



## ANNEX F (COMMUNITY INTERVENTION)

### REFERENCE:

1. Implementation Plan for the National Strategy for Pandemic Influenza, Homeland Security Council, (May 2006)
2. HHS Pandemic Influenza Implementation Plan (August 2006 Draft)
3. WHO Writing Group. Non-pharmaceutical Interventions for Pandemic Influenza, National and Community Measures. *Emerging Infectious Diseases* 12(1), (January 2006), 88-94
4. CDC. Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions, February 2007.

### 1. SITUATION

- a. The “center of gravity” of the pandemic response will be in local communities. Preparedness at the State/Local/Territorial/Tribal (SLTT) levels is critical to the country’s ability to respond to and recover from an influenza pandemic. For influenza pandemic preparedness to be effective, it must be a coordinated, multifaceted effort engaging both traditional public health and health care partners and other public, private, and non-governmental organization (NGO) sector partners. All case, population, and personal based intervention strategies are applicable in U. S. communities.
- b. 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 transmission during patient care. However, when a pandemic emerges, a vaccine will not be immediately available, the supply of antiviral drugs may be limited, and the magnitude of their effect against a novel influenza strain cannot be predicted with certainty. Therefore, nonpharmaceutical public health strategies and techniques (augmented by selective use of antiviral drugs) will be essential to



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minimize infection, delay spread, and reduce the impact of pandemic disease, especially during the initial wave (s).

- c. Nonpharmaceutical approaches include voluntary home isolation of ill persons, home and facility quarantine of those exposed, community social distancing measures (e.g., closure of public places, closure of specific worksites, stoppage of public transportation, student dismissals), personal hygiene measures, and infection control in healthcare and other venues. Local health officials should be prepared to implement, monitor, and evaluate these non-pharmaceutical techniques as dictated by disease dynamics in their communities.

## 2. MISSION

Communities will employ pharmaceutical and nonpharmaceutical measures to counter the effects of an influenza pandemic. CDC will provide timely guidance and support to communities.

## 3. EXECUTION

### a. Concept of Operations

From the initial emergence of an influenza pandemic and through subsequent pandemic waves, the public health and healthcare sectors can utilize an assortment of intervention strategies and operational techniques to stop (contain) or slow/limit (mitigate) emergence, importation, spread, and impact of pandemic influenza. Interventions can be classified as case-based, population-based, or personal-based.

Case-based interventions for pandemic influenza focus on direct management of ill persons and their close contacts to prevent new infections and limit chains of transmission.

Operational techniques involve recognition, confirmation, isolation and treatment of case-patients plus the identification, quarantine, and antiviral prophylaxis of contacts. Case based interventions would be used during the pandemic alert period as part of international or domestic containment efforts to stop a pandemic from emerging or delaying amplification of transmission in a community.



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Population-based interventions include actions directed at susceptible groups or entire communities to delay spread. These include a variety of social distancing techniques as well as mass prophylaxis (used in specialized containment efforts) and mass vaccination. Personal-based interventions are behavioral risk-reduction actions that further limit exposure among susceptible persons. These include voluntary self-sheltering, standard infection control practices among healthcare workers, hand hygiene, respiratory etiquette, and disinfection of potentially contaminated surfaces.

These three classes of intervention strategies and techniques are summarized in Table 6, on Page E-2.

This Annex focuses on public health interventions in general and highlights the importance of pharmaceutical interventions (antiviral drugs and vaccines) and nonpharmaceutical interventions (community mitigation) and their roles in an influenza pandemic, to include CDC's responsibilities for them.

Domestic Response. If containment abroad and efforts to prevent importation fail, and an introduction of pandemic influenza into the United States appears inevitable or has begun, U.S. communities will be required to mobilize resources and implement interventions directed at stopping, limiting or otherwise slowing the spread of disease throughout the country. This could minimize suffering and death, reducing economic and social effects of an influenza pandemic. CDC will provide containment and mitigation support to community efforts via ESF #8.

**b. Pharmaceutical and Medical Countermeasures**

COTPER (DSNS) works closely with SLTT governments during their pandemic preparedness efforts and focuses on providing assistance with planning, coordinating, and distributing pharmaceutical and medical countermeasures (antiviral drugs, intravenous antibiotics, PPE, ventilators, and other medical supplies). Unlike other commodities discussed here, the PanFlu vaccine is NOT an SNS asset. The development of candidate vaccine strains and distribution of industry produced vaccine are specific tasks of CDC. The Federal government will own and control pandemic influenza vaccine up to the point

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where physical possession of and accountability for vaccine is turned over to SLTT authorities at project area ship-to sites. Appendix 2 to Annex F describes this process. Cooperative agreements have provided SLTT partners with Federal funds to accomplish influenza planning and preparedness. COTPER (DSNS) has provided SLTT governments with planning guidance and training assistance to increase their readiness. In the State and Local Pandemic Influenza Planning Checklist, HHS/OS encourages SLTT governments to provide adequate planning to receive, stage and store (RSS) SNS assets, to have the necessary infrastructure in place to disseminate SNS assets to local facilities and to provide the necessary physical and protective security measures for storage and transport of SNS assets. CDC may request additional security measures for SNS from other agencies through coordination with the HHS SOC.

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#### 4. COUNTERMEASURE TASKS (ANTIVIRAL DRUGS)

##### Inter-Pandemic Period: (WHO Phases 1-2; USG Stage 0)

###### 1) DSNS

- a) Procure and maintain antiviral drugs and other countermeasures in accordance with goals established by the U.S. Government.
- b) Develop plans to distribute antiviral drugs and other countermeasures in accordance with allocations and priorities set by the U.S. Government

###### 2) NCIRD

Develop protocols and procedures and appropriate partnerships for safety and effectiveness monitoring of Antiviral drugs.

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##### Pandemic Alert Period: (WHO Phases 4-5; USG Stage 2)

###### 1) DSNS

- a) On order, distribute up to 5% of antiviral drugs to international sites.
- b) Push out antiviral drugs *pro rata* to 62 project areas.
- c) Distribute masks and respirators *pro rata* to 62 project areas. Refer to Appendix 1 (Antiviral Drug Distribution and Use) to ANNEX F.





- d) On order, ship additional SNS assets (PPE, ventilators, intravenous antibiotics, and medical supplies), *pro rata* to project areas. Refer to Appendix 1 (Antiviral Drug
- e) Distribution and Use) to ANNEX F.
- f) Acquire replacements for all above as funds become available.

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**2) NCIRD**

Ensure that procedures and protocols are in place and ready for implementation, in order to be prepared to carry out safety and effectiveness monitoring of antivirals during pandemic period

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**Pandemic Period: (WHO Phase 6; USG Stages 3-6)**

**1) DSNS:**

- a) Coordinate the distribution of antiviral drugs and other countermeasures to SLTT RSS.
- b) Plan for receipt and utilization of additional pandemic funds.
- c) Pack replacement antiviral drugs and other countermeasures in preparation for shipment to newly designated locations.
- d) Containment stockpile (domestic) - TBD

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**2) NCIRD:**

- a) Monitor the effectiveness of antiviral drugs.
- b) Monitor the safety of antiviral drugs.

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**5. COUNTERMEASURE TASKS (VACCINES)**

**Inter-Pandemic Period: (WHO Phase 1-2; USG Stage 0)**

**1) NCIRD:**

- a) Provide guidelines and training for SLTT health care providers.
- b) Assist SLTT groups with planning for the allocation and distribution of vaccines to pre-designated sites, as well as the receipt and further distribution of vaccines to the end user.





- c) Negotiate vaccine purchase contracts to include stipulations that manufacturers must provide vaccine security during the manufacturing process and shipment to pre-designated sites.
- d) Work with manufacturers in developing a distribution and notification of shipment plan to facilitate direct shipping to pre-designated sites.
- e) Develop guidance for SLTT groups for designing immunization clinic layout, identifying key functions, recruiting clinic staff to fill key functions, and training clinic staff on patient flow management and vaccination procedures.
- f) Develop vaccination messages directed to providers, the press, and the general public about influenza, influenza vaccine, rationale for use of priority groups, administration of additional vaccine doses if required.
- g) Assist the US Government in developing guidelines for prioritization and sub-prioritization of immunizations.
- h) Plan for vaccine effectiveness studies.

- 2) **Science Vision and Alliances Team, Office of Chief Science Officer (OCSO):**  
Identify and disseminate guidance to CDC Leadership Team on all ethical issues regarding vaccines.

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**Pandemic Alert Period: (WHO Phase 4-5; USG Stage 2)**

1) **NCIRD:**

- a) On order, notify vaccine manufacturers to distribute vaccine to pre-designated sites.
- b) Notify SLTT pre-designated sites, via a contract call center, about shipment tracking numbers to ensure safe delivery.
- c) Disseminate US Government priority and sub-priority vaccination guidelines through public and private sector partners.
- d) Provide information to SLTT groups on vaccine receipt procedures, and storage of vaccines and ancillary supplies.
- e) Establish plans for tracking population vaccination coverage levels (with National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)).

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**Pandemic Period: (WHO Phase 6; USG Stages 3-6)**

**1) NCIRD:**

- a) Assist with the revision of US Government prioritization guidelines based upon the characteristics of the pandemic.
- b) Following decision to distribute pre-pandemic influenza vaccine along with ancillary supplies to states, assure administration to priority groups in accordance with USG guidance
- c) Compile and analyze vaccine dose tracking information and share with SLTTs (with NCPHI).
- d) Assess vaccine effectiveness.
- e) Monitor the impact of antigenic drift on the potential efficacy of different vaccination approaches.
- f) Track population vaccination coverage levels (with NCCDPHP).

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**2) OCSO:**

Monitor the safety of vaccines.

**6. COORDINATING INSTRUCTIONS:**

To request a current copy of the "Receiving, Distributing and Dispensing National Stockpile Assets, A Guide for Preparedness" email the CDC Division of Strategic National Stockpile, Program Preparedness Branch at SNS\_PPB@cdc.gov.

Refer to Appendix 1 (Informatics) to Annex K (Information Management) for tracking countermeasures.

For antiviral and vaccine specific taskings on a webpage, access CDC Influenza Pandemic Action Register. Enter COTPER/DEOC portal ( <http://eocportal.cdc.gov> ); scroll down to Pandemic Flu Planning event window, and click on CDC Influenza Pandemic Action Register. Select "Strategic National Stockpile" in the drop down box entitled "Division for DSNS Taskings." Select "ISD" in the drop down box entitled "Division for Vaccine Taskings."

See Annex E Reference 6 and Appendix 3 (Community Mitigation) to Annex F for more detailed information on nonpharmaceutical intervention strategies.



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## **7. SUPPORT SERVICES**

Refer to Base OPLAN paragraph 4.

## **8. MANAGEMENT AND COMMUNICATIONS**

Refer to Annex K (Information Management).

## **APPENDIXES**

1. Use of Antiviral Drugs
2. Pandemic Influenza Vaccinations
3. Community Mitigation
4. Management and Distribution of Antiviral Drugs and Other Countermeasures



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## APPENDIX 1 (USE OF ANTIVIRAL DRUGS)

### 1. SITUATION.

The Influenza Pandemic Threat: Refer to [Annex B \(Disease Intelligence\)](#).

Mission and Intent of Higher and Supporting Organizations: Refer to the [Base OPLAN](#).

Environment: Refer to [Annex B \(Disease Intelligence\)](#).

#### a. Background/Assumptions

1) The Secretary, HHS, in consultation with the HHS Assistant Secretary for Preparedness and Response (ASPR) and the Director, CDC, will determine when to activate the SNS to begin the distribution of antiviral drugs and medical countermeasures based on the WHO Phase characterization and the severity of the disease. Upon the decision to deploy countermeasures, the Director will choose a “metered” or “sequential” distribution of on hand Stockpile assets.

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2) All 62 CDC Public Health Emergency Preparedness (PHEP) Project Areas (all 50 states, Los Angeles County, New York City, Chicago, District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the six Pacific Island Jurisdictions (American Samoa, Commonwealth of N. Mariana Islands (CNMI), Guam, Marshall Islands, Palau, Fed. States of Micronesia), have incorporated distribution of medical countermeasures into their pandemic plans. Plans include the ability to receive, stage, store, and distribute.

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3) In addition to the antiviral drug regimens maintained by SNS, the 62 Project Areas will be responsible for the distribution of the antiviral drug regimens they procure on their own, including those purchased with the Federal subsidy.

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### 2. MISSION.:

a. Antiviral drugs will be used to contain or suppress an initial pandemic outbreak wherever it occurs in the world and when cases are first introduced into the United States.

b. Antiviral drugs will be employed in support of community efforts to mitigate the effects of an influenza pandemic (USG, Stage 5).

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### 3. EXECUTION:

#### a. Inter-Pandemic and Pandemic Alert Periods

##### 1) Overview

- a) Antiviral drugs (“antivirals”) recommended for inclusion in the stockpile include oseltamivir and zanamivir, distributed at 80% and 20%, respectively. In addition, several million regimens of rimantadine, purchased in a season of influenza vaccine shortage, are still held in the SNS. SNS has a current approved target of 50 million, ten capsule, antiviral drug regimens.
- b) Use of these agents during an influenza pandemic may reduce morbidity and mortality and diminish the overwhelming demands that will be placed on the healthcare system.
- c) Antiviral drugs might also be used during the Pandemic Alert Period in limited attempts to contain small disease clusters and potentially reduce transmission and slow the spread of novel influenza viruses.
- d) SLTT health departments should coordinate with NCIRD to develop plans for measurement and monitoring of safety and effectiveness of antivirals.

##### 2) Factors Affecting Use of Antiviral Drugs

- a) Availability of antiviral drugs, either through the SNS, State or local stockpiles or the private sector.
- b) Decisions regarding appropriate use of antivirals, i.e. treatment, prophylaxis, or both, and priority groups to receive antivirals. Current policies are under review and revision.
- c) Susceptibility of the pandemic influenza strain to available antiviral drugs.
- d) Evidence of the effectiveness of antiviral drugs to reduce the mortality and/or severe morbidity of the pandemic strain based on clinical and epidemiological information collected at the start of the pandemic.

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**3) Use of Antiviral drugs for Treatment**

A patient with a suspected case of avian Influenza A (H5N1) or another novel strain of influenza should be treated with oseltamivir or zanamivir twice a day for 5 days, administered as early as possible, ideally within 48 hours after onset of symptoms, and placed in isolation. This policy is subject to modification as new scientific data become available.

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**4) Use of Antiviral drugs for Targeted Containment of Disease Clusters**

a) In special circumstances, state and local health departments could consider antiviral treatment of ill patients and “targeted antiviral post-exposure prophylaxis” of close contacts as a community-based measure for containing small clusters of infection with novel strains of influenza virus. This measure may be best suited for small, well-defined settings such as the initial introduction of a virus with pandemic potential into a small community or a military base. However, once a pandemic is underway, such a strategy may not represent an efficient use of limited antiviral supplies. Available antiviral supplies will influence local decisions to start and stop attempts at containment and priorities for antiviral use.

b) Because targeted antiviral post-exposure prophylaxis would require rapid delivery and administration of substantial stocks of antiviral drugs, its feasibility should be evaluated in light of antiviral drug supply and interim recommendations on antiviral drug use during a pandemic. Containment efforts may also involve community mitigation strategies and would require effective communication with the affected community.

**5) Use of Antiviral drugs for Prophylaxis**

a) Other than antiviral drugs reserved for containment, the current federal strategy for state and federal stockpiled antiviral agents prioritizes the use of antiviral drugs for treatment. Decisions regarding USG procurement and other options are pending. Prophylaxis with antiviral drugs may be administered following exposure

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(PEP) or for the duration of influenza virus transmission during a pandemic outbreak.  
Guidance on priority groups for prophylaxis are under development.

6) Pandemic Periods

a) If Pandemic Influenza is reported abroad, State and local health departments should:

- (1) Meet with local partners and stakeholders to review the State-based antiviral drug distribution plan.
- (2) Modify the distribution plan to take into account possible updated recommendations on target groups, priorities for antiviral use, and updated information on projected supplies of antiviral drugs.
- (3) Notify the medical community about the status of the plan and the availability of antiviral drugs.
- (4) Disseminate public health guidelines that encourage drug-use practices that help minimize the development of drug resistance.
- (5) Provide the public with information on interim recommendations and their rationale for the use of antiviral drugs during an influenza pandemic.
- (6) Finalize the development of plans to measure effectiveness of antivirals and implement activities with pre-defined partners.

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b) When there is limited transmission of pandemic influenza in the United States, State and local health departments in consultation with HHS and CDC should:

- (1) Attempt local containment of the novel strain of influenza virus by using antiviral drugs to treat suspect cases and provide post-exposure prophylaxis to their close contacts in addition to community mitigation strategies (non-pharmaceutical interventions), as deemed necessary.
- (2) Activate State pandemic plans, including antiviral use plans for identifying priority groups for prophylaxis and treatment.
- (3) Continue to work with healthcare partners to ensure appropriate use of antiviral drugs in the medical management of early cases and contacts.

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- (4) Assist hospitals in implementing appropriate infection control measures and in developing procedures for early detection and treatment of influenza in healthcare workers.
  - (5) Work with Federal partners to begin monitoring the safety and effectiveness of drugs and ensure that available antiviral drugs are used in accordance with Federal and local recommendations.
- c) When there is widespread transmission of pandemic influenza in the United States
- (1) Priorities for antiviral use will depend upon local antiviral supplies. The paramount goal should be to treat ill patients. Depending on antiviral supplies prioritization of antiviral agent use may be necessary, i.e. treat those at highest risk of severe illness and death and to preserve the delivery of healthcare and other essential critical services through early treatment of targeted persons. Community mitigation strategies (non-pharmaceutical strategies) and effective communication will also be important components of pandemic response.
  - (2) After a vaccine becomes available, antiviral drugs may be used to protect persons who have an inadequate vaccine response (e.g., the elderly and those with underlying immunosuppressive disease) as well as persons with contraindications to vaccination, such as anaphylactic hypersensitivity to eggs or other vaccine components.
  - (3) Until the pandemic has waned, State and local health departments should continue to work with healthcare and Federal partners to monitor the safety and effectiveness of antiviral drugs, monitor strains for evidence of resistance to the drugs, and to encourage appropriate drug use practices that help minimize the development of drug resistance. These data should be used to modify policies for antiviral drug use in subsequent waves
- b. If an emergency is declared by the Secretary, HHS, justifying an Emergency Use Authorization (EUA), the FDA Commissioner may authorize the use of an unapproved

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medical product or an unapproved use of an approved medical product. Conditions of an  
EUA may include:

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- 1) Record keeping (e.g., recipient's name, contact information and other information, as required.
- 2) Preparation and distribution of information sheets to health care providers and patients.
- 3) Adverse event reporting .



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## APPENDIX 2 (PANDEMIC INFLUENZA VACCINATION)

### REFERENCE:

1. Centers for Disease Control and Prevention, Pandemic Influenza Vaccination: A Guide for State, Local, Territorial and Tribal Planners, December 11, 2006
2. Control and Prevention. Draft Pandemic Influenza Vaccine Plan. December 2007.
3. US Government Interagency Working Group on Pandemic Influenza Vaccine Prioritization. Draft Guidance on Allocating and Targeting Pandemic Influenza. 17 October 2007.

OVERVIEW: The overarching mission of CDC’s vaccine planning activities for pandemic influenza is to protect the public’s health and minimize the impact of an influenza pandemic by facilitating the manufacture, distribution, and administration of safe and effective pre-pandemic and pandemic influenza vaccines. At the operational level, facilitating the timely administration of vaccine to priority groups as vaccine becomes available will involve successful execution of an overall vaccine readiness strategy.

### 1. SITUATION

#### a. Assumptions

- 1) CDC’s planning assumptions are based upon the National Response Framework, Federal pandemic and all hazard plans, DHHS pandemic plans, and discussions and coordination with Federal departments and agencies; SLTT health departments; and industry partners.
- 2) CDC will provide vaccine manufacturers with seed viruses for pre-pandemic and pandemic influenza vaccine development and manufacturing.
- 3) The Federal government will own and control pre-pandemic and pandemic influenza vaccine up to the point where physical possession of and accountability for vaccine is turned over to SLTT authorities at ship-to sites designated by the 62 CDC Public Health

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Emergency Preparedness Project Areas (50 states; Washington, DC; New York City; Chicago; Los Angeles County; and 8 U.S. territories and freely associated states).

- 4) Manufacturers and/or distributors will ship vaccine to the project areas under the direction of the Federal government.
- 5) Non-licensed pre-pandemic and pandemic influenza vaccine will be administered under an EUA.
- 6) CDC is the Federal agency responsible for coordinating pre-pandemic and pandemic vaccine distribution, monitoring vaccine distribution, monitoring vaccine doses administered and coverage, assessing vaccine effectiveness, and monitoring vaccine adverse events
- 7) Pre-pandemic and pandemic influenza vaccine in the early stages of a pandemic will likely be in relatively short supply and will be reserved for priority groups.
  - a) Vaccine production will require a minimum of 4 to 5 months from the time the pandemic vaccine strain is isolated until initial vaccine distribution is begun.
  - b) Only U.S.-manufactured vaccines will be available for U.S. purchase during a pandemic.
  - c) Availability of pandemic vaccine will be a function of both manufacturing capacity and use of adjuvants. Planners should assume that the amount of vaccine produced monthly will cover 1.5% of the population (with 2 doses). Planners should note that supply could be greater or smaller. Up to 20 million persons, critical to the maintenance of the national infrastructure will be vaccinated with stockpiled pre-pandemic vaccine once sustained person-to-person transmission has been documented anywhere in the world.
  - d) Priority groups for pandemic vaccination are currently under review by the U.S. Government. Draft guidance was published for public comment in October 2007. Recommendations are subject to change based on epidemiological information once a pandemic begins.
  - e) Priority groups are divided into occupationally-defined groups and risk-based groups.

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8) Medical materiel (syringes and needles) to support the administration of vaccinations will be procured and distributed by the USG.

9) Planning Considerations

a) A pandemic vaccination program may take place over many months and will involve vaccinating an unprecedented number of persons. It will likely unfold in several phases:

(1) Phase 1: Vaccination with stockpiled pre-pandemic influenza vaccine, conducted by public health authorities.

(2) Phase 2: Vaccination with pandemic influenza vaccine, conducted by public health authorities (or designees).

(3) Phase 3: Vaccination with pandemic influenza vaccine, conducted by the private sector.

b) Vaccine administration must be carefully controlled due to limited supply, and should be initially targeted to priority groups.

c) Vaccine availability may be more or less than planned; therefore, flexibility in planning is essential.

d) Maintaining sufficient staffing for the vaccination effort will be a key challenge given the anticipated duration of the pandemic vaccination program. Delegation of vaccination to other institutions or agencies, where appropriate, will help free up public health personnel for other activities.

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## 2. VACCINE DISTRIBUTION AND ALLOCATION

Project areas will determine allocation of vaccine within their jurisdictions. Distribution of vaccine will involve shipment to pre-arranged, ship-to sites in each project area. Project areas will be responsible for security and proper storage of vaccine at these sites.

### a. Planning actions by project areas

1) Estimate weekly allocation of vaccine based on vaccine availability assumptions and population size.





- 2) Designate numbers of ship-to sites (up to an average of one per county). These sites may be local or tribal health departments, as well as clinical settings such as hospitals.
- 3) Determine allocation of vaccine to each site.
- 4) Determine further allocation of vaccine from ship-to sites to secondary ship-to sites or points of dispensing (PODs).
- 5) Ensure availability of sufficient cold storage at all locations, to include back-up power for vaccine refrigerators.
- 6) Determine how vaccine will be transported to each vaccinating site.
- 7) Develop chain of custody procedures.
- 8) Develop a vaccine security plan.

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**b. Distribution considerations**

- 1) The major advantage of having limited storage sites is greater control over vaccine stocks.
- 2) The major disadvantage of having limited storage sites is the increased need for repackaging, local transport, and security. Repackaging will be done in compliance with proper medical practices and legal guidance.

**c. Allocation considerations**

- 1) For occupationally-defined groups, allocation of vaccine within project areas will need to be based on location of employment.
- 2) For risk-based groups, vaccine should be allocated based upon total population size.

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**d. Security considerations**

- 1) The limited supply of pre-pandemic and pandemic influenza vaccine will render it an extremely valuable resource. Security planning at all levels, from ship-to sites to administration, must be comprehensive and rigorous.
- 2) Law enforcement must be an active partner in planning at both state and local levels with clear delineation of roles and expectations.

**3. VACCINATION OF PRIORITY GROUPS**



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**a. Planning actions**

- 1) Develop a comprehensive plan to vaccinate priority groups as vaccine becomes available.
- 2) Develop memoranda of agreement (MOAs), where applicable.

**b. Develop protocols for verification of priority group membership.**

**1) Considerations for vaccination of specific groups:**

a) Inpatient healthcare workers and support staff.

(1) Vaccination delegated to hospitals, nursing homes, etc. A point-of-contact at each institution should be identified to be responsible for ensuring that all eligible staff are vaccinated and that dose tracking requirements are met.

(2) When vaccinations are provided by the public health department, the healthcare institution should provide a list of eligible personnel.

b) Outpatient healthcare workers and support staff.

(1) Distribution sites should be designated where medical office staff may pick up vaccine stocks.

(2) Public healthcare departments may elect to centralize vaccination of medical offices to prevent waste.

(3) Medical offices may be required to prioritize staff recipients of vaccine within the office to best enable them to continue to provide services.

(4) Public safety personnel may be vaccinated by public health departments or delegated to healthcare institutions.

(5) Large police and fire departments may have internal resources to administer vaccines.

(6) EMS groups may be called upon to vaccinate personnel.

c) Persons responsible for critical infrastructure: TBD

d) Persons at risk of serious outcomes and their contacts: TBD

**2) Considerations for verification of priority group membership.**

a) Validated lists should be provided to ensure that vaccine is not used for persons outside the priority group (such as family members).

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- b) Risk-based groups membership may be verified by requiring a doctor's statement or copies of prescriptions.
- c) Public health departments should encourage persons with chronic conditions to seek documentation before the onset of a pandemic.

#### 4. LOGISTICS ISSUES

##### a. Planning actions

- 1) Determine number and location of PODs.
  - 2) Determine staffing and resource requirements for each clinic to support long term activity.
  - 3) Identify sources of staffing and develop MOAs.
  - 4) Develop training plans.
  - 5) Develop security plans which consider crowd control and vaccine security.
  - 6) Develop incident response plans for potential riots and other incidents.
  - 7) Develop plans for administration of additional doses, if needed, which consider provision of information about need and scheduling.
  - 8) Develop infection control plan.
  - 9) Conduct vaccination clinic exercises.
- Develop materiel and supply lists for the effective conduct of clinics.

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##### b. Planning considerations

- 1) Large scale vaccination planning must consider both accessibility to clinics and available staffing.
- 2) Infection control measures may include:
  - a) Separate potential influenza cases from non-ill persons.
  - b) Select large facilities to lessen crowding.
  - c) Minimize wait times by issuing tickets or reservations.
  - d) Hold open air clinics where feasible.

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- e) Offer hand hygiene materials, tissues, lavatory/hand washing facilities and waste receptacles (to include biomedical (sharps) containers) on site.
- f) Consider provision of masks for clinic staff, and potentially to vaccinees where clinic crowding cannot be avoided.

**3) Tribal Populations**

- a) No separate allocation for IHS-served populations, so IHS and tribal planners must be included in state and local planning.
- b) Cross border planning must occur where appropriate.
- c) Indian Health Service and tribal community healthcare personnel should staff tribal vaccination PODs.

**4) Special Needs Populations**

- a) Ensure information is available in local languages.
- b) Accommodate personnel without transportation and those requiring specialized transportation.
- c) Accommodate the needs of people with physical disabilities..
- d) Plan for vaccinating homebound persons.
- e) Ensure communication with special needs populations.
- f) Vaccinate large groups of special needs people at their sites, if possible.

**5. DOSE ADMINISTRATION.**

**a. Planning actions:**

- 1) Determine how minimum data elements and other project area-required data will be collected at PODs (minimum data elements: date of administration, age group, priority group, 1st or 2nd dose). (CDC)
- 2) Determine method of data transmission from PODs to local and State health departments. (SLTT)
- 3) Determine option for data transmission from project area health departments to CDC. (CDC)

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- 4) Determine personnel needs. (SLTT)
- 5) Develop a training plan. (SLTT)
- 6) Determine equipment needs. (SLTT)

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**b. Planning considerations for tracking of vaccine doses administered:**

There will be 3 main options for transmission of these data: use of Immunization Information Systems, direct entry of patient level information into the Countermeasure Response Administration (CRA) system, or manual data collection with entry of aggregate information into CRA (only aggregate information will be transmitted to CDC).

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**c. Planning consideration for ascertainment of vaccine coverage.**

National coverage will be estimated using population based surveys. Those immunized should receive a written proof of immunization. Patient information must be protected in accordance with appropriate privacy laws and procedures.

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**6. VACCINE SAFETY MONITORING.**

**a. Planning actions:**

- 1) Designate a vaccine safety coordinator. (SLTT)
- 2) Review policies for reporting adverse events. (CDC, SLTT)
- 3) Develop a plan to ensure timely reporting of adverse events when volume is large. (CDC)
- 4) Familiarize program staff with reporting procedures. (CDC, SLTT)
- 5) Planning considerations: VAERS will serve as the foundation for adverse event monitoring, and will be augmented in ways to strengthen its capacity. (CDC, SLTT)

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**b. Administering vaccine under Emergency Use Authorization:**

- 1) If the Secretary, HHS, declares an emergency justifying an Emergency Use Authorization (EUA), the FDA Commissioner may authorize the use of an unapproved medical product or an unapproved use of an approved medical product. EUA requirements include:
  - 2) Record keeping (vaccinee's name and contact information)
  - 3) Distribution of information sheets to healthcare providers and patients.
  - 4) Adverse event reporting via VAERS.





## APPENDIX 3 (COMMUNITY MITIGATION)

### REFERENCE:

Centers for Disease Control and Prevention. Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions, February 2007.

### 1. SITUATION

#### a. Center of Gravity:

During a nation-wide influenza pandemic, the main thrust of domestic pandemic response will occur in local communities. CDC's operational role in nonpharmaceutical interventions (NPI) will be guidance, interpretation, assessment, monitoring, and evaluation.

#### b. Goals:

The goals of the Federal Government's response to an influenza pandemic (USG Stage 5) are to limit the spread of a pandemic, mitigate disease, suffering, and death; and sustain infrastructure and lessen the impact on the economy and the functioning of society.

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#### c. Background:

- 1) Mathematical modeling and historical analysis of influenza pandemic scenarios in the United States suggest that pandemic mitigation strategies utilizing multiple NPIs may decrease transmission substantially. Even greater reductions may be achieved when such measures are combined with the targeted use of antiviral medications for treatment and prophylaxis.
- 2) Recent preliminary analyses of cities affected by the 1918 pandemic show a highly significant association between the early use of multiple NPIs and reductions in peak and overall death rates. Without mitigating interventions such as NPIs, even a less severe pandemic would likely result in dramatic increases in the number of hospitalizations and deaths. In addition, an unmitigated severe pandemic would likely overwhelm our nation's critical healthcare services and impose significant stress on our nation's critical infrastructure. Ultimately, reducing the number of persons infected is a primary goal of



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pandemic planning. NPIs may help reduce influenza transmission by reducing contact between sick and uninfected persons, thereby reducing the number of infected persons.

- 3) Reducing the number of persons infected will also lessen the need for healthcare services and minimize the impact of a pandemic on the economy and society. The surge of need for medical care that would occur following a poorly mitigated severe pandemic can be addressed only partially by increasing capacity within hospitals and other care settings. Reshaping the demand for healthcare services by using NPIs is an important component of the overall mitigation strategy. In practice, this means reducing the burdens on the medical and public health infrastructure by decreasing demand for medical services at the peak of the epidemic and throughout the epidemic wave, by spreading the aggregate demand over a longer time, and, to the extent possible, by reducing net demand through reduction in patient numbers and case severity.
- 4) Communities must be prepared for the cascading second- and third-order consequences of the interventions, such as increased workplace absenteeism related to child-minding responsibilities if schools dismiss students and childcare programs close.

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**d. Assumptions**

- 1) A well-matched pandemic strain vaccine will not be available when a pandemic begins.
- 2) At the onset of a first pandemic wave, there will not be sufficient quantities of influenza antiviral medications available for general distribution.
- 3) Existing antiviral medications may not be effective against a future pandemic strain.
- 4) Implementing targeted, layered NPIs in a timely and coordinated fashion will require advanced planning.

**2. MISSION**

Communities will target those at the nexus of transmission and will implement layered, multiple nonpharmaceutical interventions to mitigate the effects of a pandemic by reducing transmission to the greatest extent possible.



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### 3. EXECUTION

#### a. Concept

- 1) The use of NPIs for mitigating a community-wide epidemic has three major goals:
- 2) Delay the exponential growth in incident cases and shift the epidemic curve to the right in order to “buy time” for production and distribution of a well-matched pandemic strain vaccine.
- 3) Decrease the epidemic peak.
- 4) Reduce the total number of incident cases, thus reducing community morbidity and mortality.

#### b. Intent

The use of non-pharmaceutical interventions to mitigate an influenza pandemic is one component of a comprehensive community mitigation strategy that includes both pharmaceutical and non-pharmaceutical measures. Combining the use of antiviral medications with these interventions may enhance the overall effectiveness of non-pharmaceutical strategies.

#### c. Framework

- 1) The pandemic mitigation framework that is proposed is based upon an early, targeted, layered application of multiple, partially effective, non-pharmaceutical measures. Measures should be initiated early before explosive growth of the epidemic and, in the case of severe pandemics, maintained consistently during an epidemic wave in a community. The pandemic mitigation interventions include:
  - a) Isolation and treatment with influenza antiviral medications of all persons with confirmed or probable pandemic influenza. Isolation may occur in the home or healthcare setting, depending on the severity of an individual’s illness and/or the current capacity of the healthcare infrastructure.
  - b) Voluntary home quarantine of members of households that are in contact with confirmed or probable influenza case(s) of pandemic influenza.

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- c) Dismissal of children from school classrooms and child care programs along with preventing the re-congregation of children in similarly dense enclosed spaces.
  - d) Use of social distancing of adults in the community which may include cancellation of large public gatherings.
  - e) Implementation of telecommunicating and/or staggered schedules in the workplace.
- 2) All such community-based strategies should be used in combination with individual infection control measures, such as hand washing and cough etiquette.

**d. Role of SLTT**

- 1) Decisions about what tools should be used during a pandemic will be made by SLTT authorities and should be based on the observed severity of the event, its impact on specific subpopulations, the expected benefit of the interventions, the feasibility of success in modern society, the direct and indirect costs, and the consequences on critical infrastructure, healthcare delivery, and society.
- 2) The most controversial elements (e.g., prolonged dismissal of students from schools and closure of child care programs) are not likely to be needed in less severe pandemics, but these steps may save lives during severe pandemics. Just as communities plan and prepare for mitigating the effect of severe natural disasters (e.g., hurricanes), so they should also plan and prepare for mitigating the effect of a severe pandemic.

**4. COORDINATING INSTRUCTIONS**

**a. The Pandemic Severity Index (PSI)**

- 1) The Pandemic Severity Index, which uses case fatality ratio as the critical driver for categorizing the severity of a pandemic (Figure 6), is designed to enable estimation of the severity of a pandemic on a population level to allow better forecasting of the impact of a pandemic and to enable recommendations to be made on the use of mitigation interventions that are matched to the severity of future influenza pandemics.
- 2) Categories: Future pandemics will be assigned to one of five discrete categories of increasing severity (Category 1 to Category 5). The Pandemic Severity Index provides

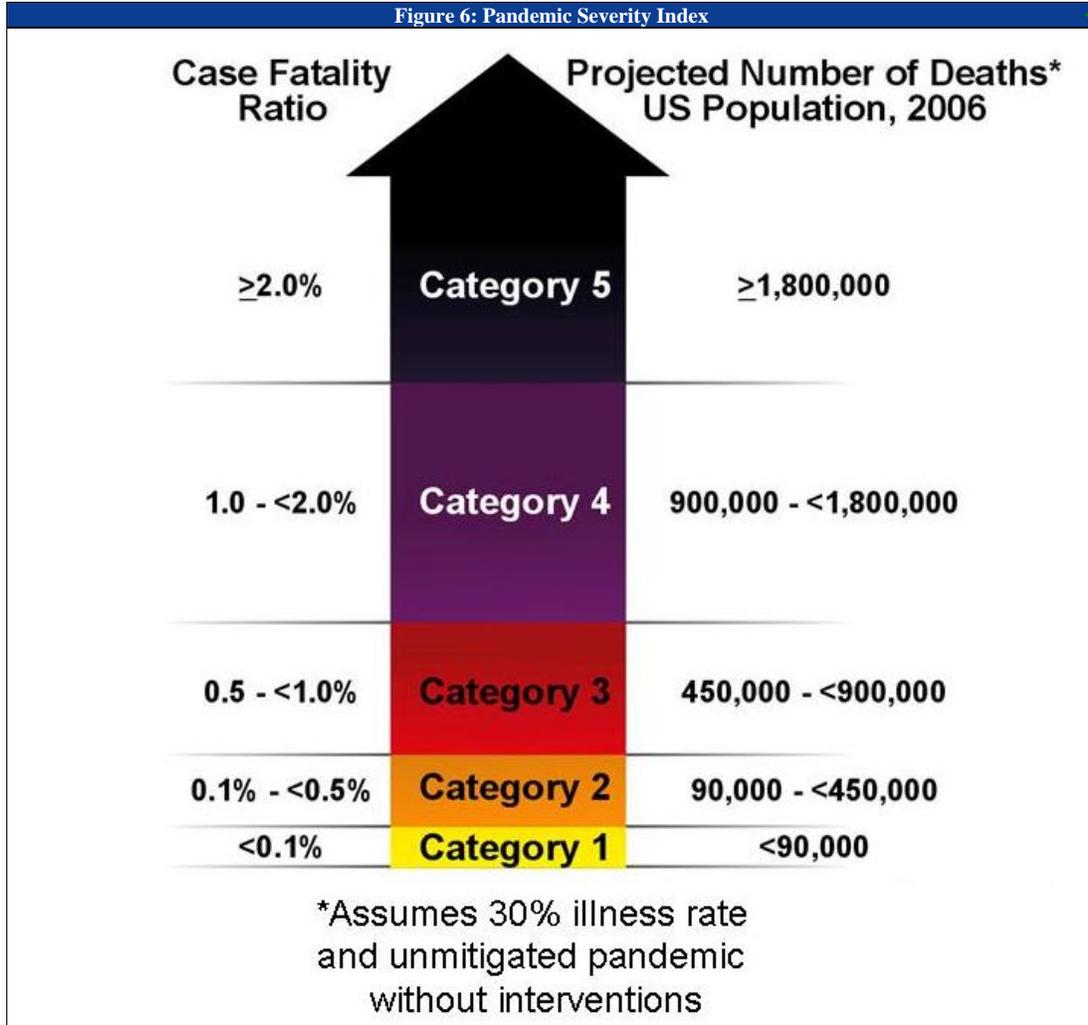
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communities a tool for scenario-based contingency planning to guide local pre-pandemic preparedness efforts. Accordingly, communities facing the imminent arrival of pandemic disease will be able to use the pandemic severity assessment to define which pandemic mitigation interventions are indicated.

Figure 6: Pandemic Severity Index



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**b. Use of Nonpharmaceutical Interventions by Severity Category**

- 1) CDC's interim NPI guidance proposes a community mitigation strategy that matches recommendations on planning for use of selected NPIs to categories of severity of an influenza pandemic. These planning recommendations are made on the basis of an assessment of the possible benefit to be derived from implementation of these measures weighed against the cascading second- and third-order consequences that may arise from their use. Cascading second- and third-order consequences are chains of effects that may arise because of the intervention and may require additional planning and intervention to mitigate. The term generally refers to foreseeable unintended consequences of intervention. For example, dismissal of students from school may lead to the second-order effect of workplace absenteeism for child minding. Subsequent workplace absenteeism and loss of household income could be especially problematic for individuals and families living at or near subsistence levels. Workplace absenteeism could also lead to disruption of the delivery of goods and services essential to the viability of the community.
- 2) For Category 4 or Category 5 pandemics, a planning recommendation is made for use of all listed NPIs (Table A). In addition, planning for dismissal of students from schools and school-based activities and closure of childcare programs, in combination with means to reduce out-of-school social contacts and community mixing for these children, should encompass up to 12 weeks of intervention in the most severe scenarios. This approach to pre-pandemic planning will provide a baseline of readiness for community response. Recommendations for use of these measures for pandemics of lesser severity may include a subset of these same interventions and potentially for shorter durations, as in the case of social distancing measures for children.
- 3) For Category 2 and Category 3 pandemics, planning for voluntary isolation of ill persons is recommended; however, other mitigation measures (e.g., voluntary quarantine of household members and social distancing measures for children and adults) should be

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implemented only if local decision-makers determine their use is warranted due to characteristics of the pandemic within their community. Pre-pandemic planning for the use of mitigation strategies within these two Pandemic Severity Index categories should be done with a focus on a duration of 4 weeks or less, distinct from the longer timeframe recommended for the more severe Category 4 and Category 5 pandemics.

- 4) For Category 1 pandemics, voluntary isolation of ill persons is generally the only community-wide recommendation, although local communities may choose to tailor their response to Category 1-3 pandemics by applying NPIs on the basis of local epidemiologic parameters, risk assessment, availability of countermeasures, and consideration of local healthcare surge capacity. Thus, from a pre-pandemic planning perspective for Category 1, 2, and 3 pandemics, capabilities for both assessing local public health capacity and healthcare surge, delivering countermeasures, and implementing these measures in full and in combination should be assessed.

**Table :** Summary of the Community Mitigation Strategy by Pandemic Severity

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Interventions* by Setting	Pandemic Severity Index		
	1	2 and 3	4 and 5
<b>Home</b> <b>Voluntary isolation</b> of ill at home (adults and children), combine with use of antiviral treatment as available and indicated	Recommend †§	Recommend †§	Recommend †§
<b>Voluntary quarantine</b> of household members in homes with ill persons†¶ (adults and children); consider combining with antiviral prophylaxis if effective, feasible, and quantities sufficient	Generally not recommended	Consider **	Recommend **
<b>School</b> <b>Child social distancing</b> -dismissal of students from schools and school based activities, and closure of child care programs -reduce out-of school social contacts and community mixing	Generally not recommended	Consider: ≤4 weeks ††	Recommend: ≤12 weeks §§
<b>Workplace / Community</b> <b>Adult social distancing</b> -decrease number of social contacts (e.g., encourage teleconferences, alternatives to face-to-face meetings) -increase distance between persons (e.g., reduce density in public transit, workplace) -modify, postpone, or cancel selected public gatherings to promote social distance (e.g., stadium events, theater performances) -modify work place schedules and practices (e.g., telework, staggered shifts)	Generally not recommended	Consider	Recommend



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Generally Not Recommended = Unless there is a compelling rationale for specific populations or jurisdictions, measures are generally not recommended for entire populations as the negative consequences may outweigh the benefits.

Consider = Important to consider these alternatives as part of a prudent planning strategy, considering characteristics of the pandemic, such as age-specific illness rate, geographic distribution, and the magnitude of adverse consequences. These factors may vary globally, nationally, and locally.

Recommended = generally recommended as an important component of the planning strategy.

\*All these interventions should be used in combination with other infection control measures, including hand hygiene and cough etiquette, and may include use of personal protective equipment such as face masks. Additional information on infection control measures is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

†This intervention may be combined with the treatment of sick individuals using antiviral medications and with vaccine campaigns, if supplies are available

§Many sick individuals who are not critically ill may be managed safely at home

¶The contribution made by contact with asymptotically infected individuals to disease transmission is unclear. Household members in homes with ill persons may be at increased risk of contracting pandemic disease from an ill household member. These household members may have asymptomatic illness and may be able to shed influenza virus that promotes community disease transmission. Therefore, household members of homes with sick individuals would be advised to stay home.

\*\*To facilitate compliance and decrease risk of household transmission, this intervention may be combined with provision of antiviral medications to household contacts, depending on drug availability, feasibility of distribution, and effectiveness; policy recommendations for antiviral prophylaxis are addressed in a separate guidance document.

††Consider short-term implementation of this measure—that is, less than four weeks.

§§Plan for prolonged implementation of this measure—that is, one to three months; actual duration may vary depending on transmission in the community as the pandemic wave is expected to last six to eight weeks.

**c. Triggers for Initiating Use of Nonpharmaceutical Interventions**

- 1) The timing of initiation of various NPIs will influence their effectiveness. Implementing these measures prematurely may result in economic and social hardship without public health benefit and, over time, may result in “intervention fatigue” and erosion of public adherence. Conversely, implementing these interventions after extensive spread of pandemic influenza illness in a community may limit the public health benefits of employing these measures. Identifying the optimal time for initiation of these interventions will be challenging because implementation needs to be early enough to preclude the initial steep upslope in case numbers and long enough to cover the peak of the anticipated epidemic curve while avoiding intervention fatigue.
- 2) CDC NPI guidance suggests that the primary activation trigger for initiating interventions be the arrival and transmission of pandemic virus. This trigger is best defined by a laboratory-confirmed cluster of infection with a novel influenza virus and evidence of community transmission (i.e., epidemiologically linked cases from more than one household).

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- 3) Defining the proper geospatial-temporal boundary for this cluster is complex and should recognize that our connectedness as communities goes beyond spatial proximity and includes ease, speed, and volume of travel between geopolitical jurisdictions (e.g., despite the physical distance, Hong Kong, London, and New York City may be more epidemiologically linked to each other than they are to their proximate rural provinces/areas). In order to balance connectedness and optimal timing, it is proposed that the geopolitical trigger be defined as the cluster of cases occurring within a U.S. State or proximate epidemiological region (e.g., a metropolitan area that spans more than one State's boundary). It is acknowledged that this definition of "region" is open to interpretation; however, it offers flexibility to State and local decision-makers while underscoring the need for regional coordination in pre-pandemic planning.
- 4) From a pre-pandemic planning perspective, the steps between recognition of a pandemic threat and the decision to activate a response are critical to successful implementation. Thus, a key component is the development of scenario-specific contingency plans for pandemic response that identify key personnel, critical resources, and processes. To emphasize the importance of this concept, guidance on triggers introduces the terminology of Alert, Standby, and Activate, which reflect key steps in escalation of response action.
- 5) Pre-pandemic planning for use of these interventions should be directed to lessening the transition time between Alert, Standby, and Activate. The speed of transmission may drive the amount of time decision-makers are allotted in each mode, as does the amount of time it takes to fully implement the intervention once a decision is made to Activate.

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**Table 3: Triggers for Implementation of Mitigation Strategies by Pandemic Severity Index and U.S. Government Stages**

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<b>Pandemic Severity Index</b>	<b>WHO Phase 6, U.S. Government Stage 3*</b>	<b>WHO Phase 6, U.S. Government Stage 4† and First human case in United States</b>	<b>WHO Phase 6, U.S. Government Stage 5§ and First laboratory-confirmed cluster in State or region¶</b>
<b>1</b>	<b>Alert</b>	<b>Standby</b>	<b>Activate</b>
<b>2 and 3</b>	<b>Alert</b>	<b>Standby</b>	<b>Activate</b>
<b>4 and 5</b>	<b>Standby**</b>	<b>Standby/Activate ††</b>	<b>Activate</b>

Alert: Notification of critical systems and personnel of their impending activation.  
 Standby: Initiate decision-making processes for imminent activation, including mobilization of resources and personnel.  
 Activate: Implementation of the community mitigation strategy.

\*Widespread human outbreaks in multiple locations overseas.  
 †First human case in North America.  
 §Spread throughout the United States.  
 ¶Recommendations for regional planning acknowledge the tight linkages that may exist between cities and metropolitan areas that are not encompassed within state boundaries.  
 \*\*Standby applies. However, Alert actions for Category 4 and 5 should occur during WHO Phase 5, which corresponds to U.S. Government Stage 2.  
 ††Standby/Activate Standby applies unless the laboratory-confirmed case cluster and community transmission occurs within a given jurisdiction, in which case that jurisdiction should proceed directly to Activate community interventions defined in Table A.

6) For the most severe pandemics (Categories 4 and 5), Alert is implemented during WHO Phase 5/U.S. Government Stage 2 (confirmed human outbreak overseas), and Standby is initiated during WHO Phase 6/U.S. Government Stage 3 (widespread human outbreaks in multiple locations overseas). Standby is maintained through Stage 4 (first human case in North America), with the exception of the State or region in which a cluster of laboratory-confirmed human pandemic influenza cases with evidence of community

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transmission is identified. The recommendation for that State or region is to implement the appropriate NPIs when identification of a cluster with community transmission is made. Other States or regions implement appropriate interventions when they identify laboratory-confirmed human pandemic influenza case clusters with evidence of community transmission in their jurisdictions.

- 7) For Category 1, 2, and 3 pandemics, Alert is declared during U.S. Government Stage 3, with step-wise progression by States and regions to Standby based on U.S. Government declaration of Stage 4 and the identification of the first human pandemic influenza case(s) in the United States. Progression to Activate by a given State or region occurs when that State or region identifies a cluster of laboratory-confirmed human pandemic influenza cases with evidence of community transmission in their jurisdiction.

#### **d. Duration of Implementation**

- 1) It is important to emphasize that as long as susceptible individuals are present in large numbers, disease spread may continue. Immunity to infection with a pandemic strain can only occur after natural infection or immunization with an effective vaccine. Preliminary analysis of historical data from selected U.S. cities during the 1918 pandemic suggests that duration of implementation is significantly associated with overall mortality rates. Stopping or limiting the intensity of interventions while pandemic virus was still circulating within the community was temporarily associated with increases in mortality due to pneumonia and influenza in many communities.
- 2) It is recommended for planning purposes that communities be prepared to maintain interventions for up to 12 weeks, especially in the case of Category 4 or Category 5 pandemics, where recurring epidemic waves may have significant impact. However, for less severe pandemics (Category 2 or 3), a shorter period of implementation may be adequate for achieving public health benefit. This planning recommendation acknowledges the uncertainty around duration of circulation of pandemic virus in a given community and the potential for recrudescence of disease when use of NPIs is limited or stopped, unless population immunity is achieved.

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**e. Critical Issues for the Use of Nonpharmaceutical Interventions**

- 1) A number of outstanding issues should be addressed to optimize the planning for use of these measures. These issues include the establishment of sensitive and timely surveillance, the planning and conducting of multi-level exercises to evaluate the feasibility of implementation and the identification and establishment of appropriate monitoring and evaluation systems.
- 2) Policy guidance in development regarding the use of antiviral medications for prophylaxis, community and workplace-specific use of personal protective equipment, and safe home management of ill persons must be prioritized as part of future components of the overall community mitigation strategy. In addition, generating appropriate risk communication content/materials and an effective means for delivery, soliciting active community support and involvement in strategic planning decisions, and assisting individuals and families in addressing their own preparedness needs are critical factors in achieving success.

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## APPENDIX 4 (MANAGEMENT AND DISTRIBUTION OF ANTIVIRAL DRUGS AND OTHER COUNTERMEASURES)

### 1. SITUATION

a. Medical materiel from the Strategic National Stockpile (SNS) is a key component of the nation's pandemic influenza response. These assets include antiviral drugs and other countermeasures (N95 respirators, surgical masks, additional personal protective equipment (PPE), intravenous antibiotics, and ventilators) and are stored in secure locations, ready for rapid distribution.

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b. SNS influenza pandemic response is multi-dimensional, including antiviral drug distribution to selected locations for international and U.S. containment as well as large scale distribution of materiel to Public Health Emergency Preparedness (PHEP) Project Areas on a *pro rata* basis. Federal Medical Stations (FMS) may also be deployed to meet surge requirements. Pre-pandemic and pandemic vaccines are not included in the SNS and will be managed and distributed separately.

#### c. Assumptions

- 1) The Division of Strategic National Stockpile (DSNS) procures, maintains, and ships SNS assets as directed for an influenza pandemic response.
- 2) Pre-pandemic and pandemic vaccines will not be stockpiled or managed by DSNS.
- 3) DSNS must always retain readiness to respond to a potential second event (bioterrorist or natural disaster related).
- 4) DSNS TARU (Technical Advisory Response Unit) will not deploy in an influenza pandemic response.
- 5) Sufficient time will exist from a triggering event to allow distribution of materiel without the use of emergency contracts with commercial partners or the need for additional funding to surge infrastructure.

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**2. MISSION:**

On order, DSNS distributes Federally held antiviral drugs and other countermeasures in support of the nation's efforts to contain or mitigate the effects of an influenza pandemic.

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**3. EXECUTION:**

a. This plan outlines the distribution of Federally held assets in the SNS that will be used during an influenza pandemic.

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b. It is assumed that the most likely initial outbreak of human-to-human transmission of a novel influenza subtype will occur overseas, however many other plausible scenarios need to be planned for including early human-to-human transmission in the United States. (With an international outbreak, the basic premise is that sufficient time will exist from a triggering event to allow distribution of materials without the use of emergency contracts with commercial partners.) DSNS acknowledges the need to have the ability to ship materiel more quickly, if the scenario for the outbreak varies. For example, if the outbreak begins in the U.S. or spreads more rapidly than predicted, the DSNS will plan for an emergency distribution scenario that initially targets distribution to the affected regions in the country. Delivery of assets from the SNS can also be prioritized based on disease spread or other factors.

c. Response. In the broadest pandemic context, the DSNS response needs to remain flexible and scalable. Response options need to address small regional outbreaks and mild pandemic strains as well as rapidly spreading, highly lethal strains that impact the entire country simultaneously. The unknown severity, duration, and start point of a pandemic make it difficult to define the most suitable pandemic response and the optimum mix of materiel in advance. The response options outlined below offer the flexibility and scalability to deal with this wide range of potential scenarios. There are three main components to the DSNS pandemic response: international containment, domestic U.S. containment, and large scale *pro rata* deployment of antiviral drugs and countermeasures to 62 Project Areas.





a. International containment. Up to 5% of available antiviral drugs in the SNS may be deployed in support of international containment. Initial planning has focused on Southeast Asian countries where the majority of humans with avian influenza infections have occurred. SNS continues to forecast other potential international storage and delivery locations. SNS has pre-deployed antiviral drugs and other material in Asia and has readied additional material that can be rapidly deployed from domestic storage locations.

1) Domestic containment. The DSNS role in domestic containment is still being defined; however the United States government has designated 6 million courses of oseltamivir within the SNS for containment purposes. It is anticipated that DSNS will manage and prepare a multi-faceted strategic reserve of antiviral drugs for deployment. This reserve will be used, in addition to other mitigation strategies, for initial domestic containment, continuity of government, ~~or for other strategic priorities.~~ The primary use of the strategic reserve, however, is to stop or slow early person-to-person transmission of a novel influenza strain in the United States. It is impossible to predict the precise location that the reserve may be used; however, DSNS has done preliminary planning for likely locations and scenarios.

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2) The DSNS pandemic response will require a massive sustained effort to distribute antiviral drugs and countermeasures to 62 Project Areas. DSNS will push material to Project Areas as directed to ensure the assets are available at the time and place they are needed. Pushing product to the Project Areas will allow the ~~Federal~~ government to be proactive, anticipate needs, and achieve pandemic mitigation goals. Shipping product out at the first signs of a pandemic anywhere in the world is necessary to guarantee distribution of the ~~Federal assets through State and local levels to the point of need.~~ Also, there is a high likelihood that resources such as personnel and trucks will be in limited supply during a pandemic, possibly impacting SNS response time.

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3) The DSNS has developed two options for countermeasure deployment. In both options, all assets will be pushed prior to request from Project Area officials to one location in





each of the 62 Project Areas. It will take up to 28 days for project areas to receive their total *pro rata* allocation of pandemic SNS assets. The total quantity of assets that each Project Area receives remains the same with each option. CDC leadership will direct the appropriate option based on the pandemic situation.

- a) Option 1 – The “metered package” option provides a mix of all *pro rata* allocated SNS influenza pandemic countermeasures (antiviral drugs, N95 respirators, surgical masks, additional PPE, IV antibiotics, and ventilators) in each of 3 parts of the deployment. This option is flexible and provides a package of all SNS countermeasures in each part of the deployment, which may be particularly important for responding to transmission in the U.S. that is not preceded by an overseas outbreak. It is scalable in the sense that it can be stopped after each part of the deployment to deliver only a portion of the total SNS inventory to meet the particular needs of the situation.
  - (1) Part 1 – Deployment of 25% of Project Area allocated quantities of antiviral drugs, masks, respirators, additional PPE (protective face shields, gowns, gloves), IV antibiotics, and ventilators. This part of the deployment will take an estimated 7 days. Depending on the severity of the pandemic and the need for additional countermeasures, deployment can be stopped after Part 1.
  - (2) Part 2 – Deployment of an additional 25% of Project Area allocated quantities of antiviral drugs, masks, respirators, additional PPE (protective face shields, gowns, gloves), IV antibiotics, and ventilators. This second deployment of assets will take an estimated 7 days. Depending on the severity of the outbreak and the need for additional countermeasures, deployment can be stopped after Part 2.
  - (3) Part 3 – Deployment of the remaining 50% of Project Area allocated quantities of antiviral drugs, masks, respirators, additional PPE (protective face shields, gowns, gloves), IV antibiotics, and ventilators. This deployment of assets will take an estimated 14 days.



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- b) Option 2 – The “sequential item” option ships all Project Area allocated quantities of antiviral drugs in Part 1; followed by N95 respirators and surgical masks in Part 2; and then PPE, IV antibiotics, and ventilators in Part 3. If the need for large quantities of antiviral drugs is deemed most critical in a developing pandemic, this option provides all allocated quantities of antiviral drugs initially, followed sequentially by other items.
- (1) Part 1 – Deployment of all allocated quantities of antiviral drugs to all Project Areas. This part of the deployment is estimated to take 7 days.
  - (2) Part 2 - Deployment of all allocated quantities of surgical masks and N95 respirators to all Project Areas. This second deployment of assets will take an estimated 7-10 days.
  - (3) Part 3 – Deployment of all allocated quantities of ventilators, other PPE (face shields, gowns, gloves), and IV antibiotics. This third part of the deployment is estimated to take 10-14 days.

b. Additional Information for Project Areas. The DSNS pandemic response plan is different from the normal DSNS response model routinely used in bioterrorism and other scenarios. Assets will be allocated and pushed on a *pro rata* basis rather than in response to Project Area requests.

- 1) The quantity of antiviral drugs each Project Area will receive has been predetermined based on population; there may be changes at the time of an event based on HHS direction and established priority groups. In order to assist Project Areas in planning efforts and to estimate the quantity of space needed for the storage of SNS countermeasures, the Project Area projected allocations of antiviral drugs from the SNS are listed on the pandemicflu.gov website at <http://www.pandemicflu.gov/state/antivirals.html>. Estimated *pro rata* allocation tables for respiratory protective devices and ventilators can be found in the SNS Medical Countermeasure Distribution for Pandemic Influenza Exercise.

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- 2) It is critical that all Project Areas pre-identify Receipt, Storage, and Staging (RSS) sites and keep the DSNS informed of those locations.
- 3) When assets are delivered, Project Areas must be prepared to accept them in accordance with SNS policies already in place (highlighted in SNS Version 10.02) with the exception that DSNS Technical Advisory Response Unit (TARU) teams will not deploy. Once a Project Area accepts Federal assets, they will become the property of that Project Area.
- 4) Project Areas will need to be prepared for a larger scale of material and a more robust RSS warehouse operation than some other SNS response scenarios such as bioterrorism. A significant amount of material will arrive in a very short period of time; thus, additional RSS space may be needed.
- 5) Project Areas need to be prepared to conduct RSS operations for an extended period of time and sustain operations throughout the duration of a pandemic.
- 6) State health departments must be prepared to coordinate distribution of antiviral drugs to multiple local facilities (arrangements to be made using pre-existing state mechanisms or perhaps via contracts with private distributors).

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## 2. COORDINATING INSTRUCTIONS

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- a. Project Area *pro rata* allocations for antiviral drugs can be found at <http://www.pandemicflu.gov/plan/states/antivirals.html>. Estimated *pro rata* allocation tables for respiratory protective devices and ventilators can be found in the SNS Medical Countermeasure Distribution for Pandemic Influenza Exercise Guide distributed to Project Areas.
- b. The DSNS will consult with FDA regarding plans for the deployment of medical products (e.g. non-FDA cleared N95 respirators) that might need to be used under and Emergency Use Authorization (EUA).
- c. The DSNS will retain the flexibility to withhold selected items from shipment.



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Antiviral drugs will be withheld if the outbreak strain is resistant to antiviral drugs in the SNS.

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1) Ventilators may be held back (if the need for immediate use is uncertain) since they are only available in limited quantities.

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2) Receipt, Storage and Distribution

d. Challenges

A huge and uncoordinated demand for antiviral drugs early in a pandemic could rapidly deplete national and local supplies. Because limited supplies of the drugs are anticipated, detailed operational plans must be developed in collaboration with federal and SLTT governments and the medical community to ensure equitable distribution and access. In addition, components of the plan will include proposed methods for tracking drug use and monitoring for adverse events and resistance.



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e. Receipt

States will assume and maintain local control and security until distribution to points of patient care (e.g. hospitals, primary care clinics).

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f. Storage

Locally maintained antiviral drugs will be held in a temperature-controlled, secure location that is consistent with the manufacture's labeled storage conditions and any FDA-established criteria that may apply.

g. Distribution

Distribution of antiviral drugs to different facility types will depend on the available supply. Facilities that receive stockpiled antiviral drugs must agree to their use in compliance with protocols established by the Federal government in coordination with SLTT agencies. Protocols will require that facilities can assure appropriate security for the medication, limit distribution to priority groups, maintain accurate records to track usage, and report adverse events.

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Table : Classes Of Intervention Strategies And Techniques

Intervention Strategy	Intervention Technique
<b>Case-Based Interventions</b>	
Separate ill or infectious persons from others in the general population to restrict interaction with susceptible persons	Case (patient) management—Isolation (pending or following laboratory confirmation)
Treat symptomatic persons to mitigate disease symptoms and attempt to reduce infectiousness and risk of mortality.	Case (patient) management—Antiviral treatment
Separate exposed persons (prospective or potential cases) from the general population to stop new chains of transmission from beginning	Contact management—Contact quarantine (voluntary) (following contact tracing)
Provide medical prophylaxis to exposed persons to prevent disease	Contact management—Antiviral prophylaxis (active)
<b>Population-Based Interventions</b>	
Separate exposed groups from the general population to stop new chains of transmission from beginning	Contact management—Group quarantine (voluntary) (following exposure in a defined group or site)
Reduce the interaction of potentially exposed groups and infectious persons in the general environment to stop new chains of transmission from beginning	Social distancing including: Limitations on location-based gatherings/events (compulsory and voluntary) (e.g., schools, work sites, mass gatherings, public transportation, etc. ) Travel restrictions (compulsory and voluntary) to and from affected areas (domestic and international)
Provide medical prophylaxis to potentially exposed groups to prevent disease	Risk group antiviral prophylaxis (passive)
Provide mass medical prophylaxis to potentially exposed groups to treat sub-clinical infection	Risk zone antiviral prophylaxis (active/targeted as in a containment event)
Actively reduce susceptibility in the general population	Immunization with pandemic vaccine
<b>Personal-Based Interventions</b>	
Reduce the interaction of susceptible and infectious persons in the general environment to stop new chains of transmission from beginning	Self-sheltering (voluntary)
Use personal physical barriers that reduce the risk of infection in frequently exposed individuals	Personal protective equipment (PPE) and infection control.
Preventively remove infectious organisms acquired by inadvertent contact with infectious persons or contaminated objects	Hand hygiene
Limit respiratory spread of infectious organisms	Respiratory etiquette
Disinfect or dispose of objects contaminated by infectious persons	Environmental disinfection in EMS, healthcare, and other settings