



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](mailto: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.