHS's Office of the Assistant Secretary for Public Affairs responsibility for coordinating pandemic health messages across all HHS agencies and with state and local communications staff in order to ensure that all HHS agencies work closely together to make public statements that are timely, consistent, and accurate.

HHS has named spokespersons within HHS to deliver messages to the public before and during an outbreak.⁹⁴ HHS has trained federal, state, local, and private sector public affairs officials to communicate with the general public about a pandemic. The Crisis and Emergency Risk Communication training modules developed by HHS clarify the role of spokespersons, describe the psychology of communicating during a crisis, and provide best practices for working with the media during a crisis. HHS has held 10 Crisis and Emergency Risk Communication training sessions for nearly 500 senior federal officials and public affairs staff, and 11 regional training sessions for approximately 900 state and local leaders. Two additional trainings are scheduled in 2008. HHS also held Crisis and Emergency Risk Communication training sessions in June 2007 for Red Cross leaders and in January 2007 for stakeholders. Nearly 900 training sites participated in these sessions via the Internet.

During a pandemic, the HHS communications effort will operate out of its Emergency Communications Center. The center's capabilities include originating or accessing video feeds, news conferencing, posting mass

⁹³Department of Health and Human Services, *U.S. Department of Health and Human Services Pandemic Influenza Communications Plan* (Washington, D.C.: November 2006).

⁹⁴The following individuals have been identified as primary spokespeople for the medical response in a pandemic—HHS Secretary, HHS Deputy Secretary, Assistant Secretary for Health, Assistant Secretary for Preparedness and Response, Deputy Assistant Secretary for Preparedness and Response, HHS Science Advisor, Director of the National Vaccine Program Office, Director of CDC, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, Assistant Secretary for Public Affairs, Deputy Assistant Secretary for Public Affairs, Director of the HHS Press Office, and Director of Media Affairs (regional media).

electronic mailings, responding to media telephone inquiries, receiving, vetting, and clearing messages to be released by HHS. HHS will use a departmental public affairs conference line to provide telephone connections for public affairs staff throughout the department. These phone connections will allow HHS public affairs personnel to work from dispersed sites during the crisis, coordinate messages, receive guidance or direction, and provide information to those needing it. The DHS National Incident Communications Conference Line will also be used by HHS to exchange information with other federal agencies.

In addition, the Office of the Assistant Secretary for Public Affairs conducts media outreach to strengthen the relationship between the media and HHS and to support pandemic planning and education. Periodic briefings are scheduled between senior department officials, including the HHS Secretary, and members of the press. For example, in early 2007 HHS held a series of roundtable discussions on pandemics with the major broadcast and cable television networks, wire services, and bloggers to raise awareness of pandemics; the secretaries of HHS and Department of Agriculture participated. HHS press-office staff members also talk to the media regularly to answer questions and provide updates on pandemic planning and related issues. In January 2007, HHS began holding a series of tabletop exercises⁹⁵ with key media leaders and senior government officials in six major cities to facilitate effective communication to help insure the timely dissemination of accurate information to the general public through the use of media outlets during a pandemic.

HHS Has Developed Pandemic Educational Materials to Communicate Messages to the General Public before and during a Pandemic

HHS has developed and disseminated educational materials for communicating critical information to the general public and is in the process of developing additional materials. HHS has identified some of the critical information that the general public will require during a pandemic and has developed message maps—communications tools used to help organize complex information—to convey that information in a concise format before an outbreak. HHS has developed 82 message maps. HHS's message maps are each designed to distill three primary, easily understood messages on issues such as the differences between avian influenza, pandemic influenza, and seasonal influenza, as well as what HHS is doing

⁹⁵A tabletop exercise is a facilitated analysis of a hypothetical emergency situation. The purpose of the exercise is to have participants examine problems based on current plans and to identify where those plans need to be refined.

to prepare for a pandemic. Each of these primary messages has three supporting messages that can be used as appropriate to provide context for the issue being mapped.⁹⁶ HHS message maps take the form of a series of questions and answers and are made public so that spokespersons from across the government or from private organizations can use the maps to convey accurate and consistent background information to their constituents before an outbreak. Table 4 shows an example of an HHS message map.

Table 4: Example of an HHS Message Map

How fast would pandemic influenza spread?	
1	When a pandemic influenza begins, it is likely to spread very rapidly. <ul style="list-style-type: none"> • Influenza is a contagious disease of the lungs. • Influenza usually spreads by infected people coughing and sneezing. • Most people will have little or no immunity to pandemic influenza.
2	Efforts to prepare for pandemic influenza are continuing. <ul style="list-style-type: none"> • Public health officials are building on existing disease outbreak plans, including those developed for SARS. • Researchers are working to produce additional vaccine more quickly. • Countries are working together to improve detection and tracking of influenza viruses.
3	Public participation and cooperation will be important to the response effort. <ul style="list-style-type: none"> • Severe pandemic influenza could produce changes in daily life, including limits on travel and public gatherings. • Informed public participation and cooperation will help public health efforts. • People should stay informed about pandemic influenza and be prepared as they would for any emergency.

Source: HHS.

Note: *HHS Pandemic Influenza Pre-Event Message Maps*, Washington, D.C., 2006.

HHS has several means of disseminating information regarding a pandemic. HHS manages www.pandemicflu.gov, the official U.S. government Web site for disseminating information on pandemics to the public before and during a pandemic. The Web site is updated with new information as it becomes available and provides the public, public health and emergency preparedness officials, government and business leaders,

⁹⁶Messages are written to a sixth grade reading level and presented in 3 short sentences that convey 3 key messages in 27 words. The approach is based on surveys showing that lead or front page media and broadcast stories usually convey only three key messages, typically in less than 9 seconds for broadcast media or 27 words for print.

school systems, and local communities with comprehensive governmentwide information on a pandemic. In addition, HHS will use a variety of other information systems to distribute pandemic information including telephone hotlines, such as 1-800-CDC-INFO; educational sessions through teleconferencing, such as the Clinician Outreach and Communication Activity to which the public can call-in; satellite informational broadcasts; and radio and television public service announcements.

HHS has developed public service announcements for use on television and radio that urge the general public to learn about and prepare for a pandemic and has created an archive of materials—video footage, posters, and fact sheets—for conveying key pandemic messages to the general public. HHS also has developed planning checklists for specific audiences—such as medical providers, schools, and businesses—to raise awareness and to assist these audiences in preparing for a pandemic.⁹⁷ For example, the planning checklists identify issues that should be considered, such as storing additional infection control supplies (such as hand cleansing products and tissues); establishing pandemic-specific policies, procedures, and roles and responsibilities; planning to maintain continuity of operations; coordinating activities with local stakeholders; practicing infection control; and developing communications plans.

Despite HHS's Preparations, Communicating with the General Public during a Pandemic Will Be Challenging

HHS officials told us that communicating messages to the general public during a pandemic will be challenging despite the department's preparations. The first challenge is that a pandemic will create an immediate, intense, and sustained demand for information from both the general public and the groups to whom the public will be turning for information, such as the media and health care community. In addition, the general public will likely turn to numerous sources other than HHS for information, including other federal agencies, state and local authorities, the media, health care providers, the Internet, hotlines, employers, peers, family, and community leaders. HHS will not be able to ensure that messages delivered to the general public by non-HHS entities are

⁹⁷HHS has developed planning checklists for state and local jurisdictions, medical offices and clinics, emergency medical service and non-emergent (medical) transport organizations, home health care services, individuals and families, businesses, school districts (K-12), childcare and preschool facilities, colleges and universities, faith-based and community organizations, long-term care and other residential facilities, the travel industry, and health insurers.

coordinated and consistent with HHS messages, and the communications may cause confuse the general public.⁹⁸

A second challenge concerns the public's reception to HHS's communications. HHS has found a low level of public understanding on pandemic issues, some unwillingness to comply under certain circumstances with the messages that HHS plans to deliver, and anxiety over particular messages (such as why pre-pandemic vaccines and some antivirals will not be made available to the general public). For example, a nationally representative survey on pandemic issues found that 58 percent of the general public in the United States did not know what a pandemic is.⁹⁹ The survey also found that the public is less willing or is unable to follow some of the recommendations that HHS plans to communicate during a pandemic. For example, HHS plans to recommend that sick individuals who do not require hospital care observe voluntary home isolation and treatment; however, 24 percent of the people surveyed said that they did not have someone to take care of them in their homes. The same study also found that 35 percent of respondents would go to work if requested by their employer even if public health officials recommended that people stay at home during a pandemic.

Furthermore, HHS tabletop exercises have identified several issues that will prove challenging when communicating with the public during a pandemic, particularly the sensitivity of certain messages, the use of specialized public health terms in the messages, and the inadequacy of HHS message maps to address the complexity of the issues being communicated. Discussions during these tabletop exercises will help HHS to develop plans to resolve these identified challenges. For example, HHS's messages will have to communicate clearly the difference between specialized terms such as isolation and quarantine, and the meaning of the phrase "altered standards of care." Because of the complexity of the issues in its message maps, HHS plans to develop additional educational materials to distribute to the public before a pandemic in order to make these complexities more comprehensible.

⁹⁸In addition, we have cited concerns about multiple and potentially confusing or conflicting messages coming from many agencies at all levels of government during a pandemic. See [GAO-08-36](#), 5.

⁹⁹Harvard School of Public Health Project on the Public and Biological Security, "Pandemic Influenza and the Public: Survey Findings," presentation at the Institute of Medicine (Oct. 26, 2006).

Conclusions

Although HHS has made progress in identifying issues that need to be addressed and in funding research and vaccine production, significant challenges remain, many of which are beyond HHS's control or which cannot be quickly addressed. Such challenges include coping with the potentially high absentee rate among health care providers during a pandemic and the length of time it will take to develop a pandemic vaccine once the virus is identified. One important activity, however, that is within HHS's control that HHS could address before a pandemic is finalizing the guidance on how limited pharmaceutical interventions should be used during a pandemic.

A severe pandemic, such as that of 1918-19, has the potential to result in widespread illness and death and is expected to overwhelm the nation's ability to respond. According to HHS, initial batches of the most effective protective measure—a pandemic vaccine—may take as long as 20 to 23 weeks after the start of the pandemic to become available. Although the federal government has provided some guidance, final decisionmaking will fall on state and local officials who will have to decide how to allocate pharmaceutical interventions and whom interventions should go to first, and when.

HHS, in consultation with other federal agencies, has been tasked with revising guidance to assist state and local jurisdictions in identifying groups that should be considered a priority for receiving limited pharmaceutical interventions. In 2008, HHS released guidance on prioritizing target groups for pandemic vaccine and draft guidance for public comment on how antivirals may be used during a pandemic. However, HHS has not yet released draft guidance for public comment on prioritizing target groups for pre-pandemic vaccine. We and others have reported since 2000 how problems related to pandemic planning—such as those problems with the distribution and administration of pharmaceutical interventions—can arise if target groups are not established in advance. This lack of essential information could slow the initial response at the state and local levels and complicate the general public's understanding of the necessity for rationing these interventions. Additionally, the general public should continue to be engaged in the process of priority setting, as public participation is an essential component for acceptance of tough decisions that will be required unless and until greater capacity or a universal vaccine can be developed.

Recommendation for Executive Action

To improve the nation's preparedness for a pandemic, we are recommending that the Secretary of HHS expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and pre-pandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine.

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report which we have reproduced in appendix III. HHS also provided technical comments, which we have incorporated as appropriate.

In its comments, HHS noted that it has taken and plans to take additional actions related to our recommendation since we provided the draft report to the department for its review. HHS indicated that the final guidance for pandemic vaccine allocation was released on July 23, 2008, and that this guidance describes the groups who should be targeted and prioritized for receiving pandemic vaccine. HHS also indicated that the department released draft guidance on how antivirals may be used during a pandemic in June 2008, and that HHS will release for public comment proposed draft guidance on pre-pandemic vaccine allocation in the near future. We updated the text of the report to reflect these developments. We also revised the wording of our recommendation in light of HHS's comment that HHS recommends that antivirals in public-sector stockpiles should be used primarily for the treatment of individuals sick with influenza. We first identified the need for finalized guidance on how limited pharmaceutical interventions should be used during a pandemic, including target groups where appropriate, in 2000. We believe that finalizing guidance on the use of pharmaceutical interventions will be crucial for responding to a pandemic outbreak and that the necessary guidance documents should be finalized as soon as possible.

Throughout its comments, HHS described aspects of its pandemic preparedness activities that it believed could be presented more clearly in our report and presented additional details about its activities. We have revised the language in the report to reflect HHS's comments where it was necessary. In particular, we revised our discussion of pharmaceutical interventions to clarify our presentation of the three types of pharmaceuticals and how pre-pandemic vaccine will be distributed and administered during a pandemic. We also revised the report to reflect HHS's objection to our statement that the use of antivirals early in a pandemic could slow the spread of the pandemic. HHS commented that the magnitude of the impact of pharmaceuticals on pandemic spread is

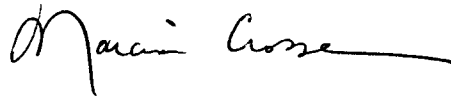
uncertain given “...limited countermeasure supplies, unclear effectiveness, and operational challenges...”

Many of HHS’s comments addressed the scope of the department’s actions in relation to the responsibilities of states and local jurisdictions. For example, HHS noted that it will directly oversee the administration of pre-pandemic vaccine to members of the critical workforce, rather than fully delegate that task. For antivirals, HHS agreed that states are free to administer antivirals in their own stockpiles to anyone they like, but also noted that state plans have been reviewed by CDC to ensure that the plans reflect the national recommendation to use antivirals primarily for treatment of individuals sick with influenza. Thirdly, HHS emphasized that health care personnel surge capacity in a pandemic is a local responsibility. Although the 2005 *HHS Pandemic Influenza Plan* recommends deployment of federal medical responders to supplement the number of health care providers, HHS noted that the federal government does not have adequate health care personnel to provide surge capacity. On that topic, HHS also noted that its planning documents for allocating scarce health care resources were intended as “...planning documents for consideration by communities, not for the purposes of establishing definitive standards.”

Finally, HHS proposed alternate terms for some of the concepts in our report (we have noted these instances in the report). For example, HHS disagreed with our use of the term “altered standards of care” and said that the more appropriate term is “standards of care appropriate to the situation.” Because we believe that “altered standards of care” is an accurate description of what may happen as the result of the allocation of scarce health care resources in a pandemic emergency and because HHS used this phrase in its guidance to state and local jurisdictions, we did not make this change.

We are sending copies of this report to the Secretary of HHS and to interested congressional committees. We will also make copies available to others on request. In addition, the report will be available at no charge on GAO’s Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or CrosseM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal stroke at the end.

Marcia Crosse
Director, Health Care

Appendix I: Summaries of Select Federal Documents Relevant for Preparing for and Responding to Influenza Pandemic

National Response Framework

The *National Response Framework* lays out, in part, the manner in which the federal government responds to domestic incidents.¹ The plan is a guide for an all-hazards response, categorizing the types of federal assistance into specific emergency support functions. Primary and supporting agencies are listed for each emergency support function. “Emergency Support Function #8 – Public Health and Medical Services Annex” of the *National Response Framework* directs the Department of Health and Human Services (HHS) to provide support as the primary agency, with 16 other agencies, including the Departments of Homeland Security and Agriculture.

The *National Response Framework* replaced the *National Response Plan* in March 2008, which, in turn, replaced the *Federal Response Plan* in April 2005. The *Federal Response Plan*, originally drafted in 1992 and revised in 1999, established the process and structure for the federal government’s provision of assistance in response to any major disaster or emergency declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). The purpose of the Stafford Act is “to provide an orderly and continuing means of assistance by the federal government to state and local governments in carrying out their responsibilities to alleviate the suffering and damage which result” from disasters and emergencies.²

National Strategy for Pandemic Influenza

On November 1, 2005, the President of the United States released the *National Strategy for Pandemic Influenza*, which provides a framework for future planning efforts for how the country will prepare for, detect, and respond to an influenza pandemic.³ The strategy reflects the federal government’s approach to the pandemic threat and is based on three main types of activities: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment.

¹Department of Homeland Security, *National Response Framework* (Washington, D.C.: January 2008).

²Pub. L. No. 93-288 § 101, 88 Stat. 143 (1974) (as amended) (codified as amended at 42 U.S.C. § 5121).

³Homeland Security Council, *National Strategy for Pandemic Influenza* (Washington, D.C., Nov. 1, 2005).

National Strategy for Pandemic Influenza Implementation Plan

On May 3, 2006, the President of the United States released the *National Strategy for Pandemic Influenza Implementation Plan*, which further clarifies the roles and responsibilities of governmental and nongovernmental entities—including federal, state, local, and tribal authorities and regional, national, and international stakeholders—and provides preparedness guidance for all segments of society.⁴ This plan addresses the following topics: U.S. government planning and response; international efforts and transportation and borders; protecting human health; protecting animal health; law enforcement, public safety, and security; and institutional considerations. The federal government has identified approximately 300 action items to address the threat of a pandemic. These items include 199 action items led or co-led by HHS. As stated in the plan’s preface, the plan will be reviewed on a continuous basis and revised as appropriate to reflect changes in the understanding of the threat and the development of new technologies.

Since the release of the implementation plan, the Homeland Security Council released the *National Strategy for Pandemic Influenza Implementation Plan One Year Summary* on July 17, 2007.⁵ This document summarizes the federal government’s efforts to prepare for an influenza pandemic.

HHS Pandemic Influenza Plan

Because HHS has primary responsibility for coordinating the nation’s response to public health emergencies under “Emergency Support Function #8,” the department has developed the *HHS Pandemic Influenza Plan*.⁶ The first part of this plan provides HHS’s strategic plan for dealing with an influenza pandemic. This includes information on recommendations on the use of vaccines and antivirals, legal authorities, key HHS activities, HHS research activities, and international partnerships on avian and pandemic influenza. Preparing for and responding to a

⁴Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* (Washington, D.C.: May 3, 2006).

⁵Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan One Year Summary* (Washington, D.C.: July 17, 2007).

⁶Department of Health and Human Services, *HHS Pandemic Influenza Plan* (Washington, D.C.: November 2005).

Appendix I: Summaries of Select Federal Documents Relevant for Preparing for and Responding to Influenza Pandemic

pandemic will not be purely a federal responsibility; it will primarily be a local response. And because a pandemic is likely to occur in multiple areas simultaneously, resources cannot be geographically shifted as is often done with other emergencies; every community will need to rely on its own planning and resources to respond to the outbreak. Therefore, the second part of the *HHS Pandemic Influenza Plan* consists of 11 supplements that provide guidance to state and local officials on response elements necessary for preparation for a pandemic (see table 5).

Table 5: Response Elements Needed for Preparing for and Responding to an Influenza Pandemic and Examples of Priority Activities for Each Response Element

Response elements	Examples of priority activities
Pandemic influenza disease surveillance	<ul style="list-style-type: none"> • Health departments provide weekly reports on the overall level of influenza in their states and territories • State and local officials implement virologic, outpatient, hospital, and mortality surveillance
Laboratory diagnostics	<ul style="list-style-type: none"> • Clinical and hospital laboratories work with state and local health departments to train personnel in management of respiratory specimens during an influenza pandemic • Clinical and hospital laboratories will send selected specimens from possible pandemic influenza patients to state or local health departments
Healthcare planning	<ul style="list-style-type: none"> • Healthcare facilities' officials will develop planning and decision-making structures for responding to pandemic influenza • Healthcare facilities' officials will identify and isolate all potential patients with pandemic influenza
Infection control	<ul style="list-style-type: none"> • Patients with known or suspected pandemic influenza should be isolated for a minimum of 5 days from the onset of symptoms • Follow standard facility procedures for post-discharge cleaning of an isolation room
Clinical guidelines	<ul style="list-style-type: none"> • State and local public health agencies will help educate health care providers about pandemic influenza • Health care providers will report pandemic influenza cases or fatalities as requested by health departments
Vaccine distribution and use	<ul style="list-style-type: none"> • HHS agencies will work with manufacturers to expedite public-sector vaccine purchasing contracts during a pandemic • HHS agencies will revise recommendations on vaccination of priority groups, guided by epidemiologic information about the pandemic virus
Antiviral drug distribution and use	<ul style="list-style-type: none"> • HHS, in concert with the Congress and in collaboration with the states in advance of an influenza pandemic, will acquire sufficient quantities of antivirals to treat 25 percent of the U.S. population • HHS will revise recommendations for treatment and prophylaxis with antivirals for priority groups, if necessary, guided by accumulating data about the pandemic virus
Community disease control and prevention	<ul style="list-style-type: none"> • Community officials will help identify potential isolation and quarantine facilities • Community officials will help ensure that legal authorities and procedures exist for various levels of movement restrictions

Appendix I: Summaries of Select Federal Documents Relevant for Preparing for and Responding to Influenza Pandemic

Response elements	Examples of priority activities
Management of travel-related risk of disease transmission	<ul style="list-style-type: none"> • State and local officials will work with the Centers for Disease Control and Prevention quarantine stations and federal partners to evaluate and manage arriving ill passengers who might be infected with influenza strains with pandemic potential • State and local officials will evaluate the need to implement or terminate travel-related containment measures as the pandemic evolves
Public health communications	<ul style="list-style-type: none"> • State and local officials will assess and monitor readiness to meet communications needs in preparation for an influenza pandemic, including regular review and update of communications plans • State and local officials will tailor communications services and key messages to specific local audiences
Psychosocial workforce support services	<ul style="list-style-type: none"> • HHS agencies will create, collect, and provide educational and training materials on psychosocial issues related to pandemic influenza for use by hospital administrators, emergency department staff, safety and security professionals, behavioral health providers, social workers, psychologists, chaplains, and others • Health care institutions, state and local agencies, first responder organizations, and employers of essential service workers will provide psychological and social support services for employees and their families

Source: HHS.

Note: *HHS Pandemic Influenza Plan*, Washington, D.C., Nov. 2005.

The third part of the plan, which details the critical actions items for which HHS has the lead as described in the *National Strategy for Pandemic Influenza Implementation Plan*, was produced as a separate plan—the *Pandemic Influenza Implementation Plan*—and was released in November 2006.⁷ The *Pandemic Influenza Implementation Plan* also includes a second part that contains the HHS agencies’ operational plans.

The *HHS Pandemic Influenza Plan* will be reviewed on a continuous basis and revised as appropriate to reflect changes in the understanding of the threat and new technologies. HHS has released five updates regarding the progress of the department’s preparedness efforts on March 13, 2006; June 29, 2006; November 13, 2006; July 18, 2007; and March 17, 2008, respectively.

⁷Department of Health and Human Services, *Pandemic Influenza Implementation Plan* (Washington, D.C.: November 2006).

Homeland Security Presidential Directive-21: Public Health and Medical Preparedness

On October 18, 2007, the President of the United States released the *Homeland Security Presidential Directive-21: Public Health and Medical Preparedness*,⁸ which provides a strategy for protecting the health of the U.S. population against all disasters, including a pandemic. This directive describes four critical components of public health and medical preparedness: biosurveillance, countermeasure distribution (including pharmaceuticals), mass casualty care, and community resilience. All four critical components will include coordination of efforts at the federal, state, and local levels, as well as with private sector, public health, and medical disaster response resources.

Guidance on Allocating and Targeting Pandemic Influenza Vaccine

On July 23, 2008, HHS, in coordination with DHS, released the *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*.⁹ This guidance provides a framework to state and local jurisdictions on how to allocate limited supplies of pandemic vaccine to targeted groups, with the goal of providing this vaccine to all who choose to receive it. According to the guidance, groups targeted for vaccination varies depending on the severity of the pandemic.

⁸White House, *Homeland Security Presidential Directive-21: Public Health and Medical Preparedness* (Washington, D.C.: Oct. 18, 2007).

⁹Department of Health and Human Services and Department of Homeland Security, *Guidance on Allocating and Targeting Pandemic Influenza Vaccine* (Washington, D.C.: July 23, 2008).

Appendix II: HHS Activities for Acquiring Pharmaceutical Interventions for an Influenza Pandemic within the United States

According to HHS officials, it is important to have a stockpile of pharmaceutical interventions, when possible, for use during the early stages of a pandemic. HHS allotted portions of its total fiscal year 2006 appropriation for pandemic-related purposes—\$5.683 billion—to the acquisition and development of pharmaceutical interventions.¹ Specifically, approximately \$1.1 billion was targeted for investment in antivirals and approximately \$3.2 billion was dedicated for vaccines.² HHS has also established goals for amounts of pharmaceutical interventions to be stockpiled nationally (see table 6).

Table 6: HHS Goals for Amounts of Pharmaceutical Interventions to Be Stockpiled Nationally

Antiviral goal 1	To provide 75 million treatment courses of antivirals
Antiviral goal 2	To provide antivirals for strategic use for limited containment at the onset of a pandemic – 6 million treatment courses
Vaccine goal 1	To establish and maintain a pre-pandemic influenza vaccine stockpile sufficient for 20 million persons ^a (at 2 doses per person)
Vaccine goal 2	To provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration – 600 million doses of pandemic vaccine

Source: HHS.

Note: Statement by Gerald W. Parker, Principle Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response on Pandemic Influenza Preparedness: Update on the Development and Acquisition of Medical Countermeasures before the Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, U.S. Senate, Jan. 24, 2007.

¹See Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-149, 119 Stat. 2833, 2857 (funds not limited to purposes related to pandemic or avian influenza); Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, 119 Stat. 2680, 2783, 2786; Emergency Supplemental Appropriations Act for Defense, the Global War on Terror and Hurricane Recovery, 2006, Pub. L. No. 109-234, 120 Stat. 479 (includes \$30 million to be transferred to the U.S. Agency for International Development). HHS also received appropriations specifically available for pandemic-influenza-related purposes, among other purposes, totaling \$50 million in fiscal year 2004, \$182 million in fiscal year 2005, and \$100 million in fiscal year 2007. 2004: Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, 118 Stat. 3, 251; 2005: Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, 118 Stat. 2809, 3138, Emergency Supplemental Appropriations Act, 2005: War on Terror, and Tsunami Relief, 2005, Pub. L. No. 109-13, 119 Stat. 231, 276, 280; 2007: Revised Continuing Appropriations Resolution, 2007, Pub. L. No. 110-5, 121 Stat. 8, 33. Many of these appropriations are available without fiscal year limitation.

²Also, approximately \$179 million of the appropriated funds was dedicated to international collaboration, with the remainder going to other areas, such as state and local preparedness and risk communications.

**Appendix II: HHS Activities for Acquiring
Pharmaceutical Interventions for an Influenza
Pandemic within the United States**

⁹In May 2006, the Secretaries of HHS and DHS tasked the National Infrastructure Advisory Council with, among other things, providing recommendations regarding the prioritization and distribution of pharmaceutical countermeasures to the critical workforce. According to this Council's report, the number of the most essential critical infrastructure workers is approximately 12 million. See National Infrastructure Advisory Council, *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group: Final Report and Recommendations by the Council*. Washington, D.C.: Jan. 16, 2007. According to HHS, the 20 million people in the critical workforce include the approximately 12 million identified by the National Infrastructure Advisory Council as the most critical as well as other essential personnel such as military personnel, including the National Guard and critical government workers, such as border protection personnel.

HHS has invested millions of dollars into the stockpiling of antivirals to achieve its two goals for antivirals. Table 7 summarizes the approximate number of courses stockpiled as of May 2008. In addition, in March 2006, HHS allotted \$200 million dollars to the development of additional antivirals, and in January 2007, the department awarded a 4-year contract of about \$103 million for further development of the new antiviral peramivir.

Table 7: Approximate Number of Treatment Courses of Antivirals in the Strategic National Stockpile as of May 2008

Antivirals	Approximate number of treatment courses available
Neuraminidase inhibitors	
Oseltamivir (Tamiflu)	40 million
Zanamivir (Relenza)	10 million

Source: HHS.

HHS has also awarded contracts to purchase pre-pandemic vaccines from manufacturers to add to the federal stockpile. See table 8 for HHS's efforts to stockpile pre-pandemic vaccines. HHS officials told us that the greatest challenge to preparing for an influenza pandemic and implementing its plans for using pharmaceutical interventions is the lack of vaccine manufacturing capacity within the United States. We found in prior work that the lack of U.S. vaccine manufacturing capacity is cause for concern among experts because it is possible that countries without domestic manufacturing capacity will not have access to vaccines in the event of a pandemic if the countries with domestic manufacturing capacity prohibit the export of the pandemic vaccine until their own needs are met.³

³GAO, *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), 26.

**Appendix II: HHS Activities for Acquiring
Pharmaceutical Interventions for an Influenza
Pandemic within the United States**

Table 8: HHS Efforts to Acquire Pre-Pandemic Vaccine as of August 2007

Viral strain for pre-pandemic vaccine	Number of awarded contracts	Value of awarded contracts	Duration of contracts	Goals	Progress
H5N1 Vaccine Clade 1 ^a (2004) ^b	1	\$21 million	2004-08	Provide 0.47 million doses at 90 micrograms (mcg.) per dose	As of May 2008, HHS has stockpiled enough of this pre-pandemic vaccine for at least 13 million people or 26 million doses.
H5N1 Vaccine Clade 1 (2005)	2	\$243 million	2005-08	Provide 8 million doses at 90 mcg. per dose	
H5N1 Vaccine Clade 2 (2006)	3	\$241 million	2006-08	Provide 4.9 million doses at 90 mcg. per dose	As August 2007, HHS has stockpiled enough vaccine for 3 million people or approximately 6 million doses.
H5N1 Vaccine (2007)	To be determined	To be determined	Intended to cover 2007-09	Intended to provide doses for pre-pandemic stockpile using H5N1	Not applicable

Source: GAO analysis of HHS data.

^aClades refer to different circulating viral strains of a single virus. For example, researchers have divided the H5N1 avian influenza virus into 2 clades – clade 1 refers to the H5N1 virus strain circulating in Cambodia, Lao People’s Democratic Republic, Malaysia, and Vietnam, while clade 2 refers to the H5N1 virus strain circulating in Africa, Europe, Indonesia, and the People’s Republic of China.

^bIn April 2007, HHS announced that the Food and Drug Administration licensed the first vaccine based on the 2004 H5N1 strain for humans in the United States.

Table 9 describes other HHS initiatives to establish domestic manufacturing infrastructure for vaccine production.

**Appendix II: HHS Activities for Acquiring
Pharmaceutical Interventions for an Influenza
Pandemic within the United States**

Table 9: HHS Efforts in Establishing Domestic Infrastructure for Vaccine Manufacturing as of June 2007

Project	Number of awarded contracts	Value of awarded contracts	Duration of contracts	Goals	Progress
Retrofit existing manufacturing facilities	2	\$132.5 million	2007-13	<ul style="list-style-type: none"> Increase domestic influenza vaccine capacity to produce 125 million doses of egg-based pandemic vaccine 	<ul style="list-style-type: none"> In June 2007, HHS announced it had awarded contracts to provide funding for renovation of domestic manufacturing facilities and for providing warm-base operations for manufacturing pandemic vaccines.^a Once operational, these facilities are expected to expand domestic pandemic vaccine manufacturing capacity by 16 percent.
Build new cell-based vaccine facilities	Request for Proposal expected in fiscal year 2007	To be determined	Intended to cover 2008-13	<ul style="list-style-type: none"> Intended for the building of domestic cell-based influenza manufacturing capacity to support pandemic needs 	<ul style="list-style-type: none"> Not applicable

Source: GAO analysis of HHS data.

^aIn warm-base operations, the contractor provides year-round vaccine production.

Other HHS activities to enhance domestic vaccine manufacturing capacity include investing in vaccine development and research. For example, HHS has invested over \$1 billion in development of a cell-based approach to influenza vaccine manufacturing, which it claims will modernize the current egg-based production process (see table 10). The current manufacturing process uses chicken eggs, and egg-based vaccines can easily become contaminated. Cell-based technology does not have these sterility issues and allows for faster development and greater production capacity. Although cell-based vaccine production has been used for other vaccines, it has not been approved for use in developing influenza vaccines. However, according to HHS, it anticipates that a licensed cell-based influenza vaccine will be manufactured in 2010. Also, in January 2007, HHS awarded contracts totaling approximately \$133 million to vaccine manufacturers for development of pre-pandemic vaccines, containing adjuvants—substances that may be added to a vaccine to

**Appendix II: HHS Activities for Acquiring
Pharmaceutical Interventions for an Influenza
Pandemic within the United States**

increase the body's immune response, thereby necessitating a lower dose of vaccine.

Table 10: HHS Progress on Vaccine Development Projects

Project	Number of awarded contracts	Value of awarded contracts	Duration of contracts	Goals	Progress
Egg-based supply	1	\$43 million	2004-2008	<ul style="list-style-type: none"> • Provide year-round egg supply for influenza vaccine manufacturing • Provide vaccines for use in clinical studies • Stockpile other vaccine manufacturing supplies, such as vials, caps, and stoppers • Develop and manufacture pandemic vaccine candidates for clinical investigation 	<ul style="list-style-type: none"> • In April 2005, a secure year-round egg supply for domestic influenza vaccine manufacturing was established • Two pandemic vaccine candidates – H5N1 clade 2 and H7N7 – have been produced for clinical investigations
Cell-based vaccine	6	\$1.1 billion	2005-2011	<ul style="list-style-type: none"> • Expand domestic influenza manufacturing capacity • Establish capacity to produce 475 million doses of pandemic vaccine by 2013 • Require commitments from manufacturers to establish U.S.-based manufacturing facilities with vaccine producing capacity of at least 150 million doses within 6 months of a pandemic 	<ul style="list-style-type: none"> • As of January 2007, six manufacturers were in Phase 1 clinical trials^a in the United States using cell-based production methods
Adjuvant-containing ^b vaccine	3	\$133 million	2007-2012	<ul style="list-style-type: none"> • Reduce amount of vaccine needed in order to increase the number of doses that can be produced • Support further development of adjuvant-containing vaccine for U.S. licensure 	<ul style="list-style-type: none"> • Initial studies have shown that addition of adjuvants to H5N1 vaccines have reduced 10-to-20 fold the amount of antigen needed per dose in order to stimulate an immune response believed to be acceptable during a pandemic

**Appendix II: HHS Activities for Acquiring
Pharmaceutical Interventions for an Influenza
Pandemic within the United States**

Project	Number of awarded contracts	Value of awarded contracts	Duration of contracts	Goals	Progress
				<ul style="list-style-type: none"> • Require each company to build capacity to produce within 6 months of the onset of a pandemic either (1) 150 million doses of a pandemic vaccine containing adjuvant or (2) enough adjuvant to be stockpiled for 150 million doses of a pandemic vaccine • Require each company to provide its proprietary adjuvant for U.S. government-sponsored, independent evaluation with influenza vaccines from other manufacturers 	<ul style="list-style-type: none"> • Phase 1 and 2 clinical studies^c are planned in 2007 with three new adjuvants
Next generation ^d	Request for Proposal in fiscal year 2007	To be determined	2007-2012	<ul style="list-style-type: none"> • Diversify influenza vaccine manufacturing • Reduce manufacturing time 	• Not Applicable

Source: GAO analysis of HHS data.

^aClinical trials test potential treatments in human volunteers to see if they should be approved for wider use in the general population. In Phase 1 trials, researchers attempt to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects. Usually, a small number of healthy volunteers (between 20 and 80) are used in Phase 1 trials.

^bAdjuvants are substances that may be added to a vaccine to increase the body's immune response to the vaccine's active ingredient, called an antigen.

^cPhase 2 trials include more participants (about 100-300) who have the disease or condition that the product potentially could treat. In Phase 2 trials, researchers seek to gather further safety data and preliminary evidence of the drug's beneficial effects (efficacy), and they develop and refine research methods for future trials with this drug.

^dNext generation vaccines refer to vaccines, such as DNA vaccines, developed using new technologies.

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



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, DC 20201

AUG 07 2008

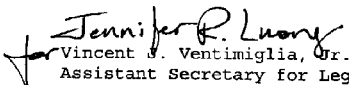
Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Crosse:

Enclosed are the comments of the U.S. Department of Health and Human Services (HHS) on the Government Accountability Office's (GAO) draft report entitled: "Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Intervention" (GAO 08-671).

The Department appreciates the opportunity to comment on this draft before its publication.

Sincerely,


for Vincent V. Ventimiglia, Jr.
Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "INFLUENZA PANDEMIC: HHS NEEDS TO CONTINUE ITS ACTIONS AND FINALIZE GUIDANCE FOR PHARMACEUTICAL INTERVENTIONS" (GAO 08-671)

General Comments – Overview

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on the above-referenced Government Accountability Office (GAO) draft report.

In the draft report HHS was given to review, GAO recommended that "...the Secretary of HHS expeditiously issue final guidance to assist state and local jurisdictions in identifying target groups for receiving supplies of pandemic vaccine, antivirals, and pre-pandemic vaccine." On July 23, 2008, HHS and DHS released final guidance on pandemic vaccine allocation. This *Guidance on Allocating and Targeting Pandemic Influenza Vaccine* provides a planning framework to help state, tribal, local and community leaders ensure that vaccine allocation and use will reduce the impact of a pandemic on public health and minimize disruption to society and the economy. The guidance's vaccination structure defines four broad target groups: people who 1) maintain homeland and national security, 2) provide health care and community support services, 3) maintain critical infrastructure and 4) are in the general population. Everyone in the United States is included in at least one vaccination target group. People who are not included in any occupational group would be vaccinated as part of the general population based on their age and health status.

In the near future HHS will release for public comment proposed guidance on pre-pandemic vaccine allocation.

In June 2008, HHS released for public comment three draft guidance documents related to antiviral drugs and respiratory protection devices: *Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic*, *Proposed Considerations for Antiviral Drug Stockpiling by Employers In Preparation for an Influenza Pandemic* and *Interim guidance on the use and purchase of facemasks and respirators by individuals and families for pandemic influenza preparedness*. HHS is now updating these three guidance documents based on comments submitted by the public.

General Comments – Supplementary Information to Be Considered

Medical Countermeasures

The GAO draft report incorrectly asserts that the use of vaccines and antiviral drugs early in an influenza pandemic is to slow the spread of the pandemic. While there is some modeling work that suggests that the use of vaccines or antiviral prophylaxis might have such an effect, a 2006 Institute of Medicine report pointed out the uncertainties associated with the predictive ability of pandemic influenza modeling. HHS strategies for vaccination and antiviral treatment are predicated on their direct effects in reducing the health, societal and economic impacts of a pandemic. Uncertainties regarding the magnitude of impact on pandemic spread given limited countermeasure supplies, unclear effectiveness and operational challenges support the recommended approach.

GENERAL COMMENTS OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "INFLUENZA PANDEMIC: HHS NEEDS TO CONTINUE ITS ACTIONS AND FINALIZE GUIDANCE FOR PHARMACEUTICAL INTERVENTIONS" (GAO 08-671)

HHS vaccine prioritization guidance, in addition to being firmly rooted in the most up-to-date scientific information available, also directly reflects the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination. As a key part of developing the guidance, HHS held day-long public engagement and stakeholder meetings throughout the country and received more than 200 written public comments on the goals and objectives of pandemic vaccination. In all the meetings, stakeholders and the public identified the same four vaccination program objectives as the most important:

- Protect persons critical to the pandemic response and who provide care for persons with pandemic illness,
- Protect persons who provide essential community services,
- Protect persons who are at high risk of infection because of their occupation, and
- Protect children.

Using pandemic vaccine to slow the spread of a pandemic also was considered but was rated by the public and stakeholders as a less important objective.

It is important to distinguish HHS policies for the use of antiviral drugs in public stockpiles from what it has proposed for private sector stockpiles in *Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic* and *Proposed Considerations for Antiviral Drug Stockpiling by Employers In Preparation for an Influenza Pandemic*. As published in the *HHS Pandemic Influenza Plan* and the *Implementation Plan for the National Strategy* public sector stockpiles are intended to be used primarily for the treatment of ill individuals. Stockpile targets were estimated based on the expected demand for treatment. Treatment should be based on medical need and is not intended to be allocated to target groups. In contrast, prophylactic antiviral drug use in the proposed guidance and the guidance to employers outlines occupational target groups that could be covered by private sector stockpiles of antiviral drugs. The national stockpiling goal in support of treatment is a combined (between Federal and Project Area stockpiles) total of 75 million treatment regimens. HHS has stockpiled an additional 6 million regimens of antiviral drugs to assist in containment activities; these antiviral drugs may be used for both treatment and prophylaxis and combined with the treatment stockpiles round out our national goal of 81 million stockpiled regimens.

The GAO draft report discusses that State and Territorial stockpiles of antiviral drugs, purchased in support of the HHS-established goal of 31 million state-owned treatment regimens, will not be in Federal hands, and therefore, jurisdictions may choose to use these public stockpiles of antiviral drugs for prophylaxis rather than for treatment. State pandemic plans, which have been reviewed by CDC for compliance with national guidance recommendations, focus on using antiviral drugs for treatment, not prophylaxis. Should States decide to use antiviral drugs for prophylaxis rather than for treatment, those States and/or Territories would exhaust their stockpiles quickly and would not have enough antiviral drugs to treat ill individuals as the pandemic evolved. The same situation applies to those States and Territories that do not stockpile their full proportion of the 31 million regimen goal.

The GAO draft report states that "Once a pandemic begins, HHS expects to make existing federal stockpiles of pharmaceutical interventions available to state and local jurisdictions to distribute to

GENERAL COMMENTS OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "INFLUENZA PANDEMIC: HHS NEEDS TO CONTINUE ITS ACTIONS AND FINALIZE GUIDANCE FOR PHARMACEUTICAL INTERVENTIONS" (GAO 08-671)

targeted groups. These interventions would include antivirals, . . . and pre-pandemic vaccines," As outlined above, antiviral drugs from the HHS Strategic National Stockpile (SNS) and other public stockpiles managed by Project Areas are not intended for target groups, rather, they are to be dispensed for treatment of ill individuals based on medical need.

The GAO draft report suggests that pre-pandemic vaccine will be administered by State and local officials to targeted individuals who have been identified to receive the vaccine based on HHS recommendations. This process is not described correctly in the draft report. Federal and State points of distribution (POD) will receive pre-pandemic influenza vaccine from vaccine manufacturers under HHS oversight and administer vaccination to critical workforce members as described in the HHS pre-pandemic vaccine prioritization schedule, which will be released soon for public comment. The GAO report should be clear that the role of HHS, in coordination with DHS and other key Federal partners, is to identify the categories of workers that should be considered for vaccination. Work is ongoing to provide guidance to critical infrastructure businesses on identifying individuals for pre-pandemic and pandemic vaccination and to develop a system that will identify them at sites where vaccine is administered.

Surge Capacity

Although the GAO draft report makes no specific recommendation related to surge capacity, the draft report fails to accurately capture a number of key surge capacity concepts including strategies, roles and responsibilities, and terminology.

The GAO draft report correctly states that HHS has initiated efforts to improve surge capacity but incorrectly suggests that HHS is responsible for healthcare personnel surge capacity. Providing for healthcare personnel surge capacity for an influenza pandemic is a local responsibility and will need to be built locally. The Federal government can assist, but does not have adequate personnel to provide for healthcare personnel surge during an influenza pandemic. The role of HHS is to provide tools to support localities in developing their healthcare personnel surge planning.

The GAO draft report states that two documents issued by HHS (1) *Altered Standards of Care in Mass Casualty Events*; and (2) *Mass Medical Care with Scarce Resources: A Community Planning Guide* provide a "framework" for the allocation of scarce resources and standards of care appropriate to the situation. HHS provided these documents as planning guidance for consideration by communities, not for the purposes of establishing definitive standards. States in conjunction with professional societies will determine the appropriate standards of care for the situation – not HHS or the Federal government. Also, throughout the draft report, GAO report uses the phrase "altered standards of care," rather than the more appropriate phrase, "standards of care appropriate to the situation."

The GAO draft report states that HHS will deploy U.S. Public Health Service (PHS) Commissioned Corps officers and National Disaster Medical System (NDMS) personnel to support healthcare personnel surge capacity. While HHS plans to utilize these personnel during the early stages of a

GENERAL COMMENTS OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "INFLUENZA PANDEMIC: HHS NEEDS TO CONTINUE ITS ACTIONS AND FINALIZE GUIDANCE FOR PHARMACEUTICAL INTERVENTIONS" (GAO 08-671)

severe influenza pandemic, these personnel will not be available for deployment once the pandemic is spreading within the United States. Furthermore, NDMS personnel are primarily local healthcare providers who will be needed by their local communities and healthcare systems during a widespread influenza pandemic, and therefore, will unlikely be deployed elsewhere. Likewise, PHS officers who provide healthcare to tribal communities will be needed in those communities. PHS officers also serve essential functions within HHS agencies, and considering that personnel at HHS and other Federal Departments will be impacted by the pandemic, many PHS personnel will not be available for deployment.

GAO may want to consider some of the other mechanisms HHS has been exploring to expand healthcare personnel surge capacity. For example:

- a. A new report that emphasizes the role of home care during a pandemic was released by HHS in July 2008 and can be found at <http://www.pandemicflu.gov/plan/healthcare/homehealth.html>. Home care may keep the less-severely ill out of the hospitals. One of the major points in this report is that telehealth can be used to support personnel surge since the health care provider would not need to visit each household and could provide care to more people.
- b. In September 2007, HHS released a report that suggests the use of call centers as intervention that can be used to keep the less severely ill out of the hospital and enhance the ability of providers to maximize the number of people who receive information that allows them to receive the highest possible standard of care under the austere conditions of the pandemic. The report can be found at <http://www.ahrq.gov/prep/callcenters/callcenters.pdf>.
- c. Another approach to expanding personnel surge is just-in-time training to assure that individuals are able to provide the highest possible standard of care under the austere conditions of a pandemic. One such program is Project Xtreme <http://www.ahrq.gov/prep/projxtreme/>.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse (202) 512-7114 or CrosseM@gao.gov

Acknowledgments

In addition to the contact named above, Martin T. Gahart, Assistant Director; George Bogart; Cathleen Hamann; Gay Hee Lee; and Deborah J. Miller made key contributions to this report.

Related GAO Products

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 Vaccine: Issues Related to Production, Distribution, and Public Health Messages. [GAO-08-27](#). Washington, D.C.: October 31, 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.

Emergency Management: Most School Districts Have Developed Emergency Management Plans, but Would Benefit from Additional Federal Guidance. [GAO-07-609](#). Washington, D.C.: June 12, 2007.

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.

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.

Influenza Pandemic: Applying Lessons Learned from the 2004-05 Influenza Vaccine Shortage. [GAO-06-221T](#). Washington, D.C.: November 4, 2005.

Influenza Vaccine: Shortages in 2004-05 Season Underscore Need for Better Preparation. [GAO-05-984](#). Washington, D.C.: September 30, 2005.

Influenza Pandemic: Challenges in Preparedness and Response. [GAO-05-863T](#). Washington, D.C.: June 30, 2005.

Influenza Pandemic: Challenges Remain in Preparedness. [GAO-05-760T](#). Washington, D.C.: May 26, 2005.

Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreak. [GAO-04-1100T](#). Washington, D.C.: September 28, 2004.

Bioterrorism: Public Health Response to Anthrax Incidents of 2001. [GAO-04-152](#). Washington, D.C.: October 15, 2003.

Infectious Diseases: Gaps Remain in Surveillance Capabilities of State and Local Agencies. [GAO-03-1176T](#). Washington, D.C.: September 24, 2003.

SARS Outbreak: Improvements to Public Health Capacity Are Needed for Responding to Bioterrorism and Emerging Infectious Diseases. [GAO-03-769T](#). Washington, D.C.: May 7, 2003.

Bioterrorism: Preparedness Varied across State and Local Jurisdictions. [GAO-03-373](#). Washington, D.C.: April 7, 2003.

Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities. [GAO-03-460](#). Washington, D.C.: March 14, 2003.

Nursing Workforce: Emerging Nurse Shortages Due to Multiple Factors. [GAO-01-944](#). Washington, D.C.: July 10, 2001.

Nursing Workforce: Recruitment and Retention of Nurses and Nurse Aides Is a Growing Concern. [GAO-01-750T](#). Washington, D.C.: May 17, 2001.

Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People. [GAO-01-624](#). Washington, D.C.: May 15, 2001.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "E-mail Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, DC 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548