Pandemic Influenza Implementation Plan

Part I of II

U.S. Department
of Health and
Human Services

November 2006

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Contents

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

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[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.

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INTRODUCTION

Influenza viruses have posed a threat to animal and human health throughout history. Efforts to develop a universal vaccine or antiviral medications with sustained efficacy are frustrated by influenza viruses' tendency to mutate. As a result of the influenza viruses' propensity to change, people may not have immunity against a new influenza strain. A pandemic occurs when a novel influenza virus spreads within a human population with little or no preexisting immunity. The extent and severity of a pandemic depend on the specific characteristics of the virus. In the 20th century, the world witnessed three human pandemics, each producing clinically apparent illness in approximately 30 percent of the world's population. It is estimated that 200,000 to 2 million Americans may die during the next severe influenza pandemic.

Also, a modern pandemic could have a significant and prolonged disruptive impact on multiple social and economic sectors of a community. A high rate of absenteeism in workplaces as a result of illness or caring for ill family members, the imposition of public health interventions (such as school and business closings) and isolation measures, or fear of infection could threaten the critical infrastructure of society and result in disruption of essential services. To mitigate the consequences of a pandemic, comprehensive preparedness and response planning is imperative by all aspects and members of a community.

The Current Influenza Pandemic Threat

Although a novel influenza virus could emerge anywhere in the world at any time, scientists are particularly concerned about the avian influenza A/(H5N1) that is currently circulating in Asia, the Middle East, Africa, and Europe. Outbreaks of H5N1 have occurred among poultry in Asia since 1997. H5N1 viruses are endemic among birds in Southeast Asia and are spreading to Europe and Africa via the transport of infected poultry and the migration of wild birds, the natural reservoir of avian influenza viruses. As of July 2006, H5N1 outbreaks have been reported in more than 54 countries in Asia, Europe, the Middle East, and Africa. Continued spread is likely. Human H5N1 cases have been reported. The reported death rate for human cases has been between 50 and 57 percent, although the true number of people exposed to and infected by the H5N1 virus is unknown. Studies investigating the seroconversion, or the presence of antibodies against H5N1 in serum, are needed to accurately document the infection rate in humans. While most of the reported cases seem to have resulted from direct contact with infected poultry, the source of infection has not been documented in every instance. Of concern are the few instances in which transmission from person to person may have occurred.

Pandemic Planning Assumptions

As a result of the widespread emergence and spread of the H5N1 virus among birds, public health experts and Government officials are escalating and intensifying their pandemic preparedness. Preparedness planning must consider such factors as the ability of the virus to spread rapidly across communities and countries, the potential of asymptomatic persons transmitting the virus to others, and the likelihood of multiple outbreaks occurring simultaneously throughout the United States and thus limiting the ability of any jurisdiction to provide assistance and support to other jurisdictions. It must also be understood that, during a pandemic, enormous demands will be placed on all health care systems. There will be shortages of medical and diagnostic devices, and delays in the delivery of vaccines and antivirals. There will be disruption to national and community infrastructures and services.

Therefore, for the purposes of drafting the **HHS Implementation Plan,** the following specific planning assumptions, as outlined in the White House Homeland Security Council (HSC) **Implementation Plan,** have been used:

- An influenza pandemic will most likely originate overseas and not in the United States.
- Susceptibility to the pandemic influenza virus will be nearly universal.
- Efficient and sustained person to person transmission will signal an imminent pandemic.
- The clinical disease attack rate will likely be 30 percent or higher. Illness rates will be highest among school aged children (about 40 percent) and decline with age. Among working adults, an average of 20 percent will become ill during a community outbreak.
- Some persons will become infected, but not develop clinically significant symptoms. Asymptomatic or minimally symptomatic individuals can transmit infection and develop immunity to subsequent infection.
- The typical incubation period (interval between infection and onset of symptoms) for influenza will be approximately 2 days.
- Persons who become infected will shed virus and may transmit infection as much as a day before the onset of illness. Persons will transmit infection for at least 2 days after the onset of symptoms. Children will shed the greatest amount of virus and are likely to pose the greatest risk for disease transmission.
- On average, each infected person will transmit infection to approximately two other people.

- Fifty percent of those who become ill will seek outpatient medical care. With the availability of effective antiviral drugs for treatment, this proportion could be higher.
- The number of hospitalizations and deaths will depend on the virulence of the pandemic virus. Two scenarios are presented based on extrapolation of past pandemic experience (Table 1). HHS planning utilizes the more severe scenario.
- Risk groups for severe and fatal infection cannot be predicted with certainty, but will likely include infants, the elderly, pregnant women, and persons with chronic medical conditions.
- Rates of absenteeism in workplaces will depend on the severity of the pandemic. In a severe pandemic, absenteeism will reach 40 percent during the peak weeks of a community outbreak, with lower rates of absenteeism during the weeks before and after the peak.
- Certain public health measures (closing schools, quarantining household contacts of infected individuals, sheltering in place ["snow days"]) will increase rates of absenteeism in workplaces.
- In an affected community, a pandemic outbreak will last about 6 to 8 weeks.
- Multiple waves (periods during which community outbreaks occur across the country) of illness will occur, and each wave could last 2–3 months. Historically, the largest waves have occurred in the fall and winter, but the seasonality of a pandemic cannot be predicted with certainty.

As with other natural disasters, during and after a pandemic, individuals will require intensive psychosocial support, including substance abuse and mental health services.

Table 1. Aggregate Number of Episodes of Illness, Health Care Utilization, and Death During Moderate and Severe Pandemic Influenza Scenarios*

Characteristic	Moderate (1958/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,875	745,500
Deaths	209,000	1,903,000

*Estimates based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics.

World Health Organization Pandemic Phases and U.S. Federal Government Response Stages

The World Health Organization's (WHO's) published guidance for national pandemic planning has classified pandemic activities into six phases. These six phases are characterized by the spread of a novel influenza strain through animals and humans. Each pandemic phase is associated with a range of preparedness and response actions. (See Table 2.)

The WHO phases reflect the progression of a pandemic worldwide, rather than in any one country. For domestic preparedness planning purposes, however, it is more useful to think in terms of the six U.S. Response Stages that reflect the immediate and specific threat of a pandemic virus that arises overseas and may pose a threat to Americans. (See Table 2.) While the WHO Phases provide a framework for evaluating the global situation, the U.S. Response Stages facilitate the implementation of domestic disease containment strategies and activities.

As of October 2006, we are in WHO Phase 3, in the Pandemic Alert Period. Current efforts of the U.S. Government are directed towards accelerating preparedness activities prior to WHO Phase 4, then initiating pandemic response actions at the onset of Phase 4, when epidemiological evidence exists that *increased human-to-human transmission* of an influenza virus with pandemic potential has occurred anywhere in the world.

The U.S. Government objectives, actions, policy decisions, and messaging considerations on pandemic influenza are identified for each of the U.S. Government Response Stages and are summarized in the **National Strategy for Pandemic Influenza Implementation Plan.** For the United States, the overarching goals are to:

- Prevent influenza transmission through consistent adherence to appropriate infection control practices across health care and community sectors during all U.S. Government Stages
- Delay the entry of a novel, pandemic influenza virus through the air- and seaports and land-border crossings of the United States and its trusts and territories during U.S. Government Stages 1–3
- Slow transmission within the United States during U.S. Government Stages 4 and 5 by implementing:
  - Non-pharmaceutical disease control methods (e.g., isolation, quarantine, school closures, and social distancing)
  - Pharmaceutical disease control methods (e.g., vaccination, antiviral medications)

Table 2. WHO Global Pandemic Phases and the Stages for Federal Government Response*

WHO Phases		U.S. Response Stages	
Inter-Pandemic Period			
1	No new influenza virus subtypes have been detected in humans. An influenza subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low.	0	New domestic animal outbreak in at-risk country
2	No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.		
Pandemic Alert Period			
3	Human infection(s) with a new subtype, but no human-to-human spread, or at most, rare instances of spread to a close contact	0	New domestic animal outbreak in at-risk country
		1	Suspected human outbreak overseas
4	Small cluster(s) with limited human-to-human transmission, but spread is highly localized, suggesting that the virus is not well adapted to humans.	2	Confirmed human outbreak overseas
5	Large cluster(s), but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).		
Pandemic Period			
6	Pandemic phase: increased and sustained transmission in general population.	3	Widespread human outbreak in multiple locations overseas
		4	First human case in North America
		5	Spread throughout the United States
		6	Recovery and preparation for subsequent waves

*U.S. Government stages 1 through 3 assume that the emergence of the pandemic strain will occur in another country. If the initial outbreak happened in the United States, U.S. Government Stage 4, the U.S. Government's goal would be to slow the spread of infection within the United States.

U.S. Response Stages 1 through 3 assume that the emergence of the pandemic strain will occur in another country. If the initial outbreak happened in the United States (U.S. Government Response Stage 4) the U.S. Government's goal is to slow the spread of infection within the United States.

Doctrine for HHS Pandemic Influenza Planning and Response

Because of the current ongoing outbreaks of avian influenza A/(H5N1) in Asia and the progression from the interpandemic period (the period prior to human infections) to a pandemic alert (once human infections have occurred), HHS has accelerated its preparedness planning and activities. In addition to the characteristics of the pandemic and planning assumptions noted above, the following principles guide HHS preparedness planning and response activities:

- Preparedness requires coordination among Federal, State, local, and tribal governments and private sector partners.
- Sustained human to human transmission anywhere in the world (WHO Phase 6) is the triggering event for a U.S. response.
- When possible and appropriate, basic public health measures will be employed to reduce person to person virus spread and prevent or delay influenza outbreaks.
- An informed and responsive public is essential for minimizing the health, social, and economic impact of a pandemic.
- At the start of a pandemic, vaccines, which will initially be in short supply, will be procured and distributed to State, local, and tribal health departments for the vaccination of predetermined priority groups.
- Domestic vaccine production capacity sufficient to provide vaccination for the entire U.S. population is critical.
- Quantities of antiviral drugs sufficient to treat 25 percent of the U.S. population will be stockpiled.
- Antiviral drugs from public stockpiles will be distributed to predetermined priority groups.

Priorities for HHS Pandemic Preparedness and Response Activities

Given the scope of pandemic preparedness and response activities presented in this Plan, prioritization is necessary. Although specific conditions and circumstances may dictate a revision of these priorities for action, the current priorities are:

- Advance international capacity for early warning and response
  - Enhance international communication and cooperation
  - Build international capacity
  - Facilitate rapid response

- Limit the arrival and spread of a pandemic into the United States
  - Ensure early warning and situational awareness
  - Establish a border and transportation strategy to delay entry into the United States of a pandemic virus detected overseas
  - Establish screening protocols at U.S. ports of entry and implementation agreements with other countries for screening passengers at airports and seaports
- Provide clear guidance to all stakeholders
  - Ensure effective risk communications including the development and provision of educational campaigns
  - Provide guidance on maximizing surge capacity with available resources
  - Provide comprehensive guidance on community shielding
  - Provide clear guidance for the private sector and institutions
- Accelerate the development of countermeasures
  - Develop rapid diagnostics
  - Establish stockpiles of pre-pandemic vaccine and antivirals
  - Advance technology and production capacity for influenza vaccine and research into the development of a universal influenza vaccine
  - Support research into new and improved antivirals

HHS has aggressively embarked on preparing for a pandemic. Many of the actions presented in this Plan are a continuation of already existing initiatives.

Since a pandemic might not unfold in a completely predictable way, regular assessments and adjustments to HHS actions and strategies will be made over time to reflect changing circumstances. HHS will monitor and evaluate its interventions, and will communicate lessons learned to health care providers, public health agencies, and others on the effectiveness of clinical and public health responses. As possible, HHS will assist State, local, and tribal health agencies in responding to outbreaks by deploying medical personnel, equipment, and supplies to augment health care capacity in affected areas. HHS will work with private industry partners and stakeholders to facilitate the production and distribution of antiviral drugs and pandemic vaccine. HHS will monitor antiviral drug and pandemic vaccine distribution, effectiveness, and any serious adverse events.

Summary of HHS Implementation Plan

This document, the **HHS Implementation Plan,** provides a roadmap for the Department's pandemic preparedness and response. It outlines specific steps to implement the actions and expectations assigned to HHS in the HSC **National Strategy for Pandemic Influenza Implementation Plan** and identified in the **HHS Strategic Plan.** (See http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html.)

Part I of this **HHS Implementation Plan** contains eight chapters on cross cutting issues covering international activities, domestic surveillance, public health interventions, the Federal medical response, vaccines, antiviral drugs, and communications, as well as State, local, and tribal preparedness. The topic of each chapter is introduced by a discussion of its importance, key planning assumptions, and HHS roles. Then each chapter presents HHS implementation steps undertaken to fulfill the HSC directives in the **National Strategy for Pandemic Influenza.** Achievement of these goals is contingent on the availability of resources.

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 the expected decreased staffing levels during a pandemic event.

As a roadmap, this **HHS Implementation Plan** is intended to facilitate coordination of Department pandemic preparedness and response programs and activities. It is a planning tool only. This document does not prescribe every intermediary step, process, or project. Rather it points the direction to more general steps or actions that the Department might undertake in its pandemic planning efforts. HHS will continue to review, revise, and update the **HHS Implementation Plan** as necessary.

Contents

CHAPTER 1: INTERNATIONAL ACTIVITIES

Introduction

The ongoing outbreak and global spread of highly pathogenic avian influenza A/(H5N1) have raised concerns that an influenza pandemic may be imminent.[1, 2, 3] Between the onset of the outbreak in Asia in December 2003 and July 2006, H5N1 outbreaks in birds have been reported in more than 54 countries in Asia, Europe, the Middle East, and Africa.[4] Spread of H5N1 into the Americas is considered likely.

As of July 14, 2006, at least 230 human H5N1 cases and 132 deaths have been reported from 10 countries.[5] Although most human infections have resulted from direct contact with diseased birds, there is increasing concern that the H5N1 virus could evolve into an easily transmissible human virus with pandemic potential.

The transcontinental spread of avian influenza underscores the interrelatedness of all countries and communities. It is imperative that we help enhance low-resourced country capacity to participate in global disease surveillance and response efforts.

In May 2005, the 58th World Health Assembly adopted a new set of International Health Regulations (IHR; WHA 58.3, 2005), which require World Health Organization (WHO) Member States to report influenza and other emerging infections that were not covered by the earlier IHR. Because the 2005 Assembly recognized that the requirements of outbreak surveillance and response exceed the capabilities of many countries, it required member countries to work together to implement the new regulations by providing financial resources, technical assistance, and logistical support (article 44.1). The dedication of U.S. financial resources to pandemic preparedness in partner countries—as

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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.

4 World Organization for Animal Health (OIE) Update on Avian Influenza in Animals (Type H5) July 26, 2006. Accessed August 4, 2006 at http://www.oie.int/downld/AVIAN%20INFLUENZA/A_AI-Asia.htm

5 WHO Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO, July 14, 2006. Accessed August 4, 2006 at: http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_04_21/en/index.html

well as to U.S. Government organizations that monitor infectious diseases overseas (e.g., HHS Global Disease Detection [GDD] Response Centers, DOD overseas laboratories, and the HHS Regional Emerging Diseases Intervention [REDI] Center in Singapore)—are directly responsive to this requirement of the new IHR.

The 58th World Health Assembly also adopted Resolution 58.5—*Strengthening Pandemic Influenza Preparedness and Response.* The Resolution urges WHO Member States "to develop and implement national plans for pandemic-influenza preparedness and response that focus on limiting health impact and economic and social disruption." The United States is committed to helping implement this resolution by assisting WHO and other countries strengthen their capacities to detect and effectively respond to outbreaks of H5N1 avian influenza or other influenza viruses with pandemic potential.

Because of modern advances in virology and telecommunications—and because the lethality of H5N1 in poultry makes it relatively easy to detect and track—global disease surveillance efforts could allow the public health community to identify the earliest stages of the evolution of an H5N1 virus into a human pathogen that is capable of sustained person-to-person spread. If a pandemic virus is detected early, and there is a rapid and well-orchestrated global response (as with the Severe Acute Respiratory Syndrome [SARS] outbreak in 2003), there is a theoretical possibility of slowing, or even containing, its spread.

The extra time gained through the HHS investment in international efforts will also allow the United States time to implement domestic public health response measures that can mitigate the impact of the disease once it arrives on U.S. shores. (See Chapter 3, Public Health Interventions, and Chapter 4, Federal Medical Response.)

Early detection and isolation of an influenza virus with pandemic potential will allow prompt identification of viral characteristics (antiviral susceptibility, antigenicity, transmissibility, and virulence) that influence medical case management as well as public health response measures. It should also facilitate development of a virus-specific vaccine.

Role of HHS in International Activities

HHS views preparedness, surveillance, and containment as the overarching goals of bilateral and multilateral efforts in the fight against pandemic influenza. The objectives under these goals include but are not limited to working with Ministries of Health, WHO, and other partners and stakeholders to facilitate:

- Avian influenza and pandemic planning, and public-health capacity strengthening
- Timely and reliable global surveillance for poultry and wild birds infected with H5N1 and other highly pathogenic avian influenza viruses
- Detection of human cases of H5N1 infection or other avian influenza viruses

- Detection and molecular characterization of H5N1 viruses and other novel influenza strains to help track their spread and monitor changes in transmission and drug susceptibilities prior to and during a pandemic
- Rapid and effective containment of H5N1 outbreaks in poultry to prevent their spread and reduce the risk of human exposure and infection
- Immediate and interpretable investigation of all cases or clusters of suspected human infection with H5N1, using standardized international investigation instruments
- Rapid containment of a nascent pandemic detected anywhere in the world

The roles of HHS in support of these goals and objectives are to assist countries conduct planning and preparedness activities, including those efforts that help develop and exercise the pandemic plans of national, provincial, regional public health, medical and animal health authorities, and public- and private-sector partners. HHS goals and objectives also include capacity strengthening for detecting and responding to human cases, outbreaks, or an emerging pandemic by public health and medical personnel; risk communications, including transparent and collaborative information sharing; public health education; and epidemiological and clinical care research to optimize case and patient outcomes.

HHS actions to further surveillance include epidemiology and diagnostic laboratory capacity-building for the early detection, characterization, and reporting of cases and outbreaks of human infection with H5N1 or other avian influenza viruses. HHS assistance on containment efforts include providing training for national and regional rapid-response teams; fostering preparedness for implementation of public health interventions (e.g., quarantine, travel restrictions, workplace and school closings); promoting capacity strengthening in appropriate infection-control practices at health care facilities and in communities; and encouraging the rational use of antivirals and vaccines, if they are available.

Another HHS key role is participation in international surveillance and response activities, such as the deployment of U.S. personnel to serve on international outbreak assessment and response teams; support of mechanisms for the timely and effective sharing of surveillance information, diagnostic specimens, and virus isolates prior to and during a pandemic; and the sharing of diagnostic laboratory and outbreak response supplies, including a predetermined stock of antivirals that may be used to augment national and WHO stocks if needed.

Specific Assumptions and Planning Considerations for HHS International Activities

The following assumptions were used to develop the context for the HHS activities listed in this chapter:

- Avian influenza A/(H5N1) viruses are the current, major international influenza threat for pandemic.
- Containment of H5N1 outbreaks (animal or human) in a country or region is of primary importance for both international and domestic U.S. risk reduction.
- In any country, if ongoing local disease surveillance efforts are insufficient to reliably evaluate the effectiveness of undertaken containment efforts, U.S. as well as international public health authorities, will be called upon to support countries with their surveillance efforts.
- If sustained human-to-human transmission of H5N1 is detected in a country, the United States, as part of the global public-health community, will be called upon to provide appropriate assistance to contain or slow the spread of the outbreak to prevent pandemic.
- Because of the unique, collaborative relations between the United States, Canada, and Mexico, cross-border considerations and initiatives are assumed not to be international activities for the purposes of this Plan. They are described in Chapter 2, Domestic Surveillance, and Chapter 3, Public Health Interventions.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

HHS international activities under Pillar One focus on building long-term, sustainable, national and international capacity in planning and preparing for an influenza pandemic. Emphasis is placed on encouraging countries to develop comprehensive national pandemic plans that foster preparedness in epidemiology and diagnostic laboratory capabilities (HSC 4.1.1); link public health and animal surveillance systems for achieving the timely information-sharing needed for effective alerts and risk-reduction actions (HSC 4.1.1); implement patient care and infection control practices that can accommodate anticipated surges in demand for health care delivery (HSC 4.1.2 and 4.1.5); and educate the public and the health care communities about practices that reduce the risk of human infection should a pandemic emerge (HSC 4.1.2, 4.1.3, and 4.1.4). HHS activities also focus on enhancing international capacity to detect other non-H5N1 pandemic threats, implementing prompt investigations and responses, and conducting research that characterizes influenza strains (HSC 4.1.2, 4.1.4, 4.1.6, and 4.1.8).

HHS activities also include communications initiatives aimed at raising pandemic influenza awareness among public health and health care workers, the potential first

detectors of early outbreaks (HSC 4.1.3). Initiatives that establish mechanisms for rapidly disseminating validated emergency public health information to international response partners are also discussed (HSC 4.1.8). International communications actions are further described in Chapter 7, Communications.

Pillar One actions concerned with international activities on vaccines and antivirals (HSC 4.1.5, 4.1.6, and 4.1.7) are covered in this chapter. Actions that cover vaccine and antiviral research-and-development issues and other domestic activities are found in Chapter 5, Vaccines, and Chapter 6, Antivirals.

Planning for a Pandemic

A. Action (HSC 4.1.1.1): HHS will work in coordination with the Department of State (DOS), the U.S. Agency for International Development (USAID), the Department of Defense (DOD), the Department of Transportation (DOT), the International Partnership on Avian and Pandemic Influenza (IPAPI), the Senior United Nations (UN) System Coordinator for Avian and Human Influenza, other international organizations (e.g., WHO, World Bank, World Organization for Animal Health [OIE], United Nations Food and Agriculture Organization [FAO]), and through bilateral and multilateral initiatives to encourage countries, particularly those at highest risk, to develop and exercise national and regional avian and pandemic response plans.

   Timeframe: Within 12 months.

   Measure of Performance: 90 percent of targeted high-risk countries have response plans and plans to test them.

   Step 1: Participate in meetings and conferences organized by DOS on avian and pandemic influenza planning and response.

   Step 2: Participate in the World Health Assembly, the Asian Pacific Economic Cooperation Forum (APEC), and other international organizations, and diplomatic and international policy-making meetings that cover avian and pandemic influenza, as appropriate.

   Step 3: Advocate for pandemic preparedness and response planning as part of its bilateral and multilateral discussions and negotiations with foreign governments and regional and international organizations.

   Step 4: On a regular basis, brief all its current and new representatives, such as Health Attachés and other in-country field staff, to share current information on avian and pandemic planning initiatives and issues, and provide guidance to overseas staff on the U.S. Government's initiatives, programs, and policies.

Step 5: Work through Health Attachés and other HHS representatives overseas, in coordination with other U.S. Government Agencies, to promote awareness of pandemic influenza and encourage pandemic planning by their host countries.

Step 6: Initiate regular teleconferences with partners in the Ministries of Health and the WHO Secretariat offices in targeted and high-risk countries to discuss the status of their preparedness.

Step 7: Work with U.S. Government partners to develop a workshop under the auspices of the APEC that will teach APEC member economies how to test their national pandemic-preparedness plans. This workshop will help to provide planning guidance and tools on the development and exercise of national influenza response plans in Asia. HHS will recruit speakers, develop the agenda, invite appropriate attendees from the Asia-Pacific region, and host a regional meeting.

Step 8: Work with U.S. Government partners to provide planning guidance and tools, as requested, on the development and exercise of national influenza response plans.

Step 9: Coordinate U.S. Government participation in the Global Health Security Initiative (GHSI) Pandemic Influenza Working Group, whose mandate is to enhance coordination and communication regarding pandemic preparedness and response activities, and to contribute to overcoming critical barriers to an effective pandemic response, especially concerning vaccine and antiviral issues. When appropriate, work with the G8 Health Ministries to effect donor coordination.

B. Action (HSC 4.1.1.2): HHS will work with USDA and USAID in promoting the use of epidemiological data supportive of animal disease and pandemic prevention and preparedness efforts, including through the provision of technical assistance to veterinarians and other agricultural scientists and policymakers in high-risk countries.

Timeframe: Within 12 months.

Measure of Performance: All targeted high-risk and affected countries have in place (1) national task forces that meet regularly with representation from both human and animal health sectors, government ministries, businesses, and non-governmental organizations (NGOs); and (2) national plans, based on scientifically valid information, developed, tested, and implemented for containing influenza in animals with human pandemic potential, and for responding to a human pandemic.

Step 1: As appropriate, attend international and intersectoral meetings and encourage planning and cooperation between animal and human health experts.

Step 2: Coordinate activities with USDA and USAID to promote consistent and meaningful messaging, evaluate the effectiveness and impact of these messages, and reinforce the need for intersector collaboration and communications in targeted at-risk and affected countries.

Step 3: Work with USDA and USAID to provide guidance to National Influenza Task Forces and Ministries of Health and Agriculture, as requested, on the following:

- The component of agricultural avian influenza A/(H5N1) response plans that covers surveillance for associated cases of human infection
- Linkage and epidemiologic analysis of animal and human influenza data

Step 4: Provide technical support to scientists who conduct disease and virologic surveillance in wild birds, live bird markets, and pigs in targeted affected and at-risk countries. (Also see Pillar Two, Action H [HSC 4.2.2.2], Step 1.)

C. Action (HSC 4.1.2.1): HHS will work with DOS to ensure strong U.S. Government engagement in and follow up on bilateral and multilateral initiatives to build cooperation and capacity to fight pandemic influenza internationally, including the APEC initiatives inventory of resources and regional expertise to fight pandemic influenza; an Asian regional tabletop exercise; a Symposium on Emerging Infectious Diseases, held in Beijing in April 2006; and the REDI Center in Singapore; the U.S.–China Joint Initiative on Avian Influenza and the U.S.–Indonesia–Singapore Joint Avian Influenza Demonstration Project; and to develop a strategy to expand the number of countries that are fully cooperating with U.S. and/or international technical agencies in the fight against pandemic influenza.

Timeframe: Within 6 months.

Measure of Performance: Finalized action plans that outline goals to be achieved and timeframes in which to achieve them.

Step 1: Participate in bilateral and multilateral initiatives to build cooperation and capacity to fight pandemic influenza internationally.

Step 2: Establish GDD Response Centers in strategic locations in all WHO regions. The HHS/GDD Response Centers, which combine epidemiologic excellence with advanced laboratory capacity, will link existing Field Epidemiology Training Programs (FETPs) and International Emerging Infections Programs (IEIPs). The HHS/GDD Response Centers will accomplish the following:

- Work with Ministries of Health to strengthen national and regional disease detection and reporting in targeted high-risk countries
- Work with the WHO Global Outbreak Alert Response Network (GOARN) to develop and train national and regional rapid-response teams

Step 3: Establish a GDD Information Center at HHS/CDC to facilitate rapid identification of influenza outbreaks that require immediate investigation. The GDD Response Center will work with the Influenza Division and other appropriate subject matter experts to accomplish the following:

- Serve as a centralized clearinghouse for international outbreak data
- Rapidly identify influenza outbreaks that warrant an immediate response
- Provide validated emergency epidemiologic data and public health information to response partners during the pandemic alert and pandemic periods

D. Action (HSC 4.1.2.2): HHS will provide financial support to staff the REDI Center in Singapore.

Timeframe: Within 3 months.

Measure of Performance: U.S. Government staff provided to REDI Center.

Step 1: Provide financial support to staff the REDI Center in Singapore with experts capable of building international training programs for surveillance and response in high-risk countries. Public health officials, researchers, clinicians, and other health professionals will attend the trainings. Emphasis will be on surveillance and rapid response to emerging infectious diseases and health security threats, as well as clinical research, laboratory techniques and safety, and regulatory practices.

E. Action (HSC 4.1.2.5): HHS, in coordination with USAID, will increase rapid response capacity within those countries at highest risk of human exposure to animal influenza by supporting national and local government capacities for human surveillance, diagnostics, and medical care, and by supporting training and equipping of rapid-response and case investigation teams for human outbreaks. (Also see Pillar Two, Actions B, G, J, K, P, and Q [HSC 4.2.1.2, 4.2.2.1, 4.2.2.4, 4.2.3.1, 4.2.3.8, and 4.2.3.9] below.)

Timeframe: Within 9 months.

Measure of Performance: Trained, deployable rapid-response teams exist in countries with the highest risk of human exposure.

Step 1: Enhance national capacities for human influenza surveillance and diagnostics by working with WHO and U.S. Government partners to accomplish the following:

- Creating a cadre of trainers to help build laboratory and epidemiologic capacity abroad and domestically
- Providing diagnostics training to staff at local public health laboratories in targeted countries, via HHS/GDD Response Centers, the REDI Center in Singapore, and/or DOD overseas research units, in collaboration with other WHO and U.S. Government assets
- Providing epidemiologic training to staff at Ministries of Health and Agriculture who are responsible for the following:
  - Analyzing and reporting influenza surveillance data
  - Outbreak investigations
- Providing epidemiologic training in collaboration with WHO, via HHS/GDD Response Centers and Field Epidemiology and Laboratory Training Programs (FELTP)
- Providing reagents and equipment to national public health laboratories in targeted high-risk countries with bilateral and multilateral support
- Facilitating the sharing of experiences and epidemiologic methods developed in countries, such as Thailand, that have identified cases of human infection with H5N1

Step 2: Work with WHO to develop, update, and disseminate simple, uniform, standardized guidance on laboratory methods for testing and training purposes.

Step 3: Work with the WHO Global Influenza Network to strengthen global capacity for influenza reference-testing during a pandemic by accomplishing the following:

- Creating laboratory surge capacity at the HHS/CDC Influenza Laboratory.
- Training national public health laboratories in targeted countries to prepare to subtype specimens of suspected avian or pandemic influenza, or to process and ship them to regional reference laboratories by using standard biosafety procedures.
- Facilitating efforts by regional public health laboratories to have equipment, reverse transcriptase-polymerase chain reaction (RT-PCR) reagents, and laboratory protocols for identifying H5N1 and other influenza subtypes and strains. During an investigation, the regional laboratories will forward samples

to HHS, as needed, for additional confirmatory testing, antiviral resistance testing, and genetic sequencing.

- Ensuring that regional laboratories are prepared to forward samples to the CDC-based WHO influenza reference laboratory for additional confirmatory testing, antiviral resistance testing, and genetic sequencing, as needed.
- Sharing information with WHO influenza reference laboratories in Australia, Japan, and the United Kingdom as needed.

Step 4: Assist the WHO Secretariat in expanding a WHO Specimen Transport Fund that enables developing countries to transport influenza samples to regional reference laboratories.

Step 5: Work with the WHO Secretariat, Ministries of Health, USAID, DOD, and other partners to enhance global capacity to detect other (non-H5) pandemic threats, by building on (and leveraging) influenza-related capacity-building and training efforts. Activities include the following:

- Providing training in epidemiology and diagnostic methods in collaboration with WHO and U.S. Government assets, via HHS/GDD Response Centers and FELTPs, focusing on detection of:
  - Influenza A subtypes other than H5N1 that could give rise to pandemic viruses
  - Other unusual or highly dangerous respiratory pathogens
- Making laboratory reagents available for the detection of viruses with pandemic potential (in addition to H5N1), via HHS/CDC-based WHO Collaborating Center Laboratories and the Laboratory Reference Network (LRN)
- Helping DOD to prioritize research to develop, refine, and validate diagnostic methods to rapidly identify pathogens of global and regional concern (also see Pillar Two, Action P and Q [HSC 4.2.3.8 and 4.2.3.9])

F. Action (HSC 4.1.3.1): HHS will work with USAID and USDA on conducting educational programs focused on communications and social marketing campaigns in local languages to increase public awareness of the risks of transmission of influenza between animals and humans.

Timeframe: Within 12 months.

Measure of Performance: Clear and consistent messages, tested in local languages in targeted countries, with information communicated via a variety of media reaching broad audiences, including health care providers, veterinarians and animal health workers, primary- and secondary level educators, villagers in

high-risk and affected areas, poultry industry workers, and vendors in open-air markets. (Also see chapter 7, Pillar One, Action A [HSC 4.1.3.1].)

Step 1: Assist USAID and USDA, in collaboration with WHO and other international partners, in developing materials for educational campaigns that teach people in high-risk countries how to avoid contracting influenza from infected poultry or other animals or birds. These materials will be aimed at different audiences (veterinarians, teachers, villagers, poultry industry employers, workers, and vendors) and translated, as needed.

Step 2: Assist USAID and USDA, in collaboration with WHO and other international partners, in developing materials for educational campaigns that teach health care and public health workers to be on the alert for cases or clusters of respiratory disease that may be associated with disease outbreaks in poultry. These materials will be translated, as needed.

G. Action (HHS 4.1.3.2*)*: HHS will work with USAID, the WHO Secretariat and other multilateral organizations, existing bilateral programs, and private-sector partners to develop community-, workplace-, and hospital-based health prevention, promotion, and education activities in priority countries. (Also see chapter 7, Pillar One, Action B [HSC 4.1.3.2].)

Timeframe: Within 12 months.

Measure of Performance: 75 percent of targeted countries are reached with local language mass-media and community outreach programs that promote avian influenza awareness and behavior change.

Step 1: Work with USAID and NGOs to prepare public health messages that ask medical and public health workers to report unusual cases of respiratory disease to local authorities, emphasizing that a cluster of severe pneumonia of unknown origin among health care workers anywhere in the world constitutes a potential international emergency. These messages will be translated and distributed, as needed. (Also see Pillar One, Action F [HSC 4.1.3.1], Step 2 above.)

Step 2: Work with USAID and appropriate partners to develop public health materials for use in community-based educational campaigns that inform people in targeted high-risk countries about infection control and public health containment (or “social distancing”) measures (e.g., quarantine, school closures, travel restrictions) that can control outbreaks of pandemic influenza. (Also see Chapter 3, Public Health Interventions.) These materials will also provide information about antiviral drugs and vaccines. (Also see Chapter 5, Vaccines, and Chapter 6, Antivirals.) These materials will be translated and distributed, as needed.

Step 3: Work with USAID and appropriate partners to develop public health materials that inform health care workers about infection control measures that can control the spread of pandemic influenza in health care facilities and in the workplace. (Also see Chapter 3, Public Health Interventions.) These materials will also provide information about antivirals. These materials will be translated and distributed, as needed.

Communicating Expectations and Responsibilities

H. Action (HSC 4.1.4.1): HHS will work with DOS, and USAID, and in coordination with other Federal agencies and global partners, to help ensure that the top political leadership of all priority countries understands the need for clear, effective coordinated public information strategies before and during an outbreak of avian or pandemic influenza. (Also see chapter 7, Pillar One, Action E [HSC 4.1.4.1].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries develop outbreak communication strategies that are consistent with the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.

Step 1: Assist DOS and USAID in encouraging priority high-risk countries to adopt WHO-recommended outbreak communications strategies in local languages, via participation in bilateral and multilateral meetings, and via informal contacts. (Also see chapter 7, Pillar One, Action A [HSC 4.1.3.1].)

Step 2: Assist DOS and USAID in providing information on pandemic influenza to U.S. citizens, businesses, and DOD personnel overseas, via the APEC Business Advisory Council, the U.S.-Association of Southeast Asian Nations (ASEAN) Council, the American Chamber of Commerce, and other governmental and nongovernmental organizations. (Also see chapter 7, Pillar One, Action F [HSC 4.1.4.2].)

I. Action (HSC 4.1.4.4): In coordination with USAID and USDA, HHS will work with the WHO Secretariat, FAO, OIE, and other donor countries to implement a communications program that supports government authorities and private and multilateral organizations in at-risk countries in improving their national communications systems, with the goal of promoting behaviors that will minimize human exposure and prevent further spread of influenza in animal populations. (Also see chapter 7, Pillar One, Action G [HSC 4.1.4.4].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries have improved national avian influenza communications.

Step 1: Work with USAID and USDA, in collaboration with international partners, to develop public health materials that inform individuals who come into contact with poultry (farmers, poultry vendors, poultry buyers) about infection control practices that can minimize their risk of infection with avian influenza. These materials will be translated and distributed, as needed. (Also see Pillar One, Action F [HSC 4.1.3.1], Step 1 above.)

Step 2: Participate in U.S. Government efforts to work with the WHO Secretariat and donor countries to develop a plan to support government authorities and private and multilateral organizations in at-risk countries in disseminating public health information in local languages. (Also see Chapter 7, Communications.)

J. Action (HSC 5.2.4.3): HHS will work with DOS and in consultation with the Department of Homeland Security (DHS), DOT, and aviation and maritime stakeholders in DOS efforts to negotiate arrangements with international organizations and foreign countries to voluntarily self-limit travel, if affected by a pandemic, and implement pre-departure screening protocols for persons with influenza-like illness.

Timeframe: Within 16 months.

Measure of Performance: Arrangements for screening protocols are negotiated.

Step 1: Work with the WHO Secretariat to develop rapid response and containment protocols that include discussions on travel restrictions and screening protocols. HHS/OS will assist the WHO Secretariat in promulgating these protocols in at-risk countries and establishing their agreement to limit travel as appropriate. Activities include:

- Providing assistance in the development of rapid response and containment protocols
- Initiating negotiations to encourage voluntary compliance with screening protocols (also see Pillar Three, Action J [HSC 4.3.2.1], Step 1 below)
- Providing assistance to countries as appropriate in their voluntary compliance

K. Action (HSC 5.2.4.4.): HHS, with DOS, and in coordination with the Department of Homeland Security (DHS), DOT, and transportation and border stakeholders, will assess and revise procedures to issue travel information and advisories related to pandemic influenza. (Also see chapter 3, Pillar Two, Action G [HSC 5.2.4.4], and chapter 7, Pillar Two, Action B [HSC 5.2.4.4].)

Timeframe: Within 12 months.

Measure of Performance: Improved interagency coordination and timely dissemination of travel information to stakeholders and travelers.

Step 1: Work with DOS, in coordination with other partners, to assess and revise procedures for issuing travel information and advisories related to pandemic influenza.

L. Action (HSC 4.2.7.1): HHS will work with DOS and in coordination with DOT, DHS, and the U.S. Trade Representative (USTR), and in collaboration with the WHO, the International Civil Aviation Organization (ICAO), and the International Maritime Organization (IMO) to assess and revise, as necessary and feasible, existing international agreements and regulations governing the movement and shipping of potentially infectious products, in order to ensure that international agreements are both adequate and legally sufficient to prevent the spread of infectious disease.

Timeframe: Within 12 months.

Measure of Performance: International regulations reviewed and revised.

Step 1: Assist DOS, as requested, in collaborating with international partners to assess and revise existing international agreements and regulations governing the movement and shipping of potentially infectious products.

M. Action (HSC 4.2.8.1): HHS, in support of USAID, will develop community- and hospital-based infection control and prevention, health promotion, and education activity materials in local languages in targeted countries. (Also see chapter 7, Pillar Two, Action A [HSC 4.2.8.1].)

Timeframe: Within 9 months.

Measure of Performance: Local language health promotion campaigns and improved hospital-based infection control activities established and using developed materials in all targeted South East Asian countries.

Step 1: Work with WHO, other international partners, and USAID to develop public health materials for use in health promotion campaigns that inform people in high-risk countries about infection control and public health containment ("social distancing") measures (quarantine, school closures, travel restrictions) that can control outbreaks of pandemic influenza. Information should also be provided about the use of antiviral drugs and vaccines. Provide these materials to USAID and the WHO Secretariat for translation, as needed. (Additional material on infection control measures and public health interventions can be found in

chapter 3, Pillar Two, Action C [HSC 4.2.8.1]; and additional material on the use of vaccines and antiviral drugs can be found in Chapter 5, Vaccines, and Chapter 6, Antivirals.)

Step 2: Develop public health materials that inform health care workers and hospital administrators about infection control measures to control the spread of pandemic influenza in health care facilities and in workplace health service facilities. Information should also be provided about the use of antiviral drugs and vaccines. Provide these materials to USAID and WHO for translation, as needed.

N. Action (HSC 4.3.1.8): HHS will collaborate with DOS and USDA, USAID, and DHS in activities with the WHO Secretariat, FAO, OIE, the World Bank and regional institutions such as APEC, ASEAN, and the European Commission (EC), on improving public affairs coordination and establishing a set of agreed upon operating principles among these international organizations and the U.S. Government that describe the actions and expectations of the public affairs strategies of these entities in the event of a pandemic. (Also see chapter 7, Pillar Three, Action A [HSC 4.3.1.8].)

Timeframe: Within 6 months.

Measure of Performance: List of key public affairs contacts developed, planning documents shared, and coordinated public affairs strategy developed.

Step 1: Disseminate recommendations developed by a Canadian workshop on risk-communications in APEC economies, held in Vietnam, May 2006.

Step 2: Ensure products from related HHS-developed activities are disseminated to APEC contacts.

Step 3: Participate as needed in U.S. delegations to bilateral and multilateral meetings that consider how best to coordinate public health communications during avian and pandemic-influenza response efforts. Partners include Ministries of Health and Agriculture, the WHO Secretariat, FAO, OIE, the World Bank, APEC, ASEAN, and EC.

Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Materiel

O. Action (HSC 4.1.5.1): HHS will work with DOS and other agencies to use the IPAPI and bilateral and multilateral diplomatic contacts on a continuing basis to encourage nations to increase international production capacity and stockpiles of safe and effective human vaccines, antiviral medications, and medical material. (Also see Chapter 5 [Vaccines] and 6 [Antivirals.)

Timeframe: Continuous.

Measure of Performance: 50 percent increase in the number of priority countries that have plans to increase production capacity and/or stockpiles.

Step 1: Develop a list of countries with the potential to increase production capacity and stockpiles of safe and effective vaccines, antiviral drugs, and medical supplies.

Step 2: Participate alongside DOS in efforts to work with IPAPI and bilateral and multilateral diplomatic contacts to reach out to identified countries and encourage them to develop plans to increase production capacity for vaccines, antiviral drugs, and medical supplies.

P. Action (HSC 4.1.5.2): HHS will work with USAID to coordinate and set up emergency stockpiles of personal protective equipment (PPE) and essential commodities, other than vaccine and antiviral medications, for responding to animal or human outbreaks.

Timeframe: Within 9 months.

Measure of Performance: Essential commodities procured and available for deployment within 24 hours.

Step 1: Develop educational materials that provide health care and public health workers with guidance on the optimal use of PPE (e.g., gloves, gowns, and masks) and other stockpiled items (other than vaccines and antiviral drugs). These materials will be provided to USAID for translation, as needed. These materials should accompany stockpiled items distributed in response to an animal or human outbreak.

Q. Action (HSC 4.1.5.3): HHS will provide technical expertise, information, and guidelines for the stockpiling and use of pandemic influenza vaccines. (Also see chapter 5, Pillar One, Action N [HSC 4.1.5.3].)

Timeframe: Within 6 months.

Measure of Performance: All priority countries and partner organizations have received relevant information on pandemic influenza vaccines and strategies for their applications.

Step 1: Work through Health Attachés and other in-country representatives to coordinate HHS communications about the U.S. Government's position on the stockpiling and use of pandemic-influenza vaccines. These representatives will serve as conduits of HHS information, guidance, and updates on stockpile and vaccine issues.

Step 2: Identify priority countries for provision of technical expertise, information, and guidelines for stockpiling and use of vaccines.

Step 3: Ensure that priority countries receive guidelines for stockpiling and use of pandemic influenza vaccine.

Step 4: Ensure that targeted countries receive technical assistance for prioritizing populations to receive limited quantities in influenza vaccine and antivirals, and strategies for their application.

Step 5: During a pandemic, modify recommendations on using influenza vaccine by taking into account the characteristics of the pandemic virus and the vaccine. (Also see Chapter 5, Vaccines.)

R. Action (HSC 4.1.6.1): HHS will continue to work with DOS and other agencies through the IPAPI and other bilateral and multilateral venues to build international cooperation, and encourage countries and regional organizations to develop diagnostic, research, and vaccine manufacturing capacity. (Also see Pillar One, Action S [HSC 4.1.6.2] below, and chapter 5, Pillar One, Action C [HSC 4.1.6.2].)

Timeframe: Within 24 months.

Measure of Performance: Global diagnostic and research capacity increased significantly compared to 24 months earlier. Significant investments made to expand international vaccine manufacturing capacity.

Step 1: Work with international partners to develop initiatives that support efforts by the private sector and by public–private partnerships in countries to develop new vaccines, antivirals, and diagnostic tests, as well as animal models and reagents suitable for research use.

Step 2: Provide support for the preclinical and clinical development of vaccines and antivirals.

Step 3: Establish a multilateral network in partnership with the Wellcome Trust, Oxford University, the WHO Secretariat, and multiple universities and hospitals in Southeast Asia for the conduct of clinical trials.

Step 4: Begin a Food and Drug Administration (FDA)-reviewed, multicenter, randomized clinical trial of approved vs. higher dose of oseltamivir.

Step 5: In collaboration with WHO, provide technical assistance for targeted countries or regions to develop diagnostic, research, and vaccine manufacturing capacity.

S. Action (HSC 4.1.6.2): HHS, in coordination with the WHO Secretariat, will establish at least six new sites for Collaborative Clinical Research on Emerging Infectious Diseases for conducting collaborative clinical research on the diagnostics, therapeutics, and natural history of avian influenza and other human emerging infectious diseases. In addition, within 18 months HHS will provide capability for in-country support for one or more countries for clinical trials that involve countermeasures against avian influenza in humans. (Also see Pillar One, Action R [HSC 4.1.6.1] above; chapter 5, Pillar One, Action C [HSC 4.1.6.2]; and chapter 6, Pillar One, Action E [HSC 4.1.6.2].)

Timeframe: 18 months.

Measure of Performance: Cooperative programs established in six new sites, to include the initiation of research protocols and design of clinical trials.

Step 1: Work with the WHO Secretariat to establish six new sites for Collaborative Clinical Research on Emerging Infectious Diseases to conduct collaborative clinical research on the diagnostic, therapeutic, and natural history of avian influenza and other human emerging infectious diseases.

Establishing Distribution Plans for Vaccines and Antiviral Medications

T. Action (HSC 4.1.7.1): HHS will work with DOS and USAID, in collaboration with the WHO Secretariat, to coordinate the U.S. Government contribution to an international stockpile of antiviral medications and other medical countermeasures, including the development and exercise of international countermeasure distribution plans and mechanisms, and an agreed prioritization of allocation. (Also see Chapters 5 [Vaccines] and 6 [Antivirals] on domestic stockpiles and countermeasure-distribution plans and mechanisms.)

Timeframe: Within 6 months.

Measure of Performance: Release of proposed WHO doctrine of deployment and concept of operations for an international stockpile.

Step 1: Work with DOS and USAID to develop a plan for U.S. Government participation in a WHO-coordinated international stockpile of antivirals and other medical countermeasures. It is essential to achieve a coordinated U.S. Government approach to the organization and functioning of any international stockpiles of antivirals and other medical countermeasures.

Step 2: Work with DOS and USAID to develop and test the distribution plans and priorities for allocation of stockpiled items.

Step 3: Work with U.S. Government partners to ensure that U.S. Government-designed protocols for organizing and distributing a stockpile of antivirals and

other medical countermeasures are integrated into the WHO Secretariat's protocols.

U. Action (HSC 4.1.7.2): HHS will collaborate with the Department of Justice (DOJ) and DOS in U.S. Government consideration of whether to seek to negotiate liability-limiting treaties or arrangements covering U.S. contributions to an international stockpile of vaccine and other medical countermeasures, in order to benefit from the protections of the Defense Appropriations Act.

Timeframe: Within 6 months.

Measure of Performance: Review initiated and decision rendered.

Step 1: At the request of DOJ and DOS, initiate interdepartmental reviews of proposals to negotiate liability-limiting treaties or arrangements.

Step 2: In the case of decisions to negotiate liability-limiting treaties, participate in negotiations as appropriate, representing HHS interests.

Step 3: In the case of decisions to negotiate liability-limiting treaties, work with DOS, other donors, and international organizations as appropriate to represent these decisions in international forums.

V. Action (HSC 6.1.13.10): HHS will work with DOJ, DHS, DOS, and DOC, in support of DOJ led efforts to develop a joint strategic plan to ensure international shipments of counterfeit vaccine and antiviral medications are detected at our borders and that domestic counterfeit drug production and distribution is thwarted through aggressive enforcement efforts. (Also see chapter 5, Pillar One, Action J [HSC 6.1.11.2], and Pillar Three, Action C [HSC 6.1.13.10]; and chapter 6, Pillar Three, Action E [HSC 6.1.13.10].)

Timeframe: As required.

Measure of Performance: Joint strategic plan developed; international and domestic counterfeit drug shipments prevented or interdicted.

Step 1: Participate and provide advice at DOJ meetings on the public health problems associated with the counterfeiting, international distribution and risk of importation into the United States of counterfeit vaccines and antivirals.

Advancing Scientific Knowledge and Accelerating Development

W. Action (HSC 4.1.8.1): HHS will support the Los Alamos H5 Sequence Database and the Institute for Genomic Research (TIGR), for the purpose of sharing avian H5N1 influenza sequences with the scientific community. (Also see Pillar One,

Action Y [HSC 4.1.8.4] below; and chapter 2, Pillar One, Actions N and P [HSC 4.1.8.1 and 6.1.15.2].)

Timeframe: Within 24 months.

Measure of Performance: Completed H5 sequences annotated and entered into both the Los Alamos database and GenBank.

Step 1: Continue to support a contract to the Institute for Genomic Research (TIGR) to fully sequence thousands of human and animal influenza viruses and place these sequences in a publicly accessible database (GenBank).

Step 2: Require HHS/NIH-funded grantees and contractors to upload H5 sequence data for rapid sharing on GenBank. GenBank sequences may be easily transferred to other databases, including the Los Alamos Sequence Database.

Step 3: Work with the WHO Global Influenza Network to obtain virus isolates from confirmed cases of human infection with avian influenza. The HHS/CDC Influenza Laboratory characterizes and sequences human isolates of H5N1 obtained via the WHO Global Influenza Surveillance Network. The sequence data are shared with GenBank and the Los Alamos H5 Sequence Database.

X. Action (HSC 4.1.8.2): HHS will enhance a regional influenza genome-reference laboratory in Singapore.

Timeframe: Within 9 months.

Measure of Performance: Capacity to sequence complete influenza virus genome established in Singapore. All reported novel animal influenza samples sequenced and made available on public databases.

Step 1: Provide input into a request to provide support to the Genome Institute of Singapore (GIS). The request for application will contain exact requirements for sequencing and making publicly available novel animal influenza samples.

Step 2: Upon receipt of acceptable application, participate in the review of GIS application. If deemed to meet the requirements of the request for application, issue the award, and monitor progress of the award.

Step 3: Coordinate closely with USDA to ensure that animal influenza genomic information from the GIS is shared appropriately with other international and U.S. Government bodies.

Y. Action (HSC 4.1.8.4): HHS, in coordination with DOS and DOD, will enhance open-source information-sharing efforts with international organizations and

agencies to facilitate the characterization of genetic sequences of circulating strains of novel influenza viruses.

Timeframe: Within 12 months.

Measure of Performance: Publication of sequences of all reported novel influenza viruses.

Step 1: Continue to support a contract to TIGR to fully sequence thousands of human and animal influenza viruses and place these sequences in a publicly accessible database (GenBank). (Also see Pillar One, Action W [HSC 4.1.8.1], Step 1 above; chapter 2, Pillar One, Actions N, O and P [HSC 4.1.8.1, 6.1.15.1, and 6.1.15.2].)

Step 2: Continue to provide technical support to the WHO Global Influenza Surveillance Network, which gathers and subtypes influenza isolates from more than 110 nations, providing seasonal-vaccine data on circulating strains and identifying new strains with pandemic potential. The Network sends new or unusual strains to CDC, including isolates from human cases of infection with H5N1, for confirmatory testing, subtyping, and sequencing. (Also see Pillar One, Action W [HSC 4.1.8.1], Step 3 above.)

Step 3: Work with USDA and academic partners in using animal and human influenza virus sequence data to accomplish the following:

- Provide diagnostic sequences for use in RT-PCR testing
- Identify potential vaccine antigens
- Provide information on viral evolution, relationships, and determinants of virulence
- Provide information on viral transmission and circulation
- Provide information on the genetic determinants of drug resistance

Step 4: Invest in the development and evaluation of rapid diagnostics for influenza (including novel subtypes like H5N1) by working with DOD, academic research centers, pharmaceutical companies, and medical-device companies. (Also see Pillar Two, Action Q [HSC 4.2.3.9] below; chapter 2, Pillar One, Action A and C [HSC 6.2.3.2 and 6.1.17.3].)

Pillar Two: Surveillance and Detection

HHS international activities under Pillar Two are intended to assist countries develop their ability to achieve early-warning alerts on pandemic threats. There is a theoretical possibility that this early-warning surveillance capability could result in containment of

outbreaks by the countries, or if necessary, allow time to mount a coordinated international response that could slow the spread of disease across borders. Once a pandemic is underway, surveillance information can help guide countries in making appropriate responses.

Pillar Two actions help the United States and other countries receive timely and accurate reports of outbreak events (HSC 4.2.1, 4.2.2, and 4.2.3) and utilize surveillance information to initiate measures aimed at limiting the spread of an outbreak in its early stages (HSC 4.2.4, 4.2.5, 4.2.7, 4.2.8, and 5.2.4.)

Ensuring Rapid Reporting of Outbreaks

A. Action (HSC 4.2.1.1): In coordination with DOS, HHS will work on a continuing basis through IPAPI, and through bilateral and multilateral diplomatic contacts, to promote transparency, scientific cooperation, and the rapid reporting of avian and human influenza cases by other nations.

Timeframe: Within 12 months.

Measure of Performance: All high-risk countries actively cooperate in improving capacity for the transparent, rapid reporting of outbreaks.

Step 1: Work with the WHO Secretariat and its Regional and Country Offices, APEC and other regional forums and through bilateral meetings and agreements with high-risk countries to promote the core principles of IPAPI (http://www.state.gov/r/pa/prs/ps/2005/53865.htm) and impress upon countries the importance of transparency and rapid reporting.

Step 2: Assist DOS in implementing bilateral and multilateral initiatives to build cooperation and capacity to fight pandemic influenza internationally. Venues include:

- WHO Collaborating Centers, WHO Headquarters, and WHO Regional Offices
- HHS/GDD Response Centers
- APEC Influenza Surveillance Workgroup
- U.S.–China Joint Initiative on Avian Influenza
- U.S.–Indonesia–Singapore Joint Avian Influenza Demonstration Project

Step 3: Work with GOARN, Ministries of Health and Agriculture, the WHO Secretariat and its Regional and Country Offices, and the HHS/GDD Information Center to improve the speed and accuracy of data provided by GOARN Member

States on suspected and confirmed cases of avian and pandemic influenza. (Also see Pillar Two, Action E and F [HSC 4.2.1.5 and 4.2.1.7] below.)

Step 4: Support the WHO Secretariat's efforts to enhance early-warning infectious disease capabilities by:

- Strengthening surveillance and communications infrastructure of the WHO Secretariat, to enable it to better coordinate information management and outbreak response globally.
- Strengthening GOARN's response capabilities. (Also see Step 3, above.)
- Strengthening the WHO Strategic Health Operations Center (mobilized on 27th December, 2004).
- Strengthening Emergency Operations Centers (EOCs) established in the WHO South East Asia Regional Office (SEARO) in New Delhi and in WHO offices in affected countries and field sites.
- Developing and piloting the WHO Global Event Management System (GEMS), a system for data-management and information-exchange to support standard operating procedures for the detection, verification, and coordination of response to public health emergencies. GEMS will enable the WHO Secretariat and WHO Regional and Country Offices to receive, appraise, and share critical information internally, as well as with GOARN partners, WHO Member States, and the public in an appropriate and timely fashion on a 24-hour-per-day, 7-day-per-week basis.

B. Action (HSC 4.2.1.2): HHS, in coordination with DOS, will pursue bilateral agreements with targeted countries on health cooperation that cover transparency, the sharing of samples and data, and the development of rapid-response protocols; and develop and train in-country rapid-response teams to assess and report quickly on possible outbreaks of avian and human influenza.

Timeframe: Within 12 months.

Measure of Performance: Agreements established with Viet Nam, Cambodia, and Laos, 100 teams throughout Asia, including China, Thailand, and Indonesia, trained and available to respond to outbreaks.

Step 1: In consultation with DOS and USAID, identify target countries and begin negotiations on Agreements and Memoranda of Understanding to ensure transparency and rapid reporting.

Step 2: Negotiate bilateral agreements with Ministries of Health on all aspects of the public health response to influenza, including:

- Providing technical assistance (laboratory and epidemiologic) to strengthen local capacity to participate in the WHO Global Influenza Surveillance Network. (Also see Pillar One, Action E [HSC 4.1.2.5], Step 1 above.)
- Developing and training in-country rapid-response teams to quickly assess and report on possible outbreaks of avian and human influenza at the village level. See Step 3 below.
- Facilitating the sharing of samples and data and developing rapid-response protocols. See Step 3 below.

Step 3: Facilitate the planning for and training of rapid-response teams by accomplishing the following:

- Assisting Ministries of Health in targeted affected countries and GOARN in developing national and regional rapid-response teams deployable within 24 hours.
- Working with WHO to train response team members and staff at Ministries of Health and Agriculture, HHS/GDD Response Centers, and other venues. Training topics will include outbreak investigations, cluster investigations, case-control investigations, and case-cohort investigations.
- Developing off-the-shelf standardized investigative instruments and rapid-response protocols in collaboration with WHO and other partners, with appropriate cultural modifications, as needed.
- Encouraging Ministries of Health to conduct drills and exercises. Activities can include tabletop exercises or the use of influenza response protocols to investigate noninfluenza disease clusters (e.g., clusters of pneumonia of unknown origin).
- Ensuring travel arrangements and procedures for shipping equipment, supplies, and biological samples are in place to facilitate U.S. participation in international outbreak teams.

C. Action (HSC 4.2.1.3): HHS will place long-term staff at key WHO offices and in targeted countries to provide coordination of HHS-sponsored activities and to serve as liaisons with HHS.

Timeframe: Within 9 months.

Measure of Performance: Placement of staff and increased coordination with the WHO Secretariat and Regional Offices.

Step 1: Review current Departmental overseas assignments to recommend changes over the next 3 to 5 years, in light of current concerns related to pandemic influenza. HHS staff may be stationed at HHS/GDD Response Centers,

U.S. Embassies, WHO Regional and Country Offices, and/or DOD overseas medical research laboratories.

Step 2: Select individuals to serve as staff at key WHO offices, U.S. Embassies, and other institutions to provide coordination of HHS-sponsored activities and to serve as liaisons with HHS.

Step 3: Work with DOS, DOD, U.S. Embassies, the WHO Secretariat and host countries to assign individuals to key locations.

D. Action (HSC 4.2.1.4): To the extent feasible, HHS will negotiate agreements with established networks of laboratories worldwide to enhance its ability to perform the laboratory analysis of human and animal virus isolates, and to train in-country government staff on influenza-related surveillance and laboratory diagnostics. (Also see Pillar Two, Action E [HSC 4.2.1.5], Step 3 below.)

Timeframe: Within 6 months.

Measure of Performance: Agreement negotiated and completed, and financing mechanism established with at least one laboratory network outside the United States.

Step 1: Continue to support and strengthen the WHO Global Influenza Surveillance Network, which gathers and subtypes influenza isolates from more than 110 nations, provides seasonal-vaccine data on circulating strains and identifies new strains with pandemic potential. The network sends new or unusual strains to HHS/CDC and/or other WHO Collaborating Centers for subtyping and sequence analysis.

Step 2: Provide diagnostic training and reagents to national public health laboratories and/or National Influenza Centers in targeted affected and high-risk countries to enhance their participation in the WHO Global Influenza Surveillance Network.

Step 3: Assist USDA, as requested, in subtyping, sequencing, and comparing avian influenza viruses isolated from poultry by international veterinary partners.

E. Action (HSC 4.2.1.5): HHS will support the WHO Secretariat to enhance the early detection, identification, and reporting of infectious disease outbreaks through the WHO's Influenza Network and GOARN. (Also see Pillar Two, Action A [HSC 4.2.1.1] above.)

Timeframe: Within 12 months.

Measure of Performance: Expansion of the network to regions not currently included.

Step 1: Assist with the prompt identification of the entrance of H5N1 into new countries and continents via infected wild or domestic birds. This will entail working with the WHO Global Influenza Surveillance Network, GOARN, USDA, Ministries of Health and Agriculture, and other partners for:

- Providing clear and simple guidance on disease surveillance and reporting that can be implemented in the poorest and most remote locations, by focusing on surveillance for bird die-offs, epidemiologically associated human cases, or clusters of respiratory infection
- Coordinating global efforts to detect and report suspect cases, by using standardized case definitions and reporting protocols
- Working with partners to enhance the education of public health and veterinary authorities, poultry workers, and the public in the recognition and reporting of potential cases of avian influenza
- Engaging nontraditional groups, such as bird-watching societies, the media, and civic organizations, in avian influenza surveillance activities

Step 2: Assist with prompt reporting of cases and clusters of human infection with H5N1 and other novel influenza viruses by:

- Providing technical support for local public health education and outreach efforts by ministries of health and agriculture, the WHO Secretariat, and WHO Regional and Country Offices
- Working with Ministries of Health, WHO, and GDD Response Centers to provide training for health care providers in identifying patients with risk factors for disease caused by H5N1
- Working with Ministries of Health, WHO, USAID, and other partners to support public health field staff or other allied personnel (nongovernmental organizations, village volunteers in districts and provinces) in detecting and reporting suspected cases of avian influenza

Step 3: Work with the WHO Global Influenza Surveillance Network, Ministries of Health, and other partners to enhance laboratory capacity to confirm suspected cases and clusters of human infection with avian influenza by accomplishing the following:

- Promoting the increased availability of diagnostic tests for H5N1 and other influenza strains at National Influenza Centers. (Also see Pillar Two, Action D [HSC 4.2.1.4], Step 2 above.)

- Increasing resources and training in targeted countries and their neighbors for subtyping influenza strains by using RT-PCR and/or forwarding specimens to regional reference laboratories.

Step 4: Work with GOARN to help ensure prompt assessment of outbreaks by accomplishing the following:

- Working with Ministries of Health to help develop and train national and regional response teams that will investigate outbreaks and rapidly identify nascent influenza pandemics
- Working with DOS to encourage at-risk countries to join GOARN
- Developing active linkages between GOARN and the HHS/GDD Information Center at HHS/CDC (also see Pillar Two, Action B [HSC 4.2.1.2], Step 3 above)

Step 5: Monitor changes in H5N1 and other novel influenza viruses with pandemic potential. Avian influenza A/(H5N1) could evolve into a virus strain that can be transmitted efficiently from person-to-person and differ from the parent virus in virulence and/or susceptibility to antiviral drugs. Activities include the following:

- Sequencing the genomes of avian influenza isolates from humans to detect changes that might affect human-to-human transmissibility (e.g., re-assortment or changes in receptor binding sites)
- Working with the WHO Influenza Network, Ministries of Health, GOARN, and other international partners to support activities that enhance the global sharing of data and isolates (e.g., paying the costs of shipping isolates to reference laboratories, providing sequence databases)

Step 6: Work with academic and industry partners to refine rapid methods for monitoring viral resistance to adamantanes and neuraminidase inhibitors. The HHS/CDC Influenza Laboratory will teach rapid methods for monitoring drug resistance to selected influenza reference laboratories.

F. Action (HSC 4.2.1.7): HHS, along with USAID, USDA, and DOS, will support FAO, OIE, WHO, the Office of the Senior UN System Coordinator for Avian and Human Influenza, host governments, and appropriate NGOs to expand the scope, accuracy, and transparency of human and animal surveillance systems, and to streamline and strengthen official protocols for reporting avian influenza cases.

Timeframe: Within 6 months.

Measure of Performance: 75 percent of targeted countries have established early warning networks, adapted international case definitions, and implemented standards for laboratory diagnostics of human and animal samples.

Step 1: Work through the WHO Secretariat, APEC and other regional forums and through bilateral meetings and agreements with targeted affected high-risk countries to promote the core principles of IPAPI (http://www.state.gov/r/pa/prs/ps/2005/53865.htm) and emphasize the importance of transparency and rapid reporting.

Step 2: Identify target countries and begin negotiations on Agreements and Memoranda of Understanding to ensure transparency and rapid reporting.

Step 3: Strengthen early warning systems for reporting human cases of infection with influenza A (H5N1) and other novel strains of influenza by accomplishing the following:

- Supporting efforts by GOARN to improve the speed and accuracy of data provided by WHO Member States on suspected and confirmed cases of human infection with H5N1 and other novel strains of influenza (also see Pillar Two, Action A [HSC 4.2.1.1], Step 3 above.)
- Working with the WHO Secretariat to provide updated influenza case definitions and diagnostic standards to the WHO Global Influenza Surveillance Network, as needed
- Encouraging targeted countries to initiate or enhance participation in the WHO Global Influenza Surveillance Network and GOARN
- Enhancing linkages between GOARN and the HHS/GDD Information Center to ensure prompt identification of potential pandemics

G. Action (HSC 4.2.2.1): HHS, in collaboration with one or more established networks of laboratories around the world, including the WHO Influenza Network, and in coordination with USDA, will help train staff from targeted countries' Ministries of Health and Agriculture, to conduct surveillance and perform epidemiologic analyses on influenza-susceptible species and manage and report results of findings. (Also see Pillar One, Action E [HSC 4.1.2.5] above.)

Timeframe: Within 12 months.

Measure of Performance: 75 percent of targeted countries have access to multi-year training programs in epidemiology and surveillance.

Step 1: Work with USDA to support local language epidemiologic training for Ministry of Health and Ministry of Agriculture staff with responsibility for the following:

- Analyzing and reporting influenza surveillance data
- Outbreak investigations

Step 2: Work with DOS to negotiate an HHS–WHO Cooperative Agreement to develop and implement a training course in influenza for the Outbreak Response Leaders program. The goal is to establish and maintain a cadre of highly experienced trainers and coordinators for GOARN Outbreak Response Field Missions.

H. Action (HSC 4.2.2.2): HHS will increase support of scientists who track potential emergent influenza strains through disease and virologic surveillance in susceptible animal species in targeted countries. HHS will coordinate this activity with that of USDA.

Timeframe: Within 9 months.

Measure of Performance: Surveillance for emergent influenza strains expanded in targeted countries.

Step 1: Support disease and virologic surveillance in wild birds, live bird markets, and pigs in Asia, and bird and pig surveillance in North America, via a contract with St. Jude Children's Research Hospital to characterize animal influenza viruses with pandemic potential and to study influenza virus transmission and pathogenicity. (Also see Pillar One, Action B [HSC 4.1.1.2] above.)

Step 2: Continue to support one or more projects to increase animal influenza surveillance capabilities in target countries.

I. Action (HSC 4.2.2.3): HHS, in coordination with DOD, will provide support to the Naval Medical Research Unit (NAMRU-2) in Jakarta, Indonesia, and Phnom Penh, Cambodia; to the Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand; and to NAMRU-3 in Cairo, Egypt, to expand and expedite geographic surveillance of human populations at-risk for H5N1 infections in those and neighboring countries through training, enhanced surveillance, and enhancement of the Early Warning Outbreak Recognition System (EWORS).

Timeframe: Within 12 months.

Measure of Performance: Reagents and technical assistance provided to countries in the network to improve and expand surveillance of H5N1 by increasing the number of specimens tested by real-time processing.

Step 1: Provide technical assistance to DOD–GEIS and DOD overseas medical research laboratories on influenza surveillance issues, training programs in influenza diagnostics, and enhancement of EWORS, as requested.

J. Action (HSC 4.2.2.4): To enhance surveillance and response to high priority infectious diseases, including influenza with pandemic potential, HHS will train physicians and public health workers in disease surveillance, applied epidemiology, and outbreak response at its HHS/GDD Response Centers in Thailand, Kenya, and Egypt, and at the U.S.–China Collaborative Program on Emerging and Re-Emerging Infectious Diseases. (Also see Pillar One, Action E [HSC 4.1.2.5] above.)

Timeframe: Within 12 months.

Measure of Performance: 50 local physicians and public health workers who live in targeted countries have received training in disease surveillance, applied epidemiology, and outbreak response.

Step 1: Support training, including in local languages, in epidemiology and diagnostics for local physicians and public health workers in targeted affected and high-risk countries, at HHS/GDD Response Centers, the REDI Center and/or DOD overseas medical research laboratories. This training will also enhance global capabilities for detecting other emerging and re-emerging pathogens.

K. Action (HSC 4.2.3.1): HHS will develop and implement training programs in laboratory diagnostics and basic laboratory techniques related to the preparation of influenza samples and diagnostics in priority countries.

Timeframe: Within 9 months.

Measure of Performance: 25 local laboratory scientists trained in the preparation of influenza samples and diagnostics.

Step 1: Provide public health laboratory staff with training in the detection of H5N1 and other viruses with pandemic potential, at the HHS/GDD Response Center in Kenya, China, Guatemala, Egypt, and Thailand, and at DOD overseas medical research laboratories. These trainees will form a cadre of trainers who can help build laboratory and epidemiologic capacity in their home countries. (Also see Pillar One, Action E [HSC 4.1.2.5] above.)

L. Action (HSC 4.2.3.2): HHS in collaboration with one or more established networks of laboratories, including the WHO Influenza Network, will train staff from targeted countries on influenza-related laboratory diagnostics.

Timeframe: Within 12 months.

Measure of Performance: 100 percent of targeted countries have training activities established.

Step 1: Support laboratory diagnostics training for staff from Ministries of Health and Agriculture with responsibility for:

- Analyzing and reporting influenza surveillance data
- Outbreak investigations (also see Pillar One, Action E [HSC 4.1.2.5], Step 1 above).

M. Action (HSC 4.2.3.3): HHS, in cooperation with the WHO Secretariat and other donor countries, will expand the existing Specimen Transport Fund that enables developing countries to transport influenza samples to WHO regional reference laboratories and collaborating centers.

Timeframe: Within 6 months.

Measure of Performance: 100 percent of priority countries funded for sending influenza samples to WHO regional reference laboratories.

Step 1: Support the WHO Specimen Transport Fund that enables developing countries to transport influenza samples to regional reference laboratories.

N. Action (HSC 4.2.3.4): HHS will enhance the ability of the global health care community to rapidly diagnose influenza by investing in the development and evaluation of more accurate rapid diagnostics for influenza. (Also see chapter 2, Pillar One, Action D [HSC 4.2.3.4].)

Timeframe: Within 18 months.

Measure of Performance: New grants and contracts issued to researchers to develop and evaluate new diagnostics.

Step 1: Facilitate the availability of diagnostic materials, such as proteins and antibodies, through its reagent repository in support of development and evaluation of point-of-care rapid diagnostic tests.

Step 2: Work with the Association of Public Health Laboratories (APHL) and the LRN to develop protocols for subtyping new strains of influenza and to provide diagnostic reagents to national and regional public health laboratories.

O. Action (HSC 4.2.3.5): HHS will work with the WHO Secretariat and private sector partners, through existing bilateral agreements, to provide support for human health diagnostic laboratories by developing and giving assistance in implementing rapid international laboratory diagnostics protocols and standards in priority countries. This work will be coordinated with USAID.

Timeframe: Within 12 months.

Measure of Performance: 75 percent of priority countries have improved human diagnostic laboratory capacity.

Step 1: Provide support for human health diagnostic laboratories to develop more rapid testing methods for influenza and to establish objectives for rapid screening, in coordination with efforts by USAID, the WHO Secretariat, and private sector partners, and through existing bilateral agreements. (Also see Chapter 2, Domestic Surveillance, for HHS Actions in facilitating diagnostic testing.)

Step 2: Work with the WHO Global Influenza Surveillance Network, APHL, and other partners to develop simple, uniform, standardized guidance on diagnostic methods that can be used for testing and training purposes at public health and clinical laboratories. These protocols will be translated and disseminated by WHO and USAID, as needed.

Step 3: Work with APHL, LRN, and WHO to disseminate RT-PCR subtyping protocols to regional reference laboratories.

Step 4: During a pandemic, the CDC Influenza Laboratory will work with the WHO Global Influenza Surveillance Network to update and disseminate diagnostic protocols, as needed.

P. Action (HSC 4.2.3.8): HHS will work with DOD in support of DOD development and refinement of the DOD–GEIS overseas virologic and bacteriologic surveillance infrastructure at the DOD overseas medical research laboratories. This work will include development and implementation of seasonal influenza laboratory surveillance and an animal/vector surveillance plan linked with WHO pandemic phases. (Also see Pillar One, Action E [HSC 4.1.2.5] above.)

Timeframe: Within 18 months.

Measure of Performance: Animal/vector surveillance plan and DOD overseas virologic surveillance network developed and functional.

Step 1: Assist DOD–GEIS, as requested, in enhancing regional surveillance for seasonal influenza strains.

Step 2: Assist DOD–GEIS, as requested, in developing and implementing a plan for monitoring influenza in birds and other animals.

Q. Action (HSC 4.2.3.9): HHS will work with DOD as requested to assist DOD prioritize its international laboratory research efforts to develop, refine, and validate diagnostic methods to rapidly identify pathogens.

Timeframe: Within 18 months.

Measure of Performance: Assistance requested and provided to DOD in completing its research plan prioritization.

Step 1: Assist DOD–GEIS and its overseas medical research laboratories, as requested, in prioritizing goals for developing new diagnostic tests for the identification of infectious pathogens of regional or global concern. Rapid, sensitive, robust, cost-effective, and field-friendly diagnostic tests for influenza and other pathogens are urgently needed. (Also see Pillar One, Action E and Y [HSC 4.1.2.5 and 4.1.8.4 Step 4]; and Chapter 2, Domestic Surveillance.)

Using Surveillance To Limit Spread

R. Action (HSC 4.2.4.1): HHS, in coordination with USAID and regional and international multi-lateral organizations, will work to develop village-based alert and response surveillance systems for human cases of influenza in priority countries.

Timeframe: Within 18 months.

Measure of Performance: 75 percent of all targeted countries have established a village alert and response system for human influenza.

Step 1: Work with the WHO Secretariat, Ministries of Health, and HHS/GDD Response Centers to enhance local influenza reporting by providing training and support for health care providers to identify patients with risk factors for disease caused by avian influenza A (H5N1). (Also see Pillar One, Action F [HSC 4.1.3.1], Step 2 above.)

Step 2: Provide technical support for outreach efforts by WHO Headquarters, WHO Regional and Country Offices, and Ministries of Health in targeted countries that increase public and professional awareness of the need to detect each and every case and cluster of human respiratory infection (family, health care, or institutional) during the pandemic alert period. (Also see Pillar One, Action F [HSC 4.1.3.1], Step 2 above.)

S. Action (HSC 4.2.5.1): HHS, in conjunction with USAID, the WHO Secretariat, and other donor countries, will develop rapid-response protocols for use in responding quickly to credible reports of human-to-human transmission that may indicate the beginnings of an influenza pandemic.

Timeframe: Within 12 months.

Measure of Performance: Adoption of protocols by the WHO Secretariat and other stakeholders. (Also see chapter 7, Pillar Two, Action A [HSC 4.2.8.1].)

Step 1: Work with USAID, in collaboration with GOARN, FETPs, HHS/GDD Response Centers, and other partners to develop off-the-shelf standardized investigative instruments and rapid response protocols. These tools will be provided to USAID for translation into local languages, with appropriate cultural modifications.

Step 2: Encourage Ministries of Health in affected and high-risk countries to conduct drills and exercises using their National Response Plan (NRP) and the investigative instruments described in Step1. Activities can include tabletop exercises or the use of influenza response protocols to investigate noninfluenza disease clusters (e.g., clusters of pneumonia). (Also see Pillar Two, Action B [HSC 4.2.1.2], Step 3 above.)

Pillar Three: Response and Containment

HHS international activities under Pillar Three focus on limiting the spread of H5N1 and other novel influenza viruses in poultry and humans. These actions involve U.S. support for, and international coordination of, immediate and reliable investigations of all suspected cases, clusters, or outbreaks of H5N1 in humans; and the conduct of rapid assessments of the possible occurrence of human-to-human spread. They include HHS collaborative participation in international rapid response teams; the possible use of predeployed HHS stockpiles of antivirals; HHS collaboration and coordination with other countries on the implementation of public health interventions (e.g., travel restrictions, quarantine, workplace and school closings); and HHS promotion of the stringent use of infection control measures at health care facilities and in communities affected by H5N1 (HSC 4.3.1, 4.3.2, 5.3.1, and 5.2.4).

In addition, HHS international activities include encouragement of the appropriate distribution and use of countermeasures such as antivirals and vaccines (HSC 4.3.3); U.S. interdepartmental consideration on the broader international security and economic issues stemming from the pandemic threat (HSC 4.3.5); and efforts to transparently communicate U.S. and HHS policy and HHS objectives in pandemic planning, surveillance, and response (HSC 4.3.6, 5.3.1, and 5.3.3).

Containing Outbreaks

A. Action (HSC 4.3.1.1): HHS will work with DOS, USDA, USAID, and DOD on the coordinated development and implementation of the U.S. Government's capability to respond rapidly to assess and contain outbreaks of avian-influenza with pandemic potential abroad. U.S. Government capability development will include the training of U.S. personnel to participate in bilateral and multi-lateral rapid response teams.

Timeframe: Ongoing.

Measure of Performance: Agreed upon operating procedures and operational support for U.S. rapid response, and for U.S. participation in international rapid response efforts, are developed and function effectively.

Step 1: Maintain a roster of experts from various disciplines who can participate in international response teams, and stay in close contact with Ministries of Health in countries that experience H5N1 outbreaks in poultry.

Step 2: Maintain a roster of U.S. Government influenza experts (in the United States and stationed abroad) who can serve on international response teams. Duties will include evaluating the severity and geographic scope of outbreaks and helping to implement public health interventions and countermeasures.

Step 3: Send epidemiologists to investigate suspected cases of human infection with H5N1, as part of WHO teams and/or at the request of Ministries of Health. HHS/CDC experts have participated in onsite investigations of H5N1 infection since the first human cases were detected in humans in Hong Kong in 1997.

B. Action (HSC 4.3.1.2): HHS, in coordination with DOS, will work with the WHO Secretariat and the international community to secure agreement (e.g., through a resolution at the World Health Assembly in May 2006) on an international containment strategy to be activated in the event of a human outbreak, including an accepted definition of a "triggering event" and an agreed doctrine for coordinated international action, the responsibilities of nations, and steps they will take.

Timeframe: Within 4 months.

Measure of Performance: International agreement on a response and containment strategy.

Step 1: Assisted DOS in working with the international community to pass a WHO resolution to endorse an international containment strategy at the World Health Assembly in May 2006. The strategy will address the following:

- Efforts to limit the spread of outbreaks of H5N1 in poultry, to prevent spread to other countries, and to reduce opportunities for human infection (also see Pillar Three, Action E [HSC 4.3.1.5], Step 4 below.)
- Immediate investigation of all cases and clusters of suspected human infection with H5N1, and rapid assessment of whether human-to-human transmission is occurring (also see Pillar Three, Action C, [HSC 4.3.1.3], Step 1 below)
- Aggressive efforts to contain a nascent pandemic that appears anywhere in the world, using all available public health tools (also see Pillar Three, Action D [HSC 4.3.1.4], Step 1 below)

Step 2: Work with DOS and other partners to encourage affected and at-risk countries in Southeast Asia and elsewhere to join GOARN, which will coordinate international containment efforts. (Also see Pillar Two, Action S [HSC 4.2.1.5], Step 4 above.)

C. Action (HSC 4.3.1.3): HHS, in coordination with DOS and the WHO Secretariat, and USDA, USAID, and DOD, as appropriate, will rapidly deploy disease surveillance and control teams to investigate possible human outbreaks through the WHO's GOARN network.

Timeframe: As required.

Measure of Performance: Teams deployed to suspected outbreaks within 48 hours of request.

Step 1: Actively support local and regional efforts to investigate reported cases of human infection with H5N1. This will entail the following:

- Maintaining close contact with Ministries of Health in affected countries, the WHO Secretariat, and GOARN
- Providing epidemiologic and laboratory training and support, as needed, to local or regional investigative teams

Step 2: Use epidemiologic and laboratory data to rapidly determine whether a confirmed case or cluster of human infection with H5N1 signals the possible emergence of a pandemic virus.

D. Action (HSC 4.3.1.4): HHS will work with DOS in its efforts to coordinate U.S. Government (HHS, USDA, USAID, and DOD) and WHO Secretariat participation in the implementation of the international strategy for influenza response and containment (e.g., assigning experts to the WHO outbreak teams and providing assistance and advice to Ministries of Health on local public health

interventions, ongoing disease surveillance, and the use of antiviral medications and vaccines if they are available).

Timeframe: Ongoing.

Measure of Performance: Teams deployed to suspected outbreaks within 48 hours of request.

Step 1: Actively support local efforts to contain an outbreak that might be caused by a pandemic influenza virus, wherever in the world it may arise, by:

- Maintaining close contact with Ministries of Health in affected countries and the WHO Secretariat.
- Assigning U.S. Government experts to international response teams, as needed. The teams will evaluate the severity and geographic scope of the outbreak and help implement public health interventions and countermeasures.
- Providing laboratory support to international response teams, as needed, in association with the WHO Global Influenza Surveillance Network.
- Consulting with Ministries of Health and the WHO Secretariat on all aspects of the public health response to pandemic influenza, including the following:
  - Local public health interventions (e.g., local travel restrictions, quarantines, and school and workplace closures)
  - Infection control measures in health care facilities and in communities
  - Ongoing disease surveillance
  - The distribution and appropriate use of antivirals and vaccines, if they are available
  - Ongoing evaluation of containment efforts

Step 2: Ensure that HHS and other U.S. Government experts stationed in affected areas (at HHS/GDD Response Centers, U.S. Embassies, or WHO Regional and country Offices) are available to serve on, support, or advise international outbreak teams.

Step 3: Test viral isolates for drug susceptibility to antiviral drugs.

Step 4: Conduct genomic sequencing of viruses isolated from human cases and compare them to isolates from other humans, birds, and animals. (Also see Pillar Two, Action S [HSC 4.2.1.5], Step 3 above.)

Step 5: Work with WHO and affected countries to provide public health information to people in local languages in affected countries. (Also see Chapter 7, Communications.)

E. Action (HSC 4.3.1.5): With USDA, USAID, DOS, and DOD, and in collaboration with relevant international organizations, HHS will support a coordinated operational deployment of rapid-response teams and provide technical expertise and technology to support avian-influenza assessment and response teams in priority countries as required.

Timeframe: Ongoing.

Measure of Performance: All priority countries have rapid access to avian influenza assessment and response teams; deployment assistance provided in each instance and documented in a log of technical assistance rendered.

Step 1: Work with USDA in assisting, as requested, the WHO Secretariat and Ministries of Health and Agriculture to investigate suspected H5N1 outbreaks in poultry, and providing advice on containment measures, such as culling flocks or vaccinating chickens. Immediate action to limit the spread of avian influenza to new countries or continents will reduce the opportunities for human infection, as well as for genetic exchanges between avian and human viruses that could hasten the evolution of a pandemic strain of human influenza.

Step 2: Advise affected countries and the WHO Secretariat on the need for intensified public health surveillance for individuals with influenza-like symptoms (e.g., for associated cases of human H5N1 infection) in areas where poultry outbreaks occur.

Step 3: Assist USDA, as requested, in reference testing of poultry specimens from outbreak areas and the sequencing of viral isolates.

Step 4: Compare genomic sequences of avian influenza viruses isolated from cases of human infection with viral sequences isolated from poultry and other birds and animals. (Also see Pillar Two, Action S [HSC 4.2.1.5], Step 5; and Step 3 above.)

F. Action (HSC 4.3.1.6): HHS will collaborate with the DOS lead on U.S. Government engagement with the international community on efforts to develop a coordinated plan for avian-influenza assistance (funds, materiel, and personnel) to streamline national assistance efforts. (Also see Pillar One, Actions A, B, C, F, G, O and T [HSC 4.1.1.1, 4.1.1.2, 4.1.2.1, 4.1.3.1, 4.1.3.2, 4.1.5.1, 4.1.7.1, 4.2.1.1, 4.2.1.2, 4.2.1.5, and 4.2.1.7]; Pillar Two, Actions M and S [HSC 4.2.3.3 and 4.2.5.1]; and Pillar Three, Actions B and C [HSC 4.3.1.2 and 4.3.1.3] above.)

Timeframe: Within 12 months.

Measure of Performance: Commitments from countries on funds, personnel, and materiel they will contribute to an integrated and prioritized international prevention, preparedness, and response effort.

Step 1: Assist DOS, as requested, in working with the WHO Secretariat, GOARN, and Ministries of Health to develop an integrated and prioritized pandemic influenza plan for the provision of emergency response assistance from donor countries. Coordination of international outbreak assistance is essential for efficient response to an influenza pandemic.

Step 2: Share information with other donor countries on U.S. Government's plans for avian influenza assistance, and will stress the need for coordination.

Step 3: As necessary, establish agreements with donor countries to ensure funds, personnel, and materiel are available and there is no duplication.

G. Action (HSC 4.3.1.7): HHS will assist with DOS, DOD, and USAID work with the international community to develop a coordinated, integrated and prioritized distribution plan for pandemic-influenza assistance that details a strategy for: (1) strategic lift of WHO response teams and stockpiles of medical countermeasures; (2) theater distribution to affected countries; (3) in-country coordination to key distribution areas; and (4) establishment of internal mechanisms within each country for distribution to urban, rural, and remote populations.

Timeframe: Within 12 months.

Measure of Performance: Commitments by countries that specify their ability to support distribution, personnel and material for such support.

Step 1: Assist DOS and DOD in working with affected and high-risk countries to develop coordinated, integrated, and prioritized in-country distribution plans for the following:

- Transport and distribution of stockpiled items
- Transport of international response teams

Step 2: Participate in internal U.S. Government discussions to develop a plan for in-country deployment of stockpiled material, including antivirals.

H. Action (HSC 5.3.1.1): HHS will work with DOS and DHS and in coordination with DOT, DOC, Treasury, and USDA, and with foreign counterparts, to limit or restrict travel from affected regions to the United States, as appropriate, and notify

host government(s) and the traveling public. (Also see chapter 3, Pillar Three, Action C [HSC 5.3.1.1].)

Timeframe: As required.

Measure of Performance: Measures imposed within 24 hours of the decision to do so, after appropriate notifications made.

Step 1: Work with WHO and U.S. Government partners to develop protocols that include determinations as to when to restrict travel to the United States. Ensure that at-risk countries are aware of these protocols as appropriate. Activities include:

- Remaining in close communication with the WHO Secretariat and other international organizations to stay current on the extent of outbreaks
- Consulting with appropriate HHS Operational Divisions (OPDIVs)
- Communicating the best advice to DOS and other U.S. Government agencies

I. Action (HSC 5.3.1.3): HHS will collaborate with DOS, DHS, and DOT as requested, concerning U.S. Government offers of transportation-related technical assistance to countries with outbreaks.

Timeframe: As appropriate.

Measure of Performance: Countries with outbreaks receive U.S. offer of technical support within 36 hours of an outbreak.

Step 1: Assist DOS, as requested, in offering transportation-related technical assistance to countries with outbreaks.

J. Action (HSC 4.3.2.1): HHS, in coordination with DOS, DHS, DOD, and DOT, and in collaboration with foreign counterparts, will support the implementation of pre-existing passenger screening protocols in the event of an outbreak of pandemic influenza. (Also see Pillar One, Action J [HSC 5.2.4.3] above; chapter 3, Pillar Three, Action A [HSC 4.3.2.1].)

Timeframe: Ongoing.

Measure of Performance: Protocols implemented within 48 hours of notification of an outbreak of pandemic influenza.

Step 1: Assist DOS in working with other countries and travel-industry partners during the pre-pandemic period to develop international travel agreements and standards for the following:

- Limiting international travel to and from affected areas, which might include mandatory measures and/or negotiated arrangements to self-limit exit travel in return for technical assistance and other support
- Implementing predeparture screening protocols for persons with influenza-like illness
- Preventing the spread of avian and pandemic strains of influenza via shipments of potentially infectious products

Step 2: Work with DOS to establish procedures for pandemic-related overseas screening of U.S. bound immigrants and refugees, who receive predeparture medical checkups as part of their visa requirements.

Step 3: Advise DOS, as needed, on when to activate international and bilateral travel agreements on the following:

- Limiting international travel
- Predeparture screening of persons with influenza-like illness
- Preventing disease spread via shipments of contaminated products (see Step 1 above)

Leveraging International Medical and Health Surge Capacity

K. Action (HSC 4.3.3.1): In coordination with DOS, USAID, USDA, and DOD, HHS will work with IPAPI to assist in the prompt and effective delivery of countermeasures to affected countries, consistent with U.S. law and regulation and the agreed upon doctrine for international action, to respond to and contain an outbreak of influenza with pandemic potential.

Timeframe: Ongoing.

Measure of Performance: Necessary countermeasures delivered to an affected area within 48 hours of agreement to meet request.

Step 1: Assist DOS and USAID, as requested, in the delivery and distribution of countermeasures to affected countries, consistent with a preestablished international containment strategy. Countermeasures can include PPE, medical supplies, antivirals, and vaccines (if available).

Step 2: Consult with Ministries of Health and the WHO Secretariat, as requested, on the use of medical countermeasures, including antivirals and vaccines, if available. (Also see Chapter 5, Vaccines, and Chapter 6, Antivirals.)

Step 3: Consult with Ministries of Health and the WHO Secretariat, as requested, on the use of nonmedical countermeasures, including:

- Local health care and infection control issues, including use of PPE
- Local containment measures, such as closings of schools or workplaces, local travel restrictions
- Dissemination of public health messages in local languages on infection control and public health containment measures (see Chapter 7, Communications)

L. Action (HSC 5.3.3.1): With USDA, and in coordination with DHS, DOT, DOS, and the Department of Interior (DOI), HHS will provide emergency notifications of potential cases and/or outbreaks to key international, federal, State, local, and tribal transportation and border stakeholders through existing networks. (Also see chapter 2, Pillar Three, Action A [HSC 5.3.3.1]; chapter 3, Pillar Three, Action P [HSC 5.3.3.1]; and chapter 7, Pillar Three, Action H [HSC 5.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.

Step 1: Maintain regular communication with key partners at Ministries of Health in targeted and at-risk countries, through Health Attachés and other in-country staff. HHS will notify DOS and other partners when news of outbreaks is received and facilitate information exchange with partners. Activities include:

- Remaining in close communication with Ministries of Health and the WHO Secretariat to stay abreast on news of potential or actual outbreaks
- Conducting inter-HHS OPDIV consultations to determine validity of such news
- Communicating the best advice to DOS and other U.S. Government agencies

Sustaining Infrastructure, Essential Services, and the Economy

M. Action (HSC 4.3.5.1): HHS will participate in a DOS-organized interagency group to analyze the potential economic and social impact of a pandemic on the stability and security of the international community.

Timeframe: Within 3 months.

Measure of Performance: Issues identified and policy recommendations prepared.

Step 1: Participate in a DOS-led interagency group, the aim of which is to analyze the potential effects of a pandemic on international stability and security, and recommend strategies to mitigate them.

Ensuring Effective Risk Communication

N. Action (HSC 4.3.6.1): HHS will participate in a DOS-coordinated interagency public diplomacy group, along with USAID, USDA, DOD, and DHS, to develop a coordinated, integrated, and prioritized plan to communicate U.S. foreign policy objectives relating to our international engagement on avian and pandemic influenza to key stakeholders (e.g., the American people, the foreign public, NGOs, international businesses). (Also see chapter 7, Pillar Three, Action I [HSC 4.3.6.1].)

Timeframe: Within 3 months.

Measure of Performance: Number and range of target audiences reached with core public affairs and public diplomacy messages, and the impact of these messages on public responses to avian and pandemic influenza.

Step 1: Participate on interagency steering committee that works with the WHO Secretariat, Canada, UK and other selected countries on a coordinated risk communication strategy.

Step 2: Participate, as needed, in DOS-led efforts to develop a coordinated, integrated, and prioritized plan to communicate U.S. foreign policy and public health objectives related to U.S. Government engagement in avian and pandemic influenza response.

O. Action (HSC 4.3.6.2): HHS will assist DOS in providing at least monthly updates to DOS foreign counterparts, through diplomatic channels and U.S. Government websites, regarding changes to national policy or regulations that could result from an outbreak, and will work with DOS to achieve coordinated posting of such information to U.S. Government websites (e.g., http://www.pandemicflu.gov). (Also see chapter 7, Pillar Three, Action J [HSC 4.3.6.2].)

Timeframe: Ongoing.

Measure of Performance: Foreign governments and key stakeholders receive authoritative and regular information on U.S. Government avian influenza policy.

Step 1: Maintain regular contact with officials at U.S. Embassies, Ministries of Health, and the WHO Regional and Country Offices to inform and update partners on changes to national policy or regulations that could result from an outbreak:

- Hosting weekly phone calls with HHS Health Attachés and other in-country representatives to inform U.S. Government personnel of changes in policies or regulations
- Hosting monthly phone calls with public health officials in other countries, including staff from Ministries of Health and WHO Regional and Country Offices, to discuss changes in policy or regulations

P. Action (HSC 5.3.1.2): HHS, in coordination with DOT, DOC, Department of Treasury, and USDA, will assist DOS and DHS in their working with foreign countries to implement agreed upon pre-departure screening based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 3, Pillar Three, Action D [HSC 5.3.1.2].)

Timeframe: As required.

Measure of Performance: Screening protocols agreed upon and put in place in countries within 24 hours of an outbreak.

Step 1: Work with the WHO Secretariat and U.S. Government partners to develop protocols that include determinations as to when to restrict travel to the United States. Ensure that at-risk countries are aware of these protocols, as appropriate. Activities include the following:

- Remaining in close communication with the WHO Secretariat and other international organizations to stay current on the extent of outbreaks
- Conducting intra-HHS OPDIV consultations and discussions
- Communicating the best advice to DOS and other U.S. Government agencies

Contents

CHAPTER 2: DOMESTIC SURVEILLANCE

Introduction

Influenza infections remain the most common cause of vaccine-preventable disease morbidity and mortality in the United States. During interpandemic years, influenza is associated with an average of 36,000 deaths and 220,000 hospitalizations annually during wintertime epidemics. Although the highest rates of death and severe disease occur among known high-risk groups, elderly persons, young children, and those with certain underlying diseases, influenza infections are common among all age groups and populations. During influenza pandemics, the disease burden associated with novel virus strains can be much higher in, and the epidemiology of the disease may be different than during seasonal pandemics.

In the United States, the HHS/CDC monitors the disease burden, timing, and strain distribution of influenza through a variety of surveillance systems. These systems include the following: outpatient disease surveillance through a network of sentinel providers; pediatric hospital-based surveillance through the Emerging Infections Program (EIP) and the New Vaccine Surveillance Network (NVSN); mortality surveillance through vital statistics offices in 122 cities, and notification of pediatric influenza-associated deaths by State, local, and tribal health departments; State and territorial epidemiologists' reports of influenza activity; and strain surveillance through a large network of laboratories. The NIH contributes to surveillance activities through its support of diagnostic research by means of grants and contracts with researchers at universities and other institutions. FDA regulates and ensures safety and effectiveness of products (reagents, instrumentation, and systems) intended for use in the collection, preparation, and examination of human specimens that are tested for influenza viruses. The FDA's regulatory process provides valuable scientific input, along with other contributions including guidance on adequate directions for diagnostic test usage.

While U.S. surveillance systems provide regular data on occurrence, strains, and magnitude of annual influenza epidemics, they are not sufficiently comprehensive or timely to address the needs of public health authorities in the event of pandemic influenza. Once sustained person-to-person spread of a pandemic influenza subtype has been documented, domestic surveillance must be able to detect new introductions of infections with the virus. This ability will ensure timely investigation and public health interventions to limit further spread of disease. Once spread has been documented in the United States, surveillance should reliably detect new clusters of illness so that communities can respond appropriately. Surveillance should be able to document disease burden and trends over time.

This chapter describes the key objectives of U.S. influenza surveillance before and during an influenza pandemic, and lists the actions required to develop surveillance systems to

achieve these objectives. The plan focuses initially on continuing to build laboratory and epidemiologic capacity for surveillance and response, and on establishing comprehensive, timely, and sensitive surveillance systems by building on existing systems and by initiating new systems where gaps currently exist.

Surveillance is the cornerstone of pandemic preparedness and response by public health officials, the U.S. health care system, and the broader framework of governmental, economic, and social organizations. Data on trends in disease activity and virus subtype circulation will inform public health decisionmaking during each of the pandemic phases. Surveillance-related activities will vary under different situations. For example, during the pre-pandemic period, enhancing existing systems for surveillance will allow for reliable and rapid detection of the introduction of a pandemic virus subtype or initial cases of illness in the country. The needs during this period will include ensuring that the laboratory systems are in place to detect novel virus subtypes, to enable detection and investigation of suspect cases in a community, and to detect sentinel increases in disease activity. Surveillance data will guide decisions regarding vaccine development, vaccination strategies (including potential revisions to the list of priority groups), use of antiviral medications, and implementation of public health measures to limit the spread of infection. Surveillance also will provide data to assess the effectiveness of public health measures to control pandemic spread and their impact, and to supply important information for public health messages.

Efforts to develop and implement surveillance systems that can effectively meet pandemic preparedness goals and response needs must address several challenges. Public health officials must identify and address programmatic and resource limitations in instituting more comprehensive and timely surveillance systems. Novel data management systems must be designed to ensure appropriately rapid data reporting, analysis, and feedback. The U.S. Government will need to coordinate surveillance activities with international and domestic partners working on other areas of the pandemic response.

Role of HHS in Domestic Surveillance

The role of HHS is to direct and coordinate domestic surveillance efforts. Responsibilities include, but are not limited to:

- Ensure that sensitive and comprehensive laboratory, epidemiologic, and clinical systems are in place to reliably detect and monitor the occurrence of pandemic influenza in each U.S. Response Stage.
- Ensure mechanisms are in place to provide active and passive surveillance during an outbreak, and that these mechanisms have been developed and exercised.
- Reliably detect and investigate initial cases of highly pathogenic avian-influenza (HPAI) disease or disease associated with other influenza virus subtypes with pandemic potential, such as H5N1. These initial cases can result from exposure to

influenza-infected domestic or wild birds, or from travelers who are exposed to avian influenza outside the United States.

- Identify and investigate initial small clusters of human cases associated with pandemic influenza.
- Determine and track trends in the impact of disease in affected areas (including deaths and hospitalizations), in the general population, and among subpopulations where there is increased and sustained transmission of pandemic influenza occurring in the general population.
- Facilitate development and sustainability of sufficient U.S. laboratory capacity and diagnostic reagents in affected domestic regions to provide rapid confirmation of cases in animals or humans.
- Facilitate the development and deployment of rapid diagnostics.
- Ensure maximal sharing of scientific information about influenza viruses among government authorities, scientific entities, and the private sector.
- Guide pandemic responses, including deployment of rapid response team, implementation of pharmaceutical and non-pharmaceutical public health interventions.
- Assess effectiveness of treatment guidelines, vaccines, antivirals, and public health interventions, and use these data to inform prevention and control strategies.

Specific Assumptions and Planning Considerations for HHS Domestic Surveillance

- All persons living in the United States will be susceptible to infection and illness caused by an influenza pandemic. Because of this susceptibility, surveillance should be able to identify cases of disease, collect specimens for virus subtyping, and monitor the disease burden in all parts of the country and in all age groups.
- The clinical attack rate will be 30 percent, and 50 percent of persons who become ill will seek medical care. Surveillance will focus on health care settings because the objectives stated below are best achieved through the detection and monitoring of the most severe cases of disease.
- Risk groups for severe disease and deaths cannot be predicted before the occurrence of a pandemic. Surveillance systems must be sufficiently comprehensive to monitor disease among all ages, and be flexible enough to undergo modifications to focus on specific subgroups if necessary.
- In an affected community, an influenza outbreak will last approximately 6–8 weeks, based on historical information and models. The surveillance needs in each community may well change during the course of a pandemic—from ensuring rapid detection of first cases and collection of clinical samples for characterizing the virus type; to monitoring virus spread and disease burden; and, to recognize the end of the pandemic period.
- The seasonality of a pandemic cannot be predicted. Sensitive, timely surveillance established in advance of the introduction of a pandemic in the United States will be critical to detect introduction. Therefore, pre-pandemic surveillance should be conducted year-round.
- An influenza pandemic occurring in the next few years will most likely be due to influenza A/(H5N1) and will originate outside the United States. Even so, the capacity to detect any unusual and novel subtype of influenza should be established in case the pandemic originates from a different influenza virus or from within the United States.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

The objectives of influenza surveillance will relate specifically to the different stages of a pandemic. However, many of the activities required to build the systems to meet these surveillance goals must be initiated beforehand, during the pandemic alert period.

HHS will support the development and sustainability of sufficient U.S. laboratory capacity and the supply of diagnostic reagents to provide rapid confirmation of U.S. cases in animals or humans.

Rapid diagnostics having greater sensitivity and reproducibility are needed to allow onsite diagnosis of pandemic strains of influenza in animals and humans, and to facilitate early warning, outbreak control, and targeting of antiviral therapy. Novel investment strategies are being explored to advance the development of next-generation influenza diagnostics and countermeasures, including new antiviral medications, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains of the influenza virus and several seasons.

Planning for a Pandemic—Development of Diagnostic Tools

A. Action (HSC 6.2.3.2): HHS, in coordination with DHS, DOD, and VA, will compile an inventory of all research and product development work on rapid diagnostic testing for influenza and will reach consensus with these Departments on sets of requirements meeting national needs and a common test methodology to drive further private-sector investment and product development. (Also see chapter 1, Pillar One, Action Y [HSC 4.1.8.4].)

   Timeframe: Within 6 months.

   Measure of Performance: Inventory developed and requirements paper disseminated.

B. Action (HSC 6.2.3.3): HHS, in coordination with DOD, VA, and DHS will encourage and expedite private-sector development of rapid subtype- and strain-specific influenza point-of-care tests.

   Timeframe: Within 12 months of the publication of requirements.

   Measure of Performance: Rapid point-of-care test available in the marketplace within 18 months.

C. Action (HSC 6.1.17.3): HHS, in coordination with DHS, will develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance. (Also see chapter 3, Pillar One, Action AA [HSC 6.1.17.3].)

   Timeframe: Within 18 months.

   Measure of Performance: New grants and contracts awarded to researchers to develop and evaluate new diagnostics.

D. Action (HSC 4.2.3.4): HHS will investigate the development and evaluation of more accurate rapid diagnostics for influenza to enhance the ability of the global health care community to rapidly diagnose influenza. (Also see chapter 1, Pillar Two, Action N [HSC 4.2.3.4].)

   Timeframe: Within 18 months.

Measure of Performance: New grants and contracts issued to researchers to develop and evaluate new diagnostics.

E. Action (HSC 6.2.3.1): HHS, in coordination with DHS and DOD, will work with pharmaceutical and medical device company partners to develop and evaluate rapid diagnostic tests for novel influenza subtypes including H5N1.

Timeframe: Within 18 months.

Measure of Performance: New investment in research to develop influenza diagnostics; new rapid diagnostic tests, if found to be useful, are available for influenza testing, including for novel influenza subtypes.

F. Action (HSC 6.1.17.2): HHS will collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), clearance/approval/licensure, and U.S.-based production of new diagnostics. Development activities will include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations will involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways toward product approval or licensure. Collaborations concerning diagnostic tests will include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. (Also see chapter 6, Pillar One, Action A [HSC 6.7.17.2].)

Timeframe: Ongoing.

Measure of Performance: Initiation of clinical trials of new influenza antiviral drugs and diagnostics.

For Actions A through F, also see Chapter 5, Vaccines [HSC 6.1.15.3, 6.1.17.1, 4.1.5.3, 4.1.6.2, and 6.1.17.1], for a description of effort associated with new influenza vaccines; and Chapter 6, Antivirals [HSC 4.1.6.2, 6.1.15.3, and 6.1.17.2], for a description of effort associated with the development, evaluation, and licensure of new antiviral agents for influenza.

The following steps will be undertaken to address Actions A through F:

Step 1: Establish a cross-agency working group to identify research and product development work on rapid diagnostic testing. Ensure that efforts will comply with the Federal Food, Drug, and Cosmetic Act (FDCA).

Step 2: Compile an inventory of the research and product development work that has been conducted, is underway, and is planned.

Step 3: Convene a meeting to review the research inventory findings; and to discuss and reach consensus on requirements needed for further research and product development efforts.

Step 4: Produce and distribute proceedings of the meeting.

Step 5: Identify funding source and mechanisms to promote research for rapid diagnostic tests.

Step 6: Establish mechanisms for carrying out the evaluations of newly developed diagnostics, beginning with disseminating the performance specifications and obtaining comments through a Federal regulatory or advisory panel, or other open forum.

Step 7: Issue Requests for Proposals and Requests for Applications for research for rapid diagnostic tests that meet the consensus requirements.

Step 8: Make available materials and data needed by researchers to develop rapid diagnostic methods.

Step 9: Coordinate specification of performance and laboratory evaluations with FDA's premarket review requirements for new diagnostics.

Step 10: Establish a cross-agency working group to identify target performance specifications for new diagnostics, standardized specimen types and collection methods, and methods for preparing any contrived samples; to develop and review protocols for evaluating performance and conducting performance testing; to facilitate evaluation by both public health and clinical labs; and, to streamline regulatory pathways.

Step 11: Perform studies to evaluate rapid diagnostic techniques and reagents/test kits currently available; disseminate results.

Step 12: Collaborate with FDA regarding accelerated regulatory pathways, including establishment of criteria used to determine whether improvements to or updating of current diagnostics represent new diagnostic tools requiring new regulatory review and approval (consistent with 21 CFR 807.81, 814.39).

G. Action (HSC 6.1.17.4): HHS will increase access to standardized influenza reagents for use in influenza tests and research. (Also see chapter 5, Pillar One, Action D [HSC 6.1.17.4] regarding the provision of reagents to assist with identifying virus reference strains for vaccine manufacturing.)

Timeframe: Within 6 months.

Measure of Performance: Standardized influenza reagents distributed to domestic and international partners within 3 business days of a request.

Step 1: Develop and test RT-PCR primers and protocols for detection of novel viruses (completed for influenza virus types H5 and H7).

Step 2: Prepare anti-sera and antigens specific for H5N1 viruses for use in laboratory assays.

Step 3: Ensure availability of reference and control reagents in known national repositories and distribute materials to State, local, and tribal health laboratories.

Step 4: Identify and address regulatory pathways to emergency distribution and use of diagnostic tests and reagents during a pandemic state of emergency and at other times when a state of emergency does not exist.

Step 5: Provide updated preparedness information regarding diagnostic tests and reagents to State, local, and tribal public health partners via the Laboratory Reference Network (LRN) and Health Alert Network (HAN).

Step 6: Continue to provide laboratory training workshops for State, local, and tribal health department personnel as needed.

Step 7: Promulgate guidance for testing approaches and specimen referrals from clinical and commercial laboratories.

Planning for a Pandemic—Facilitate Diagnostic Testing

H. Action (HSC 6.2.1.5): HHS will facilitate State, local, and tribal entities preparation to increase diagnostic testing for influenza and increase the frequency of reporting to CDC, in the event of a pandemic.

Timeframe: Ongoing.

Measure of Performance: State, local, and tribal entities are prepared and can increase their diagnostic testing and reporting to CDC when needed during a pandemic.

Step 1: Encourage State, local, and tribal public health laboratory staff to assess current surge capacity in public and clinical laboratories in their jurisdictions and to identify needs to accommodate increased demand during a pandemic.

Step 2: Develop laboratory training curriculum.

Step 3: Provide support to conduct training courses at CDC and at regionally convenient laboratories.

Step 4: Support personnel at Federal and local laboratories to plan and conduct training.

Step 5: Build capacity and framework for timely reporting to and feedback from CDC and State, local, and tribal entities.

I. Action (No HSC Action): HHS will train federal- and state-based epidemiologists and other public health professionals in pandemic influenza response and investigation to provide surge capacity to State, local, and tribal health departments.

Timeframe: Within 12 months.

Measure of Performance: Materials produced and used for training courses.

Step 1: Establish training materials (Web-based, slide sets, written documents) to prepare epidemiologists and other public health professionals in pandemic influenza response and investigation techniques.

Step 2: Identify and train course trainers.

Step 3: Conduct training course during the 2006 Epidemic Intelligence Service (EIS) Introductory Class and during the 2006 Spring EIS conference.

Step 4: Conduct training courses with the World Bank for World Bank missions to assess country needs regarding pandemic preparedness.

Step 5: Work with State, local, and tribal health departments to identify participants for training workshops and investigate mechanisms (financial and logistic) to conduct them.

Step 6: Establish plans to regularly update training materials.

Step 7: Integrate the HHS/U.S. Public Health Services (USPHS) Commissioned Corps (CC)/Office of Force Readiness and Deployment into pandemic preparedness efforts. For example, consider incorporating pandemic influenza modules into CC readiness standards. (Also see chapter 4, Pillar One, Action A [HSC 6.1.2.2], regarding preparations for deployment of Federal personnel.)

Communicating Expectations and Responsibilities

J. Action (HSC 4.1.4.1): HHS will work with DOS, and USAID, and in coordination with other Federal agencies, to help ensure that the top political

leadership of all priority countries understands the need for clear, effective, coordinated, public information strategies before and during an outbreak of avian or pandemic influenza. (Also see chapter 7, Pillar One, Action E [HSC 4.1.4.1].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries develop outbreak communication strategies that are consistent with the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.

Step 1: Further the objectives of the communications chapter of the Security and Prosperity Partnership for North America (SPP) Annex to the HHS Pandemic Flu Plan, which discusses international information-sharing and coordinated communications leading up to and during a pandemic.

K. Action (HSC 6.2.2.10): HHS will promote State, local, and tribal health departments' development of relationships with hospitals and health care systems within their jurisdictions to facilitate collection of real-time or near-real-time clinical surveillance data from domestic acute care settings such as emergency departments, intensive care units, and laboratories.

Timeframe: Ongoing.

Measure of Performance: All states will have initiated discussions with representatives of hospitals and health care systems regarding the collection of real-time or near-real-time clinical surveillance data.

Step 1: Refine current suspect case forms/systems (see **HHS Pandemic Plan**, pp S1-15–S1-19) to reflect current information about H5N1 and incorporate appropriate data standards.

Step 2: Make suspect case forms/systems available to State, local, and tribal health departments and key health care providers through the CDC Web site, CDC Epidemic Information Exchange (Epi-X) postings, HAN, and partner organizations.

Step 3: Develop and pilot test a secure, Web-based data entry system for forms and data reporting/transmission to State, local, and tribal health departments. Case and outbreak investigations will be simplified by using preestablished, easy-to-use data entry forms and computer systems to transmit these data to central nodes (such as State health departments or CDC). For States able to use a Public Health Information Network (PHIN)-compliant State system, provide guidance for submission of standard data from the form. Work with public health and legal officials to identify and address privacy concerns related to the collection,

analysis, and storage of surveillance data in new and enhanced systems. Provide training to State and local health department staff for using the systems.

Step 4: Provide guidance to public health officials and laboratories regarding case definitions, surveillance methods, and diagnostic tests to be used during different stages of a pandemic, such as procedures for conducting confirmatory testing of positive samples and further genetic and antigenic characterization at CDC.

Step 5: Build capacity and framework for timely reporting to and feedback from CDC to State, local, and tribal health departments.

Step 6: Develop systems for data analysis and feedback; incorporate a numbering system that will facilitate linkage with case or cluster investigation forms.

Step 7: Convene a series of discussions among representatives of State, local, and tribal health departments, and hospitals and health care systems to discuss surveillance data needs, reporting procedures, and data analysis and feedback procedures that will facilitate the development of relationships among these entities.

L. Action (HSC 6.2.1.4): HHS will work with Federal, State, local, tribal, and private sector medical facilities to promote the use of standardized protocols for transporting influenza specimens to appropriate reference laboratories are in place. (Also see chapter 8, Pillar Two, Action A [HSC 6.2.1.4].)

Timeframe: Within 3 months.

Measure of Performance: Transportation protocols for laboratory specimens detailed in HHS, DOD, VA, State, territorial, tribal, and local pandemic response plans.

Step 1: Distribute existing protocols and regulations on the proper collection, handling, and shipping of clinical samples and viral isolates.

Step 2: Update health care provider instructions on the collection of clinical and epidemiologic data that should accompany isolates. Incorporate numbering system that will facilitate linkage with case or cluster investigation forms.

Step 3: Develop appropriate laboratory testing algorithms and specimen handling procedures and train local staff to use them. Facilitate incorporating currently used (and available) products into testing algorithms.

Step 4: Advise States on the specific isolate selection criteria that they should use to determine what isolates should be sent to CDC as part of efforts to monitor changes in the antigenicity and antiviral susceptibility of the pandemic virus.

Step 5: Update existing data reporting and feedback systems for timelier sharing of information.

Step 6: In collaboration with USDA, when appropriate, revise laboratory Bio-Safety Level (BSL) standards and inclusion of novel viruses on the select agent list.

M. Action (No HSC Action): Ensure that health care providers and members of the general public are aware of the signs/symptoms and epidemiologic profile of possible clusters. (Also see chapter 7, Pillar One, Actions J and K [HSC 6.1.3.1 and 6.1.3.2] regarding efforts to develop a public engagement and risk communications strategy; and chapter 6, Pillar One, Action R [HSC 6.1.3.1] regarding antiviral drug messaging.)

Timeframe: 12 months.

Measure of Performance: Educational materials are developed and published on http://www.pandemicflu.gov, and are also distributed through health alert network messages and other communication systems.

Step 1: Develop and distribute educational messages targeting public and private health care workers; nursing home personnel; staff in school health facilities, and university infirmaries, large employee health programs, and jail and prison health units; infection control practitioners; pharmacists; day care providers; foreign travelers (e.g., corporate, faith-based, philanthropic); teachers; and, the general public to ensure they are aware of the signs/symptoms and epidemiologic profile of possible clusters. These educational messages must include both case-specific and cluster-associated indicators for reporting, as appropriate for each targeted group. These messages in local languages also will include information on the appropriate reporting mechanisms.

Step 2: Improve the ease of use of methods for reporting suspicious clusters. Continue to work with State, local, and tribal surveillance partners (e.g., Council of State and Territorial Epidemiologists [CSTE]; National Association of County and City Health Officials [NACCHO]; State, local, and tribal health offices) to design logistically feasible reporting mechanisms from health care providers or systems to the public health authorities.

Step 3: Increase awareness of reporting methods when suspicious clusters are identified.

Step 4: Work with State, local, and tribal public health and media to ensure that appropriate materials and processes are developed for and communicated by trade associations that represent targeted providers and systems.

Step 5: Work with the Association for Practitioners in Infection Control and Epidemiology (APIC) and Society for Health care Epidemiology of America (SHEA) on strategies to enhance disease occurrence information across hospitals and other health systems.

Advancing Scientific Knowledge and Accelerating Development

N. Action (HSC 4.1.8.1): HHS will support the Los Alamos H5 Sequence Database and TIGR, for the purpose of sharing avian H5N1 influenza sequences with the scientific community. (Also see chapter 1, Pillar One, Actions N and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 24 months.

Measure of Performance: Completed H5 sequences entered into both the Los Alamos database and GenBank and annotated.

Step 1: Identify and address barriers and constraints to direct reporting of sequences to Los Alamos H5 and GenBank.

Step 2: Review the databases to identify compatibility with information fields, and data submission and release policies.

Step 3: Establish and convene a workgroup to identify core data that will be included and ways to improve direct reporting and verification of sequences to the Los Alamos H5 database and GenBank.

Step 4: Establish system interoperability so that data can be transferred electronically between the database systems.

Step 5: Establish protocols and procedures for transferring data between the databases.

O. Action (HSC 6.1.15.1): HHS will develop capability, protocols, and procedures to ensure that viral isolates obtained during investigation of human outbreaks of influenza with pandemic potential are sequenced and that sequences are published on GenBank within 1 week of confirmation of diagnosis in index case. (Also see chapter 1, Pillar One, Actions W and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 6 months.

Measure of Performance: Viral isolate sequences from outbreaks published on GenBank within 1 week of confirmation of diagnosis.

P. Action (HSC 6.1.15.2): HHS will increase and accelerate genomic sequencing of known human and avian-influenza viruses and should rapidly make this sequence

information publicly available. (Also see chapter 1, Pillar One, Actions W and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 6 months.

Measure of Performance: Increased throughput of genomes sequenced (versus FY 2005 baseline) and decreased time interval between completion of sequencing and publication on GenBank.

The following steps will be undertaken to address Actions O and P:

Step 1: Establish working group of HHS laboratory experts with experience in sequencing of influenza to determine plans for making data available more quickly.

Step 2: Identify laboratories that currently report sequence data and query them to identify barriers and constraints to publishing sequences, including intellectual property issues, concerns of those submitting specimens for sequencing, and mis/over-interpretation of sequence information.

Step 3: Implement protocols and procedures so that sequences can be published within 1 week of confirmation.

Step 4: Evaluate timeframes of sequence postings to GenBank within 1 year and identify remaining or additional barriers and constraints.

Q. Action (HSC 6.1.15.3): HHS shall develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported influenza diagnostic evaluation studies. (Also see chapter 5, Pillar One, Actions E and L [HSC 6.1.15.3, and 6.1.17.1] regarding vaccine candidate evaluation studies; and chapter 6, Pillar One, Action D [HSC 6.1.15.3] regarding antiviral drug studies.)

Timeframe: Within 6 months.

Measure of Performance: Study data shared with Federal agencies within 1 month of analysis and publication of clinical trial data following completion of studies.

Step 1: Establish a workgroup of representatives from relevant HHS OPDIVs involved with diagnostic evaluation studies.

Step 2: Compile a list of current and planned diagnostic evaluation studies, and their expected timeframe for completion.

Step 3: Develop protocols and procedures regarding sharing of study results among Federal agencies.

Step 4: Implement protocols and procedures to ensure results are shared within 1 month of completion of data analysis.

Step 5: Evaluate timeframes of sharing results within 18 months and identify remaining or additional limitations for sharing results of diagnostic evaluation studies with Federal agencies within 1 month of completion of data analysis.

Pillar Two: Surveillance and Detection

The ability of public health officials to prevent or limit disease associated with pandemic influenza will rely on the rapid, specific identification of initial cases and clusters. Accomplishing this will require sensitive and timely surveillance, widely available laboratory testing capacity, and confirmation and reporting systems that facilitate rapid response by appropriate authorities. These surveillance systems will be linked with those systems for international surveillance, as well as with other public health efforts directed toward response, such as vaccine and antiviral distribution and non-pharmaceutical interventions.

Mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders will be developed and exercised. All levels of government, domestically and globally, will be encouraged to take appropriate and lawful action to contain an outbreak within their communities, provinces, states, or countries. HHS will leverage Federal medical capabilities, both domestic and international, to provide real-time clinical surveillance in domestic acute care settings, such as emergency departments, intensive care units, and laboratories, to provide Federal, State, local, tribal, and public health officials with continuous awareness of the profile and threat of illness in communities.

Guidance and support will be provided to poultry, swine, and related industries on their role in responding to an outbreak of avian influenza, including ensuring the protection of animal workers and initiating or strengthening public education campaigns to minimize the risks of infection from animal products. Rapid-response modeling capability to improve decisionmaking during a pandemic will be developed.

Ensuring Rapid Reporting of Outbreaks

A. Action (HSC 5.2.2.1): HHS, in coordination with DOD, will support DHS deployment of human influenza rapid diagnostic tests with greater sensitivity and specificity at borders and ports of entry to allow real-time health screening. (Also see chapter 3, Pillar Two, Actions B, I and K [HSC 5.2.2.1, 5.2.4.6 and 5.2.4.8]; as well as chapter 8, Pillar One, Action D [HSC 5.1.2.3] regarding travel and border protocols.)

   Timeframe: Within 12 months of development of tests.

Measure of Performance: Diagnostic tests, if found to be useful, are deployed; testing is integrated into screening protocols to improve screening at the 20–30 most critical ports of entry.

B. Action (HSC 6.2.3.4): HHS-, DOD-, and VA-funded hospitals and health facilities will have access to improved rapid diagnostic tests for influenza A, including influenza with pandemic potential.

Timeframe: Within 6 months of when tests become available.

Measure of Performance: Diagnostic tests, if found to be useful, are accessible to federally funded health facilities.

The following steps will be undertaken to address Actions A and B:

Step 1: Convene a working group to establish criteria for the selection of human influenza rapid diagnostic tests that would be deployed to ports of entry and to which Federally-funded facilities should have access; to determine protocols for their use; to identify potential mechanisms for deploying selected tests; and to specify critical ports of entry.

Step 2: Monitor development of more sensitive and specific human influenza rapid diagnostic tests that meet FDCA regulatory requirements or that meet Investigational Device Exemption (IDE) criteria.

Step 3: Identify human influenza rapid diagnostic tests that meet selection criteria.

Step 4: Share information about availability of improved rapid diagnostic tests with medical and laboratory directors of ports of entry and federally funded facilities.

Step 5: Integrate selected diagnostic tests in screening protocols used at the critical ports of entry and federally funded facilities.

Step 6: Use identified mechanisms to deploy and create access to selected rapid diagnostic tests.

C. Action (HSC 6.2.1.1): HHS will provide guidance to public health and clinical laboratories on the different types of diagnostic tests and the case definitions to use for influenza at the time of each pandemic stage.

Timeframe: Guidelines for the current pandemic alert phase will be disseminated within 3 months.

Measure of Performance: Dissemination on http://www.pandemicflu.gov and through other channels of guidance on the use of diagnostic tests for H5N1 and other potential pandemic influenza subtypes.

Step 1: Distribute updated protocols and regulations on the proper collection, handling, and shipping of clinical samples and viral isolates, including updated instructions on the collection of clinical and epidemiologic data that should accompany isolates. Incorporate a numbering system that will facilitate linkage with case or cluster investigation forms.

Step 2: Provide updated preparedness information regarding diagnostic tests, reagents, case definitions, and, specimen selection and handling to State, local, and tribal public health partners via the LRN and the HAN.

D. Action (HSC 6.2.1.2): HHS will ensure that testing (RT-PCR) for H5N1 and other influenza viruses with pandemic potential is available at State public health laboratories, LRN laboratories, and CDC.

Timeframe: Within 3 months.

Measure of Performance: RT-PCR for H5N1 and other potential pandemic influenza subtypes and strains in use at CDC and LRN laboratories.

E. Action (HSC 6.2.1.3): HHS, in coordination with DOD, VA, USDA, DHS, EPA, and other partners, in collaboration with its LRN Reference Laboratories, will be prepared to conduct laboratory analyses to detect pandemic subtypes and strains in referred specimens and conduct confirmatory testing, as requested.

Timeframe: Within 6 months.

Measure of Performance: Initial testing and identification of suspect pandemic influenza specimens completed at LRN Reference and National Laboratories within 24 hours.

The following steps will be undertaken to address Actions D and E:

Step 1: Monitor occurrence of and changes in influenza virus subtypes with significant pandemic potential.

Step 2: Develop and test updated RT-PCR primers and protocols for detection of novel viruses and prepare anti-sera and antigens specific for H5N1 viruses for use in laboratory assays.

Step 3: Ensure availability of reference and control reagents in known national repositories by distributing materials to State, local, and tribal health laboratories that meet FDCA laboratory regulatory requirements or that meet IDE criteria.

Step 4: Identify and address regulatory pathways to emergency distribution and use of diagnostic tests and reagents during a pandemic state of emergency and at other times when a state of emergency does not exist.

Step 5: Provide updated preparedness information regarding diagnostic tests and reagents to State, local, and tribal public health partners via the LRN, Integrated Consortium of Laboratory Networks (ICLN), and HAN.

Step 6: Continue to provide laboratory training workshops for State, local, and tribal health department personnel as needed.

F. Action (HSC 6.2.2.3): HHS, in coordination with DOD and VA, will expand the number of hospitals and cities participating in the BioSense RT program to improve the nation's capabilities for disease detection, monitoring, and situational awareness.

Timeframe: Within 12 months.

Measure of Performance: Number of hospitals (including DOD and VA facilities) participating in the BioSenseRT program increased to 350 hospitals in 42 cities.

Step 1: Analyze BioSense outpatient data to determine if patient visits with the influenza International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code correlate well with existing outpatient influenza-like illness (ILI) data and influenza laboratory data.

Step 2: Review BioSense data to determine if it is possible to identify patients with symptoms comparable to the existing outpatient ILI case definition, and if so, how well these data are correlated.

Step 3: Identify States that are receiving electronic emergency department data on ILI on a daily basis. Collaborate with a small number of State, local, and tribal health departments to pilot use of emergency department (ED)-based systems for near daily reporting of illness and compare the data to existing sentinel provider ILI data.

Step 4: Explore feasibility of harmonizing systems for transmitting such data with BioSense/State infrastructure.

Step 5: Continue to recruit and support implementation of additional emergency departments and hospitals to increase the geographic coverage and enhance numbers of hospitals providing real-time clinical data to BioSense.

Step 6: Collaborate with VA and DOD to gain access to real-time clinical and hospital data (BioSense currently receiving latent coded data only from ambulatory care sites).

Step 7: Implement real-time reporting of clinical laboratory orders and results from three of the largest national laboratory systems.

Step 8: Enhance real-time clinical data sources through the addition of ambulatory care data from the large integrated health care delivery networks and ambulatory care sites associated with the BioSense hospitals.

Step 9: Collaborate with health care information technology vendors to explore mechanisms for implementation of BioSense specifications and standards.

Step 10: Advance the science of real-time bio-surveillance, including usefulness of data, functionality of systems, and utility of BioSense data for response, by supporting rigorous evaluation of analysis and methodologies (through collaboration with key researchers in the field).

G. Action (HSC 6.2.2.4): HHS will reduce the time between reporting of virologic laboratory data from state, local, tribal, and private sector partners and collation, analysis, and reporting to key stakeholders.

Timeframe: Within 6 months.

Measure of Performance: Time delay between receipt of data and collation, analysis, and reporting of results of seven (7) days or less.

Step 1: Identify and assess potential methods for facilitating automated reporting of data from the World Health Organization (WHO) Secretariat and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories to decrease reporting time.

Step 2: Develop and implement methods for collating, analyzing, and reporting data submitted electronically from the WHO Secretariat and NREVSS collaborating laboratories.

Step 3: Revise protocols and procedures for submitting data to reflect new methods.

Step 4: Pilot test the new system prior to the next influenza season.

Step 5: Modify the protocols and procedures based upon the results of the pilot test.

H. Action (HSC 6.2.2.5): HHS will increase the frequency of reporting and the number and geographic location of reporting health care providers from which outpatient surveillance data is collected through the Sentinel Provider Network (SPN), the EIP influenza project, and the New Vaccine Surveillance Network.

Timeframe: Within 6 months.

Measure of Performance: Number of reporting health care providers increased to one or more per 250,000 population.

Step 1: Encourage State health departments to increase the geographic coverage of regularly reporting sentinel providers, including providers serving rural populations.

Step 2: Encourage State health departments to increase the number of providers who report year round.

Step 3: Develop and pilot test protocols (surveillance questionnaires, and specimen collection, handling, analysis, and reporting of results) for suspected, probable, and confirmed pandemic (or potential pandemic) cases and contacts.

Step 4: In collaboration with State and local public health agencies, communicate with providers regarding the importance of timely reporting of influenza-like illness and the definition, testing, and reporting guidelines for suspected, probable, and confirmed cases and their contacts.

I. Action (HSC 6.2.2.6): HHS will improve the speed at which it performs mortality surveillance through the 122 Cities Mortality Reporting System.

Timeframe: Within 3 months.

Measure of Performance: Mortality data collected at CDC within 1 week of decedent's demise increased by 25 percent compared with 2005.

Step 1: Encourage vital statistics offices in 122 U.S. cities to report pneumonia and influenza (P&I)-related deaths on a weekly basis.

J. Action (HSC 6.2.4.2): HHS, in coordination with Sector-Specific Agencies, DOD, DOJ, and VA, and in collaboration with the private sector, will support DHS' lead in preparations to track integrity of critical infrastructure function, including the health care sector, to determine whether ongoing strategies of ensuring workplace safety and operational continuity need to be altered as a

pandemic evolves. (Also see chapter 3, Pillar Two, Action N [HSC 6.2.4.2]; and chapter 8, Pillar Two, Action B [HSC 6.2.2.8].)

Timeframe: Within 6 months.

Measure of Performance: Tracking system in place to monitor integrity of critical infrastructure function and operational continuity in near real time.

Step 1: Convene a working group to identify key indicators of illness and absenteeism, and other measures of the integrity of critical infrastructure and operational continuity.

Step 2: Identify existing or potential mechanisms for compiling data in near real time for the identified indicators.

Step 3: Establish protocols and processes to modify existing approaches or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

K. Action (HSC 7.1.3.3): HHS, in coordination with USDA, DHS, and the Department of Labor (DOL), will work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers. (Also see chapter 3, Pillar One, Action S [HSC 7.1.3.3]; and chapter 7, Pillar One, Action P [HSC 7.1.3.3].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines developed and disseminated to poultry and swine industries.

Step 1: Work with State and local health departments, USDA, DOL, and industry/trade organizations to create, update, and implement surveillance protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines) among persons exposed to potentially infected birds (domestic/wildlife) to detect animal-to-human transmission.

Step 2: Develop isolation, quarantine, and treatment guidelines.

Step 3: Identify HHS/CDC role, including when HHS/CDC staff will deploy to assist with an outbreak investigation.

Step 4: Update, if necessary, reporting requirements and frequency.

Step 5: Develop guidelines for notification, triage, and clinical management of confirmed or suspected human illnesses identified during surveillance.

L. Action (No HSC Action): HHS, in coordination with other Federal, State, Local, and Tribal partners, will support collaborations across State, Tribal, Military, and international borders to conduct necessary activities in support of cross-jurisdictional planning, coordination, communication, program development, and exercises to enhance pandemic influenza preparedness and response capacity along the borders.

Timeframe: Within 24 months.

Measure of Performance: Cross-border collaborations have fostered the development and exercising of pandemic influenza plans and increased the capacity and capability of state and local public health and medical entities (e.g., primary care, Health Centers, rural health programs, hospitals) for regional and border-wide preparedness and response to an influenza pandemic.

Step 1: Engage federally recognized tribes along the international border in your State in cross-border infectious disease surveillance activities through mutual aid compacts, memoranda of understanding, and/or agreements. Where appropriate, include local bi-national health councils and/or Indian Tribes/Native American organizations in pandemic influenza surveillance activities.

Step 2: In coordination with local public health agencies on both sides of the border, conduct joint, cross-border assessments of information technology and apply information technology to develop or enhance electronic pandemic influenza surveillance, including electronic disease reporting from clinical and public health laboratories and linkage of laboratory results to case report information.

Step 3: Convene and conduct joint pandemic influenza surveillance and epidemiology planning workshops and exercises to discuss, plan, drill, and test cross-border surveillance and/or epidemiology-related activities. Such activities should, where feasible, involve a collaborative and regional approach with neighboring U.S. Border States, appropriate tribal nations as well as Mexico or Canada (as appropriate). These planning workshops and exercises should involve not only border health departments but, where feasible, local hospitals, tribal and Public Health Service health facilities, hospital laboratories, major community

health care institutions, emergency response agencies, and public safety agencies in order to respond in a coordinated manner.

Step 4: Work with representatives from Canada and Mexico to develop a Security and Prosperity Partnership of North America (SPP) annex to each country's pandemic influenza plan.

M. Action (HSC 5.2.4.8): HHS along with DHS, and in coordination with DOT, DOJ, and appropriate state and local health authorities, will develop detection, diagnosis, quarantine, isolation, Emergency Medical Services (EMS) transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza. (Also see chapter 3, Pillar One, Action D [HSC 5.1.1.4]; chapter 3, Pillar Two, Action K [HSC 5.2.4.8]; and chapter 7, Pillar Two, Action C [HSC 5.2.4.8] regarding the development of protocols and educational materials.)

Timeframe: Within 10 months.

Measure of Performance: Protocols developed and distributed to all ports of entry.

N. Action (HSC 5.3.1.5): HHS, in coordination with DHS, DOT, DOS, DOD, USDA, appropriate State and local authorities, air carriers/air space users, airports, cruise lines, and seaports, will implement screening protocols at U.S. ports of entry based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 3, Pillar Three, Action E [HSC 5.3.1.5].)

Timeframe: As required.

Measure of Performance: Screening implemented within 48 hours upon notification of an outbreak.

O. Action (HSC 5.3.1.6): HHS, in coordination with DHS, DOT, USDA, DOD, appropriate state, and local authorities, air carriers and airports, will consider implementing response or screening protocols at domestic airports and other transport modes as appropriate, based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 3, Pillar Two, Action B [HSC 5.2.2.1] and chapter 3, Pillar Three, Action F [HSC 5.3.1.6].)

Timeframe: As required.

Measure of Performance: Screening protocols in place within 24 hours of directive to do so.

The following steps will be undertaken to address Actions M, N, and O:

Step 1: Establish and implement surveillance and triage protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines).

Step 2: Ensure airline and cruise ship personnel are familiar with case finding protocols, and reporting and handling of suspect cases.

Step 3: Develop methods to identify and investigate suspect cases among incoming travelers.

Step 4: Work with immigration officials to update protocols on identification and triage of suspect cases.

Step 5: Develop and implement isolation, quarantine, and treatment guidelines.

Step 6: Update, if necessary, reporting requirements and frequency.

P. Action (No HSC Action): HHS will establish surveillance systems for clusters of illness among health care workers. (Also see chapter 7, Pillar Three, Action D [HSC 6.3.2.6] regarding the implementation of implement infection control campaigns for pandemic influenza.)

Timeframe: Within 6 months.

Measure of Performance: Surveillance systems established and operational.

Step 1: Work with health care providers and infection control societies to investigate current systems that would capture clusters of illnesses among health care workers.

Step 2: Work with health care institutions to develop protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines) or amended procedures to existing systems to capture new suspicious clusters.

Step 3: Pilot test new systems in a variety of locations and types of institutions and revise protocols and procedures based on the pilot test results.

Step 4: Develop guidelines for implementing systems.

Q. Action (No HSC Action): HHS will continue existing activities to conduct surveillance of disease among laboratory workers with potential for exposure to avian influenza. (Also see chapter 7, Pillar Three, Action D [HSC 6.3.2.6]

regarding the implementation of implement infection control campaigns for pandemic influenza.)

Timeframe: Ongoing.

Measure of Performance: Surveillance system operational.

Step 1: Review/revise and implement established protocols.

Step 2: Update, if necessary, reporting requirements and frequency.

Step 3: Educate laboratory staff regarding protocols and reporting requirements.

Using Surveillance to Limit Spread

R. Action (HSC 6.2.4.1): HHS, in coordination with DHS, DOD, VA, USDA, and DOS, will be prepared to continuously evaluate surveillance and disease reporting data to determine whether ongoing disease containment and medical countermeasure distribution and allocation strategies need to be altered as a pandemic evolves. (Also see chapter 8, Pillar Two, Action B [HSC 6.2.2.8] Step 4, regarding providing assistance to State, local, and tribal health agencies regarding analysis for their specific jurisdiction.)

Timeframe: Within 12 months.

Measure of Performance: Analyses of surveillance data performed at least weekly during an outbreak with timely adjustment of strategic and tactical goals, as required.

Step 1: Convene a working group to identify key indicators of the impact of pandemic influenza and necessary data for assessing effectiveness of disease containment and countermeasure usage strategies.

Step 2: Identify existing or potential mechanisms for compiling data on a weekly basis for the identified indicators.

Step 3: Establish protocols and processes to modify existing approaches or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system (including validation of assessment questions/data fields) during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

S. Action (HSC 6.2.2.7): HHS, in collaboration with DHS, DOD, VA, USDA and other Federal departments and agencies with bio-surveillance capabilities and real-time data sources, will enhance National Bio-Surveillance Integration System (NBIS) capabilities to ensure the availability of a comprehensive and all-source bio-surveillance common operating picture throughout the Interagency.

Timeframe: Within 12 months.

Measure of Performance: NBIS provides integrated surveillance data to DHS, HHS, USDA, DOD, VA, and other interested interagency customers.

T. Action (HSC 6.2.5.1): HHS, in coordination with DOD and DHS, will develop and maintain a real-time epidemic analysis and modeling hub that will explore and characterize response options as a support to policy and decision makers.

Timeframe: Within 6 months.

Measure of Performance: Modeling center with real-time epidemic analysis capabilities established.

The following steps will be undertaken to address Actions R, S, and T:

Step 1: Convene a working group to identify data needed by policy and decision makers as they consider and/or implement different response options and to identify where the hub will be located.

Step 2: Identify existing or potential mechanisms for compiling real time data for the identified indicators. Evaluate the use of novel statistical methods to define excess disease occurrences in existing and novel surveillance systems, for example, refine methods for applying the Early Aberration Reporting System (EARS) and other aberration detection algorithms to the outpatient ILI data reported by sentinel providers Apply relevant statistical tools to other existing influenza surveillance systems. Consider platforms such as BioSense that permit visualization and analysis across multiple data sources. Explore other options for statistical methods to aid in timely identification of disease clusters.

Step 3: Establish protocols and processes to modify existing or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to establish the hub and pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

U. Action (HSC 6.2.2.1): HHS will be prepared to be able to provide ongoing information from the national influenza surveillance system on the pandemic's impact on health and the health care system.

Timeframe: Within 6 months.

Measure of Performance: Surveillance data aggregated and disseminated every 7 days, or as often as the situation warrants, to DHS, Sector-Specific Agencies, and state, territorial, tribal, and local partners.

Step 1: Convene a working group to identify key indicators of the impact of pandemic influenza.

Step 2: Identify existing or potential mechanisms for compiling data on a weekly basis for the identified indicators.

Step 3: Establish protocols and processes to modify existing or to develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

V. Action (HSC 6.2.2.2): HHS, in coordination with Federal, State, local, tribal and private sector partners, will develop real-time (same-day) tracking capabilities of pneumonia or influenza hospitalizations and influenza deaths to enhance its surveillance capabilities at the onset of and during a pandemic.

Timeframe: Within 12 months.

Measure of Performance: Real-time (same-day) nationwide hospital census and mortality tracking system is operational for use during a pandemic.

Step 1: Identify existing or other potential systems for tracking the number of pneumonia or influenza hospitalizations and deaths during a pandemic, including:

- Feasibility of modifying the Hospital Available Beds for Emergencies and Disasters (HAvBED) System to collect information about the number of emergency- or disaster-related patients that are hospitalized or have died

- Using pandemic influenza as a specific example, including the following:
  - Feasibility of obtaining National Hospital Discharge Survey data in a more timely manner
  - Validity of estimating national mortality based on data from the 122 Cities Mortality Reporting System
  - Feasibility of obtaining timely mortality data from all 50 States through the Electronic Death Registration Project
  - Potential availability and utility of data from the National Association of Health Data Organizations (NAHDO)

Step 2: Modify the existing systems as required.

Step 3: If existing systems are not applicable, establish protocols and processes to develop new systems for collecting timely hospitalization and death information.

Step 4: Establish protocols and processes for analyzing and reporting the hospitalization and death information.

Step 5: Pilot test the system(s) during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

W. Action (HSC 4.2.5.2): HHS, in coordination with DOS and other Agencies under the SPP will pursue cooperative agreements on pandemic influenza with Canada and Mexico to create and implement a North American early warning surveillance and response system in order to prevent the spread of infectious disease across our borders.

Timeframe: Within 9 months.

Measure of Performance: Implementation of early warning surveillance and response system.

Step 1: Assist DOS in negotiating cooperative agreements with Canada and Mexico to improve pandemic influenza surveillance and preparedness in North America.

Pillar Three: Response and Containment

Surveillance activities will assist with the assessment and monitoring of treatment guidelines, vaccine effectiveness, antiviral effectiveness and resistance, and effectiveness of public health interventions. The surveillance activities carried out by HHS will aid in sustaining U.S. critical infrastructure and essential services, and the U.S. economy. HHS

will encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.

Containing Outbreaks

A. Action (HSC 5.3.3.1): HHS, in coordination with DHS, DOT, DOS, and DOI, will work with USDA to provide emergency notifications of probable or confirmed cases and/or outbreaks to key international, federal, state, local, and tribal transportation and border stakeholders through existing networks. (Also see chapter 1, Pillar Three, Action L [HSC 5.3.3.1]; chapter 3, Pillar Two, Action A [HSC 5.2.1.1]; and chapter 7, Pillar Three, Action H [HSC 5.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.

Step 1: Convene a cross-agency working group to identify key stakeholders; existing networks available to provide emergency notifications; criteria for providing notifications; and, notification protocols and procedures.

Step 2: Evaluate existing protocols and processes.

Step 3: Develop additional protocols and processes for providing emergency notifications, as appropriate.

Step 4: Pilot test the protocols and processes.

Step 5: Based upon the findings of the pilot test, update the emergency notification protocols and procedures.

Step 6: Maintain regular communication with key partners at Ministries of Health in targeted and at-risk countries, through Health Attaches and other in-country staff. HHS will notify DOS and other partners when news of outbreaks is received and facilitate information exchange with partners. Activities include:

- Remaining in close communication with Ministries of Health and the WHO Secretariat to stay abreast of news of potential or actual outbreaks
- Conducting inter-HHS OPDIV consultations to determine validity of such news
- Communicating the best advice to DOS and other U.S. Government agencies

B. Action (HSC 4.1.5.2): HHS will work with USAID to coordinate and set up emergency stockpiles of personal protective equipment (PPE) and essential

commodities, other than vaccine and antiviral medications, for responding to animal or human outbreaks.

Timeframe: Within 9 months.

Measure of Performance: Essential commodities procured and available for deployment within 24 hours.

Step 1: Coordinate U.S. Government participation in development of the SPP Annex to the HHS Pandemic Flu Plan that will address logistical actions and coordination requirements associated with the movement of medical materiel support across the U.S. border in support of a pandemic influenza response.

C. Action (No HSC Action): Utilize the EIP influenza project, the NVSN, Marshfield Clinic Research Foundation, and/or other sites to conduct epidemiologic studies to assess/monitor treatment guidelines, vaccine effectiveness, antiviral effectiveness and resistance, and effectiveness of public health interventions. (Also see Pillar Three, Action D [HSC 6.1.13.9] below; chapter 4, Pillar Three, Action C [HSC 6.3.4.2] regarding standards of care for medical practice; chapter 5, Pillar One, Action Q [HSC 6.1.14.1] regarding vaccine use and effectiveness; and chapter 6, Pillar Three, Action C [HSC 6.1.13.9] regarding antiviral use and effectiveness.)

Timeframe: Ongoing.

Measure of Performance: Conduct of epidemiologic studies.

Step 1: Develop protocols and processes for active population-based hospitalization surveillance including specimen collection and virologic testing from a subset of hospitalized patients in all age groups in a limited number of sites.

Step 2: Pilot test the protocols and processes.

Step 3: Revise the protocols and processes based on the results of the pilot test.

D. Action (HSC 6.1.13.9): HHS, in coordination with DOD, VA, and in collaboration with state, territorial, tribal, and local partners, will develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration: (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic. (Also see Pillar Three, Action C [No HSC number] above; chapter 5, Pillar One, Action Q and T [HSC 6.1.14.1 and 6.1.13.9]; and chapter 6, Pillar Three, Action C [HSC 6.1.13.9].)

Timeframe: Within 18 months.

Measure of Performance: Mechanism(s) to track vaccine and antiviral medication coverage and adverse events developed; vaccine- and antiviral-effectiveness study protocols developed.

Step 1: Develop protocols and processes for active population-based hospitalization surveillance including specimen collection and virologic testing from a subset of hospitalized patients in all age groups in a limited number of sites.

Step 2: Pilot test the protocols and processes.

Step 3: Revise the protocols and processes based on the results of the pilot test.

Contents

CHAPTER 3: PUBLIC HEALTH INTERVENTIONS

Introduction

The optimal strategies for prevention and control of pandemic influenza are the same as for seasonal influenza: vaccination, early detection and treatment with antiviral medications, and the use of infection-control measures to prevent infection spread during patient care. However, when a pandemic emerges, a vaccine may not be available, and the supply of antiviral drugs may be limited. Therefore, non-pharmaceutical public health interventions will be an important strategy to contain infection, delay spread, and reduce the impact of pandemic disease. In health care settings, infection-control measures will be essential. Non-pharmaceutical interventions will also be important to help limit virus transmission and therefore reduce an individual's risk for infection. Pharmaceutical interventions, including vaccination and the use of antiviral medications, are principally covered in Chapter 5, Vaccines, and in Chapter 6, Antiviral Drugs.

Current guidance from HHS on infection control for influenza is based on our knowledge of routes of influenza transmission, pathogenesis, and the effects of influenza-control measures used during past pandemics and between pandemics**.** Infection-control precautions primarily involve the application of standard precautions and precautions against droplets during patient care in health care settings (e.g., hospitals, nursing homes, outpatient offices, emergency transport vehicles). These practices also apply to health care personnel's going into the homes of patients. Preplanned public education campaigns regarding cough etiquette, hand hygiene, personal social-distancing measures (e.g., avoiding public places/meetings), and infection-control measures when caring for ill persons at home will be key non-pharmaceutical public health interventions during a pandemic. (For more information, please see the **HHS Pandemic Plan** at http://www.pandemicflu.gov).

Due to potential limitations in pharmaceutical interventions, non-pharmaceutical domestic community-containment measures will likely play an important role in slowing and limiting the spread of pandemic influenza. These measures include isolation at home of persons who are ill, home and facility quarantine of persons who are exposed, and community social-distancing measures (e.g., closure of public places, specific worksites, and schools; and stoppage of public transportation). These measures have not been applied recently for influenza, and we have at present neither the science nor the experience to create firm guidelines for their use during a pandemic. Therefore, extensive collaboration among Federal, State, local, and tribal agencies and academic institutions will be required to create practical and useful guidelines for evaluating the trigger points and logistical steps for implementing domestic community-containment measures.

This chapter considers public health interventions in community and health care settings as they relate to the seven U.S. Response Stages defined in the **HHS Pandemic Influenza Plan:**

0: New Domestic Animal Outbreak in At-Risk Country
1: Suspected Human Outbreak Overseas
2: Confirmed Human Outbreak Overseas
3: Widespread Human Outbreaks in Multiple Locations Overseas
4: First Human Case in North America
5: Spread throughout the United States
6: Recovery and Preparation for Subsequent Waves

Table 2 in the Introduction of this document indicates how these U.S. Response Stages 1–6 correspond to the WHO Pandemic Periods and Phases. The WHO phases reflect the expected progression of a pandemic worldwide and provide a framework for evaluating the global situation. The U.S. Response Stages are useful for planning domestic disease containment strategies and activities. (See page 20 of this document.)

Non-Pharmaceutical Public Health Interventions

Responding effectively to an influenza pandemic—especially given limited supplies of antiviral drugs and the initial absence of pandemic vaccines—will depend on public health interventions that prevent virus transmission by separating persons who are ill and potentially exposed persons from the rest of their community. Interventions may include infection-control measures, travel-related interventions, and non-pharmaceutical strategies for disease control. These public health interventions are the focus of this chapter.

Infection-Control Measures

Infection-control measures will be critical throughout all stages of a pandemic, but especially during U.S. Response Stages 4 and 5 when a pandemic virus is circulating in the United States. Infection-control measures in health care facilities and in homes will decrease the spread of infection from patient to health care worker and from patient to patient, thus helping States, cities, and counties sustain local health care capacity. Throughout a pandemic, health authorities will also promote communitywide infection-control measures, including hand hygiene and respiratory/cough etiquette.

Travel-Related Interventions

Efforts to delay the entry of a novel, pandemic influenza virus into the United States will require careful planning and preparation. Planning and preparation activities at ports of entry include investigating reports of travelers with influenza-like illness (ILI) to identify and evaluate individuals with a high likelihood of being infected with an avian influenza virus. Cargo inspectors at ports of entry will also identify and destroy potentially infected

animals or animal products to prevent transmission of avian influenza to birds or humans within the United States.

An increased frequency in overseas clusters of human disease caused by a virus capable of greater human-to-human transmission will signal that prevention and control activities at ports of entry should be intensified. Entry screening will shift from passive reporting of ill passengers to active screening of travelers arriving from affected areas. Public health authorities may consider quarantine and antiviral prophylaxis of potentially exposed travelers.

Other travel-related public health interventions that may be considered include:

- Restricting the number of U.S. airports that receive international arrivals
- Restricting the number of international ports from which travelers may embark for the United States
- Predeparture screening
- Enhanced medical surveillance en route
- Restricting travel to affected areas

Once pandemic influenza has been reported in the United States, Federal agencies will work closely with WHO and with individual countries to reduce the likelihood of spreading the pandemic virus internationally.

Non-Pharmaceutical Disease Control Strategies

The implementation of containment measures can help slow the spread of infection within and between communities. Non-pharmaceutical strategies include disease-control measures that affect individuals (e.g., isolation of patients and monitoring their contacts; and personal hygiene measures, such as hand hygiene and cough etiquette), as well as measures that affect groups or entire communities (e.g., quarantine of exposed persons, cancellation of public gatherings, school closures, and shelter in place [“snow days”]). Guided by epidemiologic data, local authorities will choose those measures that provide maximum impact in preventing influenza transmission and with minimum impact on individual freedom of movement. HHS will provide assistance to States and communities as the pandemic threat evolves.

Role of HHS in Non-Pharmaceutical Public Health Interventions

Responsibilities of HHS related to non-pharmaceutical public health interventions include but are not limited to:

- Non-pharmaceutical disease-control measures related to international travel
- Non-pharmaceutical disease-control measures in U.S. communities

- Infection-control practices for individuals
- Infection-control practices in health care settings

Specific Assumptions and Planning Considerations Related to Non-Pharmaceutical Public Health Interventions

- Completely preventing the importation of a novel, highly transmissible pandemic influenza virus by interception of asymptomatic persons who will later become ill, at air- and seaports and at land border crossings for long periods of time will not be possible. However, if a novel, pandemic influenza virus originates outside the United States, reducing the number of infected persons entering the country and delaying introduction of the pandemic into the United States for weeks might be possible.
- Delayed entry and reducing the number of cases entering the country can result in a delayed surge in U.S. cases and a greater lead time for developing and distributing a pandemic vaccine, greater time to move antiviral medications into areas where they are most needed, and more time to prepare for an impending entry of the virus into the community. These actions will result in a decreased mortality from a pandemic.
- Prior to the occurrence of recognized cases in the United States, the appearance of a novel, pandemic influenza virus may be multifocal (i.e., simultaneous presentation at multiple ports of entry receiving international travelers). However, some ports of entry are more likely to be the site of importation and will require staff augmentation.
- If the decision is made to screen every arriving and/or exiting international traveler when pandemic influenza is circulating globally, but is not yet present in the United States, the current number of U.S. Quarantine Station staff will be inadequate to perform this task. Local and State health department staff will not be a resource for the surge-capacity of needed personnel. Additional Federal Quarantine Station staff will be required.
- When a novel, influenza pandemic virus first begins to spread in the United States, in the absence of an effective vaccine or sufficient quantities of effective antiviral agents, personal disease control measures (e.g., hand hygiene, cough etiquette) and community containment measures (e.g., social distancing, health communications, isolation of ill persons, quarantine of exposed persons) will constitute the primary strategies for preventing the spread of pandemic influenza.
- When pandemic influenza transmission starts in the United States, the necessity of continuing activities to exclude entry of pandemic influenza through our ports and borders will be reexamined.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

Preparedness and communication are critical elements to the implementation of successful public health interventions and medical responses. Activities that should be undertaken before a pandemic emerges to ensure preparedness and to communicate expectations and responsibilities to all levels of government and society are described below.

Planning for a Pandemic

A. Action (HSC 5.1.1.1): HHS will serve as a core member, along with DOS, USDA, DOD, DOL, and DOC, in a DHS and DOT established interagency transportation and border preparedness working group that will develop planning assumptions for the transportation and border sectors, coordinate preparedness activities by mode, review products and their distribution, and develop a coordinated outreach plan for stakeholders.

Timeframe: Within 6 months.

Measure of Performance: Interagency working group established, planning assumptions developed, preparedness priorities and timelines established by mode, and outreach plan for stakeholders in place.

Step 1: Provide technical assistance to DHS and DOT for the transportation and border interagency working group by providing personnel; input into planning assumptions, outreach, and priorities; and timeframes for preparedness.

B. Action (HSC 5.1.1.2): HHS will work closely with DHS and in coordination with the National Economic Council (NEC), DOD, DOC, USTR, DOT, DOS, USDA, Treasury, and key transportation and border stakeholders, to establish an interagency modeling group to examine the effects of transportation and border decisions on delaying spread of a pandemic, and the associated health benefits, the societal and economic consequences, and the international implications.

Timeframe: Within 6 months.

Measure of Performance: Interagency working group established, planning assumptions developed, priorities established, and recommendations made on which models are best suited to address priorities.

Step 1: Work with DHS to develop an interagency working group that will routinely meet to gather subject matter expertise on non-pharmaceutical public health interventions for pandemic influenza. The purpose will be to provide

guidance on non-pharmaceutical public health interventions. The working group will develop this guidance through literature review, internal discussion, input of partners, and the conduct of targeted research.

Step 2: Identify interagency mathematical modelers (e.g., NIH collaboration with Models of Infectious Disease Study [MIDAS]) to work on modeling the effects of transportation and border decisions made by the U.S. Government. Government decisions supported by this modeling might include: screening of international travelers, quarantine of exposed passengers, diversion of flights, international travel restrictions, domestic travel restrictions, etc.

Step 3: Discuss with modelers the issues that are highest priority and the elements that would be important to include in constructing models; also, provide assumptions for data elements to be included in models being developed.

Step 4: Provide technical assistance as models are constructed, analysis is conducted, data are interpreted, and recommendations are made.

C. Action (HSC 5.1.1.3): HHS will work with DHS and in coordination with DOT, USDA, DOJ, and DOS to assess their ability to maintain critical federal transportation and border services (e.g., sustain national air space, secure the borders) during a pandemic, revise contingency plans, and conduct exercises.

Timeframe: Within 12 months.

Measure of Performance: Revised contingency plans in place at specified Federal agencies that respond to both international and domestic outbreaks; at least two interagency exercises carried out to test the plans.

Step 1: Support DHS and other agencies in their assessment and planning to maintain critical Federal transportation and border services through provision of guidance for Continuity of Operations Plan (COOP). (Also see Pillar One, Action K [HSC 9.1.1.1] below.)

Step 2: Provide technical advice and input during interagency exercises.

Step 3: Assess critical infrastructure for COOP and make contingency plans to obtain assistance to maintain needed operations during a pandemic. This effort would include the preevent training of USPHS Commissioned Corps (CC) Officers and Medical Reserve Corps (MRC) personnel to perform Quarantine Station activities.

D. Action (HSC 5.1.1.4): HHS will support DHS and DOT, in their effort to develop detailed operational plans and protocols to respond to potential pandemic-related scenarios, including in-bound aircraft/vessel/land border traffic with a suspected

case of pandemic influenza, international outbreak, multiple domestic outbreaks, and potential mass migration. (Also see Pillar Two, Actions I and K [HSC 5.2.4.6 and 5.2.4.8] below.)

Timeframe: Within 12 months.

Measure of Performance: Coordinated Federal operational plans that identify actions, authorities, and trigger points for decisionmaking and are validated by interagency exercises.

Step 1: Work with Federal partners; international airports; international airlines; State, local and tribal health departments; referral hospitals; and others in the development of plans/protocols for responding to an inbound aircraft with a suspect case of pandemic influenza at major ports of entry.

Step 2: Conduct tabletops at a minimum of the 18 major international ports of entry where Quarantine Stations are located (these ports currently serve approximately 85 percent of international travelers). The tabletops address pandemic scenarios which require joint response between public health, port agencies, first responders, health care systems, airlines, cruise lines, and other emergency response agencies that provide lodging, meals, health care, and other necessary support to persons in quarantine. These exercises will address coordination of efforts and identify gaps/physical needs to respond to and should include participation from the Governments of Canada and Mexico in accordance with the Security and Prosperity Partnership of North America.

Step 3: Expand development of plans/protocols for responding to an inbound aircraft with a suspected case of pandemic influenza at major ports of entry to maritime ports of entry and land border crossings (seen as lower risk than international airports).

Step 4: Conduct interagency exercises at priority maritime ports of entry and land border crossings.

Step 5: In support of DHS and DOT, HHS will continue to be engaged in the Homeland Security Council/National Security Council (HSC/NSC) Policy Coordination Committee process to provide technical information on response to an international outbreak of pandemic influenza that has not spread to the United States (U.S. Response Stages 1 through 3). Options for response include the following: (1) assisting affected nations that request assistance with technical advice on containment measures and exit screening; (2) instituting en route and entry screening of airline passengers from affected nations (also see Pillar Two, Action J [HSC 5.2.4.7] below); (3) isolating passengers from affected regions who are ill and quarantining exposed passengers and crew; (4) instituting travel restrictions for nonessential travel/entry into the United States (also see Pillar

Two, Action F [HSC 5.2.4.2] below); (5) reducing the number of ports that would manage inbound and outbound international flights; and (6) diverting flights carrying large numbers of passengers likely to require isolation or quarantine to airports that have adequate facilities.

Step 6: Provide technical assistance to DHS and DOT in the development of detailed operational response plans and protocols to respond to an international outbreak of pandemic influenza that has not spread to the United States (U.S. Response Stages 1–3) in accordance with the options laid out by the HSC/NSC Policy Coordination Committee.

Step 7: Develop guidance for non-pharmaceutical interventions including: (1) clarify existing legal authorities for quarantine; (2) home isolation and quarantine; (3) facility quarantine; (4) work quarantine, and measures to increase social distance (e.g., cancellation of large gatherings, school closure, closure of other public places, reduction of public transportation, workplace policies such as reduced operations and liberal leave, sheltering in place). (Also see Pillar Three, Actions H and I [HSC 6.3.2.1 and 6.3.2.2] below.)

Step 8: Share guidance with Federal partners and with State, local, and tribal health departments to comment, identify operational details (for potential implementation), and facilitate in writing plans/protocols.

E. Action (HSC 5.1.1.6): HHS will work with DOT and in coordination with DHS, DOD, DOJ, DOL and USDA to assess the Federal Government's ability to provide emergency transportation support during a pandemic under NRP Emergency Support Function (ESF) #1 (Transportation Annex; http://www.dhs.gov/xlibrary/assets/NRP_FullText.pdf) and develop a contingency plan.

Timeframe: Within 18 months.

Measure of Performance: Completed contingency plan that includes options for increasing transportation capacity, the potential need for military support, improved shipment tracking, and potential need for security and/or waivers for critical shipments, incorporation of decontamination and workforce protection guidelines, and other critical issues.

Step 1: Provide to DOT and other agencies technical expertise/guidance and written documentation on decontamination procedures and workforce protection for pandemic influenza.

F. Action (HSC 5.1.2.2): Under the leadership of DOT and in coordination with DHS and transportation stakeholders, HHS will support a series of forums with governors and mayors to discuss transportation and border challenges that may

occur in a pandemic, share approaches, and develop a planning strategy to ensure a coordinated national response. (Also see chapter 8, Pillar One, Action C [HSC 5.1.2.2].)

Timeframe: Within 12 months.

Measure of Performance: Strategy for coordinated transportation and border planning is developed, and forums initiated.

Step 1: Work with State, local, and tribal partners (e.g., public health, port agencies, first responders, health care systems, airlines, cruise lines, and other emergency response agencies) on developing response plans for pandemic influenza at airports, maritime ports, and land borders. (Also see Pillar One, Action D [HSC 5.1.1.4] above.)

Step 2: Provide technical expertise to DOT and DHS—on public health interventions that potentially would be used to slow pandemic influenza—in support of discussions on challenges that pandemic influenza will likely pose on the transportation and border sectors.

G. Action (HSC 5.1.2.3): In coordination with USDA and transportation stakeholders, HHS will assist DOT and DHS, develop planning guidance and materials for State, local, and tribal governments, including scenarios that highlight transportation and border challenges and responses to overcome those challenges, and an overview of transportation roles and responsibilities under the NRP. (Also see chapter 8, Pillar One, Action D [HSC 5.1.2.3].)

Timeframe: Within 12 months.

Measure of Performance: State, local, and tribal governments have received access to tailored guidance and planning materials.

Step 1: Continue to work with Federal, State, local, and tribal partners on developing response plans for pandemic influenza at airports, maritime ports, and land borders. (Also see Pillar One, Action D [HSC 5.1.1.4] above.)

Step 2: Support DOT and DHS in producing planning guidance and materials highlighting the challenges pandemic influenza would likely impose on the transportation and border sector; provision technical expertise on public health interventions that would potentially be used to slow pandemic influenza.

H. Action (HSC 5.1.3.1): In coordination with DOT and USDA, HHS will support DHS in conducting tabletop discussions and other outreach with private sector transportation and border entities to provide background on the scope of a

pandemic, to assess current preparedness, and jointly develop a planning guide. (Also see chapter 8, Pillar One, Action E [HSC 5.1.3.1].)

Timeframe: Within 8 months.

Measure of Performance: Private sector transportation and border entities have coordinated Federal guidance to support pandemic planning, including a planning guide that addresses unique border and transportation challenges by mode.

Step 1: Support DHS in outreach efforts to private sector transportation and border partners. (Also see Pillar One, Action F [HSC 5.1.2.2]; Step 1, above.)

Step 2: Provide technical assistance for tabletop exercises to give sector participants a sense of logistical challenges likely to be experienced in a pandemic, help identify gaps in preparedness, and assist partners (e.g., public health, port agencies, first responders, health care systems, airlines, cruise lines, and other emergency response) in developing plans for response and recovery.

I. Action (HSC 8.1.2.1): In coordination with DOL and DHS, HHS will provide technical assistance to DOJ as it convenes a forum for selected Federal, State, local, and tribal law enforcement/public safety personnel to discuss the issues they will face in a pandemic influenza outbreak and then publish the results in the form of best practices and model protocols within 4 months.

Timeframe: Within 4 months.

Measure of Performance: Best practices and model protocols published and distributed.

Step 1: Provide technical assistance to DOJ through guidance on potential non-pharmaceutical pandemic prevention and control measures (e.g., dealing with the effects of and enforcing quarantine; and social-distancing measures such as cancellation of large gatherings, closure of public places [such as shopping malls], closure of schools). These measures could adversely affect the work of law enforcement personnel, reduce public transportation, and affect workplace policies (such as reduced operations and liberal leave, sheltering in place). Other groups will provide technical assistance regarding the impact of securing vaccines and antiviral stockpiles.

Step 2: Support DOJ with expertise regarding non-pharmaceutical public health initiatives, as they may affect law enforcement and public safety personnel.

J. Action (HSC 8.1.2.4): In conjunction with DOJ, HHS will ensure consistency of the CDC Public Health Emergency Law Course with the National Strategy for Pandemic Influenza (Strategy), this Plan, and other Federal pandemic documents

and then disseminate the CDC Public Health Emergency Law Course across the U.S.

Timeframe: Within 6 months.

Measure of Performance: Distribution of presentations of reviewed public health emergency law course to all States.

Step 1: Update the CDC Public Health Law Program PowerPoint course to ensure consistency with current pandemic influenza planning guidance documents.

Step 2: Work with DOJ to distribute revised course units to participating States.

K. Action (HSC 9.1.1.1): In coordination with DOD and DOL, HHS will support DHS in providing pandemic influenza COOP guidance to the Federal departments and agencies.

Timeframe: Within 6 months.

Measure of Performance: COOP planning and personnel protection guidance provided to all departments for use, as necessary, in updating departmental pandemic influenza response plans.

Step 1: Provide written, risk-stratified guidance for management and workers in Government who provide either essential or nonessential services as a part of the foundation for COOP decisionmaking. This guidance may include information on prevention and control measures such as hand hygiene, cough etiquette, self-isolation due to illness, use of personal protective equipment (PPE; e.g., mask use, gloves, face shields, gowns), and social-distancing measures (e.g., avoidance of large gatherings, telecommuting, office closure, liberal leave policies, and work quarantine) and address the secondary effects of community mitigation measures, such as school closures.

Step 2: Provide technical assistance regarding intervention measures and share with Federal partners guidance on pandemic influenza virus prevention and control.

L. Action (HSC 9.1.1.2): HHS will assist the Office of Personnel Management (OPM), and in coordination with DHS, DOD, and DOL, provide guidance to the Federal departments and agencies on human capital management and COOP planning criteria related to pandemic influenza.

Timeframe: Within 3 months.

Measure of Performance: Guidance provided to all departments for use, as necessary, in adjusting departmental COOP plans related to pandemic influenza.

Step 1: Provide input to OPM regarding non-pharmaceutical prevention and control measures related to pandemic influenza to assist in COOP planning. (Also see Pillar One, Action K [HSC 9.1.1.1] above.)

M. Action (HSC 9.1.1.3): In coordination with DHS, DOD, and DOL, HHS will provide assistance to OPM to update the guides *Telework: A Management Priority, A Guide for Managers, Supervisors, and Telework Coordinators*; *Telework 101 for Managers: Making Telework Work for You*; and *Telework 101 for Employees: Making Telework Work for You*, to provide guidance to Federal Departments regarding workplace options during a pandemic. (Also see chapter 7, Pillar One, Action D [HSC 9.1.1.3].)

Timeframe: Within 3 months.

Measure of Performance: Updated telework guidance provided to all departments for use, as necessary, in updating departmental COOP plans related to pandemic influenza.

Step 1: Provide to OPM written, risk-stratified guidance for management and workers in Government who provide either essential or nonessential services. This guidance will include information on telework during a pandemic. (Please see Telework Annex of the HHS Pandemic Influenza Plan at http://www.pandemicflu.gov.)

Step 2: Provide technical assistance regarding non-pharmaceutical public health interventions as they relate to telework and Government organizations through OMB.

N. Action (HSC 9.1.2.1): As a Sector-Specific Agency, HHS, in coordination with DHS, will develop health care- and public health-specific planning guidelines focused on sector-specific requirements and cross-sector dependencies.

Timeframe: Within 6 months.

Measure of Performance: Planning guidelines developed for the health care and public health sector.

Step 1: Provide technical assistance through the Government Coordinating Councils (GCC) and the Sector Coordinating Councils (SCC) to support the development of planning guidelines focused on health care- and public health sector-specific requirements and cross-sector dependencies.

Step 2: Achieve approval from the GCC concerning the planning guidance.

O. Action (HSC 9.1.2.2): HHS will work with DHS in DHS' support of private-sector preparedness with education, exercise, training, and information sharing outreach programs.

Timeframe: Within 6 months.

Measure of performance: Planning guidelines developed for each sector.

Step 1: Identify HHS personnel to work with DHS.

Step 2: Meet with DHS to review DHS strategy and program for developing outreach programs.

Step 3: Provide subject matter expertise in developing the planning guidelines for each sector.

Communicating Expectations and Responsibilities

P. Action (HSC 4.1.4.3): HHS will work with DOS to ensure that adequate guidance is provided to Federal, State, tribal and local authorities regarding the inviolability of diplomatic personnel and facilities and will work with such authorities and DOS to develop methods of obtaining voluntary cooperation from the foreign diplomatic community within the U.S. consistent with U.S. Government treaty obligations. (Also see chapter 8, Pillar One, Action A [HSC 4.1.4.3].)

Timeframe: Within 6 months.

Measure of Performance: Briefing materials and an action plan in place for engaging with relevant Federal, State, tribal and local authorities.

Step 1: Provide broad guidance regarding public health interventions for pandemic influenza (e.g., quarantine, travel restrictions) that would pertain to foreign nationals.

Step 2: Provide technical assistance to DOS regarding this guidance for diplomatic personnel and facilities, as DOS works with State, local, and tribal authorities to obtain voluntary cooperation from the foreign diplomatic community.

Q. Action (HSC 5.1.4.1): HHS, in coordination with DHS, DOT, and DOL, will establish workforce protection guidelines and develop targeted educational materials addressing the risk contracting pandemic influenza. (Also see chapter 7, Pillar One, Action I [HSC 5.1.4.1].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines and materials developed that meet the diverse needs of border and transportation workers (e.g., customs officers or agents, air traffic controllers, train conductors, dock workers, flight attendants, transit workers, ship crews, and interstate truckers).

Step 1: Consult with other Government agencies (e.g., NIOSH at HHS/CDC, DHS, OSHA at DOL), travel organizations (Air Transportation Association of America, Inc. [ATA], International Air Transport Association [IATA]), and representatives from relevant occupation sectors to identify job-specific activities that may place workers at risk for occupational exposure to pandemic influenza virus.

Step 2: Consult with the aforementioned entities to determine appropriate job-related behaviors and personal protective measures to reduce risk of exposure to pandemic influenza virus, in consultation with the aforementioned entities.

Step 3: Develop workforce protection guidelines that are relevant to each of the U.S. Response Stages (1–5) for influenza pandemics, and disseminate educational materials that include job-specific guidelines to minimize risk of exposure.

Step 4: Identify points of contact in each of the above-mentioned agencies for clearance and feedback on recommendations and reports.

Step 5: Post recommendations and reports on the HHS Web site (http://www.pandemicflu.gov), and devise additional communication methods (e.g., e-mail) for just-in-time distribution to appropriate stakeholders.

Step 6: Consult with the transportation industry and Federal partners to determine other effective communications media and methods of disseminating guidance and educational materials, such as PowerPoint presentations for "train-the-trainers" programs by various work groups.

R. Action (HSC 5.1.4.3): HHS, in coordination with DHS, DOT, DOD, Environmental Protection Agency (EPA), and transportation and border stakeholders, will develop and disseminate decontamination guidelines and time frames for transportation and border assets and facilities (e.g., airframes, emergency medical services transport vehicles, trains, trucks, stations, port of entry detention facilities) specific to pandemic influenza.

Timeframe: Within 12 months.

Measure of Performance: Decontamination guidelines developed and disseminated through existing DOT and DHS channels.

Step 1: Coordinate with DHS, DOT, DOD, and EPA, as well as local, State, Federal, and private-sector transportation providers on efforts for developing guidelines and timeframes on decontamination.

Step 2: Work with experts on subject matter (influenza and infection control) to develop U.S. Response Stage-specific protocols in regard to influenza and to develop environmental as well as occupational health guidance on cleaning agents, PPE, and custodial procedures for decontamination of specific locations or items (e.g., airline seats, lavatories, baggage inspection services, airport waiting areas). Protocols are also needed for transportation vehicles (e.g., airplanes, cruise ships, cargo vessels) carrying a suspected case-patient (passenger or crew) to the United States from affected regions and for port areas or transportation stations that may have been contaminated by a suspect case or by a bird or bird products.

Step 3: Based on feedback, work with Federal agency partners (DOT and DHS) to update protocol(s).

Step 4: Work with travel industry and Federal agency partners (DOT and DHS) to disseminate cleaning protocols and environmental health information to custodial personnel at airlines, commercial shipping lines, and international ports of entry facilities.

S. Action (HSC 7.1.3.3): HHS, in coordination with USDA, DHS, and DOL, will work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers. (Also see chapter 2, Pillar Two, Action K [HSC 7.1.3.3] and chapter 7, Pillar One, Action P [HSC 7.1.3.3].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines developed and disseminated to poultry and swine industries.

Step 1: Provide written, risk-stratified guidance for management and workers to prevent avian influenza. Guidance will include a description of risk factors faced by animal workers in the poultry and swine industries. This guidance will include information on sanitizing hands, cough etiquette, self-isolation due to illness, use of PPE (e.g., mask use, gloves, face shields, gowns), and social-distancing measures (e.g., work quarantine). Guidance may also include recommendations intended to decrease the risk of genetic reassortment of avian and human influenza (e.g., seasonal influenza vaccination).

Step 2: Draft guidance will be shared with USDA and DHS for discussion and finalization of guidance. Because of its existing strong relationship with the poultry and swine industries, USDA will work with representatives of those

industries to publish and disseminate the developed guidance and encourage inclusion of recommended measures into the routine practices of these industries.

Step 3: Provide further technical assistance to USDA when the written guidance does not fully address specific situations being faced or when new policy is needed.

T. Action (HSC 8.1.3.1): HHS, in coordination with DOL, will provide clear guidance to law enforcement and other emergency responders on recommended preventive measures including pre-pandemic vaccination, to be taken by law enforcement and emergency responders to minimize risk of infection from pandemic influenza. (Also see chapter 7, Pillar One, Action Q [HSC 8.1.3.1].)

Timeframe: Within 6 months.

Measure of Performance: Development and dissemination of guidance for law enforcement and other emergency responders.

Step 1: Provide written, risk-stratified guidance on prevention measures for management and workers in Government and the private sectors who provide either essential or nonessential services. This guidance will include information on sanitizing hands, cough etiquette, self-isolation due to illness, use of PPE (e.g., mask use, gloves, face shields, gowns), and social-distancing measures (e.g., avoidance of large gatherings, telecommuting, reduced business operations, liberal leave policies, work quarantine) and address the secondary effects of community mitigation measures such as school closures.

Step 2: Publish the risk-stratified guidance on http://www.pandemicflu.gov and in other appropriate publications serving this work sector.

Step 3: An interagency non-pharmaceutical interventions working group will provide technical assistance to law enforcement and emergency response organizations when written guidance does not adequately cover specific situations being faced or when new policy is needed.

U. Action (HSC 9.1.3.1): As a Sector-Specific Agency, HHS will support DHS as it conducts forums, conferences and exercises with key critical infrastructure private sector entities and international partners to identify essential functions and critical planning, response and mitigation needs within and across sectors, and validate planning guidelines. (Also see chapter 7, Pillar One, Action R [HSC 9.1.3.2].)

Timeframe: Within 6 months.

Measure of Performance: Planning guidelines, validated by collaborative exercises which test essential functions and critical planning, response, and mitigation needs.

Step 1: Provide technical assistance to DHS as that department conducts forums, conferences, and exercises with key infrastructure private-sector entities to identify essential functions and critical planning.

Step 2: Provide technical assistance to DHS as that department works with major industry and professional organizations to educate them on the effects pandemic influenza may have on critical infrastructure.

V. Action (HSC 9.1.3.2): As a Sector-Specific Agency, HHS will provide assistance to DHS in its effort to develop and coordinate guidance regarding business continuity planning and preparedness with the owners/operators of critical infrastructure and develop a Critical Infrastructure Influenza Pandemic Preparedness, Response and Recovery Guide tailored to national goals and capabilities and to the specific needs identified by the private sector. (Also see chapter 7, Pillar One, Action R [HSC 9.1.3.2].)

Timeframe: Within 6 months.

Measure of Performance: Critical Infrastructure Influenza Preparedness, Response, and Recovery Guide developed and published on http://www.pandemicflu.gov.

Step 1: Provide technical assistance to DHS through coordination with the SCC. The occupational health and educational materials Sub-Council has begun development of seminars on pandemic influenza preparedness. Part 1 of the seminars will address issues for occupational health professionals; Part 2 will focus on issues that corporations, medical centers, small- and medium-sized companies, and community-based occupational health clinics face in developing a response plan surrounding pandemic influenza.

Step 2: These DHS seminars for the occupational health sector will be followed by further HHS technical assistance to DHS as it reaches out to the other subsectors within the public health and health care communities to develop equivalent seminars.

W. Action (HSC 9.1.4.1): HHS, in coordination with DHS, DOL, OPM, Department of Education, VA and DOD, will develop sector-specific infection control guidance to inform personnel, governmental and public entities, private sector businesses, and community-based organizations (CBO), and faith-based organizations (FBO). (Also see chapter 7, Pillar One, Action S [HSC 9.1.4.1].)

Timeframe: Within 6 months.

Measure of Performance: Sector-specific guidance and checklists developed and published on http://www.pandemicflu.gov.

Step 1: Provide written, risk-stratified guidance on infection control for persons working or taking part in Government, private, voluntary, or FBO and CBO activities that provide both essential and nonessential services. This guidance will include information on sanitizing hands, cough etiquette, self-isolation due to illness, use of PPE (e.g., mask use, gloves, eye protection, gowns), and social-distancing measures (e.g., avoidance of large gatherings, telecommuting, reduced business operations, liberal leave policies, work quarantine) and address the secondary effects of community mitigation measures such as school closures.

Step 2: Publish this general risk-stratified guidance and checklists on http://www.pandemicflu.gov and in other appropriate publications serving many sectors of society, in accordance with HHS/CDC's National Center for Health Marketing.

Step 3: Provide technical assistance to organizations and sector-specific publications to assure that appropriate guidance is communicated with their constituents. Technical assistance also will be provided when written guidance does not adequately cover specific situations being faced or when new policy is needed.

X. Action (HSC 9.1.4.2): HHS, in coordination with DHS, DOL, EPA, Department of Education, VA and DOD, will develop interim guidance regarding environmental management and cleaning practices including the handling of potentially contaminated waste material and will revise as additional data becomes available. (Also see chapter 7, Pillar One, Action T [HSC 9.1.4.2].)

Timeframe: 3 months for development of initial guidance, then ongoing.

Measure of Performance: Development and publication of guidance and checklists developed and published on http://www.pandemicflu.gov and through other channels.

Step 1: Consult with DHS, DOL, EPA, ED, VA, and DOD to identify environmental management and cleaning activities that may place employees at risk for exposure to a pandemic influenza virus.

Step 2: In consultation with the aforementioned entities, determine appropriate job-related behaviors and personal protective measures to reduce risk of exposure to pandemic influenza virus.

Step 3: Develop guidance for environmental management and cleaning practices to prevent exposure.

Step 4: Develop workforce protection guidelines that are relevant to each U.S. Response Stage, and disseminate educational materials on pandemic influenza that include job-specific guidelines to minimize risk of exposure.

Step 5: Identify points of contact in each of the aforementioned agencies for clearance of recommendations and reports.

Step 6: Post recommendations and reports on http://www.pandemicflu.gov, and devise additional communication methods (e.g., e-mail, etc.) for just-in-time distribution to appropriate stakeholders.

Step 7: Consult with the involved partners to determine other effective communication media and methods of disseminating the guidance and educational materials, such as PowerPoint presentations to "train the trainers" for the various work groups.

Y. Action (HSC 5.2.4.10): HHS will work closely with DHS, DOT, and in coordination with DOS, State, community, and tribal entities, and the private sector to develop a public education campaign on pandemic influenza for travelers, which raises awareness prior to a pandemic and includes messages for use during an outbreak. (Also see chapter 7, Pillar Two, Action D [HSC 5.2.4.10].)

Timeframe: Within 15 months.

Measure of Performance: Public education campaign developed on how a pandemic could affect travel, the importance of reducing nonessential travel, and potential screening measures and transportation and border messages developed based on pandemic stages.

Step 1: Develop and evaluate content of public education campaign.

Step 2: Assess the most effective ways of disseminating information to travelers.

Step 3: Ensure that State health departments, Customs and Border Protection (CBP), and other port partners are aware of the educational tools and methods of dissemination.

Z. Action (HSC 5.2.5.1): HHS will work with DHS, and in coordination with DOS, DOT, DOD, and international and domestic stakeholders, to develop vessel, aircraft, and truck cargo protocols to support safe loading and unloading of cargo while preventing transmission of influenza to crew or shoreside personnel.

Timeframe: Within 12 months.

Measure of Performance: Protocols disseminated to minimize influenza spread between vessel, aircraft, and truck operators/crews and shoreside personnel.

Step 1: Consult with other Government agencies (e.g., DHS, OSHA) and representatives from the relevant private-sector partners to identify job-specific activities that may place crew or shoreside workers at risk for exposure to pandemic influenza virus.

Step 2: Determine job-related behaviors and personal protective measures to reduce risk of occupational exposure to pandemic influenza virus.

Step 3: Develop workforce protection guidelines that are relevant to each U.S. Response Stage and disseminate educational materials on pandemic influenza that include job-specific guidelines to minimize risk of exposure.

Step 4: Identify points of contact in each of the aforementioned agencies for clearance of recommendations and reports.

Step 5: Post recommendations and reports on http://www.pandemicflu.gov, and devise additional communication methods (e.g., e-mail) for timely distribution to appropriate stakeholders.

Step 6: Consult with cargo industry and other partners to determine other effective communication media and methods of disseminating the guidance and educational materials, such as PowerPoint presentations for train-the-trainers programs for various work groups.

Advancing Scientific Knowledge and Accelerating Development

AA. Action (HSC 6.1.17.3): HHS, in coordination with DHS, will develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance. (Also see chapter 2, Pillar One, Action C [HSC 6.1.17.3].)

Timeframe: Within 18 months.

Measure of Performance: New grants and contracts awarded to researchers to develop and evaluate new diagnostics.

Step 1: Plan for a point-of-entry screening program for pandemic influenza (in collaboration with DHS) at priority sites, and implement such a program in the event of U.S. Response Stage 2 being reached.

Step 2: Deploy new, rapid, influenza diagnostic screening tests to be used at priority ports of entry into the United States if the new tests are found sufficiently sensitive and specific for screening use in border and port-of-entry settings.

Pillar Two: Surveillance and Detection

Surveillance and detection are critical elements in the implementation of successful public health interventions. In many cases, the impact of non-pharmaceutical interventions on the spread of a pandemic depends on the swift identification of an outbreak and the efficacy of public health interventions. This impact may only be known through the generation and analysis of accurate surveillance data. The activities described below should be undertaken before a pandemic emerges and during a pandemic to ensure outbreaks are detected and their spread is limited.

Ensuring Rapid Reporting of Outbreaks

A. Action (HSC 5.2.1.1): HHS, with USDA, and in coordination with DHS, DOT, DOS, DOD, DOI, and State, local, and international stakeholders, will review existing transportation and border notification protocols to ensure timely information sharing in cases of quarantineable disease. (Also see chapter 2, Pillar Three, Action A [HSC 5.3.3.1].)

Timeframe: Within 6 months.

Measure of Performance: Coordinated, clear, interagency notification protocols disseminated and available for transportation and border stakeholders.

Step 1: Identify and contact key partners in transportation and border sectors (e.g., port agencies, airlines, cruise lines, conveyance owner/operators, and other emergency response agencies that serve the ports/borders).

Step 2: Review and update suggested protocols.

Step 3: Establish and communicate criteria for activating notification protocols (e.g., call-down lists).

Step 4: Establish and test call-down lists and notification trees.

B. Action (HSC 5.2.2.1): HHS will work in coordination with DOD to support DHS deployment of human influenza rapid diagnostic tests with greater sensitivity and specificity at borders and ports of entry to allow real-time health screening. (Also see Pillar Three, Action F [HSC 5.3.1.6] below; and chapter 2, Pillar Two, Action A [HSC 5.2.2.1].)

Timeframe: Within 12 months of development of tests.

Measure of Performance: Diagnostic tests, if found to be useful, are deployed; testing is integrated into screening protocols to improve screening at the 20–30 most critical ports of entry.

Step 1: Plan for a point-of-entry screening program for pandemic influenza at priority ports of entry, and implement the program in the event of reaching U.S. Response Stage 2. (Also see Pillar Three, Action F [HSC 5.3.1.6] below.)

Step 2: Evaluate the sensitivity and specificity of new, rapid, influenza diagnostic screening tests in compliance with Federal Food, Drug and Cosmetic Act (FDCA). (Also see chapter 1, Pillar One, Action Y [HSC 4.1.8.4] Step 4, and Pillar Two, Action Q [HSC 4.2.3.9]; and chapter 2, Pillar One, Actions A, F, and C [HSC 6.2.3.2, 6.1.17.2 and 6.1.17.3].)

Step 3: Deploy new, rapid, influenza diagnostic-screening tests, if they are found to have sufficient sensitivity and specificity to be useful screening tools in border and ports-of-entry settings. These tests are to be used at U. S. points-of-entry chosen on the basis of the number of travelers entering through these ports. (Note: Ports at which Quarantine Stations are located serve 85 percent of international travelers and would be the highest priority sites for deployment of new screening tools.)

C. Action (HSC 4.2.8.1): HHS, in coordination with USAID, will develop community- and hospital-based infection control and prevention, health promotion, and education activities in local languages in priority countries. (Also see chapter 1, Pillar One, Action M [HSC 4.2.8.1].)

Timeframe: Within 9 months.

Measure of Performance: Local language health-promotion campaigns and improved hospital-based infection-control activities established in all Southeast Asian priority countries.

Steps During U.S. Response Stage 0

Step 1: Create a work group and develop partnerships among offices and divisions within HHS, quarantine field stations, health educators, risk-communication specialists, WHO Regional Offices, and USAID missions.

Step 2: Begin planning and strategy development to determine priority countries for the campaign, evaluate public health infrastructure in these countries, and identify needs.

Step 3: Identify elements to prevent transmission of infectious agents in health care settings and in the community, including the following:

- Determine optimal infection-control precautions to limit the person-to-person spread of infection in health care settings
- Determine environmental infection-control recommendations for appropriate decontamination of the health care environment to reduce exposure via contaminated equipment, surfaces, etc.

Step 4: Develop recommendations for community containment and outbreak mitigation, including isolation of cases, quarantine of contacts, social-distancing measures, and personal hygiene measures.

Step 5: Provide content and support the development of infection-control training material.

Step 6: Initiate a preevent messaging project to provide information to hospital-infection-control programs and communities.

Steps During U.S. Response Stages 1–2

Step 7: Pilot test materials/activities with representatives and members of target audiences.

Step 8: Revise communication and education activities, using feedback from the pilot test to make revisions and finalize materials/activities.

Step 9: Implement the program through continuous shifting toward crisis communication, evaluation, and changes, as necessary.

Step 10: Monitor the educational program.

Steps During U.S. Response Stages 3–5

Step 11: Shift from risk-communication to crisis-communication model.

Using Surveillance to Limit Spread

D. Action (HSC 5.2.3.1): In coordination with DOT, DOS and DOD, HHS will support DHS in its efforts to closely work with domestic and international air carriers and cruise lines to develop and implement protocols (in accordance with U.S. privacy law) to retrieve and rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza. (Also see chapter 2, Pillar Two, Actions M, N and O [HSC 5.2.4.8, 5.3.1.5, and 5.3.1.6].)

Timeframe: Within 6 months.

Measure of Performance: Aviation and maritime protocols implemented and information on potentially infected travelers available to appropriate authorities.

Step 1: Support DHS education efforts for airlines and cruise lines regarding the reporting of illnesses having public health significance.

Step 2: Support the development of protocols to retrieve and rapidly share information on travelers for purposes of public health investigation, including the sharing of information collected through Customs Form 6059B (Customs Declaration), the Advance Passenger Information System (APIS), and Passenger Name Record (PNR) data.

Step 3: Work with States to utilize existing means (e.g., EPI-X Forum) for timely sharing of traveler information between HHS and States for public health investigation in accordance with applicable privacy requirements and international agreements on passenger privacy.

E. Action (HSC 5.2.4.1): HHS, in coordination with DHS, DOT, DOS, DOC, and DOJ, will develop policy recommendations for aviation, land border, and maritime entry and exit protocols and/or screening and review the need for domestic response protocols or screening.

Timeframe: Within 6 months.

Measure of Performance: Policy recommendations for response protocols and/or screening.

Step 1: Gather best evidence (from international partners and science) regarding effective exit- and entry-screening measures.

Step 2: Review existing screening and response protocols with CBP, USCG, and other Federal partners at ports of entry and other domestic transportation hubs; identify gaps.

Step 3: Update protocols to include more advanced screening and detection of public health threats (e.g., health declarations), and identify gaps in existing domestic policy to implement such protocols.

Step 4: Update response protocols to public health threats (to include control measures such as isolation/quarantine of travelers at airports, border crossings, and maritime ports isolation); identify gaps in existing policy for implementing such protocols.

Step 5: Based on identified gaps, develop policy recommendations that facilitate exit- and entry-screening measures at ports and borders for public health threats. To inform further policy development, include real-time evaluation of the measures when implemented.

F. Action (HSC 5.2.4.2): HHS, working collaboratively with DHS and DOT and in coordination with DOS, DOC, Treasury, and USDA, will develop policy guidelines for international and domestic travel restrictions during a pandemic, based on the ability to delay the spread of disease and the resulting health benefits, associated economic impacts, international implications, and operational feasibility. (Also see Pillar One, Action D [HSC 5.1.1.4] above.)

Timeframe: Within 8 months.

Measure of Performance: Interagency travel curtailment policy guidelines developed that address both voluntary and mandatory travel restrictions.

Step 1: Coordinate with DHS, DOT, DOS, DOC, Treasury, and USDA on assessment of the impact of international and domestic travel restrictions on public health, the economy, diplomatic relations, and travel industry.

Step 2: Based on the above assessment, develop criteria and policy guidelines on voluntary versus mandatory international and domestic travel restrictions for use during a pandemic.

Step 3: Determine effective methods of implementing travel restrictions, such as through limitation of entry of persons into the United States, imposition of requirements for exit screening from countries experiencing an influenza pandemic, the closure of certain modes of domestic public transportation, or the closure of international ports of entry.

G. Action (HSC 5.2.4.4): HHS, working with DOS and in coordination with DHS, DOT, and transportation and border stakeholders, will assess and revise procedures to issue travel information and advisories related to pandemic influenza. (Also see chapter 1, Pillar One, Action K [HSC 5.2.4.4]; and chapter 7, Pillar Two, Action B [HSC 5.2.4.4].)

Timeframe: Within 12 months.

Measure of Performance: Improved interagency coordination and timely dissemination of travel information to stakeholders and travelers.

Steps During U.S. Response Stages 0–2

Step 1: Work with domestic and international partners to define appropriate trigger points for issuing Travel Health Advisories.

Step 2: Develop and maintain up-to-date Travel Health Advisories on the CDC Travelers' Health Web site through all pandemic U.S. Response Stages.

Step 3: Identify steps and methods for rapidly obtaining clearance and publicly posting Travel Health Advisories (within 24 hours).

Step 4: Identify domestic and international response partners who should be notified in advance regarding new Travel Health Advisories (e.g., DOT, DOS, DHS, FAA, ATA.WHO, GHSI, International Partnership on Avian and Pandemic Influenza (IPAPI), consular officials, Ministries of Health in affected countries, and IATA).

Step 5: Confirm an appropriate point of contact for each of these partners, and develop and implement a means for timely communication to these points of contact regarding new Travel Health Advisories.

Steps During U.S. Response Stages 1–5

Step 6: Continue activities initiated in Stage 0.

Step 7: Work with travel industry partners, Federal agency partners, and port facilities managers to ensure rapid distribution of key Travel Health Advisories to travelers at international ports of entry.

H. Action (HSC 5.2.4.5): HHS will provide technical assistance to DOT and DHS, which will in turn work in coordination with DOD, DOS, airlines/air space users, the cruise line industry, and appropriate State and local health authorities to develop protocols to manage and/or divert inbound international flights and vessels with suspected cases of pandemic influenza that identify roles, actions, relevant authorities, and events that trigger response.

Timeframe: Within 12 months.

Measure of Performance: Interagency response protocols for inbound flights completed and disseminated to appropriate entities.

Step 1: Provide technical assistance to DOT and DHS regarding potential triggers for dynamic management/diversion of inbound international flights/vessels having passengers with suspected pandemic influenza and sites to which vessels could be diverted. Possible circumstances requiring diversion of flights/vessels

would include high-risk situations en route (e.g., occurrence of multiple cases, suspected outbreak, or conditions for high probability of transmission of confirmed pandemic influenza). Additionally, diversion may be warranted for situations such as a destination airport/port that is overwhelmed by a concurrent quarantine situation or is otherwise unable to implement adequate control measures.

Step 2: Work with airlines and airports; State, local and tribal health departments; and Federal partners on developing or refining protocols for standard management of flights with passengers who have suspected cases of pandemic influenza.

Step 3: Work with the North American cruise industry, maritime ports, the USCG, DHS, and other Federal partners to develop standard protocols for management of vessels carrying persons who have suspected cases of pandemic influenza.

I. Action (HSC 5.2.4.6): HHS, in coordination with DHS, DOT, DOS, DOD, air carriers/air space users, the cruise line industry, and appropriate State, local, and tribal health authorities, shall develop en route protocols for crew members onboard aircraft and vessels to identify and respond to travelers who become ill en route and to make timely notification to Federal agencies, health care providers, and other relevant authorities. (Also see Pillar One, Action D [HSC 5.1.1.4] above, and Pillar Two, Actions K and B [HSC 5.2.4.8 (below) and 5.2.2.1 (above)]; and chapter 2, Pillar Two, Action A [HSC 5.2.2.1].)

Timeframe: Within 12 months.

Measure of Performance: Protocols developed and disseminated to air carriers/airspace users and cruise line industry.

Step 1: Establish criteria and case definitions (based on symptoms and high-risk exposures, e.g., travel, activity) for case reporting.

Step 2: Develop protocol, including use of appropriate infection-control practices, for management of passengers with suspected influenza identified en route.

Step 3: Develop and implement training for international conveyance crews and operations staff for recognition of, response to, and reporting of cases.

Step 4: Update surveillance and response protocols based on refined case definitions—as well as the potential availability of new, rapid, virologic screening tests and updated infection-control practices—as new knowledge is gained regarding a pandemic influenza strain.

J. Action (HSC 5.2.4.7): HHS, working closely with DHS and DOT, and in coordination with transportation and border stakeholders and appropriate State and local health authorities will develop aviation, land border, and maritime entry and exit protocols and/or screening protocols (Protocols will be revised as new rapid diagnostic tests become available) and education materials for non-medical, frontline screeners and officers to identify potentially infected persons or cargo. (Also see Pillar One, Action D [HSC 5.1.1.4] Step 5, above.)

Timeframe: Within 10 months.

Measure of Performance: Protocols and training materials developed and disseminated.

Steps During U.S. Response Stages 0–1

Step 1: Gather the best scientific evidence for effective port entry/exit screening (e.g., thermal scanners, health declarations, x rays) and response measures (isolation, quarantine) for persons and goods, and the best response at U.S. ports of entry.

Step 2: Use knowledge from Step 1 above, and engage port agencies (e.g., CBP, Transportation Security Administration [TSA], USCG) in the design of a surveillance system for inbound and outbound travelers and goods (directly or indirectly) from/to target areas at U.S. ports of entry.

Step 3: Identify and design data collection tools for information gathering (e.g., the airline, airport, flight number, symptoms, exposure history, immediate actions taken, and followup actions taken).

Step 4: Establish response protocols and criteria for identifying a person for further medical evaluation or public health action (e.g., isolation, quarantine, medical surveillance).

Step 5: Establish response protocols for cargo posing a public health threat.

Step 6: Develop training materials for nonmedical, frontline screeners and officers who will conduct surveillance and response.

Step 7: Train nonmedical, frontline screeners to conduct surveillance and response at port of entry.

Steps During U.S. Response Stages 2–3

Step 8: Initiate active surveillance measures—entry and/or exit screening, using updated case definitions for pandemic influenza.

Step 9: Update education of all frontline staff at ports of entry in surveillance and response as well as in personal protection measures.

Steps During U.S. Response Stages 4–5

Step 10: Discontinue entry-screening efforts and implement exit-screening efforts.

Step 11: Update education of all frontline staff at ports of entry in exit-screening measures.

K. Action (HSC 5.2.4.8): With DHS, and in coordination with DOT, DOJ, and appropriate State, local, and tribal health authorities, HHS will work to develop detection, diagnosis, quarantine, isolation, EMS transport, reporting and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza. (Also see Pillar One, Action D [HSC 5.1.1.4] above, and Pillar Two, Actions B and I [HSC 5.2.2.1 and 5.2.4.6] above; and chapter 2, Pillar Two, Action A [HSC 5.2.2.1].)

Timeframe: Within 10 months.

Measure of Performance: Protocols developed and distributed to all ports of entry.

Step 1: Develop U.S. Response Stage-specific response protocols for travelers and undocumented aliens with signs and symptoms of influenza or with significant history of exposure. These protocols will be based on U.S. Response Stage-specific case definitions for detection, as well as on criteria for isolation, quarantine, and transport to medical facility for further treatment and evaluation.

Step 2: Identify stakeholders required for implementing the above protocols.

Step 3: Develop Memoranda of Understanding (MOUs) with appropriate stakeholders.

Step 4: Develop and distribute protocols to stakeholders.

Step 5: Develop and distribute to all ports of entry, educational materials (based on above protocols) for potential travelers and undocumented aliens apprehended between ports of entry.

L. Action (HSC 5.2.4.9): HHS will provide technical assistance to DHS, and work in coordination with DOS, Treasury, and the travel and trade industry, to assist DHS tailor existing automated screening programs and extended border programs to increase scrutiny of travelers and cargo based on potential risk factors (e.g., shipment from or traveling through areas with pandemic outbreaks).

Timeframe: Within 6 months.

Measure of Performance: Enhanced risk-based screening protocols implemented.

Step 1: Study existing traveler- and cargo-screening programs, e.g., Automated Manifest System (AMS).

Step 2: Identify gaps in existing programs and appropriate stakeholders.

Step 3: Assess current techniques of interviewing travelers, and identify as well as develop enhanced techniques to identify as rapidly as possible persons who are ill.

Step 4: Determine potential triggers for the interruption of refugee/immigrant travel to the United States.

Step 5: Define potential risk factors to be included in screening/response protocols.

Step 6: Develop, with appropriate partners, risk-based protocols to increase scrutiny of potentially infected persons and goods (with criteria for seizing and destroying cargo, when necessary).

M. Action (HSC 5.2.5.2): HHS will provide technical assistance to USDA and coordinate with DHS and DOI as USDA reviews the process for withdrawing permits for importation of live avian species or products and identify ways to increase timeliness, improve detection of high-risk importers, and increase outreach to importers and their distributors.

Timeframe: Within 6 months.

Measure of Performance: Revised process for withdrawing permits of high-risk importers.

Step 1: Review, revise, and if necessary develop regulations (such as 9 CFR 94.6) that are adequate to prohibit entry of high-risk birds and bird byproducts from countries affected by H5N1.

Step 2: Obtain access to CBP's AMS to allow identification of shipments with birds or bird products.

Step 3: Assess the volume of shipments containing birds and bird products entering the United States during a 1-month period.

Step 4: Increase staffing at ports of entry to accommodate increased inspections of shipments.

Step 5: Ensure each Quarantine Station has the means to safely dispose of birds or bird products that are denied entry.

Step 6: Promote better communication between HHS, USDA, CBP, and U.S. Fish and Wildlife Service (FWS) through regular conference calls and e-mail distribution lists.

Step 7: Work with USDA as it reviews its process for identifying high-risk shipments and/or importers and for withdrawing permits.

N. Action (HSC 6.2.4.2): HHS will work with DHS, and in coordination with Sector-Specific Agencies, DOD, DOJ, and VA, and in collaboration with the private sector, to prepare to track the integrity of critical infrastructure function, including the health care sector, to determine whether ongoing strategies of ensuring workplace safety and continuity of operations need to be altered as a pandemic evolves. The collection of personal information, if and where necessary, will be performed in accordance with U.S. privacy law. (Also see chapter 2, Pillar Two, Action J [HSC 6.2.4.2].)

Timeframe: Within 6 months.

Measure of Performance: Tracking system in place to monitor integrity of critical infrastructure function and continuity of operations in nearly real time.

Step 1: In collaboration with DHS, convene a panel of subject matter experts to identify the types and forms of data to establish operational status of the critical infrastructure sectors of health care and public health.

Step 2: Analyze the feedback and update the HHS Critical Infrastructure Data System to address more accurately the infrastructure tracking needs.

Step 3: Work with OMB to have the Critical Infrastructure Data System revised to accept the necessary technical edits.

Pillar Three: Response and Containment

In approaching the problem of pandemic influenza, HHS supports a layered strategy of response and containment. In the event of sustained and efficient human-to-human transmission of an influenza virus with pandemic potential, HHS will first leverage available resources and interventions to contain the outbreak at its source and to delay or limit its introduction to the United States If such efforts fail, HHS resources and recommended interventions will be directed to limiting or otherwise delaying the spread of pandemic within the United States; minimizing suffering and death; sustaining critical infrastructure and a Constitutional form of Government; and reducing the economic and social effects of the pandemic. Currently, HHS is basing its response and containment

protocols and policy discussions on scientifically sound modeling assumptions. As more experience with pandemic influenza is gained, HHS will use evidence-based decisionmaking to further revisit and refine its response protocols, strategies, and policies.

Containing Outbreaks

A. Action (HSC 4.3.2.1): HHS, in coordination with DHS, DOD and DOT, and in collaboration with foreign counterparts, will assist DOS in DOS support of the implementation of pre-existing passenger screening protocols in the event of an outbreak of pandemic influenza. (Also see chapter 1, Pillar Three, Action J [HSC 4.3.2.1].)

Timeframe: Ongoing.

Measure of Performance: Protocols implemented within 48 hours of notification of an outbreak of pandemic influenza.

Steps During U.S. Response Stage 0

Step 1: Develop standards and procedures for conducting and evaluating exit screening for all travelers (U.S. and non-U.S. citizens) for pandemic influenza, and travel exclusion for persons who are ill at international points of embarkation, including land borders, in collaboration with the WHO Secretariat and Ministries of Health of other countries.

Step 2: Develop binational and multinational arrangements regarding exit screening and travel exclusion for persons who are ill; these arrangements include standards, procedures, oversight, and assessment.

Step 3: Develop logistical and operational plans with the WHO Secretariat and other countries for conducting medical exit screening and travel exclusion for persons who are ill in affected countries.

Step 4: Work with the WHO Secretariat and IATA to develop predeparture screening/exclusion guidelines on ILI for transport organizations, including international passenger airlines and cargo carriers (for crew).

Step 5: Develop system for collection of data on number of persons screened, number of persons with travel restrictions, criteria for restriction and disposition.

Steps During U.S. Response Stage 1

Step 6: As part of the HHS and DOS process to issue Travel Advisories, inform the public that affected countries may begin predeparture screening.

Step 7: In collaboration with the WHO Secretariat and affected countries, assist in the institution, oversight, and assessment of predeparture exit-screening in affected countries, according to predetermined standards and arrangements.

Step 8: Assess the adequacy of affected countries' predeparture exit screening and exclusion of persons who are ill, and provide feedback.

Steps During U.S. Response Stages 2–3

Step 9: Potentially limit international ports of embarkation to the United States to ensure adequate screening.

Step 10: Reevaluate existing exit-screening and exclusion measures in affected countries, and provide feedback.

Step 11: Apply criteria for conducting exit screening of U.S.-bound persons coming from affected areas.

Step 12: Implement enhanced medical exit-screening measures and protocols.

Step 13: Conduct ongoing evaluation of the effectiveness of screening efforts.

B. Action (HSC 4.3.2.2): HHS will support DOD efforts, in coordination with DOS, DOT, and DHS to limit DOD military travel between affected areas and the U.S.

Timeframe: Within 6 months.

Measure of Performance: DOD identifies military facilities in the U.S. and outside continental U.S. (OCONUS) that will serve as the points of entry for all official travelers from affected areas.

Step 1: Provide technical assistance to DOD regarding travel restrictions to affected areas and entry screening of official travelers coming from affected areas.

C. Action (HSC 5.3.1.1): HHS will assist DOS and DHS, in coordination with DOT, DOC, Treasury, and USDA in their work with foreign counterparts to limit or restrict travel from affected regions to the U.S. as appropriate, and notify host government(s) and the traveling public. (Also see chapter 1, Pillar Three, Action H [HSC 5.3.1.1].)

Timeframe: As required.

Measure of Performance: Measures imposed within 24 hours of the decision to do so, after appropriate notifications made.

Step 1: Support DHS and DOS in limiting travel from affected regions by providing technical advice regarding voluntary and mandatory travel-restriction options and overseas exit screening in affected countries.

D. Action (HSC 5.3.1.2): HHS will assist DOS, in coordination with DOT, DHS, DOD, air carriers and cruise lines, as DOS works with host countries to implement predeparture screening based on disease characteristics and the availability of rapid-detection methods and equipment. (Also see chapter 1, Pillar Three, Action P [HSC 5.3.1.2].)

Timeframe: As required.

Measure of Performance: Screening protocols agreed upon and put in place in affected countries within 24 hours of an outbreak.

Steps During U.S. Response Stage 0

Step 1: Develop standards and procedures for conducting and evaluating exit screening for all travelers (U.S. and non-U.S. citizens) for pandemic influenza and travel exclusion for persons who are ill at international points of embarkation, including land borders, in collaboration with the WHO Secretariat and Ministries of Health.

Step 2: Develop binational and multinational arrangements regarding exit screening and travel exclusion for persons who are ill; these arrangements include standards, procedures, oversight, and assessment.

Step 3: Develop logistical and operational plans with the WHO Secretariat and other countries for conducting medical exit screening and travel exclusion for persons who are ill in affected countries.

Step 4: Work with the WHO Secretariat and travel organizations (e.g., IATA and International Council of Cruise Lines [ICCL]) to develop predeparture screening/exclusion guidelines for ILI for transport organizations, including international passenger airlines and cargo carriers (for crew).

Step 5: Develop a system for collection of data on the number of persons screened, number of persons with travel restrictions, criteria for restriction and disposition.

Step 6: Develop prevention and containment measures for cases and contacts in affected countries.

Steps During U.S. Response Stage 1

Step 7: Inform the public that affected countries may begin predeparture screening as part of the HHS and DOS process to issue Travel Advisories.

Step 8: In collaboration with the WHO Secretariat and affected countries, assist in the institution, oversight, and assessment of predeparture exit screening in affected countries, according to predetermined standards and arrangements, in collaboration with WHO and other affected countries.

Step 9: Assess the adequacy of predeparture exit screening and exclusion by affected countries of persons who are ill, and provide feedback.

Steps During U.S. Response Stages 2–3

Step 10: Potentially limit international ports of embarkation to the United States to those with enhanced predeparture exit screening.

Step 11: Re-evaluate existing exit-screening and exclusion measures in affected countries, and provide feedback.

Step 12: Implement enhanced medical exit-screening measures and protocols.

Step 13: Potentially implement more restrictive visa requirements for all non-U.S. citizens.

E. Action (HSC 5.3.1.5): HHS will work closely with DHS and in coordination with DOT, DOS, DOD, USDA, appropriate State, and local, authorities, air carriers/air space users, airports, cruise lines, and seaports to implement screening protocols at U.S. ports of entry based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 2, Pillar Two, Action N [HSC 5.3.1.5].)

Timeframe: As required.

Measure of Performance: Screening implemented within 48 hours upon notification of an outbreak.

Steps During U.S. Response Stage 0

Step 1: Design, in collaboration with frontline port agencies (e.g., CBP, TSA, and USCG), a new surveillance system for inbound travel at U.S. international airports and seaports that receive passengers (directly or indirectly) from target areas.

Step 2: Specify entry data to be collected for each traveler or crew member (e.g., the airline, airport, flight number, cruise line, vessel, symptoms, exposure history, immediate actions taken, and followup actions taken).

Step 3: Design a data collection form.

Step 4: Evaluate the usefulness of thermal scanning.

Step 5: If thermal scanning is deemed useful, install thermal scanners at international ports of entry, and train personnel how to use them.

Step 6: Establish criteria for identifying a person for further medical evaluation.

Step 7: Develop training materials for frontline officers who will conduct surveillance.

Step 8: Train port agencies (e.g., CBP, TSA, USCG officers) to conduct surveillance.

Step 9: Develop a mechanism for data transmission to HHS on a daily basis (e.g., via Web-based reporting).

Step 10: Develop a mechanism for merging data from multiple sources.

Steps During U.S. Response Stage 1

Step 11: Pilot test a surveillance system at several ports of entry, and identify issues.

Step 12: Find solutions to issues, and update system/training.

Steps During U.S. Response Stages 2–3

Active surveillance (entry screening) for pandemic influenza (not yet in the United States):

Step 13: Implement entry-screening measures, by using updated case definitions for pandemic influenza.

Step 14: Potentially restrict arrivals to a limited number of U.S. ports of entry.

Step 15: Establish criteria for identifying a screened person for further medical evaluation.

Step 16: Detail previously identified staff (e.g., CBP, TSA) to support enhanced surveillance activities.

Step 17: Meet all flights with travelers on board who have symptoms suggestive of influenza, and do the following:

- Evaluate travelers who are ill; isolate them and arrange for treatment, if needed
- Collect specimens for virologic testing, as appropriate

Step 18: Meet all flights from affected areas to accomplish the following:

- Distribute Travel Health Advisories and Warnings to all travelers
- Collect contact information from all travelers
- Collect epidemiologic information from all travelers (via questionnaire) to evaluate likelihood of overseas exposure
- Evaluate travelers for evidence of fever and other ILI symptoms

Step 19: If a traveler who is ill with suspected pandemic influenza is identified:

- Quarantine exposed travelers (e.g., fellow passengers or crew) onsite or at home
- Consider antiviral prophylactic therapy for exposed travelers (this would apply to travelers exposed on the airplane due to contact with a traveler who is ill on the same plane)
- Implement contact tracing and followup if the traveler who is ill is determined to have a pandemic strain

Steps During U.S. Response Stages 4–5

Step 1: As instructed by HHS, discontinue entry-screening efforts and return to U.S. Response Stage 0 level of passive surveillance of all travelers.

F. Action (HSC 5.3.1.6): HHS will work closely with DHS, in coordination with DOT, HHS, USDA, DOD, appropriate State, and local authorities, air carriers, and airports, in DHS consideration of implementing response or screening protocols at domestic airports and other transport modes, as appropriate, based on disease characteristics and availability of rapid-detection methods and equipment. (Also see chapter 2, Pillar Two, Action O [HSC 5.3.1.6].)

Timeframe: Ongoing.

Measure of Performance: Screening protocols in place within 24 hours of directive to do so.

Step 1: Evaluate utility of screening at domestic airports, if appropriate; assess resources needed to implement screening and develop trigger points for such implementation.

Step 2: Investigate potential screening measures/technology (e.g., thermal scanning) and, if appropriate, procurement, availability of equipment, probable location in individual domestic airports for both entry and exit screening, and staffing and training requirements; develop protocols for implementation and evaluation.

Step 3: If deemed appropriate, develop protocols, staffing and training requirements, and evaluation/data collection plan for medical screening at entry and exit, to include evaluation for fever and of symptoms.

Step 4: If deemed appropriate, develop epidemiologic questionnaires for entry and exit screening, and plan for distribution to travelers as well as collection, interpretation, and data collection/evaluation.

Step 5: Investigate resource requirements for the collection and laboratory testing of medical specimens for virus isolation; develop protocols for use (including data management and evaluation) as well as a staffing and training plan.

Step 6: Update protocols and training as new, rapid-screening tests become available.

G. Action (HSC Action 5.3.2.1): HHS will, in coordination with DHS, DOS, DOT, and USDA, issue travel advisories/public announcements for areas where outbreaks have occurred, and ensure adequate coordination with appropriate transportation and border stakeholders. (Also see chapter 7, Pillar Three, Action B [HSC 5.3.2.1].)

Timeframe: Ongoing.

Measure of Performance: Coordinated announcements and warnings developed within 24 hours of becoming aware of an outbreak, and timely updates provided, as required.

Steps During U.S. Response Stage 0

Step 1: Work with domestic and international partners to define trigger points for issuing Travelers' Health Advisories during the Pandemic Alert and Pandemic Periods.

Step 2: Develop and maintain up-to-date Travel Health Advisories on the HHS/CDC Travelers' Health Web site through all pandemic stages. Identify steps for rapid clearance and posting (within 24 hours).

Step 3: Identify domestic and international response partners who should be notified in advance about new Travel Health Advisories (e.g., DOT, DOS, DHS, FAA, IATA, the WHO Secretariat, consular officials, Ministries of Health in affected countries, the IATA).

Step 4: Confirm a point of contact for each of these partners, and develop and test a means for rapid communication to these points of contact (e.g., e-mail blast, mass fax) regarding new Travel Health Advisories.

Steps During U.S. Response Stages 1–5

Step 5: Continue activities from Stage 0.

Step 6: Work with travel industry partners, Federal agency partners, and managers of port facilities to ensure the rapid distribution of Travel Health Advisories to travelers at ports of entry.

Step 7: Ensure that appropriate Federal, international, and private partners are notified in advance of all Travel Health Advisories.

H. Action (HSC 6.3.2.1): HHS, in coordination with DHS, DOT, Education, DOC, DOD, and Treasury, will provide State, local, and tribal entities with guidance on the combination, timing, evaluation, and sequencing of community containment strategies (including travel restrictions, school closings, "snow days", and quarantine during a pandemic) based on currently available data, and update this guidance as additional data becomes available. (Also see Pillar One, Action D [HSC 5.1.1.4] Step 7 above.)

Timeframe: Within 6 months.

Measure of Performance: Guidance provided on community influenza containment measures.

Step 1: Explore data on effective sequencing and combination of various community-containment strategies from modeling, past outbreak response, and scientific studies.

Step 2: Share above findings with State, local, and tribal entities to assess feasibility of implementation.

Step 3: Work with State, local, and tribal entities to agree on authorities and triggers for implementing community-containment measures consistently across jurisdictions.

Step 4: Develop guidance regarding each containment strategy: the steps required to complete this action item are numerous, and the required work cannot be adequately reflected in the three brief, consolidated steps above. Because few data exist for most of these containment strategies, the steps below outline the requirements for providing guidance on 10 community-containment strategies being considered.

1. Strategy: Home Isolation and Quarantine

Steps During U.S. Response Stages 0–3

Step 1: Develop guidance for State, local, and tribal health departments for monitoring contacts of persons infected with suspected or confirmed pandemic influenza, including procedures for passive monitoring, active monitoring without activity restrictions, and active monitoring with activity restrictions (quarantine). (See **HHS Pandemic Influenza Plan**, Supplement 8, Appendix 1.) This guidance includes the following:

- Recommendations for implementing home isolation
- Training for individuals assessing home quarantine feasibility
- Security/enforcement issues relating to home quarantine
- Infection control recommendations to fit the specific needs of patients receiving care in the home setting as well as the infection-control needs of other persons in the household

Steps During U.S. Response Stages 4–5

Step 2: HHS, through consultation, will assist State, local, and tribal health departments in the implementation of home isolation and quarantine.

Step 3: Evaluate the effectiveness of home isolation and quarantine in decreasing transmission, and address logistical problems.

Step 4: Provide updated guidance on home-quarantine infection-control practices, as needed.

2. Strategy: Facility Quarantine

Steps During U.S. Response Stages 0–3

Step 1: Determine definition of facility quarantine.

Step 2: Develop Federal guidance document for quarantine facilities that describes the needs of particular population groups (e.g., international travelers, the elderly, special needs populations, the homeless, students at colleges and universities) and addresses issues related to staffing, supplies, transportation, infection control, and security.

Step 3: Local health departments are to develop plans and facilities for quarantine.

Step 4: Work with States, localities, and tribes to further encourage local governments to identify facilities for housing individuals not qualified for home quarantine.

Steps During U.S. Response Stages 4–5

Step 5: Local and State authorities are to implement facility quarantine as needed.

Step 6: Evaluate the effectiveness of facility isolation and logistical problems. Update recommendations based upon findings.

3. Strategy: Work Quarantine

Steps During U.S. Response Stages 0–3

Step 1: Develop and disseminate guidance documents and materials for work quarantine, addressing issues related to transportation, symptom monitoring, PPE, and psychological support.

Steps During U.S. Response Stages 4–5

Step 2: State, local, and tribal governments are to implement work quarantine as needed.

Step 3: Evaluate the effectiveness of work quarantine.

4. Strategy: Cancellation of Public Events

Steps During U.S. Response Stages 0–3

Step 1: Develop guidelines that identify key public events that might facilitate the spread of influenza, and identify trigger points for restriction of public events by local authorities.

Step 2: Encourage State, local, and tribal authorities to identify large public events scheduled during upcoming months that have a high potential for facilitating the spread of influenza, and obtain contact information for organizers of these events.

Steps During U.S. Response Stages 4–5

Step 3: Advise State, local, and tribal health departments on implementation of public event cancellations, as needed.

5. Strategy: Closure of Schools

Steps During U.S. Response Stages 0–3

Step 1: Identify trigger points for school closure.

Step 2: Contact the Department of Education and State education departments to determine that plans exist to deal with school closures in the event of an influenza pandemic.

Step 3: Encourage education departments to establish/enhance ways of communicating with staff and students during school closures (e.g., e-mail, phone trees, local media).

Step 4: Encourage State, local, and tribal education departments to consider the development of home curricula/distance-based learning for use during school closure. Consideration may be given to working with home schooling authorities.

Step 5: Work with State, local, and tribal entities, including the educational sector, to agree on authorities and triggers for implementing school closures consistently across jurisdictions.

Step 6: Determine the Federal role in determining timing and coordination of school closures.

Steps During U.S. Response Stages 4–5

Step 7: Provide technical assistance to State, local, and tribal partners as they implement school closure and home education, as needed.

6. Strategy: Closure of Other Public Places

Steps During U.S. Response Stages 0–2

Step 1: Develop guidelines for closing public places, including shopping malls and recreation facilities, during a pandemic.

Step 2: Work with State, local, and tribal public health staff, as well as the private sector, to develop guidelines for closing public places.

Steps During U.S. Response Stages 3–5

Step 3: Provide technical assistance to State, local, and tribal partners as they implement closures of public places.

7. Strategy: Closure of Public Transportation

Steps During U.S. Response Stages 0–2

Step 1: Develop options for reducing local public transportation in the event of a pandemic, and assess the potential impact on functioning of essential services.

Steps During U.S. Response Stages 3–5

Step 2: Provide technical assistance to State, local, and tribal partners as they implement closure of public transportation systems.

8. Strategy: Closure of Specific Worksites

Steps During U.S. Response Stages 0–2

Step 1: Provide guidance to State, local, and tribal governments as well as businesses regarding the potential role of worksite closure in the containment of pandemic influenza.

Step 2: Provide technical assistance to State, local, and tribal health departments in identifying employers and worksites in local jurisdictions that deliver nonessential services.

Steps During U.S. Response Stages 3–5

Step 3: Local governments are to work with large local employers to discuss the role of worksite closures in their State/local pandemic plans and to educate workers on means of preventing influenza transmission and on the necessity of staying home from work while they are ill.

Step 4: Provide technical assistance to State, local, and tribal authorities as they implement worksite closures as needed.

9. Strategy: Sheltering in Place ("Snow Days") Restrictions

Steps During U.S. Response Stages 0–2

Step 1: Develop guidelines that describe the role of sheltering in place in the control of pandemic influenza and steps in implementation.

Step 2: Provide technical assistance to State, local, and tribal partners in their decisions regarding which services are necessary and which employees should be exempt from sheltering in place.

Step 3: State, local, and tribal governments are to work with businesses and education sectors (including colleges and universities, daycare/preschool) on the role of sheltering in place in their respective pandemic plans.

Steps During U.S. Response Stages 3–5

Step 4: Provide technical assistance to State, local, and tribal health departments as they implement sheltering in place in response to pandemic influenza, as needed.

Step 5: State, local, and tribal governments to work with businesses and the education sector (e.g., colleges and universities, daycare/preschool) on the role of sheltering in place in their respective pandemic plans.

10. Strategy: Thermal Scanning in Public Places

Steps During U.S. Response Stages 0–1

Step 1: Review data on the effectiveness and cost-effectiveness of thermal scanning in prevention of disease transmission, and make recommendations on potential use of thermal scanning during influenza pandemic. If thermal scanning is recommended:

- Determine whether there are legal considerations that need to be addressed regarding thermal scanning in public places
- Develop options for using thermal scanning, such as using thermal scanning to discourage febrile people from attending large public gatherings
- Research the availability of thermal-scanning equipment

- If this technology, upon evaluation, is found to be feasible, effective, cost-effective, and appropriate, consider the purchase and the stockpiling of thermal-scanning equipment

Steps During U.S. Response Stages 2–5

Step 2: Consider the installation and use of thermal-scanning equipment in key public areas, if recommended.

I. Action (HSC 6.3.2.2): HHS will provide guidance on the role and evaluation of the efficacy of geographic quarantine in efforts to contain an outbreak of influenza with pandemic potential at its source, within 3 months. (Also see Pillar One, Action D [HSC 5.1.1.4] Step 7, above.)

Timeframe: Within 3 months.

Measure of Performance: Guidance available within 72 hours of initial outbreak.

Steps During U.S. Response Stages 0–2

Step 1: Evaluate efficacy of geographic quarantine (from modeling, past international experience, and other scientific means).

Step 2: Develop and disseminate guidance materials on the use of *cordon sanitaire* (enforcement, maintenance of basic infrastructure, transportation, medical monitoring, and communication mechanisms).

Steps During U.S. Response Stages 3–5

Step 3: Work with State and local governments to determine if *cordon sanitaire* should be implemented in specific situations.

J. Action (HSC 6.3.2.3): HHS, in coordination with DHS and DOD and in collaboration with mathematical modelers, will complete research identifying optimal strategies for using voluntary home quarantine, school closure, snow-day restrictions, and other community infection-control measures.

Timeframe: Within 12 months.

Measure of Performance: Guidance developed and disseminated on the use of community control.

Steps During U.S. Response Stages 0–2

Step 1: Review existing research on community-containment methods, and work with partners to fill the gaps in present knowledge (e.g., sensitivity and specificity

of thermal scanning, effect of holiday school closure on seasonal influenza rates, rates of compliance for recommended home isolation and quarantine.)

Step 2: Work with the MIDAS network and/or other groups of mathematical modelers to evaluate the potential effectiveness of specific community-containment methods.

Step 3: Act as a liaison between State, local, and tribal health departments and mathematical modelers to interpret and distribute findings and to issue guidance.

Steps During U.S. Response Stage 3

Step 4: Work with international partners to help evaluate the impact of community-containment methods in affected nations and to disseminate findings/ recommendations.

Steps During U.S. Response Stages 4–5

Step 5: Evaluate the impact of containment methods in the United States.

K. Action (HSC 6.3.2.5): All HHS- (as well as all DOD-, and VA-) funded hospitals and health facilities will develop, test, and be prepared to implement infection control campaigns for pandemic influenza. (Also see chapter 7, Pillar Three, Action C [HSC 6.3.2.5].)

Timeframe: Within 3 months.

Measure of Performance: Guidance materials on infection control developed and disseminated on http://www.pandemicflu.gov and through other channels.

Step 1: Review existing guidelines, recommendations, and factsheets; identify gaps.

Step 2: Develop and/or update as needed, recommendations and factsheets for health care settings, including:

- Inpatient and acute-care hospitals
- Nursing homes and long-term-care facilities
- Outpatient and community health facilities
- Dialysis centers
- Prehospital care (EMS)
- Factsheets on home care during an influenza pandemic

Step 3: Disseminate recommendations and factsheets by publishing them on http://www.pandemicflu.gov. Additional dissemination mechanisms that may be considered include the following:

- HHS public health outreach systems, including the HAN, Epi-X, and the National Healthcare Safety Network (NHSN)
- HHS' influenza- and health care-related Web sites (e.g., CDC, HRSA, and CMS)
- HHS' Emergency Communications System (ECS) including the Clinician Outreach and Communication Activity (COCA)
- HHS' National Center for Health Marketing, Division of Public Private Partnerships
- Conference calls with health care partners and organizations such as the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), the American Hospital Association (AHA), the Infectious Disease Society of America (IDSA), the American Medical Association (AMA), the American College of Physicians (ACP), the American College of Emergency Physicians (ACEP), the American Medical Directors Association (AMDA), the American Nurses Association, the American Public Health Association (APHA), the American Academy of Physician Assistants (AAPA), the American Osteopathic Association, and schools of public health

L. Action (HSC 6.3.2.7): HHS, in coordination with DHS, DOC, DOL, and Sector-Specific Agencies, and in collaboration with medical professional and specialty societies, will develop and disseminate infection control guidance for the private sector. (Also see chapter 7, Pillar Three, Action E [HSC 6.3.2.7].)

Timeframe: Within 12 months.

Measure of Performance: Validated, focus group-tested guidance developed and published on http://www.pandemicflu.gov and in other forums.

Step 1: Discuss with HHS partners and provide written, risk-stratified guidance for management and workers in Government and the private sectors that provide both essential and nonessential services. This guidance may include information on sanitizing hands, cough etiquette, self-isolation due to illness, use of PPE (e.g., mask use, gloves, face shields, gowns), and social distancing measures (e.g., telecommuting, office closure, work quarantine).

Step 2: Share the draft on risk-stratified guidance, produced by the interagency non-pharmaceutical interventions working group, with medical professional and specialty societies for comment and improvement.

Step 3: Give the updated infection-control guidance to CDC's National Center for Health Marketing for development of communication materials that will be focus-group tested.

Step 4: Publish the infection-control guidance on http://www.pandemicflu.gov.

M. Action (HSC 6.3.3.1): HHS, in coordination with DHS, VA and DOD, will develop and disseminate guidance that explains steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic.

Timeframe: Within 3 months.

Measure of Performance: Guidance published on http://www.pandemicflu.gov and through VA and DOD channels.

Step 1: Develop general guidance for individuals regarding measures they can take to decrease their risk and others' risk for infection with influenza. This guidance will include information on hand hygiene, cough etiquette, self-isolation due to illness, indications for use of PPE (e.g., masks, gloves, eye protection), and social-distancing measures (e.g., avoiding public gatherings, telecommuting, work quarantine).

Step 2: Publish the risk-stratified guidance on http://www.pandemicflu.gov and in other broadly distributed publications.

N. Action (HSC 6.3.3.2): HHS, in coordination with DHS, DOD, VA, and DOT and in collaboration with State, local, and tribal partners, shall develop and disseminate lists of social distancing behaviors that individuals may adopt, and update guidance as additional data becomes available. (Also see chapter 7, Pillar Three, Action F [HSC 6.3.3.2].)

Timeframe: Within 6 months.

Measure of Performance: Guidance disseminated on http://www.pandemicflu.gov and through other channels.

Step 1: Gather information on possible effective social-distancing behaviors.

Step 2: Develop guidance on social-distancing methods.

Step 3: Develop guidance on avoidance of public places.

Step 4: Develop guidance for curtailing nonessential travel.

Step 5: Develop guidance for limiting nonessential visits to physicians.

Step 6: Create a list of social-distancing behaviors for individuals, and determine the best way to communicate these behaviors to the public.

Step 7: Share communication materials and guidance with stated partners, and publish these items on http://www.pandemicflu.gov.

Step 8: Update guidance and materials as new information becomes available.

O. Action (HSC 8.3.1.1): HHS, in coordination with DOJ, DOS and DHS, will determine when and how it will assist States in enforcing their quarantines and how it will enforce a Federal quarantine.

Timeframe: Within 9 months.

Measure of Performance: Guidelines on quarantine enforcement available to all States.

Step 1: Define roles of Federal agencies in the enforcement of Federal quarantine, both on and off Federal property.

Step 2: Clarify roles and responsibilities for enforcement authority at Federal and State level.

Step 3: Communicate the role of Federal agencies in the enforcement of quarantine with States.

Sustaining Infrastructure, Essential Services, and the Economy

P. Action (HSC 5.3.3.1): HHS with USDA, and in coordination with DHS, DOT, DOS, and DOI will provide emergency notifications of probable or confirmed cases and /or outbreaks to key international, Federal, State, local and tribal transportation and border stakeholders through existing networks. (Also see chapter 1, Pillar Three, Action L [HSC 5.3.3.1]; chapter 2, Pillar Three, Action A [HSC 5.3.3.1]; and chapter 7, Pillar Three, Action H [HSC 5.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Emergency notification occurs within 24 hours or less of events of probable or confirmed cases or outbreaks.

Step 1: Work with domestic and international partners to define trigger points for issuing emergency notifications of probable or confirmed cases and/or outbreaks.

Step 2: Identify domestic and international response partners who should be notified.

Step 3: Confirm a point of contact for each of these partners, and develop and test a means for rapid communication (e.g., e-mail blast, mass fax) regarding notifications to these points of contact.

Step 4: Ensure that appropriate Federal, international, and private partners are notified of probable or confirmed cases and/or outbreaks.

Q. Action (HSC 5.3.5.6): HHS will provide support to DOT and DHS, and work in coordination with NEC, Treasury, DOC, and DOS and the interagency modeling group, in a DOT and DHS assessment of the economic, safety, and security related effects of the pandemic on the transportation sector, including movement restrictions, closures, and quarantine, and develop strategies to support long-term recovery of the sector.

Timeframe: Within 6 months of the end of a pandemic.

Measure of Performance: Economic and other assessments completed and strategies implemented to support long-term recovery of the sector.

Step 1: Support DOT and DHS by providing information to facilitate modeling, including expertise in selection of data elements to be used in models and assumptions chosen in construction of models (e.g., the expected length of time measures would be in place).

Step 2: Review model results and provide comment on the interpretation of the results.

Contents

CHAPTER 4: FEDERAL MEDICAL RESPONSE

Introduction

An influenza pandemic will place extraordinary demands on the health care system requiring an integrated response by and across all local, State, and Federal jurisdictions and partners. Efficient use of existing Federal assets will be crucial in meeting the medical surge requirements. For medical resources to be most efficiently utilized, effective response plans must be developed and tested. Plans must include a command structure compatible with the DHS National Incident Management System (NIMS) at all levels of response, a Federal 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 by the Federal Government to all partners and stakeholders. These guidelines must offer approaches to the allocation of scarce resources and the altering of medical care, if needed, such that scarce resources are distributed and applied in the most appropriate manner. Working groups organized by the Federal Government to develop guidelines, determine medical resource needs, and determine the response framework should include multidisciplinary partners from Government, private, and volunteer organizations, as well as academic medical and health training programs.

This chapter addresses the Federal medical response only, recognizing that State and local medical responders are essential partners in the U.S. effort to prepare for pandemic influenza. For preparedness guidance for State and local partners, see the **HHS Pandemic Influenza Plan** (Part 2—Public Health Guidance for State and local Partners Supplement 3, Healthcare Planning: see http://www.hhs.gov/pandemicflu/plan/sup3.html) and Chapter 8, State, Local, and Tribal Preparedness. There are specific HHS-sponsored programs that provide additional guidance to States regarding their public health and medical preparations. CDC and HRSA are working closely with States in the areas of public health and hospital preparedness, and have entered into cooperative agreements with States to provide funding for implementing this guidance (CDC: http://www.bt.cdc.gov/planning/coopagreement/#fy05 and HRSA: http://www.hrsa.gov/bioterrorism). Additionally, DHS has developed a series of National Preparedness Goals. Within these goals are specific planning scenarios, including one that addresses pandemic influenza (see http://www.dhs.gov). See these resources and Web sites for further information and detail about preparedness planning.

Surge Capacity Strategies

Federal medical support will augment, to the extent possible dictated by availability, existing local and State infrastructure. Federal resources include the National Disaster Medical System (NDMS), the Commissioned Corps of the U.S. Public Health Service (USPHS), the Strategic National Stockpile (SNS), and Federal volunteers and temporary

employees. At all levels, the success of medical response to an influenza pandemic will be determined by how medical providers and facilities implement interventions that enable them to meet the increased medical demands resulting from the pandemic. Strategies, developed through Federal regional approaches, are needed for enhancing the health care system's provider and facility surge capacity as well as the abilities to accept, distribute equitably, and utilize the medical resources that may be brought in from outside organizations, including Federal medical support.

Altered Standards of Care and Other Tools for Medical Surge Capacity

Even if health care systems fully maximize their internal surge capacity and fully utilize alternative health care sites, it is likely that under the worst case scenario, health care systems will need to modify their standards of care in such a way that patients can receive treatment without a significant compromise to clinical outcomes.[1] While these difficult decisions must be based on a variety of conditions and there is no single set of standards that addresses every situation, guidance regarding the process of altering standards can be made using existing medical knowledge.

States have also initiated other steps to enhance their surge capacity, including developing alternate health care facilities and exploring the concept of home care by lay persons, creating rosters of volunteers, enhancing hospital bed tracking systems, and providing mutual aid compacts or agreements. A number of models and tools have been developed and disseminated by HHS to State, local, and tribal planners to enhance their planning for medical surge capacity (http://ahrq.gov/browse/bioterbr.htm#tools). There is a list of tools in the appendix to the **HHS Pandemic Plan** (Part 2—Public Health Guidance for State and Local Partners Supplement 3 Healthcare Planning: see http://www.hhs.gov/pandemicflu/plan/sup3.html). Tools for hospitals include: AHRQ Altered Standards of Care in Mass Casualty Events_4-20051.pdf and DHHS Medical Surge Capacity and Capability Handbook_8-2004.pdf.

Stockpiling Guidance

There are a variety of different guidelines disseminated by the Federal Government that address the issue of stockpiled medications and supplies. SNS has a program that is assisting States with their pharmaceutical distribution plans. CDC offers training to States for the receipt and distribution of SNS material (see http://www.bt.cdc.gov/stockpile/).

Recommendations From Private Sector Partners

Private sector entities have also issued recommendations for building State and local medical surge capacity that are applicable to all hazard situations. For example, the American Hospital Association (AHA) has recommended that individual hospitals have a 24-hour supply of pharmaceuticals and that they develop a list of required

[1] Initial work on altering standards of care has been published, including a white paper from AHRQ (Altered Standards of Care in Mass Casualty Events, May 2005, http://ahrq.gov/research/altstand/altstand.pdf). JCAHO has also begun to address the issue (see http://www.jointcommission.org).

medical/surgical equipment and supplies (see AHA Hospital Resources for Disaster Readiness: http://www.aha.org/aha_app/issues/Emergency-Readiness/index.jsp). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommends a 48–72-hour capability of medications and supplies (JCAHO Health Care at the Crossroads: Strategies for Creating and Sustaining Community-wide Emergency Preparedness Systems, 2003; see http://www.usaprepare.com/ep3-12-03.pdf). HRSA recommends a 72-hour supply of pharmaceuticals. During an influenza pandemic, the needs for medical surge capacity and stockpiles will be similar to those needed during other types of hazards; however, the specific requirements for a pandemic will also need to be addressed.

Role of HHS in Federal Medical Response

Deployment of Federal medical response assets will use the National Response Plan (NRP) as a framework for the coordination of Federal support. Additionally, the Federal resource inventory includes the Federal Medical Stations (FMS). These facilities are designed to provide care to special needs persons and others who do not require hospitalization, yet may need frequent or continuous medical supervision.

From an incident management perspective, the NRP (Emergency Support Function [ESF] #8) assigns HHS as the lead Federal agency responsible for coordinating the health and medical responses to a biological event such as a pandemic. Specifically with respect to the Federal medical response, the HHS role is to:

- Coordinate the deployment of Federal medical resources available through ESF #8
- Provide guidance regarding surge capacity
- Distribute stockpile medications and supplies

Specific Assumptions and Planning Considerations for HHS Federal Medical Response

The NRP will serve as the pandemic response framework for the Federal medical response.

The spectrum of Federal medical services can include clinical care, immunization, patient transport, establishing augmentation facilities, backfilling existing facilities, fatalities management, and mental health. But, the number of Federal health care providers is limited, and it will be unlikely that the Federal Government will be able to meet requests for personnel in the event of a pandemic.

- The USPHS Commissioned Corps and NDMS resources will be tasked with the primary responsibility for providing the main body of Federal responders.
- Federal resources other than personnel will also be scarce, and a mechanism is required for their equitable distribution.
- The Federal medical response must be sustainable for several months during a pandemic.
- Federal responders are multidisciplinary and come from a variety of sources, including screened volunteers and temporary Federal employees.
- HHS will establish an interagency management system that will be based on the HHS Incident Response Coordination Team (IRCT) and the utilization of existing regional entities to coordinate and support the Federal medical effort.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

Preparedness and communication are critical elements to the implementation of successful public health interventions and medical responses. Described below are activities that should be undertaken before a pandemic to ensure preparedness and to communicate expectations and responsibilities to all levels of government and society. Specifically, this section includes the actions and steps necessary to develop the strategies for deploying Federal resources, guidance needed for allocating scarce non-Federal health and medical resources, and the medical materiel requirements of the SNS and stockpiles based in States and communities. HHS has developed public communications guidelines that are discussed in Chapter 7, Communications.

Planning for a Pandemic

A. Action (HSC 6.1.2.2): HHS, DHS, DOD, and VA will develop a joint strategy defining the objectives, conditions, and mechanisms for deployment under which NDMS assets, USPHS Commissioned Corps, Epidemic Intelligence Service (EIS)

officers, and DOD and VA health care personnel and public health officers would be deployed during a pandemic. (Also see chapter 2, Pillar One, Action I [No HSC number], Step 7.)

Timeframe: Within 9 months.

Measure of Performance: Interagency strategy completed and tested for the deployment of Federal medical personnel during a pandemic.

Step 1: Convene ESF #8 working group to review ESF #8 incident management and to define the conditions and mechanisms for equitable deployment of Federal medical assets noted above. The NRP will be used as the framework to coordinate the deployment of Federal resources. Review the HHS Incident Management Team (IMT) for consideration as the pandemic influenza "Incident Management System."

Step 2: Identify triggers for deployment of Federal resources to include the following:

- Declaration of a public health emergency
- Request for assistance from States
- Emergency or disaster declaration by President
- International deployment

Step 3: Document incident management strategy and deployment triggers and disseminate strategy to Federal partners and State, local, and tribal health counterparts.

Step 4: Draft results of Steps 1 and 2 into a working summary and send out for comment to State and local public health and medical organizations. Results will be integrated with State and local plans. Incorporate revisions as appropriate and establish documents as Standard Operating Procedures.

Step 5: Conduct a facilitated discussion with ESF #8 partners to test the Federal public health and medical response strategy.

Step 6: Revise plans, strategies, and materiel, based on exercises and partner feedback.

B. Action (HSC 6.1.2.4): HHS, in coordination with DHS, DOD, and VA, and in collaboration with medical professional and specialty societies, within their domains of expertise, will develop guidance for allocating scarce health and medical resources during a pandemic. (Also see chapter 8, Pillar One, Action CC [HSC 6.1.13.6].)

Timeframe: Within 6 months.

Measure of Performance: Guidance developed and disseminated.

Step 1: Convene ESF #8 partners and private collaborators (AHA, AMA, ACEP, JCAHO, NGOs, IDSA, SHEA, and APIC) to discuss options for scarce resource allocation. AHRQ with the Office of Public Health Emergency Preparedness (OPHEP) guidance convened this working group on June 1–2, 2006, to develop a Community Based Planning Guide for State, local, and tribal health planners who are responsible for developing medical response plans. The guide will be released in late summer 2006 and be disseminated to local and State jurisdictions.

Step 2: Define scarce resources for local, State, and Federal:

- Personnel—which specialties and disciplines—hospital, prehospital, and other local health care providers
- Equipment—ventilators, monitoring equipment, PPE, and masks
- Supplies—pharmaceuticals
- Services—intensive care, respiratory care, laboratory, diagnostics

Step 3: The working group will review existing guidance for allocation of scarce resources and recommend options for maximizing resource utilization such as:

- Developing clinical algorithms
- Using clinical "extenders"
- Using alternate health care facilities

Step 4: Develop consensus document on allocation of scarce resources.

Step 5: Disseminate new guidance to Federal, State, and local partners.

Step 6: Revise plans, strategies, and materiel, based on exercises, evaluations, and partner feedback.

C. Action (HSC 6.3.4.8): All hospitals should be prepared to treat patients with pandemic influenza (i.e., equipped and ready to care for: (1) a limited number of patients infected with a pandemic influenza virus, or other novel strain of influenza, as part of normal operations; and (2) a large number of patients in the event of escalating transmission of pandemic influenza).

Timeframe: 24 months.

Measure of Performance: Hospital pandemic influenza plans completed and tested.

Step 1: Ensure that HHS-supported hospitals and clinics are prepared to treat patients with pandemic influenza by reviewing their disaster plans and identifying resources necessary to enhance surge capacity.

Producing and Stockpiling Countermeasures and Medical Materiel

D. Action (HSC 6.1.6.2): HHS, in coordination with DOD, VA, and State, local, and tribal partners, will define critical medical material requirements for stockpiling by the SNS and States to respond to the diversity of needs presented by a pandemic.

Timeframe: Within 9 months.

Measure of Performance: Requirements defined and guidance provided on stockpiling.

Step 1: Convene meeting between the HRSA Bioterrorism Hospital Preparedness Program and CDC to build a medical requirements list for pandemic influenza to include the following:

- Identify critical medical materiel requirements based on population
- Identify what State stockpiles exist and list contents
- Review SNS and State stockpiles to determine gap between the HHS Essential Materials List (EML) and stockpiles

Step 2: Develop a budget for procurement of additional material.

Step 3: Disseminate these materials to Federal, State, and local partners, as materiel becomes available from manufacturers.

Step 4: Revise plans, strategies, and materiel, based on exercises, evaluations, and partner feedback.

E. Action (HSC 6.3.4.10): All health care systems, individually or collaborating with other facilities to develop local or regional stockpiles maintained under vendor managed inventory systems, should consider stockpiling consumable critical medical materiel (including but not limited to food, fuel, water, N95 respirators, surgical and/or procedural masks, gowns, and ethyl-alcohol based gels) sufficient for the peak period of a pandemic wave (2-3 weeks).

Timeframe: 24 months.

Measure of Performance: Stockpiling plans completed.

Step 1: Ensure that HHS-supported health care systems consider stockpiling consumable critical medical materiel, either on an individual or regional basis.

Establishing Distribution Plans

F. Action (HSC 6.1.13.7): HHS, in coordination with DHS, DOT, DOD, and VA, will work with State, local, and tribal governments and private sector partners to develop and test plans to allocate and distribute critical medical materiel (e.g., ventilators with accessories, resuscitator bags, gloves, face masks, gowns) in a health emergency. (Also see chapter 8, Pillar One, Action DD [HSC 6.1.13.7].)

Timeframe: Within 6 months.

Measure of Performance: Plans developed, tested, and incorporated into department plan, and disseminated to States and tribes for incorporation into department plan, and disseminated to States and tribes for incorporation into their pandemic response plans.

Step 1: Convene meeting with Federal, State, and local partners to develop regional distribution plans for medical materiel:

- Review the appropriateness of distribution plans developed by the States
- Modify distribution plans as appropriate

Step 2: Work with States and local partners to develop coordinated regional distribution exercises. Utilize existing Federal, State, local, and tribal exercises whenever possible and appropriate.

Step 3: Conduct exercises with evaluations of plans.

Step 4: Revise plans, strategies, and materiel, based on exercises, evaluations, and partner feedback.

Pillar Two: Surveillance and Detection

Federal medical response actions and steps are carried out either in the pre-pandemic preparedness or pandemic response periods. Surveillance and detection actions that identify the beginning of a pandemic or trigger deployment of Federal medical resources are covered elsewhere in this document. (See Chapter 2, Domestic Surveillance and Chapter 8, State, Local, and Tribal Preparedness.)

Pillar Three: Response and Containment

HHS supports a layered strategy of influenza pandemic response and containment. In the event of sustained and efficient human-to-human transmission of an influenza virus with pandemic potential, HHS will first leverage available resources and interventions to contain the pandemic at its source and to delay its introduction into the United States. If such efforts fail, HHS resources and recommended interventions will be redirected to limiting or otherwise delaying the spread of the pandemic within the United States, minimizing suffering and death, sustaining critical infrastructure and a constitutional form of government, and reducing the economic and social effects of the pandemic. This section covers the deployment of Federal medical resources and the review of clinical care algorithms.

Containing Outbreaks

A. Action (HSC 6.3.2.6): HHS health care facilities will develop test and be prepared to implement infection control campaigns for pandemic influenza.

Timeframe: 6 months.

Measure of Performance: HHS will have initiated infection control campaigns on pandemic influenza in its health care facilities.

Step 1: Review existing infection control strategies within HHS health care facilities.

Step 2: Develop infection control campaigns for pandemic influenza for HHS health care facilities based on the findings of Step 1.

Step 3: Beta test the infection control campaigns.

Step 4: Implement the infection control campaigns for pandemic influenza.

Leveraging National Medical and Public Health Surge Capacity

B. Action (HSC 6.3.4.1): HHS will work in collaboration with DHS, DOD, and VA to assist major medical societies and organizations in developing and disseminating protocols for changing clinical care algorithms in settings of severe medical surge. (Also see chapter 8, Pillar Two, Action B [HSC 6.2.2.8]; and chapter 7, Pillar Three, Actions D, E, and H [HSC 6.3.2.6, 6.3.2.7, and 6.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Evidence-based protocols developed to optimize care that can be provided in conditions of severe medical surge.

See Pillar One, Action B [HSC 6.1.2.4] for steps.

C. Action (HSC 6.3.4.2): HHS will develop, in coordination with DHS, DOD, and VA, and in collaboration with States, localities, tribal entities, and private sector healthcare facilities, strategies and protocols for expanding hospital and home healthcare delivery capacity in order to provide care as effectively and equitably as possible. (Also see chapter 8, Pillar Three, Action A [HSC 6.3.4.2], and Actions in chapter 2, Pillar Three.)

Timeframe: Within 6 months.

Measure of Performance: Guidance and protocols developed and disseminated.

Step 1: Review medical literature for best practices regarding evidence-based clinical care algorithms for medical practice, including mental health, in mass casualty incidents.

Step 2: Convene Federal, State, and private partners to develop options based on review of literature in Step 1, above. The workgroup will develop guidance for consensus.

Step 3: Disseminate options to Federal medical responders and private partners through Federal agency Web sites and teleconferencing.

D. Action (HSC 6.3.4.4): HHS assets, such as the USPHS Commissioned Corps and FMS's, along with DHS assets, such as NDMS medical materiel and mobile medical units, will be deployed in a manner consistent with pre-defined strategic considerations.

Timeframe: Within 6 months.

Measure of Performance: Development of strategic principles for deployment of Federal medical assets in a pandemic; consistency of deployments during a pandemic with these principles.

Step 1: HHS-convened working group of ESF #8 partners will develop strategic principles for the deployment of the HHS assets in a pandemic.

Step 2: Strategic principles are shared with State and local partners.

E. Action (HSC 6.3.4.6): HHS will deploy the USPHS Commissioned Corps and FMS's, if available and in combination or separately as circumstances warrant, to augment efforts of State/local governments as part of the Federal response.

Timeframe: Within 9 months.

Measure of Performance: USPHS Commissioned Corps personnel trained on FMS; Commissioned Corps personnel and FMS's deployed within 72 hours of order to mobilize during a pandemic.

Step 1: Work with OPHEP, USPHS Office of Force Readiness and Deployment (OFRD), CDC, and MRC to identify USPHS Commissioned Corps deployable resources—with this chapter's planning assumptions in mind.

Step 2: Develop concept of operations for FMS.

Step 3: Determine challenges/barriers to deployment of FMS, if any, and enhance logistic support for FMS deployment.

Step 4: Develop optimal configuration (staffing and material) for FMS to respond to pandemic influenza. Procure any material deficiencies. Adjust staffing as necessary.

Sustaining Infrastructure, Essential Services, and the Economy

F. Action (HSC 6.3.7.1): HHS, in coordination with DHS, DOD, VA, and DOT, and as the lead for ESF #8 (Public Health and Medical Services, see http://www.dhs.gov/xlibrary/assets/NRP_FullText.pdf), will identify public health and medical capabilities required to support a pandemic response and work with other supporting agencies to identify and deploy or otherwise deliver the available capability or asset, if available.

Timeframe: Within 6 months.

Measure of Performance: Inventory of public health and medical capabilities; available public health or medical capabilities or assets deployed or delivered during a pandemic.

Step 1: Convene partners to develop medical/public health capabilities requirements list for the following areas:

- Personnel
- Equipment
- Supplies
- Facilities
- Services

Step 2: ESF #8 partners identify their respective public health and medical capabilities available to respond to pandemic.

Step 3: Review by ESF #8 partners of how capabilities will be deployed through ESF #8 IMT infrastructure.

Step 4: Develop and conduct an exercise to evaluate the 72-hour deployment capabilities to respond to a pandemic.

Step 5: Revise plans, strategies, and materiel, based on exercises, evaluations, and partner feedback.

Contents

CHAPTER 5: VACCINES

Introduction

Vaccination offers one of the most effective measures for minimizing the morbidity and mortality related to influenza virus infection. Annual influenza vaccination has been the primary method by which the disease burden of seasonal influenza epidemics has been reduced in the United States and globally.

An influenza pandemic, however, will challenge public health officials to make critical decisions about vaccine use and distribution beyond what is routinely done for seasonal influenza. Decisions need to be made prior to a pandemic and, accordingly, HHS has already begun to undertake efforts to facilitate critical vaccine-manufacturing capacity building and rapid implementation of pandemic influenza vaccination. Vaccines produced for pandemic influenza prevention must be safe, readily produced in large quantities, and delivered quickly, and must protect the largest number of individuals possible. The rapid production and clinical evaluation of investigational lots of pandemic vaccines must be a top priority for the United States and the global public health community. This chapter describes specific HHS actions on pandemic vaccine research, development, manufacturing infrastructure building, preparedness, and response for vaccine usage.

Before a vaccine against the circulating pandemic virus strain becomes available, pre-pandemic vaccine from stockpiles (if closely matched to the circulating virus) may be made available to persons in designated priority groups. Once a well-matched vaccine against the circulating pandemic virus strain becomes available, its distribution and use will become a major focus of pandemic response efforts.

The primary areas of concern for vaccines relative to pandemic planning and response include the following:

- Selection of pre-pandemic influenza virus isolates for vaccine development
- Applicability and linkage of vaccine development and clinical evaluation projects for pandemic vaccine candidates to prepare vaccine stockpiles for pandemics
- Availability of influenza virus reference strains for vaccine manufacturing
- Domestic surge capacity for influenza vaccine manufacturing of pre-pandemic vaccine stockpiles and well-matched pandemic vaccines
- Regulatory review processes for the utilization of and acceptance of pre-pandemic and pandemic vaccines
- Utility of mismatched pre-pandemic vaccines at the precipice of pandemics
- Positioning of pre-pandemic and pandemic vaccines for distribution

- Funding sources and procurement mechanisms that include liability immunity for pre-pandemic and pandemic vaccine manufacture
- Vaccine safety and efficacy
- Mechanisms for deployment of pre-pandemic and pandemic vaccines from stockpiles
- Communication of messages about vaccines during pre-pandemic and pandemic periods

The scenarios covered by this implementation plan on pandemic vaccines include preparations for and actions during pre-pandemic and pandemic phases.

Role of HHS in Vaccines

The role of HHS with respect to vaccines is to facilitate the development, production, distribution, and utilization of pre-pandemic and pandemic vaccines. Specifically, HHS will:

- Establish and maintain sufficient stockpiles (~ 40 million doses) of pre-pandemic influenza vaccine—obtained from U.S.-licensed influenza vaccine manufacturers—against circulating influenza virus with pandemic potential without interrupting seasonal influenza vaccine manufacturing during pre-pandemic periods
- Expand seasonal influenza domestic vaccine production (to cover the U.S. population for whom vaccine is recommended) through normal commercial markets
- Develop virus reference strains from human clinical isolates, and qualify and ship them from HHS and WHO-collaborating virus reference laboratories to designated U.S.-licensed influenza vaccine manufacturers for vaccine development and manufacturing
- Work, in concert with Federal partners and the pharmaceutical industry, to expand and diversify domestic vaccine-manufacturing surge capacity sufficient to produce vaccine for the entire U.S. population (~ 300 million persons) within 6 months of the start of a pandemic
- Work with pharmaceutical industry and FDA to expedite the production and testing of virus reference antigen and serum reagents for vaccine potency assays
- Complete priority group planning and revise priorities periodically during a pandemic as warranted
- Work, in concert with Federal partners, with the pharmaceutical industry to procure vaccine directed against the pandemic strain and to distribute vaccine to

State, local, and tribal public health authorities for predetermined priority groups based on preapproved State plans

- Provide a well-matched pandemic vaccine within 6 months of the start of a pandemic for *pro rata* allocation of pandemic vaccine as available to the States for distribution to the 300 million people
- Provide a physical security plan for domestic influenza manufacturing and distribution facilities
- Promote the linkage between influenza surveillance and vaccine development
- Encourage the monitoring for and reporting of post-vaccine-administration adverse events to ensure safety and indicate trends
- Encourage usage of pneumococcal vaccine, especially in elderly populations, prior to and during an influenza pandemic
- Distribute vaccine according to the prioritization schedule outlined in the "HHS Pandemic Influenza Plan" to prevent disease and virus spread and to provide continuity of a constitutional government and maintain social and economic order
- Evaluate vaccine safety and efficacy

Specific Assumptions and Planning Considerations for HHS on Vaccine Issues

- As susceptibility to the pandemic influenza subtype will be universal, all persons should have the opportunity for vaccination during a pandemic.
- Indemnification will be considered for non-U.S. Government suppliers of pre-pandemic and pandemic influenza virus reference strains and U.S. pandemic influenza vaccine manufacturers.
- Antigenic drifts or new clades of pre-pandemic influenza viruses will require the continual production of working virus seeds for vaccine production and vaccine candidates for clinical evaluation for safety, antigenic dosing, and immunogenicity.
- Although pre-pandemic vaccines may not be well matched to pandemic viruses and may not provide complete protection, stockpiles of pre-pandemic vaccines that exhibit cross-clade protection and/or virus neutralization should provide limited and life-saving immunity to healthy critical workforce persons.
- A HHS pre-pandemic influenza vaccine stockpile should be of sufficient size to immunize up to 20 million persons (U.S. military, critical government workforce, and critical infrastructure and medical workforces).
- The provision of adequate security will be required to protect vaccine components and stocks during manufacturing, shipping, and storage, and at administration sites.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

HHS facilitation and support for the research and development of an influenza pandemic vaccine encompasses influenza vaccine type, component, and delivery development, evaluation, and production; refinement of vaccination protocols; and enhancement of vaccine manufacturing and government policies for expanding vaccine manufacturing surge capacities. It also includes the establishment and testing of vaccine distribution and monitoring networks. Inherent in this HHS effort and support is the concomitant building of resources needed for regulatory advice and vaccine production oversight.

Pillar One components of HHS actions listed in this chapter are intended to integrate HSC actions and expectations concerning pandemic vaccines into a comprehensive package for influenza vaccine research and development (HSC 6.1.16, 6.1.17), domestic commercial scale vaccine production (HSC 6.1.7, 6.1.8, 6.1.10), pre-pandemic vaccine stockpiling (HSC 4.1.5, 6.1.7, 6.1.14), pandemic vaccine surge capacity building (HSC 6.1.16), and vaccine distribution and monitoring (HSC 6.1.6, 6.1.13, 6.1.16, 6.1.13, 6.3.5). Communication of HHS vaccine recommendations is also embodied in these actions (HSC 6.1.12). These actions cover HHS provisions for Federal advice and oversight of vaccine production (HSC 6.1.11) and usage (HSC 6.1.13, 6.1.13, 6.1.14).

Advancing Scientific Knowledge and Accelerating Development

A. Action (HSC 6.1.17.1): HHS will continue to support the development and clinical evaluation of novel vaccines and vaccination strategies (e.g., adjuvants, alternative delivery systems, common epitope vaccines).

   Timeframe: 12 months.

   Measure of Performance: Research grants and/or contracts awarded to support the development of influenza vaccines (including polyvalent influenza vaccines), adjuvants and dose-sparing strategies, and more efficient delivery systems, leading to initiation of phase I and II clinical trials to evaluate influenza vaccines and vaccination strategies.

   Step 1: Fund manufacturers for production of new vaccines to study and answer questions about vaccine dose schedule.

   Step 2: Prepare, acquire, and provide access to virus reference strains representative of target influenza viruses.

   Step 3: Provide advice, and advise on manufacturing issues.

Step 4: Stimulate and coordinate development of adjuvant vaccines and other immune-enhancing and antigen-sparing approaches.

Step 5: Engage in Cooperative Research and Development Agreement (CRADA) with academia and industry to facilitate vaccine development (e.g., CRADA between the Laboratory of Infectious Diseases [LID], National Institute of Allergy and Infectious Disease [NIAID], and MedImmune on the development of live, attenuated pandemic vaccine reference strains).

Step 6: Award contracts for advanced development of cell-based influenza vaccines to enhance and enlarge domestic pandemic vaccine manufacturing capacity.

Step 7: Provide contracts for advanced development of pandemic influenza vaccines that afford enhanced immunity (e.g., stimulated protective immunity, fewer doses) and/or doses-sparing effects (e.g., less antigen in vaccine) using live, attenuated influenza vaccines, adjuvants, immunostimulants, immune cytokines, or medical devices toward U.S. licensure.

Step 8: Provide contracts for advanced development of "universal" influenza vaccines that may provide cross-protective immunity against influenza subtype and strains toward U.S. licensure. The vaccines are expected to be targeted against conserved influenza M2 proteins or peptides and other viral and/or host proteins.

B. Action (HSC 6.1.16.1): HHS will continue to support the advanced development of cell-culture based influenza vaccine candidates.

Timeframe: Within 6 months.

Measure of Performance: Research grants and/or contracts awarded to develop cell-culture based influenza vaccines against currently circulating influenza strains with pandemic potential.

Step 1: Provide support and advice for new manufacturers interested in producing influenza virus vaccines.

Step 2: Provide support and advice for current manufacturers interested in expanding capabilities for preparation of influenza virus vaccines.

Step 3: Provide support for advanced development of improved and new vaccine technologies, vaccine acquisition, and vaccine manufacturing facility construction.

C. Action (HSC 4.1.6.2): HHS, in coordination with the WHO Secretariat, will establish at least six new sites for Collaborative Clinical Research on Emerging Infectious Diseases to conduct collaborative clinical research on therapeutics and the natural history of avian influenza. In addition, HHS will provide in-country support for one or more partner countries for human avian influenza clinical trials. (Also see chapter 1, Pillar One, Actions R and S [HSC 4.1.6.1 and 4.1.6.2] and chapter 6, Pillar One, Action E [HSC 4.1.6.2].)

Timeframe: 18 months.

Measure of Performance: Cooperative programs established in six new sites, to include the initiation of research and design of clinical trials.

Step 1: Develop clinical protocols for implementation to evaluate the safety and immunogenicity of pandemic vaccine candidates during the interpandemic period.

Step 2: Develop clinical protocols for implementation to evaluate the safety and immunogenicity of pandemic vaccine candidates during the pandemic period.

Step 3: Establish new clinical sites overseas for pandemic vaccine and therapeutics clinical evaluation and provide technical assistance in the development of in-country vaccine and therapeutic development for pandemic influenza.

D. Action (HSC 6.1.17.4): HHS will increase access to standardized influenza reagents for use in influenza tests and research. (Also see chapter 2, Pillar One, Action G [HSC 6.1.17.4].)

Timeframe: Within 6 months.

Measure of Performance: Standardized influenza reagents distributed to domestic and international partners within three (3) business days of a request.

Step 1: Prepare and characterize virus reference strain reassortants of influenza viruses with pandemic potential for vaccine development to support laboratory research, clinical studies, and vaccine manufacturing.

Step 2: Prepare and characterize reagents (e.g., virus reference antigens, virus reference antiserum) for standardization of vaccines for strains with pandemic potential to support laboratory and clinical studies and manufacturing.

E. Action (HSC 6.1.15.3): HHS will develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported influenza vaccine evaluation studies. (Also see chapter 2, Pillar

One, Action Q [HSC 6.1.15.3] and chapter 6, Pillar One, Action D [HSC 6.1.15.3].)

Timeframe: Within 6 months.

Measure of Performance: Data shared within one (1) month of analysis or publication of completed clinical trial study.

Step 1: Prepare procedures and plans to select and secure appropriate data from HHS-supported influenza vaccine evaluation studies.

Step 2: Prepare database with previously reported pandemic information from clinical trials and other research venues.

Manufacturing Vaccines

F. Action (HSC 6.1.8.1): HHS will work with the pharmaceutical industry toward the goal of developing domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population within 6 months after the development of a vaccine reference strain.

Timeframe: 60 months.

Measure of Performance: Domestic vaccine manufacturing capacity in place to produce 300 million courses of vaccine within 6 months of development of a vaccine reference strain during a pandemic.

Step 1: Secure raw materials and other vaccine-related supplies.

Step 2: Award contracts for acquisition of domestically-manufactured pandemic vaccines based on pandemic virus strain, vaccine type and efficacy, stage of vaccine development, and vaccine availability.

G. Action (HSC 6.1.10.1): HHS, in coordination with the private sector, will assess the ability of U.S.-based pharmaceutical manufacturing facilities to contribute surge capacity and to retrofit existing facilities for pandemic vaccine production.

Timeframe: 6 months.

Measure of Performance: Completed assessment.

Step 1: Assess facility capacities in private sector to support vaccine manufacturing through requests for information and other fact-finding mechanisms.

- Expanded egg-based influenza vaccine manufacturing facilities

- New cell-based influenza vaccine manufacturing facilities
- Retrofitting of existing domestic FDA-licensed vaccine and biologics manufacturing facilities.

Step 2: Make recommendations to policymakers for request of contracts to build capacity.

H. Action (HSC 6.1.16.2): HHS will support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics and the establishment of new domestic cell-based influenza vaccine manufacturing facilities. (Also see Pillar One, Action G [HSC 6.1.10.1] above.)

Timeframe: 36 months.

Measure of Performance: Contracts awarded for renovation or establishment of domestic-cell based influenza vaccine manufacturing capacity.

Step 1: Make request for proposals to develop and/or acquire pandemic vaccines and provide assistance in the building of necessary capacity.

Step 2: Award contracts leading to the establishment and maintenance of adequate domestic pre-pandemic and pandemic vaccine manufacturing capacity.

I. Action (HSC 6.1.11.1): HHS will assess its existing authorities and develop a plan of action to address any regulatory or other legal issues related to the expansion of domestic vaccine production capacity.

Timeframe: 12 months.

Measure of Performance: Regulatory and legal issues identified in assessment.

Step 1: Determine indemnification issues for manufacturing and usage of pandemic vaccines.

Step 2: Determine intellectual property issues for pandemic vaccine manufacturing.

J. Action (HSC 6.1.11.2): HHS will develop a protocol and decision tools to implement liability protections and compensation, as authorized by the Public Readiness and Emergency Preparedness Act (P.L. 109–148).

Timeframe: 6 months.

Measure of Performance: Publication of protocol and decision tools.

Step 1: Determine product liability relief issues for manufacturing and usage of pre-pandemic and pandemic vaccines and develop advice for usage of Public Readiness and Emergency Preparedness (PREP) Act (P.L. 109–148).

Step 2: Prepare draft declarations for pre-pandemic and pandemic scenarios.

Step 3. Prepare operational protocol and agreements with interdepartmental partners (i.e., Departments of Justice and Treasury) for utilization of PREP Act for liability immunity.

K. Action (HSC 6.1.10.2): HHS, in coordination with DHS, DOD, VA, DOC, DOJ, and Treasury, will assess whether use of the Defense Production Act or other authorities would provide sustained advantages in procuring medical countermeasures.

Timeframe: Within 6 months.

Measure of Performance: Analytical report completed on the advantages/disadvantages of invoking the Defense Production Act to facilitate medical countermeasure production and procurement.

Step 1: Determine whether usage of the Defense Production Act or other authorities facilitates the procurement of pandemic countermeasures.

Step 2: Prepare draft options paper for consideration using different pre-pandemic and pandemic scenarios.

Prioritizing, Stockpiling, and Storing Vaccines

L. Action (HSC 6.1.7.1): HHS, in coordination with DHS, DOJ, and VA, in collaboration with State, local, and tribal partners, will determine the national medical countermeasure requirements to ensure the sustained functioning of medical, emergency response, and other front-line organizations. (Also see chapter 8, Pillar One, Action W [HSC 6.1.7.1].)

Timeframe: Within 12 months.

Measure of Performance: More specific definition of sectors and personnel for priority access to medical countermeasures and quantities needed to protect those groups; advice provided to State, local, and tribal governments and to infrastructure sectors for various scenarios of pandemic severity and medical countermeasure supply.

Step 1: Collect recommendations from interdepartmental working group on mechanisms to provide options and recommendations to policymakers on pre-pandemic and pandemic vaccine prioritization.

Step 2: Disseminate priority and subpriority vaccination guidelines through public and private sector partners (Association of State and Territorial Health Officials [ASTHO], NACCHO, CSTE, Association of Immunization Managers [AIM], AMA, ACP, American Academy of Pediatrics [AAP], American Association of Family Practitioners [AAFP], American Nurses Association (ANA), and National Influenza Vaccine Summit).

M. Action (HSC 6.1.7.2): HHS will establish and maintain stockpiles of pre-pandemic vaccines adequate to immunize at least 20 million persons against influenza strains that present a pandemic threat, as soon as possible within the constraints of industrial capacity. (Also see Pillar One, Actions G, K, I, and H [HSC 6.1.10.1, 6.1.10.2, 6.1.11.1, and 6.1.16.2] above.)

Timeframe: As soon as possible.

Measure of Performance: Procurement of 20 million courses of pre-pandemic vaccine against influenza strains presenting a pandemic threat.

Step 1: Assess needs within 6 months and secure raw materials and other vaccine-related supplies.

Step 2: Award contracts for acquisition of pre-pandemic vaccines based on virus strain, vaccine type, stage of vaccine development, vaccine stockpile inventory, vaccine stability, and pandemic potential.

Step 3: Within 6 months, determine product liability relief issues for manufacturing and usage of pre-pandemic vaccines and develop advice for usage of Public Readiness and Emergency Preparedness Act (P.L. 109–148).

Step 4: Facilitate domestic pandemic vaccine surge capacity building.

Step 5: Determine whether usage of the Defense Production Act or other authorities facilitates the procurement of pandemic countermeasures.

N. Action (HSC 4.1.5.3): HHS will provide technical expertise, information and guidelines for stockpiling and use of pandemic influenza vaccines. (Also see chapter 1, Pillar One, Actions Q and R [HSC 4.1.5.3 and 4.1.6.1].)

Timeframe: 6 months.

Measure of Performance: All priority countries and partner organizations have received relevant information on influenza vaccines and application strategies.

Step 1: Assess needs with interagency panel against WHO criteria and U.S. global vaccine resources and technical expertise.

Step 2: Determine best ways to assist with available local and regional vaccine manufacturing resources.

Step 3: Provide assistance with WHO advice and in collaboration with regional partners consistent with cultural sensitivities.

Distribution of Vaccines

O. Action (HSC 6.1.13.5): HHS, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, will develop plans for the allocation, distribution, and administration of pre-pandemic vaccine. (Also see chapter 8, Pillar One, Action BB [HSC 6.1.13.5].)

Timeframe: Within 9 months.

Measure of Performance: Department plans developed and advice disseminated to State, local, and tribal authorities to facilitate development of pandemic response plans.

Step 1: Develop prioritization guidelines for allocation of pre-pandemic vaccine prior to and at the onset of a pandemic.

Step 2: Develop distribution guidelines for federally purchased pre-pandemic vaccine; guidelines must include standard commercial distribution contractors for vaccines and integrated plan for physical security measures of vaccine manufacturing facilities, distribution centers, critical suppliers, and transportation routes by multilevel law enforcement team.

Step 3: Contract distribution of pandemic vaccine with private sector distributors and other carriers.

Step 4: Institute prescribed physical security measures for vaccine manufacturing, storage, and distribution centers, critical suppliers, and transportation routes using a preset pandemic plan and multilevel law enforcement team.

P. Action (HSC 6.1.13.1): HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, will work to ensure that States, localities, and tribal entities have developed and exercised pandemic influenza countermeasure distribution plans, and can enact security protocols if necessary, according to pre-determined priorities. (Also see chapter 6, Pillar One, Action Q [HSC 6.1.13.1]; and chapter 8, Pillar One, Action X [HSC 6.1.13.1].)

Timeframe: Within 12 months.

Measures of performance: Ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed, established and validated through exercises.

Step 1: Determine capabilities needed for implementation, and develop vaccine delivery plan.

Step 2: Provide training for vaccine delivery through exercises.

Q. Action (HSC 6.1.14.1): HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOJ, DOL, VA, Treasury, and State/local governments, will develop objectives for the use of, and strategy for allocating, vaccine stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity. (Also see Pillar One, Action T [HSC 6.1.13.9] below; chapter 2, Pillar Three, Actions C [No HSC number] and D [HSC 6.1.13.9]; and chapter 6, Pillar One, Action C [6.1.14.1].)

Timeframe: Within 3 months.

Measure of Performance: Clearly stated objectives for vaccine usage under different scenarios including vaccine supply and pandemic severity.

Step 1: Review existing principles and assumptions guiding the allocation plans for pre-pandemic and pandemic vaccines.

Step 2: Provide revisions to these principles and assumptions to these allocation plans and present to working groups making recommendations to policymakers.

R. Action (HSC 6.1.14.2): HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, Treasury, and State/local governments, will identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, under various pandemic scenarios, according to strategy developed in compliance with HSC 6.1.14.1. (Also see chapter 6, Pillar One, Action N [HSC 6.1.14.2].)

Timeframe: Within 9 months.

Measure of Performance: Provisional recommendations of groups who should receive priority access to vaccines established for various scenarios of pandemic severity and medical countermeasure supply.

Step 1: Review existing allocation plans for pre-pandemic and pandemic vaccines.

Step 2: Provide options paper on revisions to these allocation plans and present to policymakers for consideration.

S. Action (HSC 6.1.14.3): HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, and VA, will establish a strategy for shifting priorities based on at-risk populations, supplies and efficacy of countermeasures against the circulating pandemic strain, and characteristics of the virus.

Timeframe: Within 9 months.

Measure of Performance: Clearly stated process for evaluation and adjustment of prepandemic recommendations regarding groups receiving prior access to vaccines.

Step 1: Review pandemic vaccination priority guidelines to divide priority groups into subgroups if possible. Given pandemic influenza vaccine may become available only over a long period of time, developing smaller priority groups appears necessary.

Step 2: Develop guidelines for estimating priority group size, to ensure consistency across States and facilitate equitable vaccine distribution and critical infrastructure workforce needs.

Step 3: Disseminate priority and subpriority vaccination guidelines through public and private sector partners.

Step 4: Establish a strategy for adjusting priorities during the course of a pandemic based on the features of the pandemic strain.

Monitoring Vaccine Efficacy, Coverage, and Adverse Events

T. Action (HSC 6.1.13.9): HHS, in coordination with DOD, and VA, in collaboration with State, territorial , tribal, and local partners, will develop/refine mechanisms to (1) track adverse events following vaccine administration; (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine effectiveness studies during a pandemic. (Also see chapter 2, Pillar Three, Action D [HSC 6.1.13.9]; and chapter 6, Pillar Three, Action C [HSC6.1.13.9].)

Timeframe: Within 18 months.

Measure of Performance: Mechanism(s) to track vaccine coverage and adverse events.

Step 1: Develop guidelines for vaccine accountability and reporting, consistent with HHS/CDC's Vaccine Management Business Improvement Project.

Step 2: Define parameters for tracking system(s) of vaccine recipients, including common variables that can be used in State-based systems and reported to HHS/CDC. This system will allow monitoring of trends and progress of the pandemic vaccination program and the appropriateness of vaccine use, and will identify problems in vaccine use to target for remedial action.

- By 2007, develop a system to collect data on pandemic influenza vaccine doses administered nationally and by State, age group, recipient (priority) group, and dose (1st or 2nd), and pilot test it in 10–15 States.
- The reporting system will use the HHS/CDC Countermeasures and Response Administration (CRA) Web-based, PHIN-certified system. Because national and State or local data and analysis needs and IT capabilities vary greatly; a single, inclusive system is not likely.
- Some States may want to use a system developed by HHS/CDC; others want a standard data set expectation with a standardized data exchange format/protocol. States may consider additional data requirements to meet their own needs.
- By 2008, complete system development and disseminate to all States.

Step 3: Develop protocol for use of population-based surveys, such as HHS/CDC's Behavioral Risk Factor Surveillance System (BRFSS), to provide national- and State-level estimates and to complement the vaccine tracking system described above.

- Define variables to be collected in surveys, such as age, gender, priority group, dose of vaccine received, where and when vaccinated, and reasons for nonvaccination, and modify the BRFSS to enable it to be quickly modified to rapidly determine vaccine coverage in key populations in the event of a pandemic
- Pilot test survey in States where vaccine tracking system is tested, to assess comparability of data collections

Step 4: Help States with tracking system plans.

Step 5: Define vaccine safety monitoring approaches through consultation with State immunization program managers to designate state-level vaccination adverse event coordinators. All adverse event systems will be examined for their ability to perform under pandemic conditions, and HHS will create a plan for coordinating the systems:

- Work with States to ensure timely reporting of adverse events to Vaccine Adverse Event Reporting System (VAERS) and other systems, and timely investigation of rare adverse events and clusters of adverse events.
- VAERS and other systems enhancements: Activation of a VAERS Emergency Preparedness Module will allow for receipt and processing of an additional 40,000 reports over a 3-month period above the annual baseline of 15,000 reports. This will be accomplished via hiring and training of additional staff by the VAERS contractor in addition to expanding and enhancing VAERS data systems.
- Consult with State immunization program managers and state adverse event coordinators (where those exist).

Step 6: Define Vaccine Safety Rapid Cycle Analysis (RCA) Program role in pandemic influenza vaccine adverse event reporting:

- Expand the Vaccine Safety Datalink (VSD) role for pandemic influenza vaccine adverse event surveillance. Currently the VSD RCA assesses data from eight Health Maintenance Organizations (HMOs) weekly for rare adverse events following immunization.
- To adequately perform surveillance for rare neurological adverse events (such as Guillain-Barre Syndrome [GBS]), this system would need to be expanded to be able to accurately and rapidly assess the risk for these events following vaccination.

Step 7: Establish real-time clinical active surveillance for select neurological adverse events (e.g., GBS):

- Assess 50 cases of clinically significant neurological complications following influenza vaccination. This pilot model of influenza vaccine safety monitoring and response system for clinically significant neurological complications can serve as an effective model for future vaccine campaigns that may occur in response to public health emergencies.
- Daily screening or review of VAERS reports and timely targeted followup of selected reports will enhance completeness and accuracy of VAERS report data.

Step 8: Develop vaccine effectiveness assessments that include, at a minimum, laboratory-confirmed emergency department visits, hospitalizations, and deaths, though not all outcomes will be assessed through all mechanisms:

- Establish mechanisms/protocol for assessing effectiveness of a pandemic influenza vaccine in preventing hospitalization and death among children and adults in HHS/CDC's NVSN

- Establish mechanism/protocol for assessing the effectiveness of a pandemic influenza vaccine in preventing hospitalizations and deaths among children and adults in the EIP sites
- Establish mechanisms in the VSD sites for vaccine effectiveness assessments in all age groups

Vaccine Education and Training

U. Action (No HSC Action): HHS will develop and implement training exercises for pandemic preparedness.

Timeframe: Within 12 months.

Measures of performance: Establish training courses and conduct training exercises on different aspects of the vaccine process.

Step 1: Specific vaccine-related training needs for pandemic influenza include those that surround the large-scale administration of a licensed or unlicensed pandemic influenza vaccine. These training efforts include activities to implement (1) vaccination clinics (clinic flow setup, vaccine storage and preparation, security requirements, client tracking/data entry, vaccine accountability); (2) Emergency Use Authorization (EUA) contingencies for administering an unlicensed or unapproved vaccine during a declared emergency; and (3) vaccine adverse event reporting.

Step 2: Define role of exercises and drills for implementing vaccination clinics. As a part of the advice that is developed for States for pandemic influenza vaccine clinic planning, exercises will be identified as a part of overall planning efforts. Within the advice, HHS/CDC will develop drill recommendations that include the following target goals (e.g., setup times, throughputs) for use in pandemic influenza clinic exercises:

- Develop vaccine adverse event reporting training materials
- Consult with public and private sector partners
- HHS/CDC will work with other Federal agencies, State immunization program coordinators, and private sector partners to establish target goals for pandemic influenza vaccination efforts and measurement indicators to assess those goals for overall preparedness assessment

Step 3: Develop materials and conduct training in a variety of formats:

- Clinic guideline development and general distribution
- Satellite broadcasts

- HHS/CDC Web site posting
- Web casts

Risk Communications and Public Information Campaigns

V. Action (HSC 6.1.12.1): HHS will collaborate with health care providers, industry partners, and State, local and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination. (Also see chapter 7, Pillar One, Action O [HSC 6.1.12.1].)

Timeframe: Within 12 months.

Measure of Performance: Domestic vaccine use increased relative to historical norms.

Step 1: Determine national influenza vaccination goals for seasonal use.

Step 2: Review capabilities needed for implementation.

Step 3: Define vaccination messages regarding rationale for priority groups, timing of vaccination, need for two doses, sites for vaccination, and importance of vaccination.

Step 4: Develop draft Vaccine Information Statements.

Pillar Two: Surveillance and Detection

Vaccine countermeasures are primarily a function of the preparedness and response components of this Plan. The results of surveillance and detection serve as a trigger for deployment of pre-pandemic and pandemic vaccine.

Pillar Three: Response and Containment

In the event of a pandemic, the expedient and seamless production of pandemic vaccine from generation and testing of influenza virus reference strains, to vaccine-manufacturing and lot-release testing, to vaccine packaging and shipment are key elements in the overall domestic pandemic response. Pillar Three actions deal with HHS facilitation of the provision of pre-pandemic and pandemic vaccines, when they become available, as part of a comprehensive response and containment effort against pandemic influenza. The transitions from the identification of clinical isolates to the ultimate shipment of finished vaccines from the vaccine distributions centers and then to the States are covered under Pillar Three. More comprehensive information for regulatory advice is provided in Appendix A—Vaccine Regulatory Guidelines.

Pillar Three actions on response and containment activities involve pandemic vaccine distribution during a pandemic (HSC 6.1.14 and 6.3.5), advice on vaccination practices (HSC 6.1.11), and the tracking of vaccine-related adverse events (HSC 6.1.13).

Leveraging National Medical and Public Health Surge Capacity

A. Action (HSC 6.3.5.3): HHS, in coordination with DHS, will allocate and assure the effective and secure distribution of public stocks of antiviral drugs and vaccines when they become available. HHS and DHS are currently prepared to distribute stockpile as soon as countermeasures become available.

Timeframe: As required and dependent on availability.

Measure of Performance: Number of doses of vaccine and treatment courses of antiviral medications distributed.

Step 1: Implement plan to monitor vaccine distribution.

Step 2: Collect data on monitoring vaccine distribution.

Step 3: Revise distribution plans of medical countermeasures according to pandemic severity, outbreak sites, countermeasure availability, and data gathered on virus behavior and pathogenic characteristics.

B. Action (no HSC action): HHS provides a roadmap for obtaining the needed information for the efficient submission of high quality Investigational New Drug applications (INDs), Emergency Use Authorization (EUAs), and Biologics License Applications (BLAs) for pandemic influenza vaccines.

Timeframe: Within 6 months.

Measure of Performance: Development of web-based interface reflecting this roadmap for vaccine manufacturers and other HHS agencies.

Step 1: Initiate development (pre-IND meetings and IND submissions).

Step 2: License vaccine, including accelerated approval (Draft Guidance for Industry, Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines, http://www.fda.gov/cber/gdlns/panfluvac.pdf).

Step 3: Fast track designation (Guidance for Industry, Fast Track Drug Development Programs—Designation, Development, and application review http://www.fda.gov/cber/gdlns/fsttrk.pdf).

Step 4: Obtain FDA advice on chemistry, manufacturing, and controls (CMC) and manufacturing facilities through meetings and other resources (Guidance for

Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product http://www.fda.gov/cber/gdlns/cmcvacc.pdf).

Step 5: Obtain FDA advice on EUA (Draft Guidance on Emergency Use Authorization of Medical Products http://www.fda.gov/oc/bioterrorism/emergency_use.html).

C. Action (HSC 6.1.13.10): HHS, with other federal departments, will work with DOJ to develop a joint strategic plan to ensure international shipments of counterfeit vaccine and antiviral medications are detected at our borders and that domestic counterfeit drug production and distribution is thwarted through aggressive enforcement efforts. (Also see chapter 1 Pillar One, Action V [HSC 6.1.13.10]; and chapter 6, Pillar Three, Action E [HSC 6.1.13.10].)

Timeframe: Within 3 months.

Measure of Performance: Joint strategic plan developed; international and domestic counterfeit drug shipments prevented or interdicted.

Step 1: Investigate reports of counterfeit drugs used for pandemic treatment or prophylactic purposes and prosecute cases as evidence warrants.

Step 2: Investigate reports of counterfeit vaccines used, and prosecute cases as evidence warrants.

Step 3: Use authorities and prescribed plans to remedy the illegal distribution of medical countermeasures.

D. Action (No HSC Action): HHS will select a pandemic virus isolate for virus reference strain production, construct, qualify, and ship pandemic virus reference strain to vaccine manufacturers.

Timeframe: Within 6 weeks of pandemic declaration.

Measure of Performance: Test exercise to determine operational status.

Step 1: Perform antigenic and genetic analyses to aid in the selection of appropriate pandemic virus reference strain(s).

Step 2: Conduct reverse genetic procedures:

- Good Laboratory Practice (GLP) protocols and standard operating procedures will be followed.

- Laboratory studies will be performed under enhanced Bio-Safety Level 3 (BSL3) conditions and facilities by personnel wearing protective equipment including Powered Air Purifying Respirators (PAPRs).
- Vero cells from a vaccine-qualified master cell bank should be used to recover viruses by plasmid transfection.
- The antigenic properties of the reference virus should be assessed and shown to be identical to that of the wild type virus from which the haemagglutinin (HA) and the neuraminidase (NA) segments were obtained.
- The nucleotide sequence of the HA and NA genes of the reference virus should be determined and should be compared with the sequence of the respective clones and of the genes from the original wild-type virus. Any differences should be noted. An assessment of the level of residual plasmid in the reference virus should be made using PCR technology.
- The virus titer should be determined in the appropriate substrate (eggs or Madin-Darby Canine Kidney cells).
- Absence of bacterial and/or fungal contamination will be established by culturing.

Step 3: Conduct safety testing of resulting vaccine reference viruses.

Step 4: Request USDA exemption of the reference virus from the Select Agent List by providing the following information:

- Data regarding the source of the viruses and genes; complete nucleotide sequence of the HA
- Pathogenicity testing results in chickens, per OIE standards
- Trypsin dependence of plaque formation by the reassortant in chicken embryo fibroblasts cell mono-layers

Step 5: Transfer of vaccine reference virus via USDA transport permit to vaccine manufacturers.

E. Action (No HSC Action): HHS will provide pandemic vaccine to store and distribute pandemic vaccines. (Also see Pillar One, Action O [HSC 6.1.13.5] above.)

Timeframe: Within 6 months.

Measure of Performance: Creation of the plan and training exercise of plan.

Step 1: Contract storage and stability testing of pandemic vaccine as needed at vaccine manufacturers and other designated sites.

Step 2: Contract distribution of pandemic vaccine with private sector distributors and other carriers.

Step 3: Institute prescribed physical security measures for vaccine manufacturing, distribution centers, critical suppliers, and transportation routes using pandemic plan and multilevel law enforcement team.

F. Action (No HSC Action): HHS will develop a plan to coordinate delivery of pandemic vaccine to designated sites within 12 months upon consultation with NVPO/HHS, OPHEP/HHS, State, local, and tribal public health departments. (Also see Pillar One, Action P [HSC 6.1.13.1,] and Pillar Three, Action A [HSC 6.3.5.3] above.)

Timeframe: Within 12 months.

Measure of Performance: Issuance of a vaccine delivery plan.

Step 1: Review and revise vaccination clinic guidelines using those developed in 2004 during the influenza vaccine shortage:

http://www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf.

- Consult with public and private sector health leaders.
- Although the Public Health Service Act authorizes HHS to provide vaccines to States, it does not authorize HHS to provide vaccines directly to private entities. The Department would need new statutory authority to do the latter.

Step 2: Finalize pandemic vaccine delivery plan.

Step 3: Provide training for vaccine delivery through exercises.

G. Action (HSC 6.1.14.4): HHS, in coordination with DHS and Sector-specific agencies, DOS, DOD, DOL, VA, and Treasury, will present recommendations on target groups for vaccine and anti-viral drugs when sustained and sufficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. The recommendations will reflect data from the pandemic and available supplies of medical countermeasures. (Also see chapter 6, Pillar Three, Action B [HSC 6.1.14.4].)

Timeframe: Within 2–3 weeks of outbreak.

Measure of Performance: Provisional identification of priority groups for various pandemic scenarios.

Step 1: Assist in the assessment of global needs and available resources globally and domestically.

Step 2: Provide recommendations on plans to assist and allocate available domestic resources.

H. Action (No HSC Action): HHS will review, revise, and implement tracking plan to monitor pandemic vaccination in consultation with vaccine manufacturers, vaccine distributors, and State immunization program managers. (Also see Pillar One, Action T [HSC 6.1.13.9] above; and chapter 2, Pillar Three, Action D [HSC 6.1.13.9].)

Timeframe: 12 months.

Measure of Performance: Completion of the vaccination monitoring plan.

Step 1: Implement vaccine effectiveness assessments among NVSN/EIP/VSD sites or other settings as feasible, depending on timing and spread of pandemic influenza and vaccine availability.

Step 2: Implement survey periodically (e.g., at least monthly) for reporting results in HHS/CDC's Epi-X and Morbidity/Mortality Weekly Report. The survey may be an expansion of the existing BRFSS or a separate focused survey using BRFSS infrastructure. In addition, use of followup surveys in which particular groups of respondents are identified during the BRFSS survey and followed up with a more extensive set of health surveillance questions at a later date is a potentially efficient means of expanding the utility of the current system.

I. Action (No HSC Action): HHS will develop plans for communications of vaccines and their usages, priorities, and limitations. (Also see Pillar One, Action Q [HSC 6.1.14.1] above.)

Timeframe: Within 6 months.

Measure of Performance: Issuance of vaccine communication plan.

Step 1: Develop a communications plan on pre-pandemic and pandemic vaccine production and vaccine's allocation, distribution, and usage.

Step 2: Review and revise vaccination messages regarding rationale for priority groups, timing of vaccination, need for two doses, sites for vaccination, and importance of vaccination.

Step 3: Develop Vaccine Information Statements.

Appendix 5–A: Vaccine Regulatory Guidelines

Vaccine regulatory issues: investigational new drug usage, emergency use authorization, and licensure. Particular regulatory approaches utilized depend on whether a pandemic were to occur now, next year, or several years from now. Approaches would reflect the availability of approved and investigational vaccines and the characteristics of circulating and emerging viruses. For all of the mechanisms of expedited/facilitated development or access, early and frequent interactions between the vaccine manufacturer/sponsor (government or commercial) and FDA are of the highest importance.

Emergency Use Authority

- During an emergency declared by the HHS Secretary, FDA may authorize the use of an unapproved vaccine or an unapproved use of an approved vaccine if certain legal requirements are met.
- If a declared emergency occurs before a vaccine development process is completed and alternatives are lacking, and in particular, if the vaccine appears sufficiently promising that the SNS might consider acquiring it for investigational use, then appropriate Government agencies and sponsors should focus on ensuring that complete data are rapidly provided to FDA to support issuance of an EUA.
- Data can be provided through pre-IND or IND submissions and discussion of ongoing and future development plans, as far in advance of need as possible.
- FDA would then assess whether the data would potentially support an EUA and provide advice on any additional studies and data that may be desirable both for further development and to support emergency use as warranted.
- Analysis of whether the available data and information support issuing an EUA if requested for temporary use in a declared emergency, and the timeframe in which this could be done, may depend on multiple factors such as the adequacy of data provided in advance, including the evidence for safety and immunogenicity/efficacy and the nature of the emergency.
- Therefore, advance submission and discussion of information from completed studies and plans for additional studies will be critical to minimizing the time required for additional evaluation after onset of an emergency, but the final determination regarding whether the criteria for issuance of an EUA are met can only be made after an emergency is declared.
- The Secretary of HHS may declare an emergency, justifying an EUA if he determines that a public health emergency exists that affects or has the significant potential to affect national security.

- The FDA Commissioner may issue an EUA if, after consulting with the Directors of NIH and CDC (to the extent feasible and appropriate), he concludes that it is reasonable to believe that the product may be effective; the known and potential benefits outweigh the known and potential risks of using the product; and there is no adequate, approved, and available alternative.
- FDA shall, to the extent practicable given the circumstances of the emergency, impose certain conditions on an EUA for an unapproved product and an EUA for an unapproved use of an approved product, and may impose certain other conditions.

Biologics License Application (BLA) Licensure Issues

- Currently there are no U.S. licensed influenza vaccines approved for pandemic avian influenza strains. FDA has stated on numerous occasions, and as recently as the November 29–30, 2005, National Vaccine Advisory Committee meeting, that for licensed manufacturers of interpandemic vaccines, use of a pandemic strain—for example, H5—would not require a new BLA, and in the setting of an evolving pandemic threat or actual pandemic, would be evaluated in an expedited manner as a strain change prior approval supplement to an approved BLA.
- License supplement would require information on the manufacturing of the strain and limited clinical data—for example, immunogenicity and safety data. In an emergency situation, depending on the quality of the data, FDA's review would be completed in an expedited manner.
- If the pandemic were to occur prior to licensure of a vaccine against the pandemic strain, or at a time when an investigational vaccine has advanced to the stage of human clinical trials under IND, but sufficient data have not yet been accumulated to support licensure of a BLA, there are several potential mechanisms FDA can use to facilitate the rapid access to these products, depending on the amount and quality of data submitted to the FDA for review.
- Adjuvant, cell-culture-based, and other new technologies would be considered a new product and, thus, would require the submission of a new BLA by all manufacturers, regardless of whether they are currently licensed to manufacture an egg-based influenza vaccine.
- If adjuvants are shown to be useful in dose sparing and added to candidate pandemic vaccines, this would significantly change the manufacturing process and the product itself, requiring immunogenicity and safety data and submission of a new BLA.
- Under accelerated approval the BLA would require manufacturing, safety, and immunogenicity data, as well as post-licensure confirmatory clinical studies.

- A pandemic influenza vaccine would be designated for a priority review during the interpandemic period. The unlicensed product could also potentially be made available through an IND or EUA.
- New and non-U.S. licensed influenza vaccine manufacturers' submission of a BLA for licensure of a pandemic influenza vaccine, regardless of the technology, (e.g., egg-based, tissue culture-based, recombinant) is required now and in the future.
- Under accelerated approval, BLA requires manufacturing and facility data as well as safety and immunogenicity data and post-licensure confirmatory clinical studies. FDA would consider data from clinical studies and use under licensure (for safety) in other countries in support of U.S. licensure along with safety and immunogenicity data for accelerated approval, but the data must support safety and effectiveness of the vaccine.
- Some technologies may not be appropriate for accelerated approval (e.g., a peptide conjugate vaccine where there is not a marker for protection). In the event of a pandemic, the review time could be significantly shortened depending on the quality of the data. The unlicensed product could also be made available through an IND or EUA.

Appendix 5–B: Vaccine Virus Reference Strain Development, Production, and Qualification

Inactivated influenza vaccines are produced from seed virus that exploits the extraordinary growth efficiency in embryonated chicken eggs conferred by the A/Puerto Rico/8/1934 (PR8) internal genes. Reassortants with the PR8 internal genes and the HA and NA surface protein coding genes from the novel potentially pandemic strain will be generated in the laboratory following WHO-sanctioned protocols and Good Laboratory Practice, which streamline downstream adventitious agent testing. The virus reference stock will be transferred to vaccine manufacturers. Live, attenuated vaccines are produced similarly using plasmids encoding target HA and NA genes of pandemic virus and donor genes containing mutations for temperature-sensitive and attenuation phenotypes.

The reverse genetics procedures will be performed as described in the WHO documents entitled *WHO Guidance on Development of Influenza Vaccine Reference Viruses by Reverse Genetics* http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_6/en/index.html. The process of virus rescue by reverse genetics requires 21 days. Subsequent production of virus stock and titration requires 4 days.

The safety of the resulting vaccine reference viruses will be tested according to the established WHO guidelines as described in *Production of Pilot Lots of Inactivated Influenza Vaccines from Reassortants Derived from Avian Influenza Viruses: An Interim Biosafety Risk Assessment* http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2003_5/en/. All work with highly pathogenic avian influenza virus and their derivatives is regulated by the USDA Select Agents Program. Because removal of the polybasic amino acids from HA and re-assortment with PR8 results in loss of virulence and transmissibility in poultry, the USDA Select Agent Program is willing to review experimental evidence to this effect for each reference strain and remove it from the list if deemed safe. The reassortants that were excluded from the Select Agent regulations by USDA and meet the safety criteria of the 2003 WHO document will be made available to vaccine manufacturers for production of pilot lots of vaccine for experimental use and clinical studies.

Contents

CHAPTER 6: ANTIVIRAL DRUGS

Introduction

FDA-approved antiviral drugs with activity against influenza viruses ("antivirals") include the M2-inhibitors adamantanes (*amantadine* and *rimantadine)* and the neuraminidase inhibitors (*oseltamivir phosphate* [Tamiflu®] and *zanamivir* [Relenza®]). Appropriate use of these agents during an influenza pandemic may reduce morbidity and mortality, and may diminish the overwhelming demands that will be placed on the health care system. Antivirals might also be used during the U.S. Response Stages 0, 1, and 2 for limited attempts to contain small disease clusters and potentially slow the spread of novel influenza viruses. A huge and uncoordinated demand for antiviral drugs early in a pandemic could rapidly deplete local and national supplies. It could also facilitate the emergence of antimicrobial resistance. Preparedness planning for the optimal use of antiviral stocks is therefore essential.

This chapter focuses on one specific pharmacologic countermeasure—antivirals—rather than a broad range of potential interventions for pandemic influenza. It discusses all aspects of the development, allocation, use, and monitoring of antiviral drugs. Therefore, the chapter is organized slightly differently from the other chapters and includes activities arranged chronologically from product concept and development, to the monitoring for efficacy and side effects of antiviral drugs administered for prophylaxis and treatment.

Antiviral drug focus areas relative to pandemic planning and response include the following:

- The detection of antiviral resistance in pre-pandemic and pandemic influenza viruses
- The applicability and linkage of influenza antiviral drug development and clinical evaluation for a pandemic situation, and maintenance of pre-pandemic drug stockpiles
- The global and domestic manufacturing capacity of antiviral drugs used for prevention and/or treatment of pre-pandemic and pandemic influenza virus infections
- The regulatory review processes for, and approval of, new antiviral drugs during pre-pandemic and pandemic periods
- The procurement, staging, and positioning of antiviral drug stockpiles during pre-pandemic and pandemic periods
- The prioritization and allocation strategies of antiviral drug usage during the pre-pandemic and pandemic periods

- The mechanisms for distribution of antiviral drug stockpiles during pre-pandemic and pandemic periods
- The evaluation of the efficacy of antiviral drugs against a pandemic strain as well as any associated adverse side effects
- The communication of antiviral drug policies and implementation actions
- The use of antivirals as part of an overall pandemic containment strategy

The actions covered by this operational plan on antiviral drugs include preparations prior to, at the onset of, and during an influenza pandemic.

Role of HHS in Antiviral Drugs

HHS' role with respect to antiviral drugs is to facilitate the development and use of these countermeasures during a pandemic. Specifically, HHS will:

- Establish and maintain antiviral stockpiles
- Support research projects to optimize dosing strategies for existing antiviral medications, identify novel drug targets, and develop compounds that inhibit viral entry, replication, and maturation
- Develop guidelines to assist State and local governments and other partners and stakeholders in defining groups that should have priority access to antivirals
- Monitor activities involved in the production and distribution of counterfeit antiviral drugs

Specific Assumptions and Planning Considerations for Antiviral Drugs

- The preparedness and response goal is to provide influenza antiviral drugs for at least 25 percent of the U.S. population.
- During the pre-pandemic period, HHS stockpiles of oseltamivir phosphate and zanamivir will be needed to reach a total of at least 81 million treatment courses for use in pandemic treatment by the States. The maintenance of a stockpile of adamantane class drugs will also be needed in the event a pandemic influenza virus is shown to be sensitive to this class of drugs.
- HHS will subsidize the purchase by the States of up to 31 (of the 81) million treatment courses of oseltamivir phosphate and zanamivir on a *pro rata* basis. The Federal direct purchase and Federal-subsidized purchases by the States of influenza antiviral drugs for pandemic purposes will provide coverage for 25 percent of the U.S. population, as recommended by WHO.
- At the beginning of a pandemic in the United States, the initial HHS strategy will be to delay the spread of pandemic via the rapid deployment of an additional 6 million treatment courses from the SNS for treatment and prophylaxis of contacts of confirmed cases in specific community outbreaks.
- As the pandemic progresses, antiviral drugs will be distributed *pro rata* to States primarily for medical treatment of infected persons presenting with disease symptoms.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

Preparedness and communication as related to antiviral drugs include activities such as supporting novel research (including clinical trials) for new drugs, increasing capacity for manufacturing, facilitating antiviral drug approval, determining product assets for stockpiling, considering expansion of the Shelf Life Extension Program (SLEP), and developing Federal communications statements on antiviral use policies and recommendations for usage.

HHS actions in this chapter are intended to integrate the HSC actions and expectations concerning antiviral use during an influenza pandemic into a comprehensive domestic and global antiviral effort to include antiviral use coordination (HSC 4.1.6), planning (HSC 6.1.1), communications (HSC 6.1.3), stockpiling (HSC 6.1.5, 6.1.6, 6.1.7, 6.1.9), distribution mechanisms and allocations (HSC 6.1.13, 6.1.14), and novel strategies for development (HSC 6.1.17).

Antiviral Drug Development

A. Action (HSC 6.1.17.2): HHS shall collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), approval, and U.S.-based production of new antiviral drugs and diagnostics. Development activities should include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations should involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways towards product approval. Collaborations concerning diagnostic tests should include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. (Also see chapter 2, Pillar One, Action F [HSC 6.1.17.2].)

Timeframe: Within 6 months.

Measure of Performance: Initiation of clinical trials of new influenza antiviral drugs and diagnostics.

Step 1: Contract with manufacturers and research laboratories to support discovery, development, and preclinical and clinical evaluation of new antiviral drugs and new formulations of currently approved products; including the development of new formulations for special populations, such as infants and young children or elderly patients who cannot swallow solid oral dosage forms.

Step 2: Support clinical evaluation through the development of a clinical trial infrastructure on diagnostics, therapeutics, and natural history of avian influenza and other emerging infectious diseases.

Step 3: Contract with manufacturers and research laboratories to evaluate toxicology, pharmacokinetics, (including human challenge studies with a seasonal influenza strain), and effect of agents with antiviral potential in animal models; and, where appropriate, include potential for sublicensure from manufacturers of approved drugs.

Step 4: Ensure that results from Government-supported trials are expeditiously shared with Federal partners and submitted for publication, if appropriate.

Step 5: Evaluate initial components and activities that can be performed in the initial timeframe and ensure ongoing commitment to support and followup.

B. Action (No HSC Action): HHS will facilitate the expansion of domestic antiviral drug manufacturing capacity within 12 months.

Timeframe: Within 12 months.

Measure of Performance: The award of contracts for advanced development and U.S.-based production of new antiviral drugs and the encouragement of U.S.-based production of currently approved products acquired for the Strategic National Stockpile to expand the domestic antiviral drug manufacturers' capacity in the U.S.

Step 1: Engage current manufacturers of antiviral agents to expand domestic production.

Step 2: Award contracts for the advanced development toward U.S. approval and production of new antiviral medications.

Step 3: Identify mechanisms, including potential for sublicensure from manufacturers of approved drugs, if needed, to permit other manufacturers to produce proprietary antiviral agents.

C. Action (No HSC Action): HHS will conduct and provide advice for, respectively, clinical studies to evaluate the safety and efficacy of new antiviral agents or new formulations of existing agents to accelerate approval.

Timeframe: Within 6 months.

Measure of Performance: Publication of regulatory guidance and the initiation of collaborative clinical trials for evaluation of new influenza antiviral drugs.

Step 1: Enhance and expand collaborations with biotech and pharmaceutical companies for clinical evaluation of existing and new antiviral drugs.

Step 2: Enhance communication between FDA regulators and biotech and pharmaceutical companies evaluating existing and new antiviral drugs.

Step 3: Develop clinical protocols to test antiviral agents for safety and efficacy during the interpandemic period.

Step 4: Conduct clinical studies to assess prophylactic and therapeutic uses.

Step 5: Evaluate initial components and activities that can be performed in the initial timeframe and ensure ongoing commitment to support and followup.

Step 6: Encourage the development of new formulations for special populations, such as infants and young children, or elderly patients who cannot swallow solid oral dosage forms.

D. Action (HSC 6.1.15.3): HHS shall develop protocols and procedures to ensure timely reporting to federal agencies and submission for publication of data from HHS-supported influenza vaccine, antiviral medication, and diagnostic evaluation studies. (Also see chapter 2, Pillar One, Action D [HSC 6.1.15.3] regarding surveillance; and chapter 5, Pillar One, Action E [HSC 6.1.15.3].)

Timeframe: Within 6 months.

Measure of Performance: Study data shared with federal agencies within 1 month of analyses and publication of clinical trial data following completion of studies.

Step 1: Prepare procedures and plans to select and secure appropriate materials.

Step 2: Prepare database with previously reported pandemic information from clinical trials and other research venues.

E. Action (HSC 4.1.6.2): HHS, in coordination with the WHO Secretariat, will establish at least six new sites for Collaborative Clinical Research on Emerging Infectious Diseases to conduct collaborative clinical research on the diagnostics, therapeutics, and natural history of avian influenza and other human emerging infectious diseases. In addition, HHS will provide in-country support for one or more partner countries for human avian influenza clinical trials. (Also see chapter 1, Pillar One, [HSC 4.1.6.2]; and chapter 5, Pillar One, Action C [HSC 4.1.6.2].)

Timeframe: Within 18 months.

Measure of Performance: Cooperative programs established in six new sites, to include the initiation of research protocols and design of clinical trials.

Within the framework of supporting pharmacokinetic, animal model, and clinical studies to evaluate optimal dosing, treatment duration, and combinations of licensed antiviral medications for H5N1 and other potential pandemic strains, HHS will:

Step 1: Solicit proposals and support contracts for pharmacokinetic, animal, and clinical studies of optimal use of existing antiviral drugs for H5N1 and other potential pandemic strains.

Step 2: Award contracts to provide pharmacokinetic data and establish animal models and conduct clinical studies to evaluate antiviral drugs.

Step 3: Facilitate evaluation of current antiviral medications as treatment and prophylaxis for H5N1 and circulating influenza using a new clinical trials infrastructure with collaborative study sites in Asia.

Antiviral Drug Production, Stockpiling, and Storage

F. Action (HSC 6.1.6.1): HHS, with VA and DOD, will define quantities of specific U.S.-approved antiviral medications to include in national and state stockpiles consistent with the national pandemic response strategy, and develop and disseminate guidelines for their use during pre-pandemic and pandemic periods. (Also see chapter 4, Pillar One, Action D [HSC 6.1.6.2].)

Timeframe: Within 6 months.

Measure of Performance: Development of policy concerning selection, relative proportions, and use of antivirals in SNS and State stockpiles.

G. Action (HSC 6.1.13.2): HHS, in coordination with DOD, VA, States, and other public sector entities with antiviral stockpiles, will coordinate use of assets maintained by different organizations. (Also see chapter 8, Pillar One, Action Y [HSC 6.1.13.2].)

Timeframe: Within 12 months.

Measure of Performance: Plans developed for coordinated use of antiviral stockpiles.

H. Action (HSC 6.1.9.1): HHS will, to the extent feasible, work with antiviral drug manufacturers and large distributors to develop agreements supporting Federal procurement of available stocks of antiviral drugs during pre-pandemic and pandemic periods.

Timeframe: Within 12 months.

Measure of Performance: New antivirals procured by SNS within the constraints of industry capacity; Federal contracts in place with antiviral drug manufacturers and distributors.

I. Action (HSC 6.1.9.2): HHS, in collaboration with the States, will purchase sufficient quantities of antivirals to treat 25% of the U.S. population with reserve of 6 million treatment courses for outbreak containment.

Timeframe: Within 18 months.

Measure of Performance: 50 million treatment courses of antiviral drugs procured by SNS: States and tribes make stockpile purchases toward aggregate 31 million treatment course goal.

J. Action (HSC 6.1.7.3): HHS in collaboration with State/local partners shall procure and allocate sufficient stockpiles of countermeasures to ensure continuity of critical medical and emergency response operations.

Timeframe: Within 18 months.

Measure of Performance: Sufficient quantities of antiviral medications and other countermeasures procured and distributed between SNS and State stockpiles.

K. Action (HSC 6.1.5.1): HHS will encourage and subsidize the development of State, territorial, and tribal antiviral stockpiles to support response activities. (Also see chapter 8, Pillar One, Action U [HSC 6.1.5.1].)

Timeframe: Within 18 months.

Measure of Performance: State, territorial and tribal stockpiles of antiviral medication established and antiviral medical purchases made toward goal of aggregate 31 million treatment courses.

The following steps will be undertaken to address Actions F–K:

Step 1: Develop overall policy for national strategy with Federal partners and State, local, and tribal stakeholders consistent with the national strategy to acquire sufficient antiviral medications to treat 25 percent of the U.S. population and to contain initial U.S. pandemic outbreaks, establish an interagency working group to develop specific policies and recommendations for antiviral medications to include in national and state stockpiles.

Step 2: Develop integrated procurement plan for antiviral stockpiles consistent with interagency guidelines and manufacturers' capabilities.

Step 3: Disseminate advice for State antiviral stockpile purchases including information on Federal cost sharing.

Step 4: Negotiate and complete purchase contracts with manufacturers including ability for Federal and State purchases to be made under the Federal contracts.

L. Action (HSC 6.1.6.4): HHS, in coordination with DOD, VA and the States will maintain antiviral and vaccine stockpiles in a manner consistent with the requirements of FDA/DOD SLEP and explore the possibility of broadening SLEP

to include equivalently maintained State stockpiles. (Also see chapter 8, Pillar One, Action V [HSC 6.1.6.4].)

Timeframe: Within 6 months.

Measure of Performance: Compliance with SLEP requirements documented; decision made on broadening SLEP to State stockpiles.

Step 1: Include all currently approved antiviral drugs that are maintained in the SNS in SLEP. As needed, work with manufacturers to change the label to facilitate SLEP compliance.

Step 2: In collaboration with State and local health authorities, determine whether to extend SLEP to State and local stockpiles.

Step 3: If SLEP is extended to State and local stockpiles, develop and disseminate advice for compliance with SLEP requirements.

Antiviral Prioritization and Distribution

M. Action (HSC 6.1.14.1): HHS in coordination with DHS and Sector-Specific Agencies, as well as DOS, DOD, DOJ, DOL, VA, Treasury, and State/local governments, develop objectives for the use of and strategy for allocating vaccine and antiviral drug stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity.

Timeframe: Within 3 months.

Measure of Performance: Clearly articulated statement for objectives of use of medical countermeasure under varying conditions of supply and pandemic severity.

N. Action (HSC 6.1.14.2): HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, Treasury, and State/local governments, shall identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, under various pandemic scenarios. (Also see chapter 5, Pillar One, Action R [HSC 6.1.14.2].)

Timeframe: Within 9 months.

Measure of Performance: Provisional recommendations of groups who should receive priority access and antiviral drugs established for various scenarios of pandemic severity and medical countermeasure supply.

The following steps will be undertaken to address Actions M and N:

Step 1: Establish an interagency working group to review clinical data, animal studies, and mathematical models relevant to potential antiviral drug strategies and impacts.

Step 2: Develop and disseminate advice on antiviral drug use objectives and strategies.

Step 3: Define potential priority groups for antiviral therapy in the event of limited or inadequate antiviral drug supply, including specific critical sectors and functions within sectors that need to be maintained.

Step 4: Collaborate with State and local health authorities and private sector partners to develop and disseminate advice for dispensing antiviral drugs consistent with objectives and strategies, including addressing potential legal barriers to dispensing strategies.

Step 5: Develop and disseminate advice on a strategy to rapidly review objectives, strategies, and target groups at the time of a pandemic and propose necessary changes.

O. Action (HSC 6.1.13.4): HHS, in coordination with DOD, VA, and in collaboration with State, local, and tribal governments and private sector partners, will assist in the development of distribution plans for medical countermeasures stockpiles to ensure that delivery and distribution algorithms have been planned for each locality for antiviral distribution. The goal is to distribute antiviral medications to infected patients within 48 hours of onset of symptoms. (Also see chapter 8, Pillar One, Action AA [HSC 6.1.13.4].)

Timeframe: Within 12 months.

Measure of Performance: Distribution plans developed.

Step 1: Determine the needs and available resources afforded by current Federal, State, local, and tribal plans for antiviral drug distribution.

Step 2: Develop a coordinated plan that meets overall Federal strategy.

Step 3: Remedy deficiencies in existing distribution plans to mesh with coordinated plans.

Step 4: Develop a unit of use packaging to improve efficiency of the initial dispensing operations.

P. Action (HSC 6.3.5.3): HHS, in coordination with DHS, will allocate and assure the effective and secure distribution of public stocks of antiviral drugs and vaccines when they become available. (Also see chapter 5 [Vaccines].)

Timeframe: As required and dependent on availability.

Measure of Performance: Number of doses of vaccine and treatment courses of antiviral medications distributed. HHS and DHS are currently prepared to distribute stockpiles as soon as countermeasures become available.

Step 1: Assess the security and availability of antiviral distribution plans for Federal and State stockpiles.

Step 2: Create or revise plans to remedy deficiencies including distribution network.

Antiviral Drug Training and Communication

Q. Action (HSC 6.1.13.1): HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, will ensure that States, localities, and tribal entities have developed and exercised pandemic influenza countermeasures distribution plans, and can enact security protocols if necessary, according to predetermined priorities. (Also see chapter 5, Pillar One, Action P [HSC 6.1.13.1]; and chapter 8, Pillar One, Action X [HSC 6.1.13.1]).

Timeframe: Within 12 months.

Measure of Performance: Ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed established and validated through exercises.

Step 1: Determine size, number, and location of storage facilities and develop plan for pre-pandemic storage and product stability testing.

- Consult with pharmaceutical manufacturing and distributors industry, State and local public health departments on the possible storage facilities and storage requirements.
- Develop agreements/contracts with relevant storage facilities to include appropriate physical security measures.

Step 2: Develop distribution guidelines for stockpiles of influenza antiviral drugs that may include standard commercial distribution contractors.

Step 3: Develop an integrated plan for physical security measures of domestic antiviral drug manufacturing facilities, distribution centers, stockpiles facilities, critical suppliers, and transportation routes by multi-level law enforcement team.

Step 4: Award contracts to private distributors to transport antiviral drugs to States prior to pandemic with built-in redundancy based on severe-case pandemic scenarios.

Step 5: Ensure compliance of storage facilities with Federal regulatory requirements for storage and monitoring of approved pharmaceutical products.

R. Action (HSC 6.1.3.1): HHS, in coordination with DHS, DOS, DOD, VA, and other Federal partners, will develop, test, and implement a Federal Government public health emergency communications plan (describing the government's strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the government believes will be effective as well as those it regards as likely to be ineffective, excessively costly, or harmful). (Also see chapter 2, Pillar One, Action M [No HSC number].)

Timeframe: Within 6 months.

Measure of Performance: Containment strategy and emergency response materials completed and published on http://www.pandemicflu.gov; communications plan implemented.

Step 1: Review and revise antiviral drug prophylaxis and treatment messages regarding rationale for priority groups, timing of usage, definition of prophylaxis and treatment courses, sites for antiviral drug deployment, and importance and limitations of antiviral drugs.

Step 2: Develop Antiviral Drug Information Statements.

Pillar Two: Surveillance and Detection

Antiviral drug countermeasures are primarily a function of the preparedness and response components of this Plan. Surveillance and detection are critical to identify the onset of a pandemic and its introduction into the United States, as in each situation, antiviral drugs will be deployed as one tool of a containment response. Surveillance and epidemiological investigation will also provide data that will be critical to review and potentially revise antiviral drug use strategies.

Pillar Three: Response and Containment

HHS is responsible for containment activities using antiviral drugs including identifying (based on scientific data) priority groups to receive antiviral drugs, allocating and

delivering the antiviral drugs, communicating critical information, and monitoring the effects of the antiviral drugs in the population.

Pillar Three HHS actions listed in this chapter are intended to integrate the HSC actions and expectations concerning antiviral distribution from the SNS and other distribution centers to Federal, State, local, and tribal authorities (HSC 6.3.5).

A. Action (HSC 6.3.5.2): HHS, in collaboration with State, local and tribal governments, will develop and disseminate recommendations for the use, if any, of antiviral stockpiles for targeted post-exposure prophylaxis in civilian populations.

   Timeframe: Within 3 months.

   Measure of Performance: States, localities, and tribal entities have received recommendations for incorporation into response plans.

   Step 1: Allocate and distribute antiviral drugs from the SNS to support containment activities, if any, based on pre-pandemic planning.

   Step 2: Monitor antiviral drug distribution and dispensing.

B. Action (HSC 6.1.14.4): HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, and Treasury, will present recommendations on target groups for vaccine and antiviral drugs when sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures. (Also see chapter 5, Pillar Three, Pillar G [HSC 6.1.14.4].)

   Timeframe: Ongoing coordination.

   Measure of Performance: Provisional identification of priority groups for various pandemic scenarios through interagency process within 2–3 weeks of outbreak.

   Step 1: Assist in the assessment of global needs and available resources globally and domestically.

   Step 2: Provide recommendations on plans to assist and allocate available domestic resources.

C. Action (HSC 6.1.13.9): HHS, in coordination with DOD, VA, and in collaboration with State, territorial, tribal, and local partners, will develop/refine mechanisms to: (1) track adverse events following antiviral administration: (2) define protocols for conducting antiviral-effectiveness studies during a

pandemic. (Also see chapter 2, Pillar Three, Actions C and D [No HSC numbers]; and chapter 5, Pillar One, Action T [HSC 6.1.13.9].)

Timeframe: Within 18 months.

Measure of Performance: Mechanism(s) to track antiviral medication coverage and adverse events developed; antiviral medication coverage and adverse events developed; antiviral-effectiveness study protocols developed.

Step 1: Analysis of pandemic surveillance data and implement/communicate prophylaxis and treatment priority guidelines based on epidemiology of pandemic disease on a monthly or as needed basis during a pandemic. Antiviral drug use strategies will be revised as needed, as the pandemic progresses, to include:

- Review the epidemiology of initial pandemic influenza outbreaks including any available data on the effectiveness of antiviral drug treatment and prophylaxis and antiviral resistance
- As needed, revise advice on antiviral drug use to optimize the pandemic response
- Coordinate rapid disseminated revised advice through public and private sector partners (e.g., ASTHO, NACCHO, CSTE, AIM, AMA, ACP, AAP, AAFP, American Nurses Association (ANA), and National Influenza Vaccine Summit)

Step 2: Coordinate with VA, DOD, and State and local health departments to monitor the dispensing and impacts of influenza antiviral drugs during a pandemic within 1 month of the onset of a pandemic in the United States; by publishing a plan for coordination identifying the roles and responsibilities of each entity for the successful tracking, reporting, and utilization of gathered results to inform revision of antiviral drug strategies during a pandemic; through:

- Tracking antiviral drugs deployment:
  - Track asset allocations to each State, territorial, or local health department
  - Provide advice to Federal Agencies to allot and track antivirals distributed by Federal medical care providers (e.g., VA, Indian Health Service [IHS], Bureau of Prisons)
  - Review and revise, as needed, antiviral drug allocation and distribution among States, local and tribal governments, and Federal health care providers
- Assessing antiviral drug coverage using preestablished tracking systems and special studies

- Assessing effectiveness of antiviral treatment and prophylaxis in clinical and epidemiological studies:
  - Analyses of antiviral effectiveness must take into account characteristics that vary among individuals and those that vary with the time course of a pandemic, including diagnostic practices, length of time to initiation of therapy, and changes in the pandemic virus itself.
  - Such studies can be conducted using the existing infrastructure of the Emerging Infections Program sites and the New Vaccine Surveillance Network sites, with the allocation of additional resources.
- Monitoring adverse events associated with the treatment or prophylactic use of antivirals:
  - Review of reports to FDA through MedWatch monitoring program.
  - Assist State and local health departments and hospital and health care providers by downloading MedWatch forms (available at http://www.fda.gov/medwatch/) for distribution to each person receiving an antiviral drug, either for treatment or prophylaxis.
  - Develop a State and local campaign to educate health care workers on the mechanisms for reporting adverse events via the MedWatch program. This campaign should also address the potential side effects associated with the use of antiviral drugs for influenza.
  - Work with FDA's Adverse Events Reporting System (AERS) on a regular basis.
  - Active monitoring for adverse events among patients presenting for care in a network of emergency departments, through the existing National Electronic Injury Surveillance System Cooperative Adverse Drug Event project (NEISS-CADE), maintained by CDC and FDA.
  - HMO Research Network Center for Education and Research in Therapeutics (CERT), an integrated pharmaco-epidemiology program of 7.7 million patients, can also be used to monitor for adverse events.
- Monitoring antiviral drug resistance to pandemic influenza viruses with State and local partners

D. Action (no HSC Action): HHS and State and local health departments communicate messages on antiviral drug use and effectiveness throughout the course of a pandemic within a reasonable time period. (Also see chapter 7, Communications.)

Timeframe: Within 12 months.

Measure of Performance: Publish a plan of communications demonstrating responsible reporting of antiviral drug news to the public.

Step 1: Define messages regarding rationale for priority groups and antiviral drug use objectives and strategies.

Step 2: Develop and disseminate other key messages as needed.

E. Action (HSC 6.1.13.10): HHS with DOJ, DHA, DOS, and DOC institute an expanded plan for investigation and prosecution of cases involving counterfeit influenza antiviral drugs during a pandemic within one (1) month. (Also see chapter 1, Pillar One, Action V [HSC 6.1.13.10]; and chapter 5, Pillar Three, Action C [HSC 6.1.13.10]).

Measure of Performance: Publish an expanded and updated plan of action to handle counterfeit drugs and file indictments for cases of these counterfeit drugs.

Step 1: Investigate reports of counterfeit drugs used for pandemic treatment or prophylactic purposes and prosecute cases as evidence warrants.

Step 2: Use authorities and prescribed plans to remedy the illegal distribution of medical countermeasures.

Step 3: Monitor illicit promotion and trade of fraudulent remedies and communicate findings.

Appendix 6–A: Antiviral Drugs: IND, EUA, and Approval

There are four antiviral drugs approved for treatment and/or prophylaxis of influenza A.

A pandemic virus is expected to be a strain of influenza A, and the approved indications do not distinguish between pandemic and nonpandemic strains. The effect of a drug against different strains of influenza A is assessed using a combination of clinical trial and microbiologic data.

There are several potential mechanisms for facilitating access to unapproved drugs and unapproved uses of approved drugs, depending on the amount and quality of data submitted to FDA for review. These mechanisms include certain types of protocols under an IND or EUA, and are described briefly below.

IND

- Submission of complete IND clinical protocol for FDA review.
- Sufficient preexisting preclinical and clinical data to support protocol.
- Complete description of manufacturing process and quality control testing procedures as well as complete testing results.
- Informed consent.
- IRB approval and possible local IRB approval at every site.
- Monitoring and reporting to FDA as per 21 CFR 312.
- May require onsite facilities inspection by FDA, especially for new manufacturers.
- Certain IND requirements can be waived pursuant to 21 CFR Part 312. Informed consent cannot be waived.

EUA

See draft guidance (cited below) for recommendations on preclinical and clinical data needed to support EUA. It is often advantageous, and may be important, to submit such data in advance via a pre-IND or an IND.

- The Secretary of HHS declares an emergency justifying the EUA.
- Based on the totality of scientific evidence available, it is reasonable to believe that (1) the product may be effective; (2) the known and potential benefits outweigh the known and potential risks, and (3) there is no adequate, approved, and available alternative.

- FDA shall, to the extent practicable given the circumstances of the emergency, impose certain conditions on an EUA for an unapproved product and an EUA for an unapproved use of an approved product, and may impose certain other conditions.

For Antiviral Drugs Already on Hand in Stockpile Used for Approved Indications

No additional approval actions are required. To facilitate increased production, companies should submit proposals and information on additional facilities they wish to qualify as far in advance as possible, usually as manufacturing supplements to existing New Drug Applications (NDAs). FDA would review these submissions and conduct needed inspections as expeditiously as possible. Time required for review and inspection may vary depending on factors such as the following:

- The nature of the product. (Some antivirals have very complex manufacturing processes.)
- Complexity of the submission.
- Location of facilities. (International inspections may take months to schedule and carry out for logistic and resource reasons.)
- Staffing.

To the extent possible, such expansions of capacity should be carried out through pre-pandemic planning. If acute shortages occur in an emergency situation, FDA will work with manufacturers to expedite additional qualification of facilities and review of importation proposals. Lead time required for manufacturing the principal influenza antivirals would limit any contribution of new facilities in emergency situations. The major limiting factors in the timeline for increasing supply would be the time required for manufacturers to identify and equip facilities, conduct enough initial manufacturing to demonstrate quality, and scale up the multiple complex steps required for the principal influenza antivirals.

For Antiviral Drugs on Hand in Stockpile Used for Unapproved Indications

If use of stockpile holdings for an unapproved use is warranted, this could occur through sponsorship of an IND, for example, by a Federal entity such as CDC, which would submit the IND to FDA for review. An EUA might be appropriate (as described below) for unapproved uses of approved drugs; however, most currently stockpiled influenza products probably would be used for labeled indications.

Potential Plans for Development of Unapproved New Drugs That Might Be Useful for Future Stockpiling

During the interpandemic period, Government entities supporting drug development (e.g., HHS/NIH) should determine their level of support for new drug discovery and development, and should ensure that the Government or commercial sponsors of

appropriate new drugs or new uses of existing drugs submit as much information as possible to FDA as early in the process as possible. New drugs would require evaluation for safety and efficacy for their intended use and dosing, in addition to assessment of manufacturing information. Time constraints in the development process include time needed for sponsors to prepare data to support IND and, eventually, NDA submissions, including factors such as the following:

- Performing animal toxicology studies in vitro (and in vivo as appropriate) activity studies to support initial use in humans
- Initial safety and pharmacokinetics studies in humans to support dosing for efficacy studies
- Studies of efficacy in human influenza illness
- Chemistry, manufacturing, and controls information to support quality of product

Each of the above steps may take months, or in some instances, even years. The time needed for development studies reinforces the importance of early contact with FDA for discussion and advice to facilitate efficient approaches to development.

Facilitating and Expediting Development

FDA will be prepared to review pre-IND, IND, and NDA submissions expeditiously when adequate information is submitted. Timeframes for the review process may vary depending on the nature of the product, the type and complexity of data available, and staffing. Several mechanisms for facilitating and expediting development and approval are available, including the following:

- Pre-IND consultations: Allow early interaction for advice on development issues before enough information is available to support an IND submission for initiation of clinical studies. Contact review division for instructions on submission and early interaction.
- Fast Track designation: Allows for enhanced frequency of meetings and other interactions between FDA and sponsors of new drug development; see Guidance for Industry, Fast Track Drug Development Programs—Designation, Development, and Application Review at http://www.fda.gov/cder/guidance/5645fnl.htm.
- Priority review: Shortens usual timeframe for review of a complete NDA after suitable clinical trials are completed under IND; see Priority Review Policy at http://www.fda.gov/cder/mapp/6020–3.pdf.
- Expedited review of manufacturing supplements (Requests for Expedited Review of NDA Chemistry Supplements http://www.fda.gov/cder/mapp/5310–3.pdf).
- Accelerated approval: 21 CFR 314 Subpart H (314.500–314.560), Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, may allow

approval based on surrogate endpoints expected to be reasonably predictive of clinical benefit.

Enhancing Access to Unapproved Drugs While Development Is Ongoing

In the event of a pandemic, there are several potential mechanisms for facilitating access to an unapproved drug or an unapproved use of an approved drug, depending on amount and quality of data submitted to FDA for review. These mechanisms include the following:

- Investigational clinical protocols under standard IND regulations.
- Single-patient emergency INDs are unlikely to be useful in a pandemic setting. (See 21 CFR 312.36, Emergency use of an investigational new drug.)
- Treatment INDs (21 CFR 312.34, Treatment use of an investigational new drug).
- Emergency Use Authorization. (See draft guidance at http://www.fda.gov/oc/bioterrorism/emergency_use.html.)

Under exceptional circumstances, if an NDA is well advanced in the review process, additional expediting of approval could be considered on a case-by-case basis. For all of these alternatives, note that unapproved drugs are not usually manufactured in sufficient quantities to have a large immediate impact on total drug supply in an emergency.

Timing of Interactions

For all of the mechanisms of expedited/facilitated development or access above, early interactions between the drug sponsor (Government or commercial) and FDA are of the highest importance. Pre-IND interactions are encouraged. Review of pre-INDs and INDs (for protocols to initiate human study of a new drug) is typically accomplished within several weeks (30 days for new INDs), and review of NDAs (for marketing approval/licensure after completion and submission of adequate and well-controlled human clinical trials providing substantial evidence of efficacy and safety) typically is accomplished within 6 months for priority review. Shorter times sometimes may be possible if provisions such as rolling submission are employed, if data are compelling and provided in accessible form, and if staffing is adequate. FDA recognizes the emergency issues and the need to balance expedited turnaround with due attention to safety and efficacy. In each case the review process may identify substantial issues in development requiring further study and generation of additional data by the sponsor. In general, the limiting factor for duration of drug development will be time required by the sponsor to perform studies and submit data for review. Accumulation of adequate safety and efficacy data for risk–benefit assessment will be crucial for drugs that may be administered to thousands or millions of people on short notice, many of whom may not have serious disease without the drug (e.g., if drug is used for prophylaxis or mild disease).

EUA

Appropriate Government Agencies and sponsors should focus on ensuring that complete data are provided to FDA. Complete data are especially important if at any time during the course of development it appears that an unapproved drug or an unapproved use of an approved drug might be suitable for use under an EUA—if a declared emergency occurs before its development process is complete and alternatives are lacking, and in particular if the drug appears sufficiently promising that the SNS might consider acquiring it for investigational use. Data can be provided through pre-IND or IND submissions and discussion of ongoing and future development plans as far in advance of need as possible. FDA would then assess the ability of the data to potentially support an EUA, and provide advice on additional studies and data that may be desirable both for further development and to support emergency use as warranted. The amount of data and information needed to support an EUA will depend on the nature of the product and completed studies and the nature of the emergency. EUA use of a drug is limited to the duration of a declared emergency (and allows patients to finish treatment courses they started during an emergency), after which investigational product regulations would apply. Analysis of whether the available data and information support issuing an EUA if requested for temporary use in a declared emergency, and the timeframe in which this could be done, may depend on multiple factors, such as the adequacy of data provided in advance, the nature of the emergency, and the adequacy and availability of approved alternatives. Therefore, advance submission and discussion of information from completed studies and proposals for additional studies will be critical to minimizing the time required for additional evaluation after onset of an emergency. The final determination whether the criteria for issuance of an EUA are met can only be made after an emergency is declared.

Effect of the Timing of a Pandemic

There could be some differences in use of various emergency approaches described above, depending on whether a pandemic occurs this year or several years from now. These would not necessarily involve changes in general regulatory principles but could reflect availability of drugs and characteristics of circulating and emerging viruses. Examples of such differences include the following:

- If substantially greater quantities of approved drugs are manufactured and added to the stockpile before a pandemic, there may be less need to consider expedited addition of production facilities or use of any unapproved drugs or unapproved uses of approved drugs under EUA.
- If influenza viruses accumulate mutations to display greater resistance to approved drugs while maintaining virulence and transmissibility, the usefulness of stockpiled drugs could diminish even if supply is large, and the need to consider use of investigational drugs under IND or EUA could be greater if any new drugs with potentially better activity are at suitable stages of development.

- If drug discovery and research study efforts lead to new drugs with favorable risk/benefit for influenza treatment and prevention, and if studies are completed that support approval of any such drugs, there would be less need for EUA consideration because of availability of a greater range of marketed drugs.
- If (although currently thought to be unlikely) a pandemic strain were to arise that would be susceptible to the older adamantine influenza drugs (to which the recent H5N1 human strains have developed resistance), supply of these drugs would considerably augment the currently limited supply of the newer neuraminidase inhibitor drugs, and could decrease the need to consider expedited addition of production facilities or use of any unapproved drugs or unapproved uses of approved drugs under an EUA.

None of these possible differences is a certainty: the most important factors in regulatory interactions would still be early planning to generate data to support use of appropriate drugs, and early contacts with FDA to submit data and discuss development plans.

Differences Between Data Required for New Antiviral Drugs and New Uses of Existing Drugs

- Although INDs and EUAs might be considered either for use of new antiviral drugs or for new uses of existing drugs in an emergency if suitable data are available, the amount of new information that would have to be generated to support such use would differ depending on prior experience with the product, as well as factors such as intended population (e.g., treatment of gravely ill patients without other treatment options vs. prophylaxis of low-risk persons likely to have good outcomes without treatment).
- If there is a product already approved for human use whose unapproved use would have utility in an influenza emergency, the existing approval reflects the existence of a sufficient safety database for administration to humans under the labeled indication, and the amount of additional safety information needed to support the use against influenza might not be large depending on the intended dosing and populations. In the current situation it is unlikely that unapproved uses of approved drugs would significantly contribute to drug availability in an emergency.
- For unapproved new drugs, the amount of additional information needed to support emergency use would vary depending on the stage of development and extent of previous studies. For example, if there have already been extensive human studies of the proposed dosing regimen with data submitted for Agency review before emergency circumstances arise, evaluation of the risks and benefits for emergency use may be much more rapid and require far less additional data generation than for a drug just starting development for which available safety data are minimal and the potential for adverse events with widespread use, as well as the potential for benefit, may be extremely uncertain.

Appendix 6–B: SNS Operations—Pandemic Influenza Response

1. ***Mission.*** To deliver critical medical assets to the site of a national emergency.

2. ***Execution.***

   a. Concept: There are two main types of commodities stored in the SNS for a pandemic flu outbreak: those that are in mass quantity and will be delivered pro rata to project areas, ideally before local pandemic disease occurs; and those that are limited in quantity that will be targeted as needed during the pandemic outbreak. Whereas antiviral drugs and masks/respirators are in the former category and will be deployed in two initial phases, other medical assets are in the latter category (limited quantities) and will be deployed in a third phase.

   Phase 1: The best antiviral drug distribution strategy would be a *pro rata* phased deployment pushing product proactively to a single location in each of the 62 project areas. Upon direction of the CDC director, SNS will push antiviral drugs to the State, local, territorial, and tribal (SLTT) project areas prior to receipt of a request. This will ensure that SLTTs receive supplies before the need for assets becomes critical. Antivirals will be the first asset to be delivered to SLTTs and will comprise Phase 1 of the pandemic SNS response, estimated to take about 7 days. There is also a need to distribute antiviral drugs to Federal Agencies that provide health care such as the VA and Indian Health Service, and possibly to other sites targeted to preserve Federal government continuity of operations. Planning for these deployments will occur as prioritization and allocation decisions are made.

   Phase 2: Masks and respirators are available at the SLTT level, but they will be used up quickly. SLTTs will have a minimum surge capacity for these supplies. Masks/respirators will be allocated *pro rata* and shipped immediately after antivirals to the 62 project areas as Phase 2 of the response. This second deployment of assets will take between 7 and 10 days (after Phase 1 is completed due to the logistical challenges associated with product configuration).

   Phase 3: The final phase would be shipping SNS high demand but scarce resource commodities such as ventilators, other personal protective equipment (PPE) (protective face shields, gowns, gloves), and IV antibiotics. This last phase requires more scrutiny and a case-by-case approval process as SLTTs make their requests. Because of the relatively low numbers, SNS will be able to ship these assets on an as-requested basis. All requests must be sent to the

CDC Director's Emergency Operations Center (DEOC) through the State Governor or Governor's designee similar to a traditional SNS response as laid out in *Version 10*; *A Guide for Preparedness—Receiving, Distributing, and Dispensing Strategic National Stockpile Assets.*

Pushing product to the SLTTs in the first two phases will allow the Federal Government to be proactive and anticipate SLTT needs, increasing the chance of a successful response. It will also allow SNS to maintain surge capacity with additional items and be able to ship them rapidly during a pandemic at the time of need. Shipping product out before a pandemic and before an SLTT requests such will also ensure that the SNS staff and Federal transportation partners are available in full capacity to aid in the Federal response, and ready to respond to other events. During a pandemic, there is a high likelihood that resources such as personnel and trucks will be in limited supply, possibly affecting SNS response time.

b. Coordinating Instructions:

- A significant amount of material will arrive in a very short period of time, placing a much greater logistical burden on SLTTs. Therefore:
  - SLTTs must be prepared for large scale SNS shipments by establishing robust local Receipt, Storage, Staging (RSS) sites (12,000 square feet).
  - SLTTs must plan for additional warehouse space for storage of large quantities of material for an indefinite period of time.

Contents

CHAPTER 7: COMMUNICATIONS

Introduction

Pandemic influenza presents a massive communications challenge to all levels of our Government, our international partners, our society, and our country. Uncertainty about the course of a pandemic and unknown scientific factors, as well as unforeseen and unintended outcomes with respect to governmental actions and statements, make pandemic influenza a communications management issue of epic proportion. The economic and societal effects of a pandemic may have a significant detrimental impact on the United States.

A critical component of national preparedness for an influenza pandemic is informing the public about this potential threat and providing a solid foundation of information on which future actions can be based. To be effective, these strategies should be based on scientifically derived risk communications principles that are critical before, during, and after an influenza pandemic. Effective communication guides the public, the news media, health care providers, and other groups in responding appropriately to outbreak situations and adhering to public health measures.

Role of HHS in Communications

HHS will deploy a national communications strategy during pre-pandemic and pandemic periods that

- Delivers vital information to help reduce morbidity and mortality from pandemic influenza
- Communicates the need for preparedness at all levels of government, as well as all sectors of society
- Prepares the U.S. public and communities for a pandemic
- Provides accurate, timely, consistent, and comprehensive information about influenza and pandemic influenza
- Instills and maintains public confidence in the country's public health system and its ability to respond to and manage a pandemic influenza outbreak
- Contributes to the maintenance of order, minimization of public panic and fear, and facilitation of public protection through the provision of accurate, rapid, and complete information
- Addresses rumors, inaccuracies, and misperceptions as quickly as possible, and prevents stigmatization of affected groups

- Provides timely notice of fraudulent, unproven, dangerous, unapproved treatments or preventive interventions
- Provides timely notice of new best practices
- Provides traditional and innovative outreach programs to employers, workers in the traditional and informal economies, and persons with disabilities, etc.

Specific Assumptions and Planning Considerations for HHS Communications

- A pandemic can happen at any time; planning must proceed accordingly.
- Communications is integral to the effective implementation of pandemic countermeasures.
- Communications is a shared responsibility and requires coordination with all partners and stakeholders: international, Federal, State, local, community, private sector, etc.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

Communications is a critical component of preparedness, and both are essential to the success of public health and medical interventions. The following activities are necessary to clarify governmental and societal responsibilities and establish reasonable goals.

Planning for Pandemic Influenza

A. Action (HSC 4.1.3.1): HHS, in coordination with USAID and USDA, will conduct educational programs focused on communications and social marketing campaigns in local languages to increase public awareness of risks of transmission of influenza between animals and humans. (Also see chapter 1, Pillar One, Actions F and H [HSC 4.1.3.1 and 4.1.4.1, Step 1].)

Timeframe: Within 12 months.

Measure of Performance: Clear and consistent messages tested in affected countries, with information communicated via a variety of media have reached broad audiences, including health care providers, veterinarians, and animal health workers, primary and secondary level educators, villagers in high-risk and affected areas, poultry industry workers, and vendors in open air markets.

Step 1: Support regular coordination of local-language risk-communications activities and behavior-change communications in foreign countries deemed to be at high risk, to ensure consistency of messages and efficiency of operations.

Step 2: Facilitate development of clear and compelling messages that provide accurate information about the virus in a culturally competent fashion.

Step 3: Assist in the development of communications materials, using a variety of media tailored to specific audiences and delivered in appropriate languages to target audiences including health care providers, veterinarians, primary- and secondary-level educators, residents in high risk areas, poultry industry workers, and vendors in open air markets.

B. Action (HSC 4.1.3.2): HHS will work with USAID and in conjunction with the WHO Secretariat and other multilateral organizations, existing bilateral programs, and private sector partners to develop community- and hospital-based health prevention, promotion, and education activities in priority countries. (Also see chapter 1, Pillar One, Action G [HSC 4.1.3.2].)

Timeframe: Within 12 months.

Measure of Performance: 75 percent of priority countries are reached with mass media and community outreach programs that promote AI awareness and behavior change.

Step 1: Schedule a meeting with the WHO Secretariat and other organizations to discuss current initiatives and to determine gaps; identify priority countries; and agree on an action plan for developing and disseminating community- and hospital-based disease prevention, health promotion, and education activities.

Step 2: Initiate activities as agreed upon in the plan.

Protecting Human Health

C. Action (HSC 6.1.2.7): HHS, in coordination with DHS, DOD, VA, and the USA Freedom Corps and Citizen Corps programs, will prepare guidance for local MRC coordinators describing the role of the MRC during a pandemic. (Also see chapter 8, Pillar One, Action N [HSC 6.1.2.7].)

Timeframe: Within 3 months.

Measure of Performance: Guidance materials developed and published on MRC website (http://www.medicalreservecorps.gov).

Step 1: Meet with other Departments to develop a work plan for the development and distribution of the guidance materials.

Step 2: Pilot materials with test audience and incorporate feedback into final version. At the same time, distribute the materials to Federal partners for their review.

Step 3: Incorporate suggestions, finalize, and distribute.

Institutions: Protecting Personnel and Ensuring Continuity of Operations

D. Action (HSC 9.1.1.3): In coordination with DHS, DOD, and DOL, HHS will work with OPM, to update the guides *Telework: A Management Priority, A Guide for Managers, Supervisors, and Telework Coordinators*; *Telework 101 for Managers: Making Telework Work for You*; and, *Telework 101 for Employees: Making Telework Work for You*, to provide guidance to Federal departments regarding workplace options during a pandemic. (Also see chapter 3, Pillar One, Action M [HSC 9.1.1.3].)

Timeframe: Within 3 months.

Measure of Performance: Updated telework guidance provided to all departments for use, as necessary, in updating departmental COOP plans related to pandemic influenza.

Step 1: Contact OPM to determine their work plan to update telework guides for Federal employees.

Step 2: Provide support as needed to OPM in the development and review of the updated guides.

Communicating Expectations and Responsibilities

E. Action (HSC 4.1.4.1): HHS will work with DOS and USAID and in coordination with other Federal agencies, to help ensure that the top political leadership of all affected countries understands the need for clear, effective coordinated public information strategies before and during an outbreak of avian or pandemic influenza. (Also see chapter 1, Pillar One, Action H [HSC 4.1.4.1].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries that developed outbreak communications strategies consistent with the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.

Step 1: Meet with DOS and other agencies to identify key issues relevant to the adaptation and translation of HHS communications documents for the countries identified. Activate contracting vehicles for translation as described in the FY 2006 Pandemic Influenza Communications Budget.

Step 2: Use CDCynergy's *Crisis Communications for Leaders by Leaders* as a pilot with English-speaking senior diplomats of affected countries to explore whether this would be helpful for target audiences if translated, or whether a

similar product should be developed using political leaders from the affected regions.

Step 3: Coordinate the political leadership messages with those developed for other stakeholders in the countries to ensure consistency.

Step 4: Develop and evaluate pilot messages for language and health literacy, cultural competence, clarity, understanding, accessibility, and intended effect. Translate materials such as the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.

Step 5: Make final adjustments to materials, as needed, and produce them for dissemination.

Step 6: Distribute materials and provide consultation as requested.

Step 7: Follow up to document which countries have implemented preparedness campaigns on avian and pandemic influenza and to summarize the strategies employed.

F. Action (HSC 4.1.4.2): HHS, in coordination with DOS and other agencies, will assist in the development and implementation of programs to inform U.S. citizens, including businesses, NGO personnel, DOD personnel, and military family members residing and traveling abroad, where they may obtain accurate, timely information, including risk level assessment, to enable them to make informed decisions and take appropriate personal protective measures. (Also see chapter 1, Pillar One, Action H [HSC 4.1.4.1].)

Timeframe: Within 3 months.

Measure of Performance: Majority of registered U.S. citizens abroad have access to accurate and current information on influenza.

Step 1: Meet with DOS, DOD, and other agencies to identify current initiatives and gaps in communications about pandemic influenza with U.S. citizens residing or traveling abroad; agree upon the content of educational material; consult multinational corporations on needs of U.S. citizens working abroad.

Step 2: Work with DOS to ensure that U.S. Ambassadors and other DOS officials communicate timely and accurate information to U.S. citizen communities, especially in countries at highest risk. DOS will relate this information through (1) holding periodic town hall meetings with local U.S. citizen communities, including business and nongovernmental organizations; and (2) regularly providing timely, accurate information through its effective information systems (including the DOS warden system) to ensure that U.S. citizens are aware of the

need to prepare for a possible pandemic and actions to take in the event of an outbreak.

Step 3: Ensure that U.S. citizens residing or traveling abroad in a nonofficial capacity are provided with information advising them that the U.S. Government will not provide countermeasures to them, including antiviral drugs.

Step 4: Execute actions agreed upon to address gaps and ensure consistency of messages.

G. Action (HSC 4.1.4.4): HHS, in coordination with USAID and USDA, will work with the WHO Secretariat, FAO, OIE, and other donor countries to implement a communications program to support government authorities and private and multilateral organizations in at-risk countries in improving their national communications systems, with the goal of promoting behaviors that will minimize human exposure and prevent further spread of influenza in animal populations. (Also see chapter 1, Pillar One, Action I [HSC 4.1.4.4].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries have improved national avian influenza communications.

Step 1: Schedule a meeting with the WHO Secretariat, donor countries, and other organizations, including multinational corporations, to identify priority countries; review current initiatives and determine gaps in the existing communications infrastructure; and agree on an action plan for developing and disseminating community- and hospital-based disease prevention, health promotion, and education programs.

Step 2: Initiate activities as agreed upon in the plan.

H. Action (HSC 4.1.4.5): HHS, in coordination with DOS and USDA, will work with USAID in the USAID development and dissemination of influenza information to priority countries through international broadcasting channels, including international U.S. Government mechanisms such as Voice of America and Radio Free Asia (radio, television, shortwave, Internet), and the sharing of lessons learned and key messages from communications campaigns.

Timeframe: Within 12 months.

Measure of Performance: Local language briefing materials and training programs developed and distributed via WHO and FAO channels.

Step 1: Schedule a meeting to determine key messages to be translated for international use in priority countries.

Step 2: Agree upon ongoing feedback mechanisms to continually update and refine messages.

Transportation and Borders

I. Action (HSC 5.1.4.1): HHS, in coordination with DHS, DOT, and DOL, will establish workforce protection guidelines and develop targeted educational materials addressing the risk of contracting pandemic influenza for transportation and border workers. (Also see chapter 3, Pillar One, Action Q [HSC 5.1.4.1].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines and materials developed that meet the diverse needs of border and transportation workers (e.g., customs attendants, transit workers, ship crews, and interstate truckers).

Step 1: Convene a meeting with DHS, DOT, and DOL personnel as well as representatives of travel industry (air, rail, bus, ship, etc.) to discuss the information needs of the targeted audience and to develop an action plan.

Step 2: Develop and pilot educational materials.

Step 3: Incorporate changes and produce materials.

Step 4: Distribute materials through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

Protecting Human Health

J. Action (HSC 6.1.3.1): HHS, in coordination with DHS, DOS, DOD, VA, and other Federal partners, will develop, test, and implement a Federal Government public health emergency communications plan (describing the government's strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the Government believes will be effective as well as those approaches it regards as likely to be ineffective, excessively costly, fraudulent, or harmful). (Also see chapter 2, Pillar One, Action M [No HSC number].)

Timeframe: Within 6 months.

Measure of Performance: Containment strategy and emergency response materials completed and published on http://www.pandemicflu.gov; communications plan implemented.

Step 1: Work with Federal, State, and local authorities to identify current communications strategies and to identify gaps that need to be addressed and mechanisms for fixing them.

Step 2: Develop materials that provide the public easy-to-understand information regarding pandemic influenza, home health care during a pandemic, non-pharmaceutical personal protective actions individuals can take to reduce their risk of contracting and transmitting pandemic influenza (e.g., social distancing, face masks, and other social exposure tips), and the appropriate use of vaccines and antiviral drugs. Public outreach materials will also provide guidance on the management of personal or family illnesses, including topics such as

- How to judge whether an illness can be managed safely at home without a physician; whether an illness requires a visit to a physician's office; or if an illness should be dealt with as a medical emergency
- Infection control measures to protect noninfected household members
- The appropriate use of prescription or over-the-counter medications to relieve symptoms
- Home care for the sick

Step 3: Develop educational materials for health care workers regarding diagnosis, treatment, case management, and infection control practices.

Step 4: Develop a mechanism to both gather data from the public on pandemic influenza disease surveillance and push out messages to the public for (1) shelter in place and (2) home isolation and quarantine, to reduce surge on inpatient facilities and limit congregate care in collaboration with poison control centers, 9–1–1 call centers, and nurse triage lines.

Step 5: Develop a secure, searchable Web-based repository for pandemic influenza health communication content on http://www.pandemicflu.gov. This database will facilitate the retrieval of scientifically accurate, pretested health messages and materials that can be accessed by Federal, State, local, and tribal public health communication partners.

Step 6: Set aside funds for developing and testing a short direct-mail piece on key guidance (antiviral medications, vaccine availability, hygiene steps, etc.) that could be delivered to all U.S. residential addresses should a pandemic begin to evolve.

Step 7: Develop and support a TV studio at HHS to broadcast emergency response messages concerning the health and safety of persons throughout the United States. In the event of a health crisis, the studio would be used to develop

and deliver a number of public information messages to include press conferences, interviews with Department experts, preproduced video and audio messages, and other information designed to inform the public. The operation would expand to a full-scale live 24-hour emergency broadcast during a pandemic.

Step 8: Improve real-time environmental scanning and analysis capacity to (1) detect harmful rumors and misinformation for immediate agency response, (2) track changes in the public's information needs in order to more precisely target messages, and (3) provide trend analysis to anticipate policy and communication issues as a pandemic unfolds.

Step 9: Host media roundtables on pandemic communications to develop relationships and processes to facilitate rapid dissemination of messages to the public.

Step 10: Perform a test of the national emergency communications system for pandemic influenza.

K. Action (HSC 6.1.3.2): HHS, in coordination with DHS, will develop, test, update, and implement (if necessary) a multilingual and multimedia public engagement and risk communications strategy. (Also see chapter 2, Pillar One, Action M [No HSC number].)

Timeframe: Within 6 months.

Measure of Performance: Risk communication material completed and published on http://www.pandemicflu.gov and other venues; State summit meetings held.

Step 1: Continue work on message mapping, focusing on pre-pandemic and pandemic itself according to the six pandemic stages in the **National Strategy for Pandemic Influenza.**

Step 2: Develop, evaluate, and translate (for language and health literacy) message content derived from current initiatives on message mapping and adapt to different media technologies.

Step 3: Test messages for clarity, understanding, accessibility, and intended effect with major non-English-speaking populations.

Step 4: Finalize materials and distribute at Federal, State, and local levels.

L. Action L (HSC 6.1.3.3): HHS will coordinate with DHS, DOD, and the VA, and will collaborate with State/local health agencies and the academic community, to select and retain opinion leaders and medical experts to serve as credible

spokespersons to coordinate and effectively communicate important and informative messages to the public.

Timeframe: Within 6 months.

Measure of Performance: National spokespersons engaged in communications campaign.

Step 1: Select and retain opinion leaders and medical experts to serve as credible spokespersons to coordinate and effectively communicate important and informative messages to the public.

Step 2: Develop pandemic influenza-specific training based on the HHS/CDC Crisis and Emergency Risk Communications curriculum that focuses on the principles of risk communication for Federal, State, local, and tribal officials.

Step 3: Provide training in all 10 HHS regions, to include Departmental staff as well as State and local communicators and community leaders within the respective regions.

M. Action (HSC 6.1.4.1): In collaboration with DHS and DOL, HHS will assist State, local, and tribal public health and health care authorities in coordinating emergency communication protocols with print and broadcast media, private industry, academic, and nonprofit partners.

Timeframe: Within 6 months.

Measure of Performance: Coordinated messages from communities identified above.

Step 1: Meet with DHS and DOL and agree upon a work plan to develop communication protocols that

- Address rumors and false reports regarding pandemic influenza threats arising within or affecting the jurisdictions identified above
- As appropriate, issue timely national warnings on medical fraud associated with pandemic influenza
- Educate health care workers about pandemic influenza diagnosis, treatment, case management, and infection control practices

Step 2: Develop plans for the distribution of educational materials and guidelines for personal action that are consistent with materials prepared and disseminated by HHS.

N. Action (HSC 6.1.4.2): HHS, in cooperation with DHS and DOC, will assist DOT develop model protocols for 9–1–1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services. (Also see chapter 8, Pillar One, Action T [HSC 6.1.4.2].)

Timeframe: Within 12 months.

Measure of Performance: Model protocols developed and disseminated to 9–1–1 call centers and public safety answering points.

Step 1: Contact DOT and offer assistance in the development of model communications protocols that

- Address rumors and false reports regarding pandemic influenza threats
- As appropriate, issue timely warnings of medical fraud associated with pandemic influenza
- Educate operators about pandemic influenza diagnosis, treatment, case management, and infection control practices

Step 2: Assist DOT in developing plans for the distribution of educational materials and guidelines for personal action and ensure they are consistent with materials prepared and disseminated by HHS.

O. Action (HSC 6.1.12.1): HHS will collaborate with health care providers, industry partners, and State, local, and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination. (Also see chapter 5, Pillar One, Action V [HSC 6.1.12.1].)

Timeframe: Within 12 months.

Measure of Performance: Domestic vaccine use increased relative to historical norms.

Step 1: Identify opinion leaders from health care providers, industry partners, and State and local public health authorities to assist in the development of public information campaigns and other mechanisms to increase seasonal influenza vaccination.

Step 2: Convene meetings to develop and implement a strategy to increase seasonal influenza vaccinations.

Step 3: Develop and distribute materials through multiple media venues designed to increase the use of seasonal influenza vaccination.

Protecting Animal Handler Health and Animal Health

P. Action (HSC 7.1.3.3): HHS, in coordination with USDA, HDS, and DOL, will work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers. (Also see chapter 2, Pillar Two, Action K [HSC 7.1.3.3]; and chapter 3, Pillar One, Action S [HSC 7.1.3.3].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines developed and disseminated to poultry and swine industries.

Step 1: Convene a meeting with USDA, DHS, DOL, and representatives of the poultry and swine industries to discuss information needs of the targeted audience and to develop an action plan.

Step 2: Develop and pilot educational materials.

Step 3: Incorporate changes and produce materials.

Step 4: Distribute materials through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

Law Enforcement, Public Safety, and Security

Q. Action (HSC 8.1.3.1): HHS, in coordination with DOL, will provide clear guidance to law enforcement and other emergency responders on recommended preventive measures, including seasonal influenza vaccination, to be taken by law enforcement and emergency responders to minimize risk of infection from pandemic influenza. (Also see chapter 3, Pillar One, Action T [HSC 8.1.3.1].)

Timeframe: Within 6 months.

Measure of Performance: Development and dissemination of guidance for law enforcement and other emergency responders.

Step 1: Meet with opinion leaders of law enforcement and other emergency responder communities to identify specific vocational-related concerns and information needs.

Step 2: Develop and pilot guidance materials.

Step 3: Incorporate changes and produce materials.

Step 4: Distribute materials through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

Institutions

R. Action (HSC 9.1.3.2): As a Sector-Specific Agency, HHS will provide assistance to DHS in its effort to develop and coordinate guidance regarding business continuity planning and preparedness with the owners/operators of critical infrastructure and develop a Critical Infrastructure Influenza Pandemic Preparedness, Response, and Recovery Guide tailored to national goals and capabilities and to the specific needs identified by the private sector. (Also see chapter 3, Pillar One, Action V [HSC 9.1.3.2].)

Timeframe: Within 6 months.

Measure of Performance: Critical Infrastructure Influenza Pandemic Preparedness, Response, and Recovery Guide is developed and published on http://www.pandemicflu.gov.

Step 1: Contact and meet with DHS to determine their support needs in development of the Critical Infrastructure Influenza Pandemic Preparedness, Response, and Recovery Guide for the private sector.

Step 2: Assist DHS as needed by guiding the development and dissemination strategy.

Step 3: After review and clearance, post guide on http://www.pandemicflu.gov and other dissemination activities.

S. Action S (HSC 9.1.4.1): HHS, in coordination with DHS, DOL, OPM, the Department of Education, VA, and DOD, will develop sector-specific infection control guidance to protect personnel, governmental and public entities, private sector businesses and CBOs, FBOs. (Also see chapter 3, Pillar One, Action W [HSC 9.1.4.1].)

Timeframe: Within 6 months.

Measure of Performance: Sector-specific guidance and checklists developed and disseminated on http://www.pandemicflu.gov.

Step 1: HHS, in consultation with the other departments and agencies, will develop online infection control checklists for priority sectors that are supported by audience and market research and provide targeted, focused information for those particular stakeholders.

Step 2: After review and clearance, post all checklists on http://www.pandemicflu.gov.

Step 3: Develop and execute plan to inform all targeted stakeholders of the availability of the checklists.

T. Action T (HSC 9.1.4.2): HHS, in coordination with DHS, DOL, EPA, the Department of Education, VA, and DOD, will develop interim guidance regarding environmental management and cleaning practices including the handling of potentially contaminated waste material, and will revise this guidance as additional data becomes available. (Also see chapter 3, Pillar One, Action X [HSC 9.1.4.2].)

Timeframe: Within 3 months.

Measure of Performance: Development and publication of guidance and checklists on http://www.pandemicflu.gov and dissemination through other channels.

Step 1: HHS will coordinate with other Federal agencies and will ensure that links to all guidance material developed on environmental management and cleaning practices are readily accessible via http://www.pandemicflu.gov.

Pillar Two: Surveillance and Detection

Communications is an essential feature of effective surveillance and detection. It is the transparent sharing of accurate and timely information about influenza outbreaks. It will help guide the appropriate implementation of prevention measures to limit the spread of influenza outbreaks. It is the basis for international, State, local, and community coordination and collaboration on pandemic response and containment.

Using Preventive Measures To Limit Spread

A. Action (HSC 4.2.8.1): HHS, in collaboration with USAID, will develop community- and hospital-based infection control and prevention, health promotion and education activities in local languages in priority countries. (Also see chapter 1, Pillar One, Action M [HSC 4.2.8.1]; and Pillar Two, Action S [HSC 4.2.5.1].)

Timeframe: Within 9 months.

Measure of Performance: Local language health promotion campaigns and improved hospital-based infection control activities established in all South East Asian priority countries.

Step 1: Meet with USAID to identify priority countries and local customs, practices, resource availability, and media availability to inform product development.

Step 2: Develop messages in local languages.

Step 3: Pilot messages in designated countries to ensure that they are easy to understand and consistent with and respectful of local customs and practices.

Step 4: Incorporate any changes to messages resulting from pilot studies.

Step 5: Produce and disseminate messages through media identified above.

Step 6: Share guidance with international partners on best practices to reduce the spread of influenza, including within hospitals and clinical settings.

Transportation and Borders

B. Action (HSC 5.2.4.4): HHS will work with DOS and in coordination with DHS, DOT, and transportation and border stakeholders, to assess and revise procedures to issue travel information and advisories related to pandemic influenza. (Also see chapter 1, Pillar One, Action K [HSC 5.2.4.4]; and chapter 3, Pillar Two, Action G [HSC 5.2.4.4].)

Timeframe: Within 12 months.

Measure of Performance: Improved interagency coordination and timely dissemination of travel information to stakeholders and travelers.

Step 1: Meet with DOS, DHS, DOT, and transportation and border stakeholders to identify current initiatives and gaps in communications about avian influenza for U.S. citizens traveling and to agree upon the content of educational materials.

Step 2: Execute actions agreed upon to address gaps and ensure consistency of messages.

C. Action (HSC 5.2.4.8): HHS will work with DHS and in coordination with DOT, DOJ, and appropriate State and local health authorities, to develop detection, diagnosis, quarantine, isolation, EMS transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza. (Also see chapter 2, Pillar Two, Action M [HSC 5.2.4.8]; and chapter 3, Pillar Two, Action K [HSC 5.2.4.8].)

Timeframe: Within 10 months.

Measure of Performance: Protocols developed and distributed to all ports of entry.

Step 1: Meet with DHS, DOT, DOJ, and transportation and border stakeholders to identify current initiatives and gaps in communications protocols for travelers and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza; agree upon the content of needed educational materials.

Step 2: Execute actions agreed upon to address gaps and ensure consistency of messages.

D. Action (HSC 5.2.4.10): HHS will work with DHS and DOT and in coordination with DOS, State, community and tribal entities, and the private sector, to develop a public education campaign on pandemic influenza for travelers, which raises general awareness prior to a pandemic and includes messages for use during an outbreak. (Also see chapter 2, Pillar One, Action Y [HSC 5.2.4.10].)

Timeframe: Within 15 months.

Measure of Performance: Public education campaign developed and disseminated on how a pandemic could affect travel, the importance of reducing non-essential travel, and potential screening measures and transportation and border messages developed based on pandemic stages.

Step 1: Meet with DOS, DHS, DOT, community and tribal entities, and the private sector to identify current public education initiatives and gaps in information on pandemic influenza for travelers, and to agree upon additional material needed.

Step 2: Execute actions agreed upon to address gaps and ensure consistency of messages.

E. Action (HSC 5.2.5.6): HHS, in coordination with DOS and DOC, will support USDA, DHS, and DOI in outreach and expanded education campaigns for the public, agricultural stakeholders, wildlife trade community, and cargo and animal importers/exporters on import and export regulations and influenza disease risks.

Timeframe: Within 12 months.

Measure of Performance: 100 percent of key stakeholders are aware of current import and export regulations and penalties for noncompliance.

Step 1: Contact USDA, DHS, and DOI to determine their outreach and education plan and offer appropriate HHS subject matter expert support as needed.

Pillar Three: Response and Containment

Transparent and accurate communications about the emergence and course of outbreaks provides the information needed for evidence-based management of outbreak-response and containment actions. Communications also provides the framework for response partners' collaborations and coordination, nationally and internationally, and provides the mechanism for informing the public about outbreak response progress and events.

Containing Outbreaks

A. Action (HSC 4.3.1.8): HHS, in coordination with USDA, USAID, and DHS, and in collaboration with WHO, FAO, OIE, the World Bank and regional institutions such as APEC, ASEAN, and the EC, will support DOS initiatives to improve international public affairs coordination and establish a set of agreed upon operating principles among these international organizations and the U.S. that describe the actions and expectations of the public affairs strategies of these entities that would be implemented in the event of a pandemic. (Also see chapter 1, Pillar One, Action N [HSC 4.3.1.8].)

Timeframe: Within 6 months.

Measure of Performance: List of key public affairs contacts developed, planning documents shared, and coordinated international public affairs strategy developed.

Step 1: Support DOS initiatives and continue work with WHO communications staff on international public affairs strategies.

B. Action (HSC 5.3.2.1): HHS, in coordination with DOT and USDA, DHS, DOS, will issue travel advisories/public announcements for areas where outbreaks have occurred and ensure adequate coordination with appropriate transportation and border stakeholders. (Also see chapter 3, Pillar Three, Action G [HSC 5.3.2.1].)

Timeframe: Ongoing.

Measure of Performance: Coordinated announcements and warnings developed within 24 hours of becoming aware of an outbreak and timely updates provided as required.

Step 1: Meet with DOS, DOT, DHS, and USDA to identify current initiatives and gaps in communications about avian influenza for U.S. citizens traveling and agree upon the content of educational materials.

Step 2: Execute actions agreed upon to address gaps and ensure consistency of messages.

Step 3: Issue travel advisories and/or public announcements for areas where outbreaks have occurred and ensure adequate coordination with appropriate diplomatic, transportation, border, and international stakeholders.

C. Action (HSC 6.3.2.5): All HHS-funded hospitals and health facilities (in parallel to DOD and VA efforts) will develop, test, and be prepared to implement infection control campaigns for pandemic influenza. (Also see chapter 3, Pillar Three, Action K [HSC 6.3.2.5].)

Timeframe: Within 3 months.

Measure of Performance: Guidance materials on infection control developed and disseminated on http://www.pandemicflu.gov and through other channels.

Step 1: Contact DOD and VA to determine what guidance material is being developed for their hospital and health facility pandemic influenza infection control campaigns.

Step 2: Coordinate with DOD and VA to ensure links to all guidance material developed on pandemic influenza infection control campaigns for hospital and health facilities are readily accessible via http://www.pandemicflu.gov.

D. Action (HSC 6.3.2.6): All health care facilities should develop, test, and be prepared to implement infection control campaigns for pandemic influenza. (Also see chapter 4, Pillar One, Action B [HSC 6.1.2.4] and Pillar Three, Action B [HSC 6.3.4.1].)

Timeframe: Within 6 months.

Measure of Performance: Guidance materials on infection control developed and disseminated on http://www.pandemicflu.gov and through other channels.

Step 1: Ensure guidance material developed on pandemic influenza infection control campaigns for health care facilities is readily accessible via http://www.pandemicflu.gov.

E. Action (HSC 6.3.2.7): HHS, in coordination with DHS, DOC, DOL, and Sector-Specific Agencies, and in collaboration with medical professional and specialty societies, will develop and disseminate infection control guidance for the private sector. (Also see chapter 3, Pillar Three, Action L [HSC 6.3.2.7]; and chapter 4, Pillar One, Action B [HSC 6.1.2.4].)

Timeframe: Within 12 months.

Measure of Performance: Validated, focus group-tested guidance developed, and published on http://www.pandemicflu.gov and in other forums.

Step 1: Meet with DHS, DOC, DOL, Sector-Specific Agencies, and medical professional and specialty societies to identify required infection control guidance needed for the private sector.

Step 2: Develop and pilot guidance materials.

Step 3: Incorporate changes and produce materials.

Step 4: Distribute materials through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

F. Action (HSC 6.3.3.2): HHS, in coordination with DHS, DOD, VA, and DOT and in collaboration with State, local, and tribal partners, will develop and disseminate lists of social distancing behaviors that individuals may adopt, and update guidance as additional data becomes available. (Also see chapter 3, Pillar Three, Action N [HSC 6.3.3.2].)

Timeframe: Within 6 months.

Measure of Performance: Guidance disseminated on http://www.pandemicflu.gov and through other channels.

Step 1: Meet with DHS, DOD, VA, DOT, State, local, and tribal partners, to identify appropriate lists of social distancing behaviors.

Step 2: Develop and pilot social distancing lists.

Step 3: Incorporate changes and produce lists.

Step 4: Distribute lists through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

Leveraging National Medical and Public Health Surge Capacity

G. Action (HSC 6.3.5.1): HHS, in coordination with DHS, DOL, Department of Education, VA, and DOD, will develop and disseminate guidance and educational tools that explain steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic.

Timeframe: Within 3 months for dissemination of interim guidance; within 6 months for development of complementary educational tools.

Measure of Performance: Interim guidance disseminated on http://www.pandemicflu.gov and through VA, DOD, and other channels within three (3) months; complementary educational tools on social distancing, personal hygiene, mask use, and other infection control precautions developed within 6 months.

Step 1: Meet with DHS, DOL, Department of Education, VA, and DOD to identify current initiatives and gaps in guidance and educational tools that explain steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic.

Step 2: Develop and pilot guidance materials.

Step 3: Incorporate changes and produce materials.

Step 4: Distribute materials through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

Sustaining Infrastructure, Essential Services, and the Economy

H. Action (HSC 5.3.3.1): HHS will work with USDA and in coordination with DHS, DOT, DOS, and DOI, to provide emergency notifications of probable or confirmed cases and/or outbreaks to key international, Federal, State, local, and tribal transportation and border stakeholders through existing networks. (Also see chapter 1, Pillar Three, Action L [HSC 5.3.3.1]; chapter 2, Pillar Three, Action A [HSC 5.3.3.1]; and chapter 3, Pillar Three, Action P [HSC 5.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.

Step 1: Meet with USDA, DHS, DOT, DOS, and DOI to agree upon emergency notification protocols regarding probable or confirmed cases and/or outbreaks to key stakeholders.

Ensuring Effective Risk Communication

I. Action (HSC 4.3.6.1): HHS, in coordination with USAID, USDA, DOD, and DHS will support DOS lead, in an interagency public diplomacy group to develop a coordinated, integrated and prioritized plan to communicate U.S. foreign policy objectives relating to our international engagement on avian and pandemic influenza to key stakeholders (e.g., the American people, the foreign public, NGOs, international businesses). (Also see chapter 1, Pillar Three, Action N [HSC 4.3.6.1].)

Timeframe: Within 3 months.

Measure of Performance: Number and range of target audiences reached with core public affairs and public diplomacy messages, and impact of these messages on public responses to avian and pandemic influenza.

Step 1: Support DOS initiatives and continue work with WHO communications staff on international public affairs strategies in support of U.S. international pandemic influenza activities.

J. Action (HSC 4.3.6.2): HHS will work with DOS to provide at least monthly updates DOS its foreign counterparts, through diplomatic channels and U.S. Government web sites, regarding changes to national policy or regulations that may result from an outbreak, and will coordinate posting of such information to U.S. Government websites (e.g., http://www.pandemicflu.gov). (Also see chapter 1, Pillar Three, Action O [HSC 4.3.6.2].)

Timeframe: Ongoing.

Measure of Performance: Foreign governments and key stakeholders receive authoritative and regular information on U.S. Government avian-influenza policy.

Step 1: Contact DOS and provide support as needed for monthly international updates, including notification of new postings on http://www.pandemicflu.gov.

K. Action (HSC 5.3.6.1): HHS, in coordination with DOS and DOC, will support DOT and DHS in their conducting media and stakeholder outreach to restore public confidence in travel following containment of a pandemic outbreak.

Timeframe: As required.

Measure of Performance: Outreach delivered and traveling public resumes use of the transportation system at or near pre-pandemic levels.

Step 1: Meet with DHS, DOT, DOS, and DOC to develop postpandemic-containment outreach plan.

Step 2: Pilot postpandemic-containment outreach plan.

Step 3: Incorporate changes.

Step 4: Distribute postpandemic-containment outreach through agreed upon mechanisms.

Step 5: Evaluate the efficacy of outreach and develop lessons learned.

L. Action (HSC 5.3.6.2): HHS, in coordination with DOS, DOD, USDA, DOI, and State, local, and tribal governments, will support DHS and DOT in their providing the public and business community with relevant travel information, including shipping advisories, restrictions, and potential closing of domestic and international transportation hubs.

Timeframe: Ongoing.

Measure of Performance: Timely, consistent, and accurate traveler information provided to the media, public, and business community.

Step 1: Contact DHS and DOT to offer HHS subject matter support as needed in the development of relevant travel information.

M. Action (HSC 6.3.8.1): HHS, in coordination with DHS, DOD, and VA, will develop and disseminate a risk communication strategy, updating it as required.

Timeframe: Within 6 months.

Measure of Performance: Implementation of risk communication strategy on http://www.pandemicflu.gov and elsewhere.

Step 1: Meet with DHS, DOD, and VA to develop a work plan for the development of a risk communication strategy.

Step 2: Pilot strategy with other State and Federal partners and incorporate feedback into final version.

Step 3: Incorporate suggestions, finalize, and distribute.

N. Action (HSC 6.3.8.2): HHS will work with DOD and VA in their development and dissemination of educational materials, to assure DOD and VA messages are coordinated and complementary with those developed by HHS, but tailored to DOD and VA use.

Timeframe: Within 6 months.

Measure of Performance: Up-to-date risk communication material published on DOD and VA pandemic influenza websites, HHS website (http://www.pandemicflu.gov), and in other venues.

Step 1: Meet with DOD and VA to coordinate development of educational materials.

Step 2: Exchange material for review and comment.

Step 3: Incorporate suggestions, finalize, and distribute.

O. Action (HSC 7.3.5.1): HHS will work with USDA and in coordination with DHS and DOI, in USDA efforts to work with State, local, and tribal partners; industry groups; and other stakeholders to develop clear and coordinated pre-scripted public messages that can later be tailored to the specifics of a given outbreak and delivered by trained spokespersons.

Timeframe: Have public messages pre-scripted within 3 months.

Measure of Performance: Appropriate informational and risk mitigation messages developed prior to an outbreak, and then shared with the public within 24 hours of an outbreak.

Step 1: Convene meeting with DHS; DOI; USDA; State, local, and tribal partners; and industry groups to discuss development of prescripted public messages.

Step 2: Develop and pilot prescripted public messages.

Step 3: Incorporate changes and produce prescripted public messages.

Step 4: Distribute prescripted public messages through agreed upon mechanisms.

Step 5: Evaluate the efficacy of prescripted public messages and develop lessons learned.

P. Action (HSC 7.3.5.2): HHS will work with USDA and in coordination with DHS, State, local and tribal partners, industry groups, and other stakeholders, to develop guidelines to assure the public of the safety of the food supply during an outbreak of influenza in animals.

Timeframe: Within 6 months.

Measure of Performance: Guidelines for various outbreak scenarios produced and shared with partners; within first 24 hours of an outbreak, appropriately updated guidelines on food safety shared with the public.

Step 1: Convene meeting with USDA, DHS, State, local, and tribal partners, and industry groups to discuss development of animal influenza outbreak food supply safety guidelines.

Step 2: Develop and pilot guidelines.

Step 3: Incorporate changes and produce guidelines.

Step 4: Distribute guidelines through agreed upon mechanisms.

Step 5: Evaluate the efficacy of prescripted public messages and develop lessons learned.

Contents

CHAPTER 8: STATE, LOCAL, AND TRIBAL PREPAREDNESS

Introduction

Preparedness at the State, local, and tribal levels is critical to the country's ability to respond to and recover from an influenza pandemic because it is at these levels that the most direct response will be implemented. For pandemic influenza preparedness to be effective, it must be a multifaceted effort engaging both traditional public health and health care partners, including mental and behavioral health, and other sector partners and stakeholders such as the business community, public safety and law enforcement, emergency management, education, transportation, social services, mental health and substance abuse services, utilities, and Community-Based Organizations (CBOs) and Faith-Based Organizations (FBOs). The duration, scope, and scale of a pandemic will tax infrastructure and mutual-aid agreements with and across most, if not all, jurisdictions and sectors. One of HHS' roles with respect to State, local, and tribal preparedness is providing advice and recommendations on a number of specific topics such as surveillance, public health interventions, vaccine, antiviral drugs, and communications. These topics are covered for the most part in chapters 1–7 in this document. This chapter addresses the cross-cutting preparedness issue of HHS provision of assistance in strengthening State, local, and tribal preparedness for pandemic influenza.

In the event of an influenza pandemic, States, localities, and tribes must be prepared to respond principally with their existing resources because the ability to shift resources from one part of the country or from a neighboring State to another (as is commonly done for other types of emergencies), will be substantially limited given the widespread scope of a pandemic event. Additionally, deployable Federal personnel assets, namely the National Disaster Medical System (NDMS) and the USPHS Commissioned Corps, will be in short supply due to illness, widespread demand for assistance, and the increased need for these personnel in their primary assignments.

To date, much of the planning for population-based, health-related emergencies has occurred within the public health and health care sectors by HHS and through Federal grants and cooperative agreements to States, Territories, and selected cities. Priority public health issues include detection of a novel virus and the necessary surveillance to track its course, implementation of community containment measures, distribution of antiviral drugs and vaccine to priority groups, coordination and delivery of messages through credible spokespersons, psychosocial support for diverse populations, and development of provisions for vulnerable and difficult to access populations. While guidelines, recommendations, and some resources will emanate from Federal Agencies, requisite action must be implemented at the State, local, and tribal levels for effective preparedness and response.

State, local, and tribal efforts to implement the detection, surveillance, response, communications, and evaluation measures discussed in the preceding paragraph will require use of information systems to support the activities. A critical part of State, local, and tribal preparedness is the use of information systems that adhere to standards that are interoperable across jurisdictions and across sectors. Information-systems standards also will facilitate aggregation of relevant data and information at the Federal level. Relevant requirements and standards for preparedness systems have been developed in consultation with State, local, and tribal partners for the PHIN and are required for use in information systems developed with funds distributed through the Public Health Emergency Preparedness Cooperative Agreement.

Health care preparedness has been a major concern because most hospitals currently have limited capacity to absorb increases in patient load. Increases in patient load concomitant with reduced staffing pose an even greater challenge. The outpatient health care sector will be a critical part of the pandemic response as the majority of ill persons will not require hospital care. If the outpatient sector is overwhelmed, hospitals will be under greater pressure, and may thus compromise the ability to effectively triage those requiring acute and advanced medical care services. In addition, certain outpatient care settings serve especially vulnerable persons who, if unable to receive care, will additionally burden hospitals (and in the case of dialysis patients, for example, hospitals may be unable to provide adequate care). Therefore, planning must address maintaining continuity of services for medically fragile persons and emerging acute-care needs amongst the general population.

A key State-level initiative for identifying health personnel to meet increased patient care needs is the development of a State-based system for the advance-registration and credential verification of volunteers who may be used to augment the staff of a hospital or other health care facility. Development of these State-level systems is being supported through the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program. The Medical Reserve Corps (MRC), which establishes teams of local volunteer medical and public health professionals who can contribute their skills during times of community need, may be another source of staffing.

Also, a severe influenza pandemic would very likely affect critical infrastructure beyond the obvious impact on the health care system. As a result of absenteeism due to illness, and potentially compounded by public health measures such as school closures or shelter in place (“snow days”), substantial disruption of critical services may occur. This is especially true given the current system of “just-in-time” delivery of medical supplies and equipment. Inventories are already limited and a disruption of only a few days in delivery of goods could result in shortages of essential supplies such as food, fuel, hospital supplies, and pharmacy supplies. In addition, the ability to consistently supply utilities such as water, gas, and electricity may be compromised, resulting in spot shortages.

Therefore, identifying strategies to mitigate the consequences of absenteeism, of social distancing measures, and potentially even of border closures are an important aspect of preparedness. While contingency and continuity-of-business plans have been developed for many large businesses and utility companies, they have not been developed for a scenario of this magnitude and thus must be reworked to reflect a different set of assumptions.

Civil disturbances or a breakdown in public order may occur in situations where the health care system is overwhelmed, countermeasures such as vaccine and antiviral drugs are in limited supply, and shortages of basic necessities due to supply chain disruptions are occurring. State, local, and tribal law enforcement and public safety personnel will play an important role in providing public safety and security during an influenza pandemic. Their role will be proportional to the severity of the pandemic.

Role of HHS in State, Local, and Tribal Preparedness

The HHS role in State, local, and tribal pandemic influenza preparedness is to provide technical assistance and guidance to State, local, and tribal public health and other leadership in their efforts to prevent, prepare for, protect against, and respond to an influenza pandemic.

HHS responsibilities include, but are not limited to

- Providing guidance documents to jurisdictions outlining goals, objectives, and performance measures for pandemic influenza preparedness activities
- Providing recommendations on the essential components of an adequate jurisdictional pandemic influenza preparedness plan
- Providing subject-matter technical assistance in troubleshooting problematic areas of the jurisdiction's plan, systems, or infrastructure to prepare for or respond to an influenza pandemic
- Ranking (or proposed ranking, because HHS priorities are not the last word) priority groups for vaccine distribution
- Holding forums at the Federal level involving stakeholders across disciplines and organizations in which issues related to State, local, and tribal pandemic influenza preparedness can be discussed
- Developing and testing tools (e.g., functional exercises, drills) for use at the State, local, and tribal levels
- Dispersing Congressionally appropriated pandemic influenza preparedness funds to State, local, and tribal jurisdictions
- Providing disease surveillance data to the States before and during an influenza pandemic

Specific Assumptions and Planning Considerations for State, Local, and Tribal Preparedness

- Leadership from Governors, mayors, and tribal leaders is critical to pandemic influenza preparedness. It ensures coordination, completion, and exercising of jurisdiction-wide plans.
- The well-being, health, and safety of the U.S. population requires community-based action as well as regional coordination for effective preparedness and intervention efforts and should include all government entities, including public health, health care, mental health and substance abuse, animal health, law enforcement, social services, business, and essential services.
- There will be limited Federal personnel assets available for deployment to any one jurisdiction.
- Hospitals and other health care settings are currently unprepared to respond to increases in patient load of the magnitude anticipated in a moderate or severe pandemic.
- If the outpatient health care capacity is overwhelmed, the burden placed on hospitals will surge.
- The number of health care workers will be reduced due to illness or absenteeism while they care for ill family members.
- If health care capacity is seriously exceeded, or misconstrued to be so, public anxiety will increase. The incidence of stress-induced symptoms and disruptive or risky behaviors may increase.
- Of individuals in severely disaster-affected communities, 25–30 percent require intensive psychosocial support, as will 5–10 percent of individuals in moderately affected communities. The affect of pandemic influenza is unknown.
- The HHS Secretary will consider granting waivers and implementing other flexibilities and accommodations in order to support State, local, and tribal preparedness with respect to publicly funded health insurance programs (e.g., Medicaid, State Children's Health Insurance Program (SCHIP)).
- The implementation of community containment measures will result in disruption of a variety of services.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

Many activities must be undertaken at all levels of State, local, and tribal government and society to ensure preparedness for pandemic influenza. The role of HHS with respect to State, local, and tribal planning is primarily to provide funding to facilitate planning; to

provide guidance to assist planners; and to facilitate coordination at the State, local, and tribal levels by coordinating at the national level.

The following Pillar One activities where State and local jurisdictions play a role, but the HSC actions are covered in detail in other chapters include Chapter 3, Public Health Interventions, (HSC 5.1.4.3, 9.1.2.1 and 9.1.3.1); Chapter 4, Federal Medical Response (HSC 6.1.2.4); Chapter 5, Vaccines (HSC 6.1.13.9, 6.1.14.1, and 6.1.14.2); Chapter 6, Antivirals (HSC 6.1.6.1, 6.1.9.2, 6.1.13.9, 6.1.14.1, and 6.1.14.2); and Chapter 7, Communications (HSC 6.1.3.2, 6.1.3.3, and 6.1.12.1).

Planning for a Pandemic

A. Action (HSC 4.1.4.3): HHS will work with DOS to ensure that adequate guidance is provided to Federal, State, tribal and local authorities regarding the inviolability of diplomatic personnel and facilities and will with such authorities and DOS to develop methods of obtaining voluntary cooperation from the foreign diplomatic community within the U.S. consistent with U.S. Government treaty obligations. (Also see chapter 3, Pillar One [HSC 4.1.4.3].)

   Timeframe: Within 6 months.

   Measure of Performance: Briefing materials and an action plan in place for engaging with relevant federal, state, tribal and local authorities.

   Step 1: Disseminate to States briefing materials that explain the privileges and immunities of diplomatic personnel.

   Step 2: Disseminate to States briefing materials that explain the process for obtaining voluntary cooperation from the diplomatic community in the case of quarantine, isolation, or related issue.

   Step 3: If requested, serve as an intermediary or support for the State in working with DOS to obtain voluntary cooperation.

B. Action (HSC 5.1.2.1): HHS will work with DHS and in coordination with DOT and USDA, to review existing grants or Federal funding that could be used to support transportation and border-related pandemic planning. (Also see Chapter 3, Public Health Interventions.)

   Timeframe: Within 4 months.

   Measure of Performance: All State, local, and tribal governments are in receipt of, or have access to, guidance for grant applications.

   Step 1: Provide technical assistance to DHS as needed.

Step 2: Determine annually whether any grant programs can be used to support transportation and/or border-related pandemic planning.

Step 3: Develop and publish "allowable cost" matrices. These charts will be provided in HHS and DHS guidance.

Step 4: Post the guidance's and developed "allowable cost" matrices on agency Web sites, as well as disseminate through other established channels.

C. Action (HSC 5.1.2.2): Under the leadership of DOT and in coordination with DHS and transportation stakeholders, HHS will support a series of forums with governors and mayors to discuss transportation and border challenges that may occur in a pandemic, share approaches, and develop a planning strategy to ensure a coordinated national response. (Also see chapter 3, Pillar One [HSC 5.1.2.2].)

Timeframe: Within 12 months.

Measure of Performance: Strategy for coordinated transportation and border planning is developed and forums are initiated.

Step 1: Work with DOT and DHS and relevant associations to schedule forums.

Step 2: Provide technical assistance to DOT and DHS.

D. Action (HSC 5.1.2.3): In coordination with USDA and transportation stakeholders, HHS will assist DOT and DHS, develop planning guidance and materials for State, local, and tribal governments, including scenarios that highlight transportation and border challenges and responses to overcome those challenges, and an overview of transportation roles and responsibilities under the NRP. (Also see chapter 3, Pillar One [HSC 5.1.2.3] and Pillar Two [HSC 5.2.2.1, 5.2.4.6, and 5.2.4.8].)

Timeframe: Within 12 months.

Measure of Performance: State, local, and tribal governments have received or have access to tailored guidance and planning materials.

Step 1: Provide technical assistance to DOT and DHS as needed.

Step 2: Post guidance to HRSA and CDC Web sites that deal with pandemic influenza.

Step 3: As applicable, incorporate this information into funding guidance or send as attachments.

E. Action (HSC 5.1.3.1): In coordination with DOT and USDA, HHS will support DHS in conducting tabletop discussions and other outreach with private sector transportation and border entities to provide background on the scope of a pandemic, to assess current preparedness, and jointly develop a planning guide. (Also see chapter 3, Pillar One [HSC 5.1.3.1].)

Timeframe: Within 8 months.

Measure of Performance: Private sector transportation and border entities have coordinated Federal guidance to support pandemic planning, including a planning guide that addresses unique border and transportation challenges by mode.

Step 1: Provide technical assistance to DHS as needed.

F. Action (HSC 5.1.3.2): HHS will work with DHS and in coordination with DOT, DOC, Treasury and USDA, and with the private sector to identify strategies to minimize the economic consequences and potential shortages of essential goods (e.g., food, fuel, medical supplies) and services during a pandemic.

Timeframe: Within 12 months.

Measure of Performance: The private sector has strategies that can be incorporated into contingency plans to mitigate consequences of potential shortages of essential goods and services.

Step 1: Determine which HHS Operational Division (OPDIV) representation is essential to the workgroup and invite members to attend and participate.

Step 2: All HHS OPDIVs will, to the extent possible, share this information to all relevant grant and cooperative agreement programs and key stakeholders through various avenues that include listservs, Web sites, program letters, grantee/awardee meetings, and conference calls.

G. Action (HSC 6.1.1.1): HHS will work with other partners in the Federal Government and State, local and tribal governments to define and test actions and priorities required to prepare for and respond to a pandemic.

Timeframe: Within 6 months.

Measure of Performance: Completion and communication of national, Departmental, State, local and tribal pandemic influenza response plans; actions and priorities defined and tested.

Step 1: Set expectation that State, local, and tribal governments will coordinate their pandemic plans with businesses, education sector (including private and

public K–12, colleges and universities, and daycare/preschool), and community and faith-based organizations.

Step 2: Provide technical assistance as requested by State, local, and tribal governments to complete jurisdictional pandemic influenza response plans. Monitor public health and health care emergency preparedness cooperative agreement recipients' completion of pandemic influenza response plans. Communicate the national and HHS pandemic influenza plans to the cooperative agreement recipients to increase understanding by the awardees and help ensure that all plans are complementary to one another.

Step 3: Assist in defining pandemic influenza priorities, capabilities, and performance measures.

Step 4: Report the percentage of States with plans that address the pandemic influenza priorities. Take corrective action with those States that do not do so.

Step 5: Develop a planning guide to assist Indian Health Service (IHS) and tribal health care facilities with planning.

Step 6: Set the expectation in emergency preparedness cooperative agreements and grants that at least one exercise per year will be an exercise conducted jointly between HHS- and DHS-funded responders.

Step 7: Provide technical assistance toward assessing gaps, and planning to address gaps, between preparedness information systems and information system capabilities required to be PHIN compatible and to support pandemic flu.

Step 8: Set the expectation in relevant grant and cooperative agreement guidance documents that PHIN-compatible information systems will be available and used routinely to support public health activities that detect, respond to, and evaluate pandemic influenza and other urgent public health events.

Step 9: Disseminate draft technical guidance entitled "Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-Risk Populations in an Emergency" (http://www.bt.cdc.gov/workbook).

H. Action (HSC 6.1.1.2): HHS, in coordination with DHS, will review and approve State pandemic influenza plans to supplement and support DHS State Homeland Security Strategies to ensure that Federal homeland security grants, training, exercises, technical and other forms of assistance are applied to a common set of priorities, capabilities, and performance benchmarks, in conformance with the National Preparedness Goal.

Timeframe: Within 12 months.

Measure of Performance: Definition of priorities, capabilities, and performance benchmarks; percentage of States with plans that address priorities, identify capabilities and meet benchmarks.

Step 1: Participate in the review of DHS State Homeland Security Strategies to ensure consistency among Federal Departments.

Step 2: Project officers will routinely communicate on issues related to pandemic influenza through the established Interagency Advisory Committee. This group will serve as a forum to update agencies on issues and policies related to pandemic influenza and other Federal activities.

Step 3: The Interagency Advisory Committee will solicit project officers, senior leaders, and policymakers from DHS and HHS to define priorities, capabilities, and performance benchmarks related to pandemic influenza in conformance with the National Preparedness Goal.

Step 4: HHS and DHS will set the expectation in their respective emergency preparedness cooperative agreements and grants that at least one exercise per year will be an exercise conducted jointly between HHS and DHS funded responders.

I. Action (HSC 6.1.1.3): HHS will assist DHS and work in coordination with DOJ, DOT, and DOD in DHS preparations to provide emergency response element training (e.g., incident management, triage, security, and communications) and exercise assistance upon request of State, local, and tribal communities and public health entities.

Timeframe: Within 6 months.

Measure of Performance: Percentage of requests for training and assistance fulfilled.

Step 1: Review current training efforts to ensure consistency and coordination, and to reduce the creation of multiple training products. Focus training efforts on the behaviors to be performed differently.

Step 2: Provide technical assistance to DHS as needed.

Step 3: Inform DHS of HHS trainings.

J. Action (No HSC action): HHS will provide guidance to integrate population-based behavioral countermeasures into Federal, tribal and local communication campaigns and message mapping strategies and cross-sector exercise planning and testing to anticipate behavioral responses and impacts on continuity of critical sector-specific operations under varying conditions of medical countermeasure supply and pandemic severity. (Also see Chapter 7, Communications.)

Timeframe: 12 months.

Measure of Performance: Guidance on assisting vulnerable populations during an influenza pandemic completed and disseminated.

Step 1: Work with partners to create and disseminate guidance and technical assistance about specific vulnerable populations (e.g., people with chronic mental and/or substance use disorders); this guidance will also be used to assist States and other partners to include elements about psychosocial factors in exercise planning.

Step 2: Work with partners to create and disseminate clearly articulated statement of objectives for use of behavioral countermeasures tailored for specific populations under varying conditions of medical countermeasure supply and pandemic severity.

K. Action (HSC 6.1.2.3): HHS, in coordination with DHS, DOT, DOD, and VA, will work with State, local and tribal governments and leverage Emergency Management Assistance Compact agreements to develop protocols for distribution of critical medical materiel (e.g., ventilators) in times of medical emergency.

Timeframe: Within 6 months.

Measure of Performance: Critical medical material distribution protocols completed and tested.

Step 1: HHS OPDIVs will provide technical assistance to States and to IHS and tribal health care facilities as needed.

L. Action (HSC 6.1.2.5): HHS will package and offer to the States and Territories the core operating components of an ESAR-VHP system; and encourage all States, and tribal entities to implement the ESAR-VHP program by providing

technical assistance and orientations at State and territory request to implement and operate Federal guideline (ESAR-VHP) compliant systems.

Timeframe: Offer ESAR-VHP system within 6 months; Provide technical assistance and orientations upon request within twelve months.

Measure of Performance: Guidance and technical assistance, as requested, provided to States to implement ESAR-VHP capability, compliant with federal guidelines, in all States and U.S. territories.

Step 1: Support the development of the core operating components of an ESAR-VHP system.

Step 2: Deploy the ESAR-VHP core operating components to as many States (including the District of Columbia) and U.S. Territories as possible.

Step 3: Provide technical assistance to States, the District of Columbia, and U.S. Territories on the implementation and operation of these systems.

M. Action (HSC 6.1.2.6): HHS, in coordination with the USA Freedom Corps and Citizen Corps programs, will continue to work with States and local communities to expand the Medical Reserve Corps program.

Timeframe: Expansion of program by 20 percent within 12 months.

Measure of Performance: Increase number of Medical Reserve Corps units by 20 percent, from 350 to 420 units.

Step 1: Develop outreach and technical assistance strategies and work plans.

Step 2: Develop communications materials.

Step 3: Conduct activities in keeping with these plans at the regional and national levels.

Step 4: The MRC Program will develop guidance to allow a subset of MRC members to volunteer for Federal deployment. This subset will be identified as the Public Health Service Auxiliary. The MRC program will develop and implement procedures for the U. S. Public Health Service (USPHS)Auxiliary volunteers to be preidentified, precredentialed, trained in appropriate disaster response issues, and preprocessed thru the HHS process for unpaid intermittent Federal employees. The September 2007 goal will be to enroll 3,000 MRC members in the USPHS Auxiliary.

N. Action (HSC 6.1.2.7): HHS, in coordination with DHS, DOD, VA, and the USA Freedom Corps and Citizen Corps programs, will prepare guidance for local

Medical Reserve Corps coordinators describing the role of the Medical Reserve Corps during a pandemic. (Also see chapter 7, Pillar One [HSC 6.1.2.7].)

Timeframe: Within 3 months.

Measure of Performance: Guidance materials developed and published on Medical Reserve Corps website (http://www.medicalreservecorps.gov).

Step 1: Develop guidance based on existing documents (from HHS agencies and others), and with input from MRC regional coordinators and local MRC leaders.

Step 2: Publish materials at http://www.medicalreservecorps.gov.

O. Action (HSC 7.1.1.1): HHS, in coordination with DHS, DOD, and DOI, and will support USDA in its efforts (in partnership with State and tribal entities, animal industry groups, and [as appropriate] the animal health authorities of Canada and Mexico) to establish and exercise animal influenza response plans.

Timeframe: Within 6 months.

Measures of Performance: Plans in place at specified Federal agencies and exercised in collaboration with states believed to be at highest risk for an introduction into animals of an influenza virus with human pandemic potential.

Step 1: Assist USDA in defining avian influenza preparedness gaps, priorities, capabilities, and performance benchmarks.

Step 2: Assist USDA in developing avian influenza planning guidance documents for IHS and tribal health care facilities.

Step 3: Set the expectation in emergency preparedness cooperative agreements and grants that at least one exercise per year will include State Health and State Wildlife/Agriculture sectors.

P. Action (HSC 7.1.2.2): HHS, in coordination with DOD, DHS, and DOI, will assist USDA in partnering with States and tribal entities to ensure sufficient veterinary diagnostic laboratory surge capacity for response to an outbreak of avian or other influenza virus with human pandemic potential.

Timeframe: Within 6 months.

Measure of Performance: Plans and necessary agreements to meet laboratory capacity needs for a worst case scenario influenza outbreak in animals validated by utilization in exercises detailed in HSC 7.1.1.1.

Step 1: Provide technical assistance; assist with developing lab training curriculum and conducting training courses as appropriate.

Q. Action (HSC 8.1.1.1): HHS is working with DHS to help States ensure that State pandemic response plans adequately address law enforcement and public safety preparedness across the range of response actions that may be implemented, and that these plans are integrated with authorities that may be exercised by Federal agencies and other State, local and tribal governments.

Timeframe: Ongoing.

Measure of Performance: All submitted state plans reviewed within two months of receipt.

Step 1: Provide technical assistance to DHS as needed.

Step 2: Support the Federal-level review of all submitted State pandemic influenza plans.

Step 3: Provide technical assistance and monitor their cooperative agreement recipients' completion of pandemic influenza response plans.

Step 4: Communicate the national and HHS pandemic influenza plans to the cooperative agreement recipients.

Step 5: Encourage State, local, and tribal planners to ensure planning partners and stakeholders adequately address preparedness in prisons and jails as well as law enforcement and public safety.

Step 6: Monitor projects on pandemic planning activities to ensure that State pandemic influenza response plans adequately address preparedness plans for prisons and jails as well as law enforcement and public safety workplaces.

Step 7: Provide guidance to IHS and tribal health care facilities to ensure that pandemic response plans adequately address law enforcement and public safety preparedness.

R. Action (HSC 8.1.1.2): HHS will assist DHS, in coordination with DOJ, DOL, and DOD in developing a pandemic influenza tabletop exercise for State, tribal and local law enforcement and public safety officials that they can conduct in concert with public health and medical partners, and ensuring it is distributed nationwide.

Timeframe: Within 4 months.

Measure of Performance: Percent of State, local and tribal law enforcement/public safety agencies that have received the pandemic influenza tabletop exercise.

Step 1: Provide technical assistance to DHS regarding pandemic influenza tabletop exercises.

Step 2: Disseminate the tabletop exercise through various mechanisms to include Web sites, listservs, grantee conference calls, and meetings.

Step 3: Encourage participation of key stakeholders, including businesses, education sector (private and public K–12, colleges and universities, daycare/preschool), and CBOs and FBOs.

S. Action (HSC 8.1.2.7): HHS will, in coordination with DOJ, DOD, DOT, and other appropriate Federal Sector-Specific Agencies, work with DHS in a forum for selected Federal, State, local, and tribal personnel to discuss EMS, fire, emergency management, public works, and other emergency response issues they will face in a pandemic influenza outbreak and then publish the results in the form of best practices and model protocols.

Timeframe: Within 4 months.

Measure of Performance: Best practices and model protocols published and distributed.

Step 1: Provide technical assistance to DHS as needed.

Communicating Expectations and Responsibilities

T. Action (HSC 6.1.4.2): HHS, in cooperation with DHS and DOC, will assist DOT develop model protocols for 9–1–1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services. (Also see chapter 7, Pillar One [HSC 6.1.4.2].)

Timeframe: Within 12 months.

Measure of Performance: Model protocols developed and disseminated to 9–1–1 call centers and public safety answering points.

Step 1: Provide technical assistance regarding infection control and clinical triage protocols.

Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Materiel

U. Action (HSC 6.1.5.1): HHS will encourage and subsidize the development of State, territorial, and tribal antiviral stockpiles to support response activities. (Also see chapter 6, Pillar One [HSC 6.1.5.1].)

Timeframe: Within 18 months.

Measure of Performance: State, territorial and tribal stockpiles established and antiviral medication purchases made toward goal of aggregate 31 million treatment courses.

Step 1: Encourage States to take advantage of federally subsidized antiviral purchasing arrangements.

Step 2: Distribute any guidance on how States can access these arrangements through multiple sources with the States.

Step 3: Explore the feasibility of a stockpile of antiviral drugs for IHS and tribal health care facilities.

V. Action (HSC 6.1.6.4): HHS, as well as DOD, VA and the States, will maintain their antiviral and vaccine stockpiles in a manner consistent with the requirements of FDA's SLEP, and HHS will explore the possibility of broadening SLEP to include equivalently maintained state stockpiles. (Also see chapter 6, Pillar One, Action L [HSC 6.1.6.4].)

Timeframe: Within 6 months.

Measure of Performance: Compliance with SLEP requirements documented; decision made on broadening SLEP to state stockpiles.

Step 1: FDA, in collaboration with State and local health authorities, determine whether to extend Shelf Life Extension Program (SLEP) to State and local stockpiles.

Step 2: If SLEP is extended to State and local stockpiles, develop guidance.

Step 3: Disseminate guidance for compliance with SLEP requirements.

Step 4: Disseminate information on SLEP to IHS and tribal health care facilities.

W. Action (HSC 6.1.7.1): HHS, in coordination with DHS, DOJ, VA, and in collaboration with State, local and tribal partners, will determine the national medical countermeasure requirements to ensure the sustained functioning of medical, emergency response, and other front-line organizations. (Also see chapter 5, Pillar One, Action L [HSC 6.1.7.1].)

Timeframe: Within 12 months.

Measure of Performance: More specific definition of sectors and personnel for priority access to medical countermeasures and quantities needed to protect those groups; guidance provided to State, local, and tribal governments and to

infrastructure sectors for various scenarios of pandemic severity and medical countermeasure supply.

Step 1: Develop guidance to assist local planners, including IHS and tribal health care facilities, in determining the number of essential personnel.

Step 2: Require all applicable grant projects to ensure that numerically quantified lists of personnel from medical, emergency response, and other front-line health care organizations that require priority access to vaccine and antiviral medications are identified.

Establishing Distribution Plans for Medical Countermeasures, Including Vaccines and Antiviral Medications

X. Action (HSC 6.1.13.1): HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, will ensure that States, localities and tribal entities have developed and tested pandemic influenza countermeasure distribution plans, and can enact security protocols if necessary, according to predetermined priorities. (Also see chapter 5, Pillar One, Action P [HSC 6.1.13.1] and chapter 6, Pillar One, Action Q [HSC 6.1.13.1].)

Timeframe: Within 12 months.

Measure of Performance: Ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed established and validated through exercises.

Step 1: Work in cooperation with States and other Federal Agencies to develop and test plans for the allocation, distribution, and administration of pandemic influenza countermeasures with security protocols according to predetermined priorities.

Step 2: Require the incorporation of the pandemic influenza countermeasure allocation, distribution, and administration plans into State-level pandemic response plans.

Step 3: Encourage the development and testing of plans for the allocation, distribution, and administration of pandemic influenza countermeasures with security protocols according to predetermined priorities at the tribal and local levels.

Step 4: Ensure that PHIN-compatible information systems are available and used to support allocation, distribution, and administration of pandemic influenza countermeasures.

Y. Action (HSC 6.1.13.2): HHS will, in coordination with DOD, VA, States, and other public sector entities with antiviral drug stockpiles, coordinate use of assets maintained by different organizations. (Also see chapter 6, Pillar One, Action G [HSC 6.1.13.2].)

Timeframe: Within 12 months.

Measure of Performance: Plans developed for coordinated use of antiviral stockpiles.

Step 1: Provide technical assistance on, facilitate the discussion of, and monitor the development of State, local, and tribal pandemic influenza plans to ensure the coordinated use of antiviral stockpiles in coordination with DOD, VA, and other public sector entities with antiviral drug stockpiles.

Z. Action (HSC 6.1.13.3): HHS will, in collaboration with state, territorial, tribal, and local health care delivery partners, develop and execute strategies to effectively implement target group recommendations.

Timeframe: Within 12 months.

Measure of Performance: Guidance on strategies to implement target group recommendations developed and disseminated to State, local, and tribal authorities for inclusion in pandemic response plans.

Step 1: Build upon resource materials already developed to assist in planning for distribution of countermeasures. Aspects specific to pandemic influenza, namely the targeting of priority groups, will be addressed specifically by convening selected State, local, and tribal planners to define strategies to effectively implement target group recommendations.

Step 2: Disseminate these strategies to State, local, and tribal planners, including IHS and tribal health care facilities.

Step 3: Provide technical assistance on the implementation of these strategies.

AA. Action (HSC 6.1.13.4): HHS will, in coordination with DOD, VA, and in collaboration with State, local and tribal governments and private sector partners, assist in development and testing of distribution plans for medical countermeasure stockpiles to ensure antiviral distribution to infected patients within 48 hours of the onset of symptoms. (Also see chapter 6, Pillar One, Action O [HSC 6.1.13.4].)

Timeframe: Within 12 months.

Measure of Performance: Distribution plans developed and tested.

Step 1: Work in cooperation with States and other Federal Agencies to develop and test distribution plans for medical countermeasure stockpiles to ensure antiviral distribution to infected patients within 48 hours of the onset of symptoms.

Step 2: Require the incorporation of the distribution plans for medical countermeasure stockpiles into State-level pandemic response plans.

Step 3: Encourage the development and testing of distribution plans for medical countermeasure stockpiles at the tribal and local levels.

Step 4: Provide guidance to IHS and tribal health care facilities on the development and testing of distribution plans for medical countermeasure stockpiles.

(Also see Chapter 6, Antiviral Drugs.)

BB. Action (HSC 6.1.13.5): HHS will, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, develop plans for the allocation, distribution, and administration of pre-pandemic vaccine. (Also see chapter 5, Pillar One, Action O [HSC 6.1.13.5].)

Timeframe: Within 9 months.

Measure of Performance: Department plans developed and guidance disseminated to State, local, and tribal authorities to facilitate development of pandemic response plans.

Step 1: Work in cooperation with States and other Federal Agencies to develop and test plans for the allocation, distribution, and administration of pre-pandemic vaccine.

Step 2: Require the incorporation of the plans for the allocation, distribution, and administration of pre-pandemic vaccine into State-level pandemic response plans.

Step 3: Encourage the development and testing of plans for the allocation, distribution, and administration of pre-pandemic vaccine at the tribal and local levels.

(Also see chapter 6.)

CC. Action (HSC 6.1.13.6): HHS will work in coordination with DHS, State, local, and tribal officials and other EMS stakeholders , to support DOT development of suggested EMS pandemic influenza guidelines for statewide adoption that

address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters and other issues. (Also see chapter 4, Pillar One, Action B [HSC 6.1.2.4].)

Timeframe: Within 12 months.

Measure of Performance: Plans developed, tested and incorporated into Department- and State-level pandemic response plans.

Step 1: Provide technical expertise to DOT as needed.

Step 2: Where applicable, disseminate any guidelines that are developed and encourage the participation of key stakeholders.

DD. Action (HSC 6.1.13.7): HHS, in coordination with DHS, DOT, DOD, and VA, will work with State, local, tribal and private sector partners to develop and test plans to allocate and distribute critical medical material (e.g., ventilators with accessories, resuscitator bags, gloves, face masks, gowns) in a health emergency. (Also see chapter 4, Pillar One, Action F [HSC 6.1.13.7].)

Timeframe: Within 6 months.

Measure of Performance: Plans developed, tested, and incorporated into department plan and disseminated to State and tribes for incorporation into their pandemic response plans.

Step 1: Work in cooperation with States, tribes, and other Federal Agencies to develop and test plans for the allocation and distribution of critical medical material in a health emergency.

Step 2: Require the incorporation of the plans for the allocation and distribution of critical medical material in a health emergency into State-level pandemic response plans.

Pillar Two: Surveillance and Detection

The following Pillar Two activities where State and local jurisdictions play a role but the HSC actions are covered in detail in other chapters include Chapter 2, Domestic Surveillance (HSC 6.2.1.1, 6.2.1.2, 6.2.1.3, 6.2.2.3, 6.2.2.5, and 6.2.2.10); Chapter 3, Public Health Interventions (HSC 5.2.1.1, 5.2.4.2, 5.2.4.5, 5.2.4.6, 5.2.4.7, 5.2.4.8, and 5.2.4.10); and Chapter 7, Communications (HSC 5.2.4.10).

Ensuring Rapid Reporting of Outbreaks

A. Action (HSC 6.2.1.4): HHS, along with all other Federal, State, local, tribal, and private sector medical facilities, will ensure that protocols for transporting influenza specimens to appropriate reference laboratories are in place. (Also see chapter 2, Pillar One, Action L [HSC 6.2.1.4].)

Timeframe: 3 months.

Measure of Performance: Transportation protocols for laboratory specimens detailed in HHS, DOD, VA, State, territorial, tribal, and local pandemic response plans.

Step 1: Monitor pandemic planning activities to ensure that protocols for the transportation of laboratory specimens to appropriate reference laboratories are detailed in State, territorial, tribal, and local pandemic response plans.

Step 2: Work with key stakeholders to encourage private sector medical facilities training in the protocols for transporting influenza specimens to appropriate reference laboratories.

B. Action (HSC 6.2.2.8): HHS, in coordination with DHS, DOD, and VA, and in collaboration with State, local, and tribal authorities, will be prepared to assist State, local, and tribal authorities in collecting, analyzing, integrating, and reporting information about the status of hospitals and health care systems, health care critical infrastructure, and medical material requirements. (Also see chapter 3, Pillar Two, Action F [HSC 6.2.4.2] and chapter 4, Pillar One, Action B [HSC 6.1.2.4].)

Timeframe: Within 12 months.

Measure of Performance: Guidance provided to States and tribal entities on the use and modification of the components of the HAvBED system for implementation at the local level.

Step 1: Provide subject-matter experts to work with HHS and other relevant stakeholders in the development of guidelines and modification to the HAvBED system.

Step 2: Disseminate the guidelines to all applicable grant programs through various methods that include Web sites, conference calls, meetings, and program letters.

Step 3: The Interagency Advisory Committee, composed of HHS and DHS staff, will ensure these guidelines are disseminated across all Federal preparedness guidance documents.

Step 4: Provide guidance to IHS and tribal health care facilities to collect, analyze, integrate, and report information about the status of IHS and tribal hospitals and health care systems, health care critical infrastructure, and medical material requirements. (Also see chapter 2, Pillar Two, Action R [HSC 6.2.4.1].)

C. Action (HSC 6.2.2.11): State, local, and tribal public health departments should provide weekly reports on the overall level of influenza activity in their States or localities, with assistance from CDC epidemiologists and field officers posted within each State health department in collecting and reporting these data.

Timeframe: Ongoing

Measure of Performance: Influenza activity reports provided weekly during a pandemic.

Step 1: Assist State, local, and tribal public health departments, as requested, in providing weekly reports on the overall level of influenza activity in their jurisdictions during a pandemic.

D. Action (no HSC item): Assist State, local, and tribal entities in tracking non-hospital beds.

Step 1: Explore infrastructure capabilities to assist State Survey Agencies in standardizing real-time tracking and reporting.

Step 2: Assist States with the development and design of an information system with key elements to track and report provider status to CMS.

Step 3: Solicit input from other State Survey Agencies in broadening knowledge of the key elements of disaster tracking systems.

E. Action (HSC 6.2.3.5): State, local, and tribal public health departments should acquire and deploy rapid diagnostic tests that are specific and sensitive for pandemic influenza strains, as soon as those tested are available.

Timeframe: Ongoing

Measure of Performance: diagnostic tests, if found to be useful, are accessible to federally funded health facilities, via state public health departments.

Step 1: Assist State, local, and tribal public heath departments in acquiring and deploying rapid diagnostics tests for use at HHS-funded hospitals and clinics (e.g., IHS, NIH clinical center, USPHS hospitals).

Pillar Three: Response and Containment

The following Pillar Three activities where State and local jurisdictions play a role but the HSC actions are covered in detail in other chapters include Chapter 3, Public Health Interventions (HSC 6.3.2.2, 6.3.2.5, 6.3.2.7, 6.3.3.2, and 8.3.1.1); Chapter 4, Federal Medical Response; Chapter 6, Antivirals (HSC 6.3.5.2 and 6.3.4.1); and Chapter 7, Communications (HSC 6.3.5.2, 6.3.2.7, and 6.3.3.2).

Leveraging National Medical and Public Health Surge Capacity

A. Action (HSC 6.3.4.2): HHS will work in collaboration with DHS, DOD, and VA to assist major medical societies and organizations in developing and disseminating protocols for changing clinical care algorithms in settings of severe medical surge. (Also see chapter 3, Pillar Three, Actions L and M [HSC 6.3.2.7 and 6.3.3.1] and chapter 7, Pillar Three, Actions D and E [HSC 6.3.2.6 and 6.3.2.7].)

Timeframe: Within 6 months.

Measure of Performance: Guidance and protocols developed and disseminated.

Step 1: Provide personnel to participate in discussions with the above stakeholders and aid in the development of strategies and protocols for expanding hospital and home health care delivery capacity.

Step 2: Disseminate strategies and protocols through various mechanisms to include funding guidance documents, Web sites, grantee conference calls, and meetings as applicable.

Step 3: Provide guidance to IHS and tribal health care facilities on strategies and protocols for expanding hospital and home health care delivery capacity.

B. Action (HSC 6.3.4.3): HHS will work with State Medicaid and SCHIPs to ensure that Federal standards and requirements for reimbursement or enrollment are applied with the flexibilities appropriate to a pandemic, consistent with applicable law. Enrollment, payment, and related matters under the Medicare, Medicaid and SCHIP programs are applied with the flexibilities appropriate to a pandemic, consistent with applicable law.

Timeframe: Preliminary strategies will be developed within 6 months.

Measure of Performance: Draft policies and guidance developed concerning emergency enrollment in and reimbursement through State Medicaid and SCHIP programs during a pandemic.

Step 1: With respect to Medicaid and SCHIPs:

- Identify existing flexibilities States may immediately use to respond
- Determine relevant legal authorities, including whether new or amended authority would be required
- Develop necessary program policies and submit for approval
- Develop mechanisms to implement approved policies
- Identify means to ensure improved health care standards for providers surveyed by CMS or its agents to address disaster preparedness

Step 2: With respect to Medicare:

- Identify potential payment, coverage, and related initiatives
- Develop mechanisms to implement initiatives for which legal authority is clear
- Determine, for other initiatives, relevant legal authorities, including whether new or amended authority would be required
- Develop program policies for other initiatives and submit for approval
- Develop mechanisms to implement remaining approved initiatives

C. Action (HSC 7.3.3.1): HHS will assist USDA, in coordination with DOS, in USDA efforts to partner with appropriate international, Federal, State, and tribal authorities, and with veterinary medical associations, including the American Veterinary Medical Association, to reduce barriers that inhibit veterinary personnel from crossing State or national boundaries to work in an animal influenza outbreak response.

Timeframe: Within 9 months.

Measure of Performance: Agreements or other arrangements in place to facilitate movement of veterinary practitioners across jurisdictional boundaries.

Step 1: Provide technical assistance to USDA regarding safe disposal of animal carcasses.

D. Action (HSC 7.3.1.1): USDA, in coordination with DHS, HHS, DOI and the EPA, will partner with State and tribal entities, animal industries, individual animal owners, and other affected stakeholder to eradicate any influenza outbreak in commercial or other domestic birds or domestic animals caused by a virus that has the potential to become a human pandemic strain, and to safely dispose of animal carcasses.

Timeframe: Ongoing

Measure of Performance: at least one incident management team form USDA on site with in 24 hours of detection of such an outbreak.

Step 1: Facilitate participation by State, local, and tribal public health authorities in USDA-coordinated efforts to eradicate animal influenza, as needed.

E. Action (HSC 7.3.1.2): USDA will coordinate with DHS and other Federal, State, local, and tribal officials, animal industry, and other affected stakeholders during an outbreak in commercial or other domestic birds and animals to apply and enforce appropriate movement controls on animals and animal products to limit or prevent spread of influenza virus.

Timeframe: Ongoing

Measure of Performance: initial movement controls in place within 24 hours of detection of an outbreak.

Step 1: Facilitate participation by State, local, and tribal authorities, as needed, in USDA-coordinated efforts to apply movement controls on animals and animal products to limit or prevent spread of influenza virus during an animal influenza outbreak.

F. Action (HSC 8.3.2.2): HHS will work in coordination with DHS, DOJ, DOD, DOT, and other appropriate Federal Sector-Specific Agencies, to support DHS engagement in contingency planning and related exercises to ensure they are prepared to sustain EMS, fire, emergency management, public works, and other emergency response functions during a pandemic.

Timeframe: Within 6 months.

Measure of Performance: Completed plans (validated by exercise(s)) for supporting EMS, fire, emergency management, public works, and other emergency response functions.

Step 1: Provide technical assistance to DHS as needed.

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

AAFP	American Association of Family Practitioners
AAP	American Academy of Pediatrics
AAPA	American Academy of Physician Assistants
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
ACP	American College of Physicians
AERS	Adverse Events Reporting System
AFRIMS	Armed Forces Research Institute of Medical Sciences
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AMA	American Medical Association
AMDA	American Medical Directors Association
AMS	Advance Manifest System
ANA	American Nurses Association
AOA	Administration on Aging
APEC	Asia-Pacific Economic Cooperation
APHL	Association of Public Health Laboratories
APIC	Association for Practitioners in Infection Control and Epidemiology
APIS	Advance Passenger Information System
ASEAN	Association of Southeast Asian Nations
ASPHA	Assistant Secretary for Public Health Affairs
ASTHO	Association of State and Territorial Health Officials
ATA	Air Transportation Association of America, Inc.
BLA	Biological Licensing A
BRFSS	Behavioral Risk Factor Surveillance System
BSL	Bio-Safety Level
CBER	Center for Biologics Evaluation and Research, FDA
CBP	Customs and Border Protection
CBO	Community-Based Organization
CCID	Coordinating Center for Infectious Diseases, CDC
CDC	Centers for Disease Control and Prevention, HHS
CDER	Center for Drug Evaluation and Research, FDA

CEF	Chicken embryo fibroblasts
CERT	Center for Education and Research in Therapeutics
CMC	Chemistry, manufacturing, and controls
CMS	Centers for Medicare & Medicaid Services
CO	Commissioned Officer
COCA	Clinician Outreach and Communication Activity
COOP	Continuity of Operations Plan
CRA	Countermeasures and Response Administration
CRADA	Cooperative Research and Development Agreement
CSTE	Council of State and Territorial Epidemiologists
DEOC	Director's Emergency Operations Center
DHS	Department of Homeland Security
DMID	Division of Microbiology and Infectious Diseases
DOC	Department of Commerce
DOD	Department of Defense
DOD-GEIS	Department of Defense Global Emerging Infections System
DOI	Department of the Interior
DOJ	Department of Justice
DOL	Department of Labor
DOS	Department of State
DOT	Department of Transportation
DSNS	Division of Strategic National Stockpile
EARS	Early Aberration Reporting System
EC	European Community
ECS	Emergency Communications System (CDC)
ED	Emergency department
EIP	Emerging Infections Program
EIS	Epidemic Intelligence Service
EML	Essential Material List
EMS	Emergency Medical Services
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
EPI-X	Epidemic Information Exchange
ESAR-VHP	Emergency Systems for Advance Registration of Volunteer Health Professionals
ESF	Emergency Support Function
EUA	Emergency Use Authorization

EWORS	Early Warning Outbreak Recognition System
FAA	Federal Aviation Administration
FAO	United Nations Food and Agriculture Organization
FBO	Faith-Based Organization
FDA	Food and Drug Administration
FELTP	Field Epidemiology and Laboratory Training Program
FETP	Field Epidemiology Training Program
FDCA	Food, Drug, and Cosmetic Act
FMS	Federal Medical Station
FWS	U.S. Fish and Wildlife Service (DOI)
GBS	Guillain-Barre Syndrome
GCC	Government Coordinating Councils
GDD	Global Disease Detection
GEMS	WHO Global Event Management System
GHSAG	Global Health Security Action Group
GHSI	Global Health Security Initiative
GIS	Genome Institute of Singapore
GLP	Good Laboratory Practice
GOARN	Global Outbreak Alert Response Network (WHO)
HA	Haemagglutinin
HAN	Health Alert Network
HAvBED	Hospital Available Beds for Emergencies and Disasters
HHS	Department of Health and Human Services
HMO	Health Maintenance Organization
HPAI	Highly pathogenic avian influenza
HRSA	Health Resources and Services Administration
HSC	Homeland Security Council
IATA	International Air Transport Association
IB	Influenza Branch, CDC
ICLN	Integrated Consortium of Laboratory Networks
ICAO	International Civil Aviation Organization
ICCL	International Council of Cruise Lines
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IDE	Investigational Device Exemption
IDSA	Infectious Disease Society of America
IEIP	International Emerging Infections Program

IHS	Indian Health Service
ILI	Influenza-like illness
IMO	International Maritime Organization
IMT	Incident Management Team
IND	Investigational New Drug
IPAPI	International Partnership on Avian and Pandemic Influenza
IRB	Institutional Review Board
IRCT	Incident Response Coordination Team
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LID	Laboratory of Infectious Diseases, NIAID
LRN	Laboratory Response Network
MDCK	Madin-Darby Canine Kidney cell line
MIDAS	Models of Infectious Disease Study (NIH)
MMWR	Morbidity and Mortality Weekly Report
MRC	Medical Reserve Corps
MOU	Memorandum of Understanding
NA	Neuraminidase
NACCHO	National Association of County and City Health Officials
NAHDO	National Association of Health Data Organizations
NAMRU-2	Naval Medical Research Unit 2 in Jakarta, Indonesia
NAMRU-3	Naval Medical Research Unit 3 in Cairo, Egypt
NBIS	National Biosurveillance Integration System
NCI	National Cancer Institute
NDA	New Drug Application
NDMS	National Disaster Medical System
NEC	National Economic Council
NEISS-CADE	National Electronic Injury Surveillance System Cooperative Adverse Drug Event
NGO	Non-governmental organization
NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMS	National Incident Management System
NIOSH	National Institute for Occupational Safety and Health, CDC
NIP	National Immunization Program
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRP	National Response Plan

NSC	National Security Council
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
NVSN	New Vaccine Surveillance Network
OCONUS	Outside continental United States
OFRD	Office of Force Readiness and Deployment (HHS)
OIE	World Organization for Animal Health
OPDIV	Operational Division
OPHEP	Office of Public Health Emergency Preparedness
OPM	Office of Personnel Management
OS	Office of the Secretary, HHS
OSHA	Occupational Safety and Health Administration
PAPR	Powered Air Purifying Respirator
PCR	Polymerase Chain Reaction
PGO	Procurement and Grants Office
PER.C6	A human fetal retinoblast cell line
PHIN	Public Health Information Network
PNR	Passenger Name Record
PPE	personal protective equipment
RCA	Rapid Cycle Analysis Project
REDI	Regional Emerging Diseases Intervention Center, Singapore
RT-PCR	Reverse transcriptase-polymerase chain reaction
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SARS	Severe Acute Respiratory Syndrome
SCC	Sector Coordinating Council
SCHIP	State Children's Health Insurance Program
SEARO	WHO Regional Office for South-East Asia
SHEA	Society for Healthcare Epidemiology of America
SLEP	Shelf Life Extension Program
SLTT	State, local, territorial, and tribal
SNS	Strategic National Stockpile
SPN	Sentinel Provider Network
SPP	Security and Prosperity Partnership of North America
TIGR	The Institute for Genomic Research
TSA	Transportation Security Administration
UN	United Nations

U.S.	United States
USAID	United States Agency for International Development
USCG	United States Coast Guard
USDA	United States Department of Agriculture
USPHS	United States Public Health Service
USTR	United States Trade Representative
VA	Veterans Administration
VAERS	Vaccine Adverse Event Reporting System
VSD	Vaccine Safety Data
WHO	World Health Organization