STATEMENT BY SECRETARY LEAVITT

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

When the U.S. Department of Health & Human Services released the Pandemic Influenza Strategic Plan Part I, a year ago, I noted: "We are better prepared today than we were yesterday, and we will be better prepared tomorrow than we are today." Indeed, we are better prepared this year than we were one year ago – and, by continuing to implement the plans we have outlined, we will continue to improve our readiness into the future.

Since the release of our report last November, Congress has allotted $5.5 billion to support our preparation efforts, and our progress has been unprecedented. HHS, for example, has conducted pandemic flu summits in every state and territory, engaging state, local and tribal leaders and community representatives in preparation for an effective response to a pandemic. We are building our vaccine production capacity by investing in new technology, while continuing to grow our stockpile of medical interventions and supplies needed for response. We launched www.pandemicflu.gov, a cross-governmental internet resource used by millions of Americans seeking planning and guidance tools to increase their personal and community preparedness. In addition, we facilitated and subsidized state purchase of antiviral drugs and provided millions of dollars to states to enhance their efforts to develop an exercise preparedness plan.

This substantial commitment and investment has taken us a long way down the path of preparedness – but this should not make us complacent. Though it has not yet achieved sustained transmission between humans, the H5N1 strain of avian influenza has reached dozens of countries and claimed more than one hundred-fifty lives. A pandemic remains a serious local and global threat, and there is more work to be done to prepare for it.

Preparation is a continuum. We remain fortunate that we have not yet been faced with a pandemic and can use this time to prepare. If we continue to be vigilant in our commitment to preparedness, we will be better prepared to limit the severity and duration of a pandemic. We have an opportunity to be the first generation in history to be prepared for a pandemic and to save millions of lives in this country and around the world as a result. We must renew our commitment to seize this opportunity.

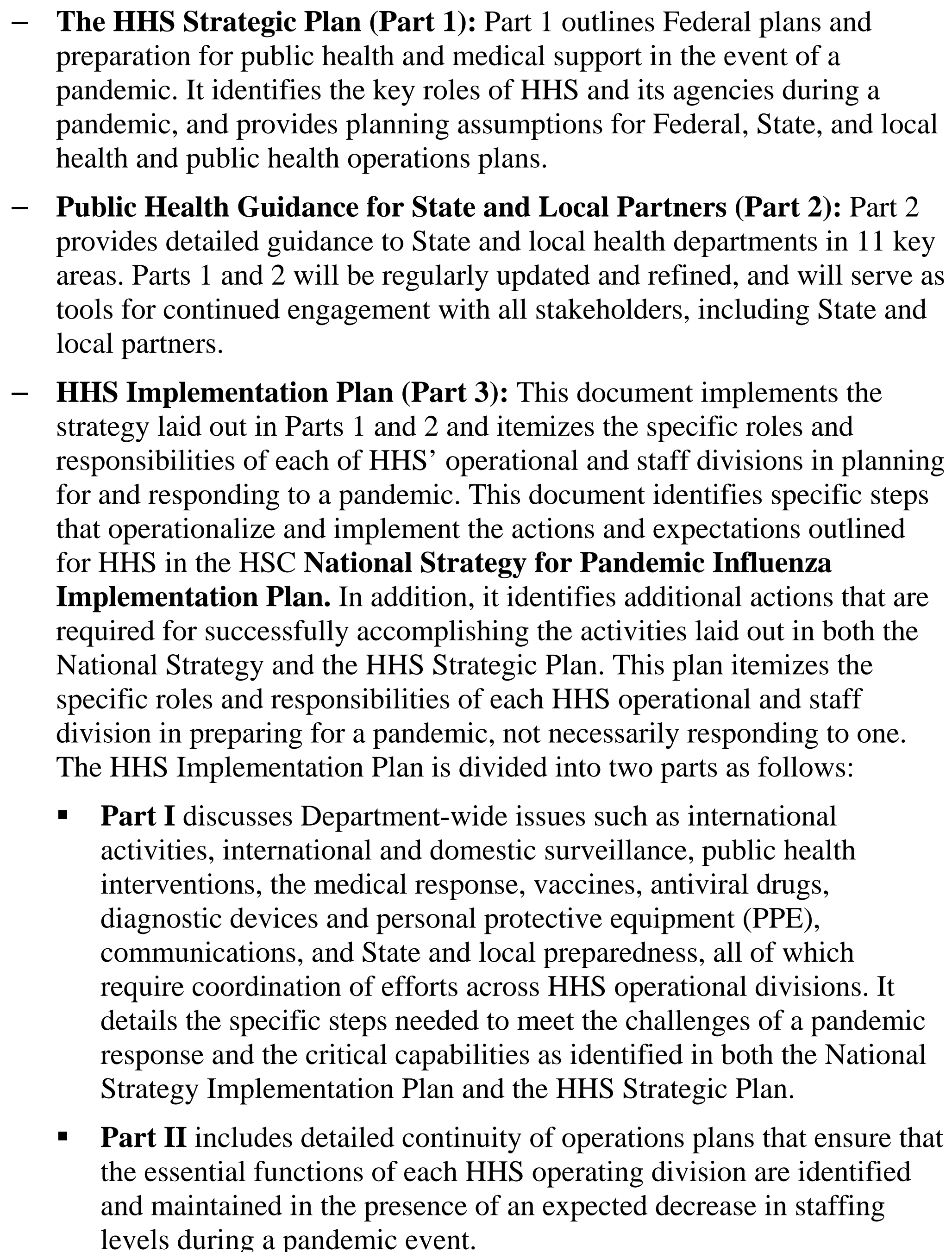
Sincerely,

Michael O. Leavitt

PREFACE

An influenza pandemic has the capacity to affect individuals and disrupt society on multiple levels. Pandemic influenza preparedness is a public health priority and a shared responsibility of the U.S. Department of Health and Human Services (HHS), the World Health Organization (WHO), and other Federal and non-Federal stakeholders across the country and abroad. The global nature of an influenza pandemic compels Federal, State, local, and tribal governments, communities, corporations, institutions, families, and individuals to learn about, prepare for, and collaborate in efforts to slow, mitigate, and recover from a pandemic. The development, refinement, integration, exercise, and communication of pandemic influenza plans by all stakeholders are critical components of preparedness. To this end, the Federal Government has developed the following documents to guide the Nation's pandemic influenza preparedness planning and response activities:

- **National Strategy for Pandemic Influenza:** On November 1, 2005, the President released the National Strategy for Pandemic Influenza, which provides a framework for the U.S. Government's pandemic influenza preparedness and response efforts. (See http://www.whitehouse.gov/homeland/pandemic-influenza.html.)
- **The National Strategy for Pandemic Influenza Implementation Plan:** The White House Homeland Security Council (HSC) released the National Strategy for Pandemic Influenza Implementation Plan in May 2006. This Implementation Plan provides a common frame of reference for understanding the pandemic threat and summarizes key planning assumptions to set a framework for effective action. It also proposes that Federal Departments and Agencies take specific coordinated steps to achieve the goals of the National Strategy, and outlines expectations for Federal and non-Federal stakeholders in the U.S. and abroad. This plan directs all Federal Departments to develop a pandemic influenza plan. (See http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html.)
- **HHS Pandemic Influenza Plan:** On November 2, 2005, HHS released Parts 1 and 2 of the HHS Pandemic Influenza Plan, which serves as a strategic blueprint for all HHS pandemic influenza preparedness planning and response activities. (See http://www.hhs.gov/pandemicflu/plan/.) The Plan builds on the actions and expectations set out in the National Strategy and its Implementation Plan, and updates the August 2004 draft HHS Pandemic Influenza Preparedness and Response Plan. The Plan integrates the changes made in the 2005 WHO classification of pandemic phases and its concomitant expansion of international guidance. It also is consistent with the National Response Plan (NRP) published in December 2004. It includes:



- **The HHS Strategic Plan (Part 1):** Part 1 outlines Federal plans and preparation for public health and medical support in the event of a pandemic. It identifies the key roles of HHS and its agencies during a pandemic, and provides planning assumptions for Federal, State, and local health and public health operations plans.
- **Public Health Guidance for State and Local Partners (Part 2):** Part 2 provides detailed guidance to State and local health departments in 11 key areas. Parts 1 and 2 will be regularly updated and refined, and will serve as tools for continued engagement with all stakeholders, including State and local partners.
- **HHS Implementation Plan (Part 3):** This document implements the strategy laid out in Parts 1 and 2 and itemizes the specific roles and responsibilities of each of HHS' operational and staff divisions in planning for and responding to a pandemic. This document identifies specific steps that operationalize and implement the actions and expectations outlined for HHS in the HSC **National Strategy for Pandemic Influenza Implementation Plan.** In addition, it identifies additional actions that are required for successfully accomplishing the activities laid out in both the National Strategy and the HHS Strategic Plan. This plan itemizes the specific roles and responsibilities of each HHS operational and staff division in preparing for a pandemic, not necessarily responding to one. The HHS Implementation Plan is divided into two parts as follows:
  - **Part I** discusses Department-wide issues such as international activities, international and domestic surveillance, public health interventions, the medical response, vaccines, antiviral drugs, diagnostic devices and personal protective equipment (PPE), communications, and State and local preparedness, all of which require coordination of efforts across HHS operational divisions. It details the specific steps needed to meet the challenges of a pandemic response and the critical capabilities as identified in both the National Strategy Implementation Plan and the HHS Strategic Plan.
  - **Part II** includes detailed continuity of operations plans that ensure that the essential functions of each HHS operating division are identified and maintained in the presence of an expected decrease in staffing levels during a pandemic event.

The **HHS Implementation Plan** is a dynamic document that will be reviewed and revised as needed as HHS efforts in pandemic preparedness mature. The plan will be tested to identify preparedness weaknesses and to promote effective implementation. Throughout this process, the pandemic influenza response will be optimized by effectively engaging partners and stakeholders during all phases of pandemic planning and response.

EXECUTIVE SUMMARY

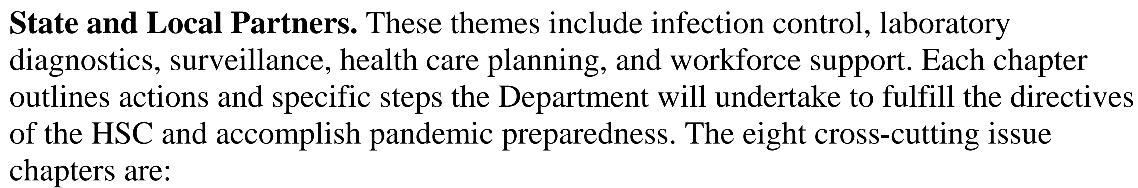
An influenza pandemic has the potential to cause more death and illness than any other public health threat. Although the timing, nature, and severity of the next pandemic cannot be predicted with any certainty, preparedness planning is imperative to lessen the impact of a pandemic. The unique characteristics and events of a pandemic will strain local, State, and Federal resources. For example, it is unlikely that there will be sufficient personnel, equipment, and supplies to simultaneously respond adequately in multiple areas of the country for a sustained period of time. Therefore, the minimization of social and economic disruption will require a coordinated response by the whole country. All governments, communities, and public- and private-sector stakeholders will need to anticipate and prepare for a pandemic by defining their roles and responsibilities, and developing continuity-of-operations plans. To this end, the President directed the Secretary of HHS to initiate a State and local preparedness process. HHS is actively working to help States, tribes, cities, schools, businesses, churches, individuals, and families across the country plan for a pandemic. HHS is collaborating with Governors' offices in every State to hold pandemic summits and exercises. HHS/Centers for Disease Control and Prevention (CDC) have developed checklists to aid in pandemic influenza preparations. These checklists provide specific guidance for State and local planning, businesses, health care providers, community organizations, individuals, and families. (See http://www.pandemicflu.gov.)

During a pandemic, and consistent with the **National Response Plan** (NRP, see http://www.dhs.gov/xlibrary/assets/NRP_FullText.pdf), as head of Emergency Support Function (ESF) #8, Public Health and Medical Services, the Secretary of HHS will lead the Federal public health and medical response efforts. The **HHS Pandemic Influenza Plan** serves as a blueprint for all HHS pandemic influenza preparedness and response planning. Part 1, the **Strategic Plan,** describes a coordinated public health and medical care strategy to prepare for, and begin responding to, an influenza pandemic. Part 2, **Public Health Guidance for State, Local, and Tribal Partners,** provides guidance on specific aspects of pandemic influenza planning and response for the development of State, local, and tribal preparedness plans.

This document, Part 3, the **HHS Implementation Plan,** operationalizes the strategy described in the White House Homeland Security Council (HSC) **National Strategy for Pandemic Implementation Plan** by detailing Department-wide HHS pandemic preparedness actions and steps (Part I) and by outlining Agencies' continuity-of-business plans (Part II).

Part I

Part I of the **HHS Implementation Plan** identifies eight cross-cutting issues that encompass many of the themes noted in the **HHS Strategic Plan and Guidance for**



State and Local Partners. These themes include infection control, laboratory diagnostics, surveillance, health care planning, and workforce support. Each chapter outlines actions and specific steps the Department will undertake to fulfill the directives of the HSC and accomplish pandemic preparedness. The eight cross-cutting issue chapters are:

- International Activities
- Domestic Surveillance
- Public Health Interventions
- Federal Medical Response
- Vaccines
- Antiviral Drugs
- Communications
- State, Local, and Tribal Preparedness

The action steps in these eight chapters are organized by the three pillars identified in the **National Strategy for Pandemic Influenza:** preparedness and communication; surveillance and detection; and response and containment. The implementation of the HHS action steps is contingent upon the availability of resources.

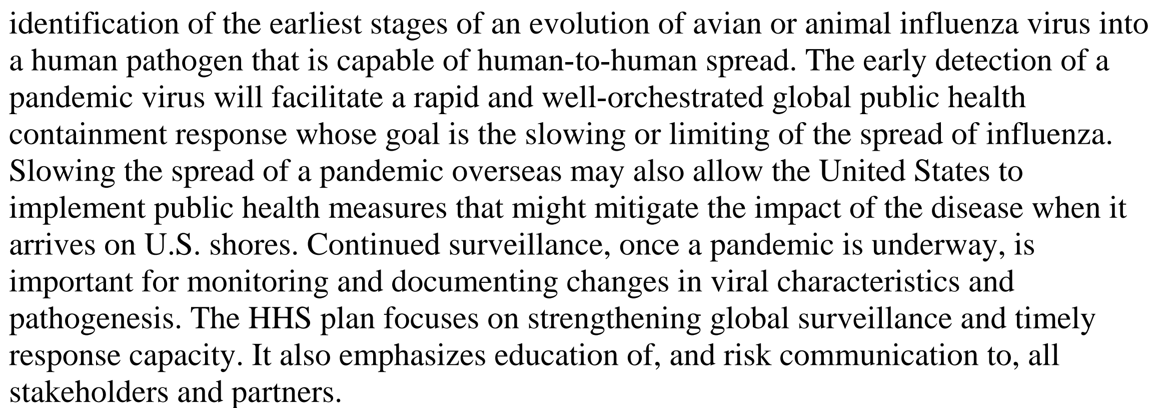
International Activities

While a novel influenza virus could emerge anywhere in the world at any time, current concern focuses on the continued spread of avian influenza A/(H5N1), which is highly pathogenic in poultry and has caused sporadic cases of severe disease in humans.[1, 2, 3] The emergence and intercontinental spread of avian influenza A/(H5N1) in birds underscores the interrelatedness of all countries and communities with respect to public health emergencies. Chapter 1 emphasizes the need to work in partnership with countries and provide technical assistance to enhance surveillance and response activities in low-resourced countries. International disease-surveillance efforts could permit the

[1] Chotpitayasunondh T, Ungchusak K, Hanshaoworakul W, Chunsuthiwat S, Sawanpanyalert P, Kijphati R, Lochindarat S, Srisan P, Suwan P, Osotthanakorn Y, Anantasetagoon T, Kanjanawasri S, Tanupattarachai S, Weerakul J, Chaiwirattana R, Maneerattanaporn M, Poolsavathitikool R, Chokephaibulkit K, Apisarnthanarak A, Dowell SF. Human disease from influenza A (H5N1), Thailand, 2004. Emerg Infect Dis. 2005 Feb;11(2):201–9.

[2] Beigel JH, Farrar J, Han AM, Hayden FG, Hyer R, de Jong MD, Lochindarat S, Nguyen TK, Nguyen TH, Tran TH, Nicoll A, Touch S, Yuen KY; Writing Committee of the World Health Organization (WHO) Consultation on Human Influenza A/H5. Avian influenza A (H5N1) infection in humans. N Engl J Med. 2005 Sep 29;353(13):1374–85. Review.

[3] Hien TT, de Jong M, Farrar J. Avian influenza—a challenge to global health care structures. N Engl J Med. 2004 Dec 2;351(23):2363–5.



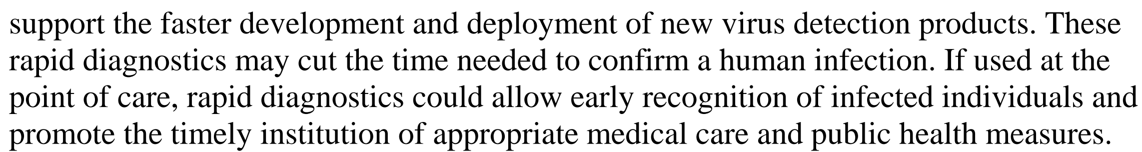
identification of the earliest stages of an evolution of avian or animal influenza virus into a human pathogen that is capable of human-to-human spread. The early detection of a pandemic virus will facilitate a rapid and well-orchestrated global public health containment response whose goal is the slowing or limiting of the spread of influenza. Slowing the spread of a pandemic overseas may also allow the United States to implement public health measures that might mitigate the impact of the disease when it arrives on U.S. shores. Continued surveillance, once a pandemic is underway, is important for monitoring and documenting changes in viral characteristics and pathogenesis. The HHS plan focuses on strengthening global surveillance and timely response capacity. It also emphasizes education of, and risk communication to, all stakeholders and partners.

Domestic Surveillance

Continuous surveillance, both domestic and abroad, will provide data on trends in disease activity and virus subtype circulation, and will inform policy and public health decisionmaking in the pre-pandemic and pandemic periods. Initially, domestic surveillance efforts are designed to detect influenza virus types and subtypes, including pandemic strains, circulating in the United States, and will focus on detecting initial cases and clusters of human illness. Early detection of initial cases ensures timely investigation and implementation of public health interventions to limit further spread of disease. Detection of early cases and appropriate laboratory investigation will facilitate the prompt identification of viral characteristics (antiviral susceptibility, antigenicity, transmissibility, and virulence) that can affect medical case management as well as public health response measures. It will also facilitate the development of both pre-pandemic and pandemic vaccines. Early delineation of viral characteristics will increase the likelihood that a vaccine could be available in a timely manner. Early identification of cases will also maximize the chances of delaying the spread of the pandemic across the country.

Surveillance requires that laboratory systems are in place to characterize viral subtypes, enable detection and investigation of suspected cases in a community, and detect sentinel increases in disease activity. Surveillance data will direct decisions on vaccine development, antiviral drug use, and the implementation and continuation of public health interventions, including diagnostic devices and personal protection equipment (PPE) use, to limit the spread of disease. Ongoing surveillance and the generation of real-time data can also help monitor the progression of a pandemic and the effectiveness of various interventions. Surveillance data may be used by researchers to model and project the trajectory of a pandemic.

HHS activities concentrate initially on continuing to build laboratory and epidemiologic capacity for surveillance and response; and on establishing comprehensive, integrated, timely, and sensitive surveillance systems; by building on existing systems and by initiating new systems where gaps currently exist. In addition, current HHS activities will



support the faster development and deployment of new virus detection products. These rapid diagnostics may cut the time needed to confirm a human infection. If used at the point of care, rapid diagnostics could allow early recognition of infected individuals and promote the timely institution of appropriate medical care and public health measures.

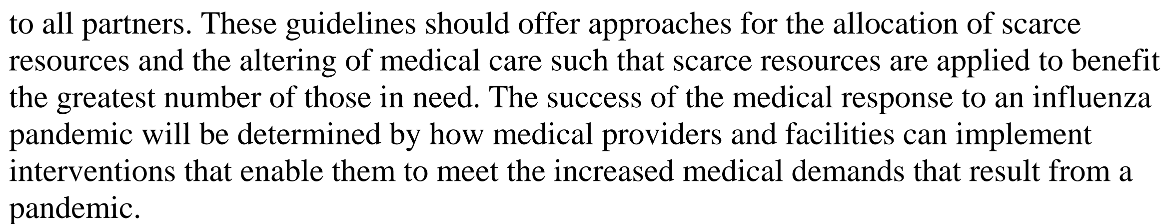
Public Health Interventions

At the start of a pandemic, a vaccine may not be widely available, and the supply of antiviral drugs may be limited. Public health interventions, such as containment strategies (isolation of infected individuals and social distancing measures), could delay the introduction and/or spread of a novel, pandemic influenza virus in the United States. In the absence of available drugs, and before a pandemic vaccine is produced, public health interventions are the main defense mechanism against viral infection. The specific interventions implemented will depend on the pandemic phase. For example, early in a pandemic that emerges overseas—before the virus is detected in the United States—local containment strategies and travel-related actions (travel advisories and precautions, including entry and exit screening of persons arriving from infected countries or regions) could impede the establishment of the pandemic virus in this country. Later, after the virus is widespread in the United States, public health interventions such as closing schools, restricting public gatherings, quarantining exposed persons, isolating infected persons, and telecommuting or working from home could reduce the number of people infected with the virus. During this time, public health interventions that retard the spread of infection could mitigate the disruptive impact of a pandemic until such medical interventions became available. The HHS Plan outlines steps to develop recommendation protocols to implement and evaluate public health interventions throughout a pandemic cycle.

Federal Medical Response

An influenza pandemic will place extraordinary demands on the U.S. health care system. Efficient use of existing medical resources and expedient deployment of Federal medical assets, including personnel, are crucial in addressing the medical surge requirements imposed by a pandemic. Because the provision of health care is almost entirely a local responsibility, planning at the State and local level is essential for pandemic preparedness. Integration of the medical response across the local, State, and Federal levels becomes critical to optimize the use of scarce medical resources. HHS is working with its State, local, and tribal partners to increase surge capacity of medical materiel and personnel.

For the most efficient use of medical resources, effective response plans must be developed and tested at all levels. Plans must include a functional command structure consistent with the National Incident Management System (NIMS), a regional approach to the stockpiling and distribution of medical materiel, and a schedule of exercises for evaluating the effectiveness of the plans. Guidelines must be developed and disseminated



to all partners. These guidelines should offer approaches for the allocation of scarce resources and the altering of medical care such that scarce resources are applied to benefit the greatest number of those in need. The success of the medical response to an influenza pandemic will be determined by how medical providers and facilities can implement interventions that enable them to meet the increased medical demands that result from a pandemic.

The **HHS Implementation Plan** describes specific steps to develop deployment strategies for Federal medical resources, including personnel, and steps to develop guidelines for the health care system to augment surge capacity, distribute medical resources, institute appropriate infection control measures, and review/modify standards of care without compromising clinical outcome.

Chapter 4, Federal Medical Response, primarily addresses the Federal medical response, and also addresses integrated planning across all jurisdictions. For additional preparedness guidance for State and local partners, see Part 2 of the **HHS Pandemic Influenza Plan (Public Health Guidance for State and Local Partners)** and Chapter 8, State, Local, and Tribal Preparedness, of this plan.

Vaccines

Historically, vaccination has been the most effective measure for minimizing the morbidity and mortality associated with influenza. Vaccines may also limit virus spread, and thus, the course of a pandemic. Since a pandemic vaccine can only be made once a pandemic virus is identified and isolated, it cannot be available during the early phases of a pandemic. Therefore, a pre-pandemic vaccine based on novel influenza viruses with pandemic potential that are known to be in circulation, and for which a vaccine has already been developed and stockpiled, may provide partial protection or immunologic priming of persons at high risk during the early phases of a pandemic.

When a pandemic is declared and a specific vaccine against the pandemic virus becomes available, its distribution and delivery will be a major focus of the pandemic response. Vaccines produced for a pandemic virus must be safe, produced in large quantities, delivered quickly, and be effective for the largest number of individuals possible to minimize mortality and morbidity. Thus, the rapid production and clinical evaluation of a pandemic vaccine and the tracking of its use and distribution, particularly if two or more doses are required, is an urgent priority of HHS pandemic planning and response preparations. HHS is currently working with private industry to increase the U.S. vaccine production capacity. The HHS Plan describes specific action steps HHS will take to facilitate vaccine development, production, and distribution. The Plan also identifies steps HHS will take to track vaccine efficacy and adverse events.

Antiviral Drugs

If used appropriately, antiviral drugs may limit the spread of influenza, reduce its morbidity and mortality, and thereby diminish the demands placed on the U.S. health care system during a pandemic. However, the susceptibility of the pandemic influenza virus strain to antiviral agents cannot be determined until the pandemic virus strain emerges. Assuming susceptibility, antivirals may also be used in attempts to contain small disease clusters and potentially slow the introduction and spread of the infection in and between communities. Indiscriminate use of antiviral drugs in a pandemic could deplete national and local supplies. Therefore, a comprehensive approach for the appropriate distribution and use of antiviral stocks is an essential component of HHS pandemic preparedness. The **HHS Implementation Plan** outlines the steps to facilitate the development, licensure/ approval, production, and availability of pandemic influenza countermeasures. It also provides guidance for evaluating antiviral efficacy and developing prioritization, allocation, and distribution strategies for antiviral stockpiles.

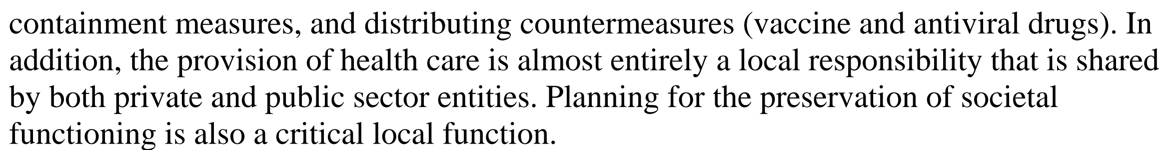
Communications

Another critical component of HHS preparedness for an influenza pandemic is a clear communications strategy and campaign that informs the public and other stakeholders about this potential threat and provides a solid foundation of information upon which future actions can be based. To be effective, this strategy should be based on scientifically derived risk-communications principles that are developed before, during, and after an influenza pandemic. The HHS Plan outlines a communications strategy and campaign that effectively provides reliable information and guides the public—including individuals and families, the news media, health care providers, and other groups—in responding to outbreak situations appropriately by adhering to public health measures and undertaking actions that protect individuals and family members.

HHS is currently developing communications and outreach materials, messages, and procedures for implementing communications plans. In addition, HHS is developing strategies for health care providers and the public to address any psychosocial concerns. During a pandemic, HHS will provide accurate and timely information on the pandemic to the public. It will also monitor and evaluate its interventions, and will communicate lessons learned to health care providers and public health agencies on the effectiveness of clinical and public health responses.

State, Local, and Tribal Preparedness

An effective pandemic response requires planning and coordination among all levels of Government and all stakeholders. The country's success in responding to and recovering from a pandemic necessarily depends on preparedness by the State, local and tribal jurisdictions. State, local and tribal leaders will be responsible for conducting surveillance, epidemiologic investigation, disseminating information, implementing



containment measures, and distributing countermeasures (vaccine and antiviral drugs). In addition, the provision of health care is almost entirely a local responsibility that is shared by both private and public sector entities. Planning for the preservation of societal functioning is also a critical local function.

Moreover, for pandemic influenza preparedness to be effective, it must be a multidisciplinary effort, engaging all stakeholders, including traditional public health and health care partners, as well as other sector partners, such as the business community, public safety and law enforcement, emergency management, education, transportation, social services, mental health and substance abuse services, public utilities, and community- and faith-based organizations. The duration, scope, and scale of the event will challenge infrastructure across most, if not all, sectors. Multi-sectored mutual aid agreements among local jurisdictions may aid in addressing the duration, scope, and scale of the pandemic.

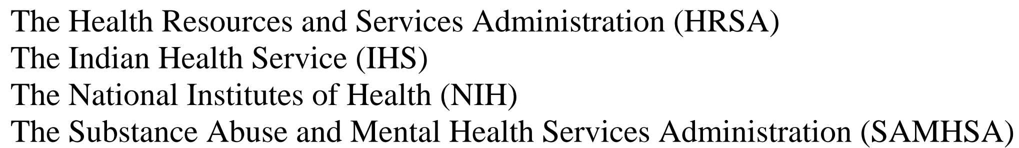
In FY06, the U.S. Congress appropriated $350 million as part of an emergency supplemental appropriation to fund local and State preparedness. HHS is currently working with its State, local, and tribal partners to increase the health care surge capacity of medical materiel and personnel. With State Governors, HHS is co-hosting pandemic summits and exercises in every State. In addition, HHS has developed checklists to aid in community-level pandemic influenza preparations. These checklists provide specific guidance for State and local planning authorities, businesses, health care providers, community organizations, and individuals and families.

The **HHS Implementation Plan** addresses cross-cutting preparedness issues for which the Department will provide further assistance for State, local and tribal pandemic preparedness. This assistance includes the development of guidelines and operational plans for the distribution of available supplies of pandemic vaccine and antiviral drugs.

Part II

HHS provides and operates many essential services and programs for individuals across the United States. Disruption of business and community operations by a pandemic can seriously jeopardize the health and well-being of many Americans. Part II provides detailed continuity of operations plans for the Office of the Secretary (OS) and HHS agencies, including:

The Administration for Children and Families (ACF)
The Agency for Health care Research and Quality (AHRQ)
The Agency for Toxic Substances and Disease Registry (ATSDR)
The Administration on Aging (AOA)
The Centers for Disease Control and Prevention (CDC)
The Centers for Medicare and Medicaid Services (CMS)
The Food and Drug Administration (FDA)



The Health Resources and Services Administration (HRSA)
The Indian Health Service (IHS)
The National Institutes of Health (NIH)
The Substance Abuse and Mental Health Services Administration (SAMHSA)

In Part II, each HHS agency and the OS identify essential activities, programs, and personnel, and provide strategies to continue departmental operations in the face of significant absenteeism during a pandemic. Agencies' plans also include leadership succession, plans for the delegation of authority, and options and procedures for alternate worksites. In addition, each plan includes steps to protect the workforce (and the agency's customers) during a pandemic. Finally, each agency outlines its role and responsibilities in a coordinated inter-agency/departmental response to a pandemic.

Given its critical mission, HHS will occupy a central position in any Federal pandemic influenza response. However, a robust, comprehensive response consistent with the National Response Plan requires coordination across Federal Departments and with international partners of the United States. Moreover, an effective pandemic response that preserves human lives and societal infrastructure requires collaboration with all State, local, and tribal partners. This **HHS Implementation Plan** provides definitive guidance and action steps to maximize our collective efforts in preparing for and responding to pandemic influenza.