

Section 7: Antiviral Medication Procurement, Distribution, and Use

- I. Overview**
- II. Objectives**
- III. Strategies for the Use of Antiviral Medications During a Pandemic**
- IV. Prioritization**
- V. Allocation**
- VI. Distribution**
- VII. Administration**
- VIII. Information Technology in Support of Antiviral Distribution**
- IX. Communication**
- X. Clinical Components of Antiviral Administration**
- XI. Staffing**
- XII. Training**
- XIII. Activities According to WHO Pandemic Period/U.S. Federal Government Response Stage**

Appendices:

- 7-A: Characteristics of Anti-Influenza Antiviral Medications
- 7-B: Recommended Daily Dosage of Antiviral Medications for Treatment and Prophylaxis
- 7-C: Antiviral Medication Priority Group Recommendations
- 7-D: Antiviral Allocation by Priority Group, New York State (Outside of New York City)
- 7-E1: Antiviral Dispensing Scenarios
- 7-E2: Antiviral Dispensing in Alternate Diagnosis and Dispensing Sites
- 7-F: Clinical Algorithm for the Use of Antiviral Medications
- 7-G: Pediatric Use of Antiviral Medications
- 7-H: Vaccine and Antiviral Medication Procurement
- 7-I: MedWatch
- 7-J: New York State Department of Health Operational Appendix, Strategic National Stockpile

I. Overview

The targeted use of antiviral agents could, as part of a response strategy to susceptible strains, decrease the health impact of an influenza pandemic. Use of antiviral prophylaxis has been up to 70% to 90% effective in preventing symptomatic influenza infection caused by susceptible strains, if prophylaxis is begun before exposure to influenza. Also, treatment with one class of agents, neuraminidase inhibitors, has been shown to decrease severe complications such as pneumonia and bronchitis and to reduce hospitalizations. These interventions may be particularly important before vaccine is available and for those for whom vaccination may be medically contraindicated. Protection afforded by antiviral medications is virtually immediate and does not interfere with the response to inactivated influenza vaccines. It is important to avoid inappropriate use of antiviral medications that may lead to viral resistance.

The Department of Health and Human Services (DHHS) and the National Vaccine Advisory Committee (NVAC), in cooperation with the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP), have provided guidance on prioritization of persons to be given antivirals during a pandemic. This guidance is under review and changes have been proposed, but are not yet in a draft format available for us. In addition, any guidance will most likely change when epidemiologic data on a specific pandemic virus becomes available or when supplies of antivirals are greatly increased. The New York State Department of Health (NYSDOH) will follow and comply with prioritization categories determined by the CDC. Where flexibility is allowed, NYSDOH will work with health care organizations, and local health departments (LHDs) to determine the prioritization of groups to receive influenza antiviral medication. All recommendations will be distributed as statewide guidelines.

It is also important to monitor the use of antiviral medications. These drugs are in frequent use both during the influenza season, and for other indications year round. There is information and data available on the side effects of antiviral medications. However, there are no data available on the large-scale use of these medications in a pandemic situation. Monitoring and tracking of antiviral use, compliance, effectiveness, resistance, and adverse events are critical aspects of responding to a pandemic.

This section of the NYSDOH Pandemic Influenza Plan provides recommendations for the acquisition, allocation, distribution and administration of antiviral drugs for treatment and prophylaxis during an influenza pandemic. It discusses the strategies available for the use of antiviral medications, including how they can be used, the timing of their use, and facilities or settings in which they may be offered. This section also reviews the issues surrounding safety, monitoring, and data collection. Methods of effective risk communication by all partners involved in pandemic response are described. Finally, the activities necessary for pandemic planning by the NYSDOH, LHDs, and health care partners are outlined.

The recommendations for the use of antivirals during the WHO Pandemic Periods are divided into three situations: 1) when no or sporadic pandemic influenza has been detected in the United States, 2) when there is limited transmission of pandemic influenza in the United States, and 3) when there is widespread transmission in the United States. The WHO Pandemic Periods are keyed to the United States Federal Response stages and to the pandemic intervals when outlining

the pandemic planning and response activities. Treatment strategies for optimizing the use of limited stocks of antiviral drugs will vary depending on the phase of the pandemic. Recommendations for optimal use of limited stocks of antivirals will be updated throughout the course of an influenza pandemic to reflect evolving information on the epidemiologic and laboratory aspects of the pandemic strain, and the antiviral supply.

II. Objectives

- Describe available strategies for using antiviral medications, the timing of their use, and facilities or settings in which they may be used;
- Plan for the acquisition, allocation, distribution, and administration of antiviral medications;
- Monitor antiviral medication use and safety during a pandemic to assure that the benefits outweigh the risks;
- Collect appropriate data on antiviral procurement, allocation, distribution, administration, safety, effectiveness, and resistance; and
- Describe and plan for risk communication activities and methods to enable the public and providers to access information on antiviral use and availability.

III. Strategies for the Use of Antiviral Medications During a Pandemic

A. Methods for the Use of Antiviral Medications: Treatment, Prophylaxis, and Post-Exposure

The option of whether to treat with antiviral medications or use them for prophylaxis depends on the pandemic period, the type of group being considered, and antiviral supply. Treatment is more efficient than prophylaxis in preventing adverse health outcomes. Treatment uses less medication and focuses on those who are ill and will directly benefit from the intervention. However, it may be hard to maintain essential services with this approach. Prophylaxis requires a greater amount of medication because it requires administration over a long period of time. Prophylaxis may be more effective than therapy in maintaining quality health care and public safety. It may prevent absenteeism due to fear of acquiring illness and prevent time lost from work while ill.

• Treatment

Planning Considerations

- The effectiveness of antivirals against a new pandemic influenza strain cannot be predicted.
- Early treatment is a more efficient use of antivirals than prophylaxis, because prophylaxis requires 6 or more weeks of daily use, instead of a 5-day treatment course.
- The choice of antiviral medication used will depend on what is known about the viral resistance pattern and the availability of a particular drug.

- It is anticipated that at least enough antivirals will be available to treat 25% of the population. This means that, given the current priority group guidelines, treatment will be the predominant way that antivirals are used.
- For more information, see Appendix 7-A: Characteristics of Anti-Influenza Antiviral Medications, and Appendix 7-B: Recommended Daily Dosage of Antiviral Medications for Treatment and Prophylaxis.

Treatment of Influenza Disease

The clinical effectiveness of antiviral medications for the treatment of novel influenza is unknown, but it is likely that the earlier treatment is initiated, the greater likelihood of benefit. Treatment strategies for optimizing the use of limited stocks of antiviral drugs will vary depending on the phase of the pandemic. As infection with the pandemic strain becomes more common, laboratory confirmation will be less necessary to initiate treatment. Strategies include:

At all stages of a pandemic:

- Treatment will be targeted to patients with onset of symptoms of less than 48 hours. Treatment after 48 hours of onset may have no benefit. Note: there are no data on the effectiveness of treatment at hospitalization. If stockpiled antiviral drug supplies are very limited, the priority of this group could be reconsidered based on the epidemiology of the pandemic and any additional data on effectiveness in this population.
- Mechanisms will be implemented to detect the emergence of drug-resistant variants by obtaining specimens from persons who develop influenza while on prophylaxis or who progress in severity despite treatment.

When pandemic influenza is reported abroad, or sporadic pandemic influenza cases are reported in the United States, without evidence of spread:

- Treatment decisions should be based on laboratory confirmation of disease caused by the pandemic strain by viral isolation, real-time polymerase chain reaction (RT-PCR), or other means recommended by CDC. Treatment may be initiated with a positive rapid antigen test for influenza A; however, a confirmatory test should be performed and treatment discontinued if influenza is not confirmed.
- Negative test results would permit cessation of treatment, given the overall low rate of infection in a particular location.
- Use of antivirals to contain small, well-defined disease clusters in order to possibly delay or reduce spread to other communities could be considered.
- Use of antivirals for prophylaxis and treatment of persons exposed to novel (e.g., avian) influenza viruses present in New York State.

When there is limited transmission of pandemic influenza in the United States:

- Treatment decisions would be based on:
 - Laboratory-confirmed identification of the pandemic subtype by viral isolation, RT-PCR, or other means recommended by CDC, OR
 - Detection of influenza A by rapid antigen test, OR
 - Epidemiologic and clinical characteristics.

- Treatment should be initiated before laboratory confirmation is obtained since early treatment is more effective. As infection becomes more common, false negatives from rapid antigen tests are more likely, and treatment should continue while awaiting confirmatory tests.

When there is widespread transmission of pandemic influenza in the United States:

- Treatment decisions will be based on clinical features and epidemiologic risk factors, taking into account updated knowledge of the epidemiology of the pandemic strain.
- Laboratory results will no longer be needed to initiate and continue treatment.

When a novel strain of zoonotic influenza (e.g., avian influenza) is detected in animals in New York State:

- Persons developing influenza-like illness following direct exposure to animals infected with zoonotic novel influenza viruses will be considered for antiviral treatment.
- Treatment decisions will be based on clinical features and epidemiologic risk factors, taking into account updated knowledge of the epidemiology of the novel strain.
- Treatment may be initiated before laboratory confirmation is obtained if there is strong epidemiologic evidence of human infection since early treatment may be more effective. Confirmatory laboratory results will be needed to continue treatment.
- Guidance for treatment and prophylaxis of humans exposed to animals infected with potentially zoonotic influenza viruses will be provided by the NYSDOH in consultation with the CDC.

- **Prophylaxis**

Planning Considerations

- Prophylaxis requires the long-term use of antiviral medications to protect the recipient from acquiring influenza.
- There will be limited supplies, increasing risk of side effects, and the potential emergence of resistance with long-term use.
- Prophylaxis must be continued until the risk of exposure is reduced.
- Prophylaxis may be more effective than therapy in maintaining quality healthcare and public safety.
- The need for prophylaxis may decrease as vaccine becomes available.
- The number of persons who receive prophylaxis should be minimized, primarily to extend supplies available to treat persons at highest risk of serious morbidity and mortality.
- Current federal priority group guidelines would only allow prophylaxis if the pandemic is mild and demand is low, or if supplies increase.

Prophylaxis against Influenza Disease

- Prophylaxis will be administered according to supply, priority group, and the severity of the pandemic.
- Prophylaxis may be used early in the pandemic to control limited outbreaks or in contained settings.

- Prophylaxis use will be determined by the susceptibility of the circulating influenza strain and the epidemiology of the pandemic.
- During the interpandemic and pandemic alert periods, prophylaxis may be indicated for persons exposed to animal sources of novel strains of influenza virus (e.g., avian influenza) to prevent human infection and illness and the potential for genetic reassortment with human influenza viruses. Decisions to initiate prophylaxis will be based on epidemiologic risk factors, taking into account current knowledge of the epidemiology of the novel strain. Please refer to the forthcoming Guidance for Investigation and Control of Human Illness Associated with Domestic Highly Pathogenic Avian Influenza Outbreaks in Animals in New York State.

- **Post-Exposure Prophylaxis**

- Planning Considerations**

- Post-exposure prophylaxis (PEP) is the administration of antivirals after a person has been exposed to the pandemic virus.
 - PEP generally lasts for 10 days.

- PEP after Contact with an Influenza Case**

- PEP may be useful to control small, well-defined disease clusters.
 - PEP may be useful to prevent disease in household contacts of pandemic influenza patients.
 - PEP may be useful to prevent disease in household contacts of person infected with novel zoonotic (e.g., avian) influenza viruses.
 - PEP may be useful to protect key personnel after vaccination and during the period between vaccination and the development of immunity (usually 2 weeks). The administration of antivirals does not interfere with the development of antibodies to influenza virus after the administration of an inactivated vaccine.
 - State and local health departments, in consultation with the CDC, will recommend which contacts should receive PEP, depending on availability of antivirals and the epidemiology of the pandemic.

B. Timing of the Use of Antiviral Medications

Recommendations during the Interpandemic and Pandemic Alert Periods -

Use of Antivirals in the Management of Cases with a Novel Influenza Strain:

- The term “novel strain of influenza” is used to refer to avian or animal influenza strains that can infect humans (like the H5N1 strain), and new or re-emergent human influenza viruses that cause cases or clusters of human disease. See Section 2: Surveillance and Laboratory Testing for a discussion of the detection and identification of novel strains.
- A person with a suspected case of a novel strain of influenza should be isolated as described in Section 8: Travel-Related Disease Control and Community Prevention, and treated according to the clinical algorithm described in Section 5: Clinical Guidelines.

- State and local health departments may consider the use of antivirals to contain small clusters of infection as a community-wide measure. This may be considered during a small outbreak or in a well-defined setting such as military base or nursing home, or among persons exposed to animal sources of novel (e.g., avian influenza virus.).
- Feasibility would need to be evaluated in terms of antiviral supply, and whether rapid delivery and administration could be accomplished.

Recommendations for the Pandemic Period -

When pandemic influenza is reported abroad, or sporadic pandemic influenza cases are reported in the United States, without evidence of spread:

- Consider the use of antivirals in treatment, prophylaxis, or PEP in the context of containing limited outbreaks or in contained settings.
- Consider the use of antiviral prophylaxis for persons at the highest risk of complications of pandemic influenza based on prioritization strategies.
- Treatment and prophylaxis should be guided by modifications to priority groups based on the epidemiology of the pandemic.
- Treatment and prophylaxis should be guided by antiviral supply, the severity of the pandemic, and the susceptibility of the pandemic strain.

Recommendations for the Pandemic Period -

When there is limited transmission of pandemic influenza in the United States:

- Antiviral drugs should be targeted to priority groups for treatment and prophylaxis, as supply, severity, and the susceptibility of the circulating strain allow.
- Strategies to contain outbreaks and give post-exposure prophylaxis to contacts will be minimized as the pandemic expands.
- Antiviral use will be decreased as a vaccine becomes available and is more widely distributed.

Recommendations for the Pandemic Period -

When there is widespread transmission of pandemic influenza in the United States

- Prioritize treatment for those at highest risk of severe illness and death if supplies are limited.
- Preserve the delivery of healthcare and other essential critical services through early treatment and prophylaxis.
- Provide protection between a first and second vaccine dose or until immunity develops after vaccination.
- Protect those that have an inadequate vaccine response (the elderly and those with underlying immunosuppression), and those with contraindications to vaccination, such as anaphylactic hypersensitivity to eggs.

IV. Prioritization

The primary objectives of the use of antiviral medication during a pandemic are to prevent morbidity and mortality from a novel influenza strain, to maintain essential services, and to minimize social disruption. Antiviral medications may also be used to limit the spread of a

human outbreak of a highly pathogenic avian influenza virus infection. Most, if not all, of the population will be susceptible to a novel influenza strain, and antiviral medication supply will likely be limited. Antiviral use will be most important during the time when vaccine supply is limited, while immunity from the vaccine is being developed, and possibly between doses if two doses are required. Federal and state stockpiles of antiviral medications have been established and are increasing in size. Nevertheless, if a large pandemic occurred in the near future, there would probably not be sufficient supplies to meet the demand.

Priority Groups

If the demand for antiviral medications exceeds the supply during an influenza pandemic, private and public stockpiles of antiviral medications would need to be allocated to priority groups to best meet the objectives above. Guidelines for the establishment of priority groups for antiviral medications have been developed by NVAC and other federal partners (For details see Appendix 7-C, Antiviral Priority Group Recommendations). However, these guidelines are undergoing further consideration at the federal, state, and local levels. Updated guidance will be provided when available.

Publicly purchased antiviral medications must be utilized according to the prioritization scheme recommended by the Federal government at the time of a pandemic. This would include all antivirals purchased by the federal government, NYSDOH, and LHDs. Where flexibility is allowed, NYSDOH will work with health care organizations, and LHDs to determine the prioritization of groups to receive influenza antiviral medication.

All prioritization recommendations will be designated by the NYSDOH as the Standard of Care in New York State. As such, it is expected that all physicians, nurses, and licensed health care facilities will adhere to these recommendations. Failure to comply may subject the individual and/or the health care facility to penalties including fines, and licensure sanctions specified in the New York State Public Health Law, or for professionals licensed by the State Education Department, referral to that agency.

Whether federal guidance will be available for use in an outbreak of highly pathogenic avian influenza is currently unknown.

V. Allocation of Antiviral Medication

Antivirals will be provided by both the Federal and the New York State governments. Federally purchased vaccine will be allocated to all states based on population size. NYSDOH will determine the allocation of federally purchased antivirals and state purchased stockpiles within the 57 upstate counties and New York City to pre-determined distribution and administration sites. In most instances, antivirals will be allocated to counties in amounts determined by the available supply and the size of each county's population. In addition, a particular concentration of critical infrastructure personnel within a county may permit additional allocation to that county for distribution to specified occupational groups. Finally, antivirals will be allocated directly to health care facilities based on the number of inpatient beds and staff.

Planning Considerations

- Antivirals will be delivered to pre-determined sites within counties. These will include local health departments, hospitals, long-term care facilities, and pharmacies.
- The amounts that will be delivered to the sites will be determined by population, critical infrastructure located within a county, bed numbers, staff size, and staff roles.
- Some antivirals will be pre-positioned within the State for easy access when needed. This will not affect the amounts allocated to counties, health care facilities, or pharmacies.

Although the State may have enough antiviral medication to treat more than one priority group at any point in time, NYSDOH will allocate enough medication to treat all of those estimated to be in a priority group before allocating antivirals to the next priority group.

Antiviral allocation for all priority groups will be based on county of residence, workplace location, and presence of health care facilities. Each county should quantify priority groups within its county to ensure that all those who need antiviral treatment are considered.

For an estimation of the size of each of the current DHHS risk groups, please see Appendix 7-D: Antiviral Allocation by Priority Group, New York State (Outside of New York City).

Use of County Pharmaceutical Stockpiles- To ensure that antivirals are most effectively allocated and distributed, counties using their own cache will adhere to Federal guidance regarding administration to priority groups. Any county with an antiviral stockpile should plan to use its own supply before requesting or receiving additional supplies from New York State. Each county should request additional medications according to the procedures established by its respective Strategic National Stockpile (SNS) plan.

Receiving Federal Antiviral Medication from the Strategic National Stockpile- Federal antiviral supplies will be delivered to one site in each state based on a “push” methodology. Requests will not be considered for SNS antiviral assets.

VI. Antiviral Medication Procurement and Distribution

For a detailed description of the logistics involved with the procurement, storage and distribution of antiviral medications, refer to Appendix 7-H: Vaccine and Antiviral Medication Procurement and Distribution. The requirements and activities described in Appendix 7-H apply to public health crises involving pandemic influenza where local and state medical treatment capabilities are exceeded, necessitating the use of Federal SNS assets, including antiviral medication, or State and locally procured supplies of antivirals.

VII. Administration of Antiviral Medications

Administration of antiviral medications is the process whereby antivirals are given to those individuals who are prioritized to receive them during a pandemic. Antivirals will most likely be prioritized to treat those individuals who are sick with influenza and will only be used for

prophylaxis if supply allows. Therefore, sites and methods for the dispensing of antivirals will require both a diagnostic component and a means of providing the medications to appropriate individuals. A great deal of work has been done in regard to planning for large-scale distribution of medications and vaccines in the context of planning for a bioterrorist event using the Point of Dispensing (POD) model. Pandemic administration plans will utilize what has been planned and learned from the POD model, but it will be necessary to augment this system with other distribution and administration methodologies and locations. Alternate Diagnosis and Dispensing Sites (ADDS) are POD-like clinics that will be able to both diagnose and assess illness and dispense needed medications. Antivirals also need to be administered as soon as possible after a person becomes ill with influenza, and within 48 hours. There must, therefore, be access to medication for ill persons 24-hours a day.

The administration of antivirals will likely take place throughout the duration of the first pandemic wave. As vaccine becomes available and more people are vaccinated, antiviral use should decrease. It may then be possible to expand the use of antivirals to other priority groups that were not initially eligible.

Planning Considerations

- Antivirals will be delivered to pre-determined sites within counties. These will include local health departments, hospitals, long-term care facilities, and pharmacies.
- The amounts that will be delivered to the sites will be determined by population size and critical infrastructure located within a county, hospital and long-term care facility bed numbers, and health facility staff size and roles.
- LHDs will need to assess their need for administration sites based on population size and location.
- Some antivirals will be pre-positioned within the state for ready access when needed. Permission to use these stockpiles will be given by the State.
- When directed, CDC/SNS will deliver antivirals to the State without waiting for a request. The amount delivered will be a pre-determined allocation based on population size.
- Antivirals will be delivered from the State stockpiles once a novel strain of influenza has been detected in New York State.
- Priority groups for antiviral use will be determined at the national level. For planning purposes, the groups outlined in the DHHS plan will be the priority groups that are used (See Appendix 7-C).
- The rank order of priority groups is subject to change based upon the epidemiology of the pandemic and antiviral supplies.
- Antiviral use guidelines will be made available by the State. All prioritization and use recommendations will be designated by the NYSDOH as the Standard of Care in New York State. As such, it is expected that all physicians, nurses, and licensed health care facilities will adhere to these recommendations.
- Antivirals will be administered to priority groups sequentially. If supply is adequate, several priority groups will be started at the same time.
- The location of antiviral administration will be based on county of residence, occupational group, and location of hospitals.

Phases of Antiviral Administration

- Phase 1: Administration of pre-positioned antivirals and antivirals stockpiled by the State that is conducted by public health in collaboration with health care facilities and providers.
- Phase 2: Administration of antivirals delivered by the Strategic National Stockpile that is conducted by public health in collaboration with health care facilities and providers. (Phases 1 and 2 may occur simultaneously, or Phase 2 may occur before Phase 1).
- Phase 3: Vaccination with pandemic vaccine begins. Administration of antivirals by public health and partners continues.
- Phase 4: Vaccination with pandemic vaccine is sufficient to allow relaxation of priority groups. Administration of antivirals is expanded and restrictions are decreased.

A. Sites for Antiviral Administration

Several sites may be used to administer antiviral medications. The appropriate combination within a county will depend on several factors including the size of the population, the number of health care facilities that are within a county, the presence of critical infrastructure, the availability of 24-hour access, and the geographic features and barriers present. Sites that can be considered for planning purposes are described below. See Appendices 7-E1 and 7-E2 for flow sheets that describe this process. For sites used, agreements will need to be put into place that guarantee that the antivirals will be used according to state guidelines, stored appropriately, kept securely, and that usage will be tracked and recorded. An appropriate individual will be designated to receive and monitor use of the antiviral supply.

The partnership model is based on the concept of the “community of solution,” in which a variety of existing community entities contribute and mobilize their resources collectively to solve a community problem. Through the partnership model, counties are better able to identify and meet the diverse needs of the priority populations within their communities.

The CDC defines partnerships as “groups of individuals brought together by an established reciprocal agreement for sharing resources and responsibilities to achieve common goals and derive mutual benefits. The basic premise of a partnership is that when individuals or organizations join together, they will be more successful in their collective efforts than they could be as individual players.” Note that the term “partnership” does not imply a formal legal entity.

Through this model, partners (community organizations) work together to ensure that the priority populations within their service area are provided appropriate education diagnosis and treatment.

Partners assist with implementation of required activities as appropriate to the mission and role of their organizations. Partners help programs by expanding and maximizing resources, coordinating services, overcoming obstacles to reach priority populations, and providing medical care. Partnership members include community organizations, health

care providers in a variety of settings, local businesses, health-related organizations, public service, and local government.

These community partners are able and qualified to identify barriers to services for their local population; qualified to design effective strategies to overcome these barriers; and more likely to support interventions that they themselves have helped develop.

Private Provider Offices and Clinics

Patients who are ill, meet clinical case definition for pandemic influenza, and are in a priority group may see their own provider and obtain a prescription for antiviral medication. Patients can then take that prescription to a participating pharmacy or to an alternative diagnosis and dispensing site (ADDS) within the county.

Emergency Rooms

Emergency rooms will be able to assess and diagnose ill patients, and administer antivirals. It is important, however, that emergency rooms be reserved for the most severely ill patients and for after-hours use. Public health messages informing communities about how best to access needed care and medications will help keep emergency rooms from being overwhelmed.

Alternate Diagnosis and Dispensing Sites (ADDSs)

If a sick individual cannot access or does not have his or her own provider, he or she can be seen at the ADDS and be assessed for eligibility for antiviral administration. ADDSs can be set up with an express service that allows individuals already assessed by their own providers and who have a prescription to receive antivirals. It may be advantageous to set up ADDSs close to emergency rooms so that patients who are less ill may be triaged or diverted from emergency departments.

If at any point there is an extremely limited supply of antivirals available, it may be necessary to operate a small, secure ADDS. There will also need to be a plan to ensure that the necessary number of dispensing sites can be established within each county.

Pharmacies

Pharmacies can be used to dispense antiviral medications obtained from State or Federal stockpiles. Ill patients can obtain a prescription from their providers. They will then be able to access antivirals at pharmacies that are willing to provide emergency medications. It is preferable for ill individuals to send well family members to the pharmacy whenever possible to minimize public contact with ill individuals. Pharmacies are only equipped to dispense medication and are not able to provide diagnostic services.

Health Care Facilities

Hospitals and long-term care facilities will be able to administer and dispense antivirals to their staff and patients. The facility will be responsible for setting up a diagnostic system 24 hours a day to evaluate ill persons and determine eligibility for antivirals.

Alternate Care Sites

During a pandemic, alternate care sites will serve as overflow facilities to care for ill persons who cannot be accommodated in a full-service hospital. These sites will be able to administer and dispense antivirals to staff and patients. The health care facility will be responsible for setting up a diagnostic system 24 hours per day to evaluate ill persons and determine eligibility for antivirals.

B. Security

Security for the antiviral supply and administration sites will be extremely important if demand exceeds supply. Each county, health care facility, and pharmacy will need to develop a security plan in conjunction with those already established by the SNS program. Law enforcement must be a partner in planning at the local and State levels.

C. Administering Antivirals to Priority Groups

Priority groups can be divided into occupationally-defined groups and risk-based groups. Occupationally-defined groups are those priority groups defined on the basis of worksite and work role, and would include individuals designated as providers of critical infrastructure services and public safety. Risk-based groups are defined on the basis of being at risk for serious outcome (e.g., 65 and older, underlying conditions) or being a household contact of high-risk persons.

An individual who becomes sick with influenza during a pandemic will need to be able to quickly obtain medical care for triage and diagnosis. If this individual meets clinical case definition and is in a priority group designated for receipt of antivirals, that person also needs to be able to access a dispensing site. Diagnosis and dispensing sites may exist at the same site or may be separate sites as described above.

Ambulatory Outpatients

Persons who are prioritized for antivirals will be able to receive them in several ways (See Appendices 7-E1 and 7-E2 for flow charts):

- They can see their own provider who will document that they meet clinical case definition, verify that they are in a priority group, and will write a prescription for antivirals. If a patient is seriously ill, the provider can send him or her to an emergency room or alternate care site.
- The prescription can then be taken to a dispensing site, by the patient or a well family member. The site may be an ADDS, a POD, or a participating pharmacy.
- If a person is unable to access their provider or does not have a provider, they can be seen in an ADDS. Patients should bring proof of risk status with them. Alternatively, their workplace may have placed them on a priority list and they would then have to provide proof of identity. They can be seen, assessed, diagnosed, and receive antivirals at that site.
- Emergency rooms will be able to see patients and dispense antivirals. However, emergency rooms should be reserved for the sickest patients to avoid overburdening the emergency care system.

There are a large number of outpatients in priority group categories and it may be necessary to sub-prioritize administration. National recommendations for sub-prioritization of antiviral administration within these large groups will be forthcoming. States may be given flexibility in defining subgroups with these larger groups.

Health Care Workers Who Work in Inpatient Settings

Antivirals will be delivered to hospitals and long term care facilities for administration to health care workers who are prioritized to receive them. Each facility needs to implement a process for verifying priority group status and the medical assessment of workers.

Health Care Workers Who Work in Outpatient Settings

Due to the large number of outpatient health care workers, it would be impractical for antivirals to be delivered to provider offices. Providers and other essential staff who are prioritized to receive antivirals will be able to receive them at one of the dispensing sites available in their communities. These may include ADDSs, PODS, pharmacies, or health care institutions with which they are affiliated. Illness can be documented by a medical provider or on site. A method must be in place to verify priority group status and identity.

Hospitalized Patients and Residents of Long-Term Care Facilities

Antivirals will be delivered to hospitals and long term care facilities for administration to ill patients and residents. All hospitalized patients and the great majority of long-term care facility residents are prioritized for antiviral administration if ill with pandemic influenza.

Persons Responsible for Public Safety

The administration of antivirals to firefighters, police, emergency medical technicians (EMTs) and other persons with responsibility for public safety will take place at ADDS or pharmacies that are available within their communities. Illness can be documented by a provider or on site. A method must be in place to verify occupation, priority group status, and identity.

Persons Responsible for Critical Infrastructure

This group is yet to be defined by the DHHS. This group will be able to receive antivirals from PODs, at an ADDS, or at their work site depending on what is available in their communities. Illness can be documented by a provider or on site. A method must be in place to verify occupation, priority group status and identity.

Persons Exposed to Potentially Zoonotic Strains of Novel Influenza Viruses

During an outbreak of influenza in animals (e.g., avian, porcine), the persons who are handling these animals for examination, testing, care or disposition or persons engaged in cleaning and disinfecting environments contaminated by these animals may be the highest priority group for antiviral use, if the virus has not yet shown pandemic potential. Persons exposed to potentially zoonotic strains of novel influenza viruses, if prioritized, will be able to receive antivirals from an ADDS or pharmacy. Illness can be documented

by a medical provider or on site. A method must be in place to verify occupation, risk status, and identity.

D. Verification of Priority Group Membership

Occupation-Based Priority Groups

Companies designated as critical infrastructure will need to prioritize their employees, and provide local public health authorities with a list of individuals considered essential to continuity of critical infrastructure or public safety in the order in which they are prioritized. Federal and State guidelines will assist employers in making these designations. LHDs need to work with these entities within their counties to facilitate the exchange of lists and to inform the companies and agencies about the procedure to obtain antivirals. Individuals in occupations prioritized to receive antivirals need to be able to provide proof of their identity and occupation or workplace. A work identification card (ID) and picture ID, such as a driver's license, would be sufficient proof.

Within hospitals and long-term care facilities, a designated person will be responsible for coordinating the decision process to determine which staff members are eligible for antiviral administration by site and work role. Federal and State guidelines will assist facilities in prioritizing their staff. Health care facilities will need to have personnel available to assess individuals, who are ill, for the need for antivirals on a 24-hour basis. The facility will need to establish procedures for ensuring that only those who are prioritized receive antivirals.

Risk-Based Priority Groups

Priority group status based on risk can be verified in the following ways:

- A note or prescription from a provider verifying risk status;
- Certain prescription bottles or copies of prescription labels with the person's name on it;
- Identification cards or driver's licenses can be used to verify age and should be used to verify identity; and
- Individuals who are at high risk or have a chronic medical condition should be encouraged to obtain documentation of risk status from their providers in advance of a pandemic.

The NYSDOH will work to provide guidelines for which medications and conditions make individuals eligible for antivirals.

Special Populations

In a state as large and diverse as New York State, there exist numerous groups that may present challenges to providing access to appropriate medical care and antivirals during a pandemic. LHDs must make an effort to identify those groups within their communities and to work with the NYSDOH to create plans to reach these populations. Examples of special population groups may include:

- Tribal communities;
- Religious groups;

- Individuals that primarily speak a language other than English;
- Individuals in home care and hospice;
- Homebound individuals;
- Disabled individuals; and
- Homeless individuals.

In regard to these groups it is important to:

- Plan in advance with groups that represent these individuals;
- Insure that materials are available in appropriate languages;
- Make sure that clinics can be accessed by public transportation;
- Ensure that the needs of the physically disabled are met at planned sites; and
- Work on ways to communicate with special needs populations.

VIII. Information Technology in Support of Antiviral Distribution

The capability to gather essential information regarding the acquisition, allocation, distribution, and use of pandemic antivirals and vaccine will be a critical aspect of the response to a pandemic. The goal is to track inventory, record the number of doses given and to whom they were given, monitor adverse events, and fulfill federal reporting requirements. An integrated system utilizing pre-existing electronic applications that have already been developed would meet the data needs of a pandemic response.

The programmatic aspects of the pandemic information system will need to specify:

- How data will be collected at the sites;
- How data will be transmitted from the sites to LHDs, the State, and the Federal government;
- Personnel needs;
- A training plan; and
- Equipment needs.

The NYSDOH will develop a strategy for monitoring antiviral drug distribution by public health. Data elements that may be collected include:

- The distribution of state and federal supplies of antiviral drugs, including:
 - Where antivirals are shipped;
 - Who has received them, including demographic information on the recipients;
 - Type of administration: treatment, prophylaxis, PEP;
 - Priority groups reached;
 - Dose and number of courses administered by person and in the aggregate; and
 - Relevant medical history.
- Adverse events following administration of antivirals; and
- Rates of severe influenza illness and death among those treated and untreated.

Workgroups will be established to map critical data flows, design the new system components that are needed and ensure that they interoperate and share data with existing data systems such

as the Communicable Disease Electronic Surveillance System (CDESS), Electronic Clinical Laboratory Reporting System (ECLRS), Clinic Data Management System (CDMS), the New York State Immunization Information System (NYSIIS), the NYSDOH Communications Directory and the Emergency Notification System for the sending of emergency messages, alerts, advisories, and updates.

The NYSDOH will continue to expand its Clinic Data Management System (CDMS.) This system provides a standardized format for the NYSDOH and LHDs to collect, store, recall and process treatment and demographic data for patients and public health responders and can be utilized in both routine and emergency situations. CDMS has the capacity to track the status of medication administration for patients as well as vaccination of or administration of prophylaxis to public health responders via paper, web or LAN-based data submissions. The system is being adapted to incorporate data collection templates and forms that are event-specific and appropriate for mass prophylaxis and/or vaccination clinics. The NYSDOH informatics workgroup is currently assessing various aspects of the CDMS, including compliance with the Public Health Information Network (PHIN) and the integration of the NYSDOH Pre-Event Smallpox Vaccination System (PVS) and NYSIIS with the Federal Countermeasure and Response Administration (CRA) system.

Additionally, the NYSDOH promoted, trained and tested Version 1.0 of the CDMS with 57 LHDs and two Tribal Nations during Points of Dispensing (POD) exercises held in 2005 and 2006. Time-study information was collected and recommendations were made resulting in further improvements to the form and system; Version 2.0 is under development.

IX. Antiviral Risk Communication

Timely, clear, consistent and effective messaging is essential to ensure that members of the public understand limitations on antiviral availability and efficacy and are willing to engage in other critical risk reduction measures (non-pharmaceutical interventions) in the event that sufficient supplies of antiviral medications are not available for all ill persons. It is also important that messages relating to antiviral availability, efficacy and prioritization are crafted to help address the problem of worried individuals over-burdening healthcare resources. To accomplish this goal the NYSDOH will:

- Provide pre-event education to various sectors using mass media, public engagement and targeted communications;
- Prepare and disseminate information for health care providers;
- Prepare public information materials pre-event and provide them to public website staff for posting on the Department's "test" website;
- Provide script templates and pre-recorded messages to the Department's contract call center operators, and also disseminate these materials to key communications partners;
- Provide information for internal audiences (e.g., DOH/Health Research, Inc employees); and
- Utilize materials provided by the Federal government and adapt for use in New York State.

Materials and messages will need to be developed that reach a broad spectrum of the public. This may mean dissemination in a variety of languages and reading levels, and the utilization of methods to reach those not ordinarily accessible by mainstream methods.

X. Clinical Components of Antiviral Administration

A. Clinical Guidelines

Clear and consistent clinical algorithms that can be altered as the epidemiology and medication supply change will be critical aspects of the implementation of antiviral distribution and use. The NYSDOH has created a clinical algorithm based on current knowledge of influenza, avian influenza, and antiviral supply to guide planning efforts (see Appendix 7-F). However, it is likely that guidelines will change and that there will be Federal mandates on how antivirals are used. During a pandemic, clinical guidelines for antiviral use will be revised by the NYSDOH and will become the standard of care. It will be essential that antivirals are used in a consistent and equitable manner throughout the State. This is necessary to avoid depletion of limited supplies and the resultant inability to treat those most in need of medication. It may also be necessary to create triage standards so that health providers feel comfortable sending sick persons to other sites if overwhelmed with patients.

B. Infection Control

An important pandemic aspect of clinic/POD planning includes implementation of appropriate infection control measures. Sick individuals should be separated from well individuals whenever possible. ADDS should be structured so that ill individuals can be seen in a location separate from an express line used for dispensing medication. Use of large or open air sites is to be encouraged, as is minimizing wait times. It may be useful to offer tickets or appointments if possible. The availability of hand hygiene materials, appropriate disposal equipment, and masks will be important. Clinic personnel must adhere to appropriate infection control guidance for health care personnel. For further discussion on infection control guidance, see Section 4: Infection Control of the NYSDOH Pandemic Influenza Plan.

C. Special Populations and Complex Medical Conditions

Antivirals are commonly used in medical practice but they are not used with the same breadth that they would be during a pandemic. Questions will arise concerning use of antiviral medications in special populations such as pediatric and geriatric populations, and persons with complicated medical conditions. The NYSDOH will establish guidelines where indicated and possible. It will also be necessary to maintain access to medical specialists, such as those in Regional Resource Centers, who can provide medical consultation as needed. There are 8 regional resource centers throughout the

upstate area. These are medical centers with a complete selection of medical specialists that can address special populations and care for and address adverse events.

D. Antiviral Medication Monitoring

Important components of antiviral medication monitoring include evaluations of antiviral drug effectiveness and resistance, contraindications, adverse event monitoring, and the use of an Investigational New Drug (IND) or Emergency Use Authorization (EUA) protocol.

Antiviral Medication Effectiveness

In a pandemic, it is likely that federal agencies will conduct antiviral drug effectiveness studies in collaboration with state and local health departments, and other health care and academic partners. The NYSDOH will coordinate, where appropriate, the distribution of protocols to New York State sites and the collection of data.

Antiviral Drug Resistance

The NYSDOH will work with the CDC and local partners to monitor the development of resistance to antivirals. Because resistance to M2 inhibitors may involve a single base pair change, resistance may develop rapidly if these drugs are used widely. Information about resistance to M2 inhibitors and neuraminidase inhibitors can be found in the July 2005 recommendations of the ACIP at <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>. Surveillance for antiviral resistance may be particularly important during the later stages of the pandemic, especially if M2 agents have been widely used. Under these circumstances, the detection of widespread M2 inhibitor resistance might require a re-evaluation of priorities for prophylaxis and treatment.

CDC will test the drug susceptibilities of viruses isolated from different age groups and geographic areas over the course of the pandemic. The NYSDOH will coordinate the collection of appropriate specimens in New York State to monitor for antiviral drug resistance. An example includes obtaining clinical specimens from patients who develop severe disease while receiving treatment or prophylaxis. In addition, the NYSDOH is considering developing the capability to test for resistance.

Contraindications

Each antiviral medication has specific contraindications and dosing requirements. Dosage needs to be adjusted for use in children, those with compromised creatinine clearance, those with hepatic dysfunction, and the elderly. There currently are no antiviral medications licensed for use in children under the age of 1 year. Those individuals with a known allergy to a medication should not receive it. For a description of antiviral medications available for the treatment of influenza, dosage, side effects, and some contraindications, see Appendix 7-A: Characteristics of Anti-Influenza Antiviral Medications; Appendix 7-B: Recommended Daily Dosage of Antivirals for Treatment and Prophylaxis; and the July 2005 recommendations of the ACIP at <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>.

Antiviral Medication Adverse Event Monitoring and Reporting

Adverse events associated with antiviral medication use inevitably will occur. Adverse events are currently monitored nationally by the Food and Drug Administration's (FDA) MedWatch system (see Appendix 7-I: MedWatch). The NYSDOH is developing an antiviral safety monitoring system that will coordinate with the MedWatch system. To accomplish this, the NYSDOH will continue to expand its Clinic Data Management System (CDMS) and its immunization registry (NYSIIS) to collect adverse event information. These systems provides a standardized format for the NYSDOH and LHDs to collect, store, recall and process treatment and demographic data for patients and public health responders and can be utilized in both routine and emergency situations. CDMS and NYSIIS have the capacity to track the status of medication administration for patients as well as vaccinated or prophylaxed public health responders via paper, web or LAN-based data submissions. The NYSDOH has identified an antiviral safety coordinator as well as a back-up antiviral safety coordinator to oversee reporting policies, methodologies and procedures.

The NYSDOH will:

- Develop or review policies for reporting adverse events;
- Ensure timely reporting of adverse events consistent with federal guidelines;
- Provide guidance for LHDs and providers;
- Train appropriate staff on reporting methodology and procedures; and
- Disseminate Federal information, letters, materials, etc.

LHDs will:

- Designate those responsible for investigating and reporting adverse events;
- Ensure timely reporting of adverse events consistent with guidelines; and
- Disseminate information on adverse events to providers.

During a pandemic, those who have received antiviral prophylaxis and have concerns about a potential adverse event, will be referred to their own health care provider or the local emergency department for medical evaluation. If a provider requires medical advice or support, he or she may call the medical director of the LHD or the designated medical regional resource center. There are 8 regional resource centers throughout the upstate area. These are medical centers with a complete selection of medical specialists that can care for and address adverse events. Physicians at the NYSDOH will be available for consultation on antiviral related adverse events, and can consult experts at the CDC if required.

Serious adverse events associated with the use of antiviral influenza drugs should be reported to the FDA, using the MedWatch monitoring program. During an influenza pandemic, NYSDOH and LHDs will assist in this effort by providing protocols and information to health care providers and encouraging them to download MedWatch forms (available at <http://www.fda.gov/medwatch/>) for distribution to patients. Adverse events reported to MedWatch are collated and analyzed by the FDA's Adverse Events Reporting System (AERS).

Use of antivirals will be much greater during a pandemic than during a regular influenza season. To help improve the detection for serious adverse effects (especially rare effects or effects in vulnerable populations), additional efforts to encourage recognition and reporting of adverse events will be needed. These efforts might include:

- Active surveillance for adverse events observed at emergency rooms, through the National Electronic Injury Surveillance System Cooperative Adverse Drug Event project (NEISS-CADE) or other surveillance systems;
- Active surveillance for adverse events among those prioritized for antiviral prophylaxis;
- Local campaigns to educate health care workers about the recognition and reporting of adverse events; and
- Distribution of MedWatch forms and descriptions of known adverse events to each provider and user of antiviral drugs.

In addition, CDC and the FDA will explore the use of existing drug-monitoring systems that have access to individual health utilization records that may allow active, population-based surveillance for adverse events following the use of antivirals for treatment or prophylaxis.

Contingency Planning for Use of an Investigational New Drug Provision or an Emergency Use Authorization

There are two mechanisms for use of unapproved medical products or unapproved uses of approved products. The first is under the FDA's Investigational New Drug (IND) provisions. IND provisions require completion of a signed consent form from each person who receives the medication, and mandatory reporting of specified types of adverse events. The NYSDOH has staffing capabilities and printing facilities to coordinate the receipt, mass production and distribution of the IND protocols and consent forms. They also require strict inventory control and record-keeping, and approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other venues. The FDA regulations permit use of a national or "central" IRB. However, it is anticipated that IND requirements will be too difficult to meet during a widespread emergency such as a pandemic.

As an alternative to IND use, DHHS may utilize the drug product under Emergency Use Authorization (EUA) procedures as described in the FDA draft guidance "Emergency Use Authorization of Medical Products" available on the FDA website at www.fda.gov/cber/gdlns/emerase.pdf. If a national emergency is declared by the Secretary of the United States DHHS, the FDA Commissioner may authorize the use of an unapproved medical product or an unapproved use of a licensed medical product. Once issued, an EUA is active for one year but may be terminated earlier if the HHS Secretary determines that it is no longer needed. EUA procedures are described in the FDA draft guidance "Emergency Use Authorization of Medical Products" available on the FDA website at www.fda.gov/cber/gdlns/emerase.pdf.

EUA requirements include record keeping, distribution of information sheets to providers and patients, and adverse event reporting. CDC plans to issue an operational plan for EUAs. Once released, NYSDOH will use that plan for further guidance in this area.

XI. Staffing

Staffing is an important component of running any type of long-term treatment and dispensing system. Insufficient staffing may limit the number of clinics and the hours that a clinic can operate. After-hours visits may have to be restricted to emergency room visits. Staffing needs can be estimated once the number of sites required is identified and the hours during which they will operate are set.

Hospitals, Medical Reserve Corps (MRCs) and LHDs should be working together to identify and recruit medical and non-medical volunteers who can assist in the dispensing of antivirals in healthcare settings, ADDS or PODs. These volunteers should be included in local emergency efforts when exercising hospital-PODs and LHD PODs. In the aftermath of September 11th, the NYSDOH developed a statewide Public Health Preparedness Volunteer Practitioner Database of licensed professionals who would be willing to volunteer their services in the event of a public health emergency. The purpose of this Volunteer Practitioner Database is to assure that New York State, New York City and the 57 remaining counties of the state have adequate resources to prepare for and respond to any public health emergency when their local volunteer resources are depleted. The database is designed not to deter or compete with volunteer recruitment efforts on the local level, but rather to supplement and serve as a logical extension of those efforts. Volunteers who agree to participate in this state-sponsored volunteer program are provided the personal liability protection of Public Officers Law § 17 if they are activated and deployed by New York State.

Staffing of security personnel will be critical. During a pandemic the demand for antiviral medications will likely be greater than the supply. In addition, it is likely that people will request antivirals to be used in ways that are not designated by the State. Therefore, control of the antiviral assets and access to them will be very important.

XII. Training

The NYSDOH has been conducting training in roles associated with mass smallpox vaccination clinics since 2003. In 2004, training was expanded to include roles associated with both mass vaccination clinics and mass prophylaxis clinics, with emphasis on transferability of skills across clinic type. In 2006, training was modified again to include pediatric clinics, as well as roles associated with push methodologies for vaccination or prophylaxis. Job action sheets have been created for all clinic roles, and a just-in-time training guide has been integrated into the NYSDOH POD Standard Operating Guide. Training has also been provided to state and local public health providers in the “Clinic Planning Model Generator,” to assist in identification of numbers of staff needed for clinics based on type of clinic, population, and other factors associated with mass clinics.

Training will continue via diverse methodologies (didactic, webinar, videoconference, online training) not only for roles associated with mass clinics, but also for roles associated with the Strategic National Stockpile (job action sheets have also been developed for each of these roles).

Additionally, volunteers have been integrated into mass clinic exercises via agreements with local Medical Reserve Corps. Just-in-time training has been provided in clinic roles at both state operated mass influenza vaccination clinics, as well as such clinics at the local level. Mass clinic exercises with associated training will continue on a yearly basis. These activities are ongoing for both short-term and long-term operationalization of the pandemic influenza plan.

XIII. Activities by WHO Pandemic Period and CDC Interval

A. Strategies for the Use of Antiviral Medications

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection, and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Plan for the use of an EUA or IND protocol.
- Plan for the implementation of treatment, prophylaxis, and PEP protocols.
- Plan for data collection.
- Plan for Risk Communication Preparedness:
 - Disseminate pandemic preparedness DVD including information about antiviral issues to LHDs for use during Town Meetings and briefings for sector-specific audiences (e.g. critical infrastructure, first responders, faith community);
 - Develop pandemic “School Action Kit” including information about antiviral issues;
 - Continue to provide information about pandemic preparedness, including antiviral issues, on the NYSDOH public web site;
 - Use HIN/HPN and “Recently on the HPN” email notifications (E-Lerts) to advise providers on availability of information resources;
 - Produce call center scripts/templates/pre-recorded messages for call center operators and work with appropriate programs staff to ensure that operators are trained in their use;
 - Produce a “shelf kit” of public information materials addressing pandemic issues (including limitations on availability and efficacy of antivirals) and pre-position kit with LHDs and NYSDOH Regional Offices;
 - Continue to provide information on pandemic issues (including limitations on availability and efficacy of antivirals) to DOH/HRI

Section 7: Antiviral Medication Procurement, Distribution, and Use

through Lotus News, the Department's "Insider" intranet and via paycheck attachments;

- Identify and/or meet with previously identified opinion leaders representing statewide constituencies most likely to perceive unfairness in rationing of health care resources and work to resolve trust issues that may arise over antiviral prioritization decisions.

Local Health Departments:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Plan for the use of an EUA or IND protocol.
- Plan for the implementation of treatment, prophylaxis, and PEP protocols.
- Determine the size of priority groups in their jurisdiction.
- Plan for Risk Communication Preparedness:
 - Use pandemic preparedness DVD and other informational materials prepared by NYSDOH during Town Meetings and meetings with sector-specific partners;
 - Distribute pandemic "School Action Kit" to school districts within the LHD's jurisdiction;
 - Provide script templates and pre-recorded messages produced by NYSDOH to the LHD's call center operators, and- as applicable- other call center operators (e.g., county hotline, 311 service) within the LHD's jurisdiction;
 - Provide information about pandemic issues (including limitations on availability and efficacy of antivirals) to LHD employees;
 - Identify and/or meet with previously identified opinion leaders representing local communities most likely to perceive unfairness in rationing of health care resources and work to resolve trust issues that may arise over antiviral prioritization decisions.

Healthcare Partners:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Continue to treat all patients admitted to the hospital with influenza within 48 hours.
- Use antivirals in the medical management of novel cases of influenza as outlined in clinical protocols.
- Plan for the use of an EUA or IND protocol.
- Plan for the implementation of treatment, prophylaxis, and PEP protocols.
- Develop plans to implement distribution of antivirals to priority groups.

Section 7: Antiviral Medication Procurement, Distribution, and Use

- Participate in pandemic risk communication planning with State and Local Health Departments.
- To the extent possible, make use of informational materials developed by NYSDOH, or adapt materials as necessary while still retaining a consistent message.

Pandemic Period - No Pandemic Influenza Detected in the United States or only Sporadic Cases Reported in the United States (*Investigation, Recognition, Initiation Intervals*)

State Health Department:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection, and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Plan for the use of antiviral drugs in the management of persons infected with novel strains of influenza and their contacts.
- Work with LHDs and health care partners to disseminate public health guidance that encourages drug-use practices that help minimize the development of drug resistance.
- Implement risk communication activities:
 - Using a multi-media approach, explain antiviral prioritization decisions and attendant implications for those who will/will not be eligible to receive them; reinforce risk reduction measures that are crucial to reduce the chance of becoming infected;
 - Ensure that public information is disseminated to clearly explain: who is eligible to receive antivirals; how eligible persons can obtain antivirals; and who is NOT eligible at this time;
 - Partner with statewide media and trusted leaders to discourage persons who are not eligible to receive antivirals from going to hospital emergency departments in hopes of obtaining them;
 - Update information on antiviral availability posted on public website, NYSDOH intranet and HIN/HPN; continue to remind healthcare providers of updated information available on the HPN via E-LERTS and/or other alert tools;
 - Work with appropriate program staff to send information to providers via blast faxing and/or “Dear Provider” letters;
 - Revise call center script templates based on event-specific information;
 - Meet with opinion leaders representing statewide constituencies most likely to perceive unfairness in rationing of health care resources and reinforce rationale underlying prioritization decisions;
 - Carry out an educational campaign stressing the importance of getting vaccinated for protection against seasonal influenza and pneumococcal infection; reinforce the difference between seasonal and pandemic influenza.

Local Health Departments:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection, and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Plan for the use of antiviral drugs in the management of persons infected with novel strains of influenza and their contacts.
- Work with health care providers to disseminate public health guidance that encourages drug-use practices that help minimize the development of drug resistance.
- Implement Risk Communication Activities:
 - Utilize pandemic “Shelf Kit” templates and/or ensure that any other informational material disseminated is consistent with messages given by NYSDOH;
 - Partner with local media and trusted leaders to discourage persons who are not eligible to receive antivirals from going to hospital emergency departments in hopes of obtaining them;
 - Ensure that local call center operators are provided with updated “Just In Time” information;
 - Post updated information on public website, if applicable;
 - Disseminate updated information to local healthcare providers;
 - Meet with opinion leaders representing local communities most likely to perceive unfairness in rationing of health care resources and reinforce rationale underlying prioritization decisions.

Healthcare Partners:

- Continue the administration of seasonal influenza and pneumococcal vaccine to reduce the possibility of co-infection, and to maintain and develop influenza vaccination infrastructure.
- Continue the use of antivirals to control nosocomial outbreaks.
- Plan for the use of antiviral drugs in the management of persons infected with novel strains of influenza and their contacts.
- Target treatment to influenza patients admitted to a hospital who present within 48 hours of symptom onset.
- Administer antivirals to all persons sick with influenza that enter the hospital based on clinical algorithms.
- Begin treatment of patients with influenza-like illness and a positive rapid antigen test for influenza A.
- Base the continuation of treatment decisions on laboratory confirmed subtype identification of the pandemic strain by viral isolations, RT-PCR, or other means recommended by CDC, or the severity of disease and susceptibility of the infective strain in illness caused by other influenza subtypes.
- Help to develop and implement health guidance that encourages drug-use practices that minimize the development of drug resistance.

- Ensure that information disseminated regarding antiviral prioritization/efficacy is consistent with messages given by NYSDOH.

Pandemic Period - When Pandemic Influenza is Detected in the United States (*Initiation Interval*)

State Health Department:

- Revise the strategies for the use of antivirals as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain, susceptibility of the pandemic strain, and on when a vaccine becomes available.
- In conjunction with CDC, authorize the use of antivirals to treat and control the spread of disease from individuals and small clusters, if cases of novel influenza should occur in the US.
- In conjunction with CDC, authorize contact tracing and use of antivirals to provide PEP to close contacts of persons with novel influenza.
- Monitor the amount of people that receive antivirals for prophylaxis to preserve and extend supplies available to treat those persons at the highest risk of serious morbidity and death.
- Assist with the acquisition, distribution, and administration of antivirals to identified priority groups.
- Implement mass distribution of antivirals if needed. Work with LHDs and health care partners to provide updated information about availability and efficacy of antivirals;
- Communicate changes regarding who is now eligible for antivirals and how to obtain them using a multi-media approach and targeted information to key partners;
- Continue to reinforce non-pharmaceutical risk reduction measures that people should be taking;
- Review scripts/pre-recorded messages being used by call center operators and revise as necessary.
- Review information posted on public web site, HIN/HPN, NYSDOH intranet and revise as necessary.

Local Health Departments:

- In conjunction with NYSDOH, CDC, and health care partners, administer antivirals to control the spread of disease in small cluster outbreaks or outbreaks in contained settings.
- Trace and prophylax close contacts of confirmed cases if authorized to do so by CDC and NYSDOH.
- Assist with the distribution and administration of antivirals to identified and confirmed priority groups.
- Implement mass distribution of antivirals if needed.
- Continue to ensure that information disseminated regarding antiviral availability/efficacy is consistent with messages given by NYSDOH.

Healthcare Partners:

- With increasing disease activity base treatment decisions on:
 - Laboratory confirmation of infection with a pandemic subtype,
 - Detection of influenza A by rapid antigen test, or
 - Epidemiologic and clinical characteristics.
- Initiate treatment before laboratory confirmation is obtained.
- Continue treatment awaiting confirmatory tests.
- Target prophylaxis to priority groups.
- Use PEP to control small well-defined disease clusters and to protect individuals with a known exposure to a pandemic virus, such as household contacts.
- PEP may be used to protect those prioritized during the period between vaccination and the development of immunity.
- If possible, reserve the use of antivirals for prophylaxis only during period of peak viral circulation if that information is available.
- Continue to ensure that information disseminated regarding antiviral availability/efficacy is consistent with messages given by NYSDOH.

Pandemic Period – When there is Widespread Transmission of Pandemic Influenza in the United States (*Initiation, Acceleration, Peak, Deceleration Interval*)

State Health Department:

- Revise the strategies for the use of antivirals as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain, susceptibility of the pandemic strain, and on when a vaccine becomes available.
- Distribute information about changes in the prioritization guidelines, viral susceptibility, resistance, or supply as available.
- As the pandemic becomes more widespread, it may no longer be practical or useful to provide prophylaxis against outbreaks.
- Monitor the number of people who receive antivirals for prophylaxis to preserve and extend supplies available to treat those persons at the highest risk of serious morbidity and death.
- Assist with the acquisition, distribution, and administration of antivirals to identified priority groups.
- Assist with the distribution and administration of antivirals to identified and confirmed priority groups.
- Continue mass distribution of antivirals if needed.

Local Health Departments:

- Distribute information about changes in the prioritization guidelines, viral susceptibility, resistance, or supply as available.
- Assist with the distribution and administration of antivirals to identified and confirmed priority groups.
- Decrease use of antivirals as needed once a vaccine is available
- Continue mass distribution of antivirals if needed.

Healthcare Partners:

- As the pandemic becomes more widespread, treatment decisions are made more on clinical characteristics and epidemiologic features. Laboratory confirmation will no longer be necessary.
- Treat those at highest risk of severe illness and death if antiviral supplies are limited.
- Decrease use of prophylactic antivirals as needed once a vaccine is available.
- Continue to administer antiviral prophylaxis between the first and second dose, or until immunity develops if recommended.
- Continue to administer antiviral prophylaxis to those for whom the vaccine is contraindicated or whose response to the vaccine is likely to be inadequate.

B. Prioritization

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department:

- Develop state specific guidelines for prioritization of the use of antivirals based on the national guidelines in conjunction with LHDs, health care partners, other state agencies, community groups, and others.
- Establish and convene a prioritization committee.
- Identify, define, and quantify priority groups for antiviral use.
- Communicate with the media, LHDs, and health care partners about prioritization decisions.
- Develop relationships and agreements with groups within the state to facilitate antiviral distribution and use. Examples of such groups include tribal authorities and religious groups.
- Identify and quantify the sites that would be needed to administer antiviral drugs (for example hospitals, clinics, nursing homes, alternative care facilities, etc.).
- Plan for the use of standing orders to administer antivirals.
- Plan for mass distribution of antivirals to priority groups if needed.

Local Health Departments:

- Identify, define, and quantify priority groups in local jurisdictions that are prioritized for antiviral use.
- Communicate with the media and health care partners about prioritization decisions.
- Plan for mass administration of antivirals to priority groups if needed.

Healthcare Partners:

- Identify, define, and quantify priority groups for antiviral use.
- Plan for administration of antivirals to priority groups within health care facilities and practices.

Pandemic Period (*Recognition, Initiation, Acceleration, Peak, Deceleration Intervals*)

State Health Department:

- Review modifications, if any, to interim recommendations on antiviral use in selected groups.
- Activate plans for distributing and administering antivirals to persons in priority groups.
- Accelerate training on appropriate use of antiviral drugs among public health staff and health care partners.
- Distribute and deliver stockpiled supplies of antiviral, as appropriate to delivery sites that will administer them to priority groups.
- Communicate updates in the guidelines for appropriate use of antivirals as the pandemic continues.
- Continue to work with health care providers to ensure appropriate use of antivirals in the medical management of early cases and contacts.
- Assist hospitals in implementing procedures for early detection and treatment of influenza in health care workers (see Section 4: Infection Control).

Local Health Departments:

- Activate plans for distributing and administering antivirals to persons in priority groups.
- Distribute and deliver stockpiled supplies of antiviral, as appropriate to delivery sites that will administer them to priority groups.
- Communicate updates in the guidelines for appropriate use of antivirals as the pandemic continues.
- Continue to work with health care providers to ensure appropriate use of antivirals in the medical management of early cases and contacts.

Healthcare Partners:

- Limit the use of antivirals when the pandemic becomes more widespread to treat those who are at the highest risk of severe illness and death and to preserve the delivery of health care services and other essential critical services through early treatment and limited prophylaxis.
- After vaccine becomes available use antivirals for those that may not have an optimal response to the vaccine or for whom the vaccine is contraindicated.
- Target prophylaxis to priority groups.

C. Antiviral Medication Acquisitions and Distribution

See Appendix 7-H.

D. Antiviral Medication Safety

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department:

- Work with CDC to plan for the capability to monitor drug susceptibility of the pandemic strain and monitor change over time.
- Plan for the use of an IND protocol with a potential requirement to do active surveillance for all those receiving antiviral medication.
- Plan for antiviral effectiveness and resistance studies and laboratory capacity.
- Establish an antiviral adverse event monitoring system.
- Appoint a physician to be the Adverse Event Coordinator for NYS.
- Identify and train NYSDOH and LHD staff that will provide adverse event monitoring.
- Plan for active surveillance.

Local Health Departments:

- Establish antiviral adverse event monitoring procedures based on the NYSDOH monitoring system.
- Identify staff members who will be responsible for adverse event monitoring.
- Identify physicians who can provide medical consultation for adverse events.
- Plan for reporting and case investigation of adverse events.
- Plan for active surveillance based on NYSDOH recommendations.

Healthcare Partners:

- Establish antiviral adverse event monitoring and reporting procedures based on the NYSDOH monitoring system.
- Identify staff that will be responsible for adverse event monitoring.
- Identify physicians who can provide medical consultation for adverse events.

WHO Pandemic Period/USFGR Stage 3, 4, and 5 (*Initiation, Acceleration, Peak, Deceleration*)

State Health Department:

- Work with LHDs and HCPs to evaluate the effectiveness of antivirals for prophylaxis and treatment.
- Monitor the incidence of antiviral adverse events.
- Monitor the emergence of antiviral resistance.
- Make antiviral adverse events reportable in NYS by emergency regulation.
- Report adverse events to the FDA using the MedWatch monitoring program.
- Provide protocols and information to health care providers and encouraging hospitals to download MedWatch forms for distribution to patients.
- Engage in active monitoring for adverse events observed at emergency rooms and health care facilities.

- Educate health care workers and LHD staff about the recognition and reporting of adverse events.
- Distribute MedWatch forms to each end-user that receives antivirals.
- Work with CDC to monitor the development of resistance.
- Encourage clinicians to obtain specimens from patients who develop severe disease while receiving treatment of prophylaxis.

Local Health Departments:

- Investigate and report all antiviral adverse events.
- Engage in active surveillance of antiviral adverse events.
- Distribute MedWatch forms to providers and patients as needed.
- Work with NYSDOH to monitor resistance and effectiveness of antivirals
- Encourage clinicians to obtain specimens from patients who develop severe disease while receiving treatment of prophylaxis.
- Provide protocols and information to health care providers and encouraging hospitals to download MedWatch forms for distribution to patients.

Healthcare Partners:

- Monitor all staff taking antivirals for adverse events.
- Report all adverse events to LHD.
- Participate with the LHD to investigate all adverse events.
- Obtain viral specimens from patients who develop severe disease while receiving treatment or prophylaxis and submit to Wadsworth or CDC according to established protocol.
- Provide medical consultation for those in the community who have concerns about potential adverse events.

E. Data Collection

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department:

- Work with DHHS, LHDs, and HCPs to implement guidance on specifications for tracking distribution, effectiveness, and safety of antivirals.
- Work with the Data Management Workgroup to develop the ability to collect important antiviral data.
- Provide information to health professionals and the public on issues related to availability and use of antiviral drugs during an influenza pandemic.
- Plan for the use of an EUA or IND protocol which would require the collection of detailed information on inventory control, participants, consent, and adverse events.

Local Health Departments:

- Plan for the participation in the data collection system established by the NYSDOH.
- Educate staff about their roles in this system.

Healthcare Partners:

- Plan for participation in the data collection system established by the NYSDOH.
- Educate staff about their roles in this system.

WHO Pandemic Period/USFGR Stage 3 and 4 (Recognition, Initiation, Acceleration, Peak)

State Health Department:

- Track antiviral supply in the state and redistribute as needed.
- Track the speed with which antivirals are able to be delivered.
- Collect data on state supplies of antiviral drugs.
- Collect data on adverse events following administration of antiviral drugs.
- Participate in federal efforts to collect data on the effectiveness of treatment and prophylaxis.
- Participate in federal efforts to collect data on the development of drug resistance.

Local Health Departments:

- Track antiviral supply in the county and redistribute as needed and permitted.
- Collect required data using the data collection system established during the interpandemic period.
- Provide feedback on the use of the data system to the NYSDOH reporting any problems encountered or modifications recommended.

Healthcare Partners:

- Track antiviral supply within health care facilities.
- Collect required data using the data collection system established during the interpandemic period.
- Provide feedback on the use of the data system to the NYSDOH reporting any problems encountered or modifications recommended.

Characteristics of Anti-Influenza Antiviral Medications

	Inhibits	Acts on	Administration	Common Side Effects
Amantadine	M2 ion channel	Influenza A	Oral	CNS, GI
Rimantadine	M2 ion channel	Influenza A	Oral	CNS, GI (less often than Amantadine)
Oseltamivir	Neuraminidase	Influenza A and B	Oral	GI
Zanamivir	Neuraminidase	Influenza A and B	Inhaler	Bronchospasm

These agents differ in mechanisms of action, pharmacokinetics, FDA-approved indications, dosages, cost, and potential for emergence of drug resistance (see July 2005 recommendations of the AHIC: <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>.)

The neuraminidase inhibitors and rimantadine are superior with regard to the frequency of side effects.

The use of M2 inhibitors, particularly for treatment, is likely to lead to the emergency and spread of drug-resistant influenza viruses.

(Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7)

Recommended Daily Dosage of Antivirals for Treatment and Prophylaxis

(Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7)

ANTIVIRAL AGENT	AGE GROUPS (YEARS)				
	1–6	7–9	10–12	13–64	≥65
Amantadine^a					
Treatment, influenza A	5mg/kg body weight/day up to 150 mg in two divided doses ^b	5mg/kg body weight /day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	≤100 mg/day
Prophylaxis, influenza A	5mg/kg body weight /day up to 150 mg in two divided doses ^b	5mg/kg body weight /day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	≤100 mg/day
Rimantadine^d					
Treatment, ^e influenza A	NA ^f	NA	NA	100 mg twice daily ^{c,g}	100 mg/day
Prophylaxis, influenza A	5m/kg body weight /day up to 150 mg in two divided doses ^b	5mg/kg body weight /day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	100 mg/day ^h
Zanamivir^{i,j}					
Treatment, influenza A and B	NA	10 mg twice daily	10 mg twice daily	10 mg twice daily	10 mg twice daily
Oseltamivir					
Treatment, ^k influenza A and B	dose varies by child's weight ^l	dose varies by child's weight ^l	dose varies by child's weight ^l	75 mg twice daily	75 mg twice daily
Prophylaxis, influenza A and B	NA	NA	NA	75 mg/day	75 mg/day

NOTE: Amantadine manufacturers include Endo Pharmaceuticals (Symmetrel (R)-tablet and syrup) and Geneva Pharms Tech (Amantadine HCL-capsule); USL Pharma (Amantadine HCL-capsule and tablet); and Alpharma, Carolina Medical, Copley Pharmaceutical, HiTech Pharma, Mikart, Morton Grove, and Pharmaceutical Associates (Amantadine HCL-syrup), and Sandoz. Rimantadine is manufactured by Forest Laboratories (Flumadine (R)-tablet and syrup); Corepharma, Impax Labs (Rimantadine HCL-tablet), and Amide Pharmaceuticals (Rimantadine HCL-tablet). Zanamivir is manufactured by GlaxoSmithKline (Relenza (R)-inhaled powder). Oseltamivir is manufactured by Roche Pharmaceuticals (Tamiflu (R)-tablet). Information based on data published by the U.S. Food and Drug Administration at www.fda.gov, accessed 3/30/2005.

^a The drug package insert should be consulted for dosage recommendations for administering amantadine to persons with creatinine clearance ≤ 50 ml/min/1.73m².

^b 5 mg/kg body weight of amantadine or rimantadine syrup = 1 tsp/2.2 lbs.

^c Children aged ≥ 10 years who weigh < 40 kg should be administered amantadine or rimantadine at a dosage of 5 mg/kg body weight /day.

^d A reduction in dosage to 100 mg/day of rimantadine is recommended for persons who have severe hepatic dysfunction or those with creatinine clearance ≤ 10 mL/min. Other persons with less severe hepatic or renal dysfunction taking 100 mg/day of rimantadine should be observed closely, and the dosage should be reduced or the drug discontinued, if necessary.

^e Approved by FDA only for treatment among adults.

^f Not applicable.

^g Rimantadine is approved by FDA for treatment among adults. However, certain experts in the management of influenza consider it appropriate for treatment among children. (See American Academy of Pediatrics, 2003 Red Book.)

^h Older nursing-home residents should be administered only 100 mg/day of rimantadine. A reduction in dosage to 100 mg/day should be considered for all persons aged ≥ 65 years if they experience possible side effects when taking 200 mg/day.

ⁱ Zanamivir administered via inhalation using a plastic device included in the medication package. Patients will benefit from instruction and demonstration of the correct use of the device.

^j Zanamivir is not approved for prophylaxis.

^k A reduction in the dose of oseltamivir is recommended for persons with creatinine clearance < 30 ml/min.

^l The dose recommendation for children who weigh ≤ 15 kg is 30 mg twice a day. For children who weigh > 15 to 23 kg, the dose is 45 mg twice a day. For children who weigh > 23 to 40 kg, the dose is 60 mg twice a day. And for children who weigh > 40 kg, the dose is 75 mg twice a day.

^a Information on seasonal outbreaks of interpandemic influenza, including public health measures to contain outbreaks, can be found at <http://www.cdc.gov/flu/>.

^b McKimm-Breschkin JL. Resistance of influenza viruses to neuraminidase inhibitors - a review. *Antiviral Res.* 2000, 47:1-17.

^c Tisdale M. Monitoring of viral susceptibility: new challenges with the development of influenza NA inhibitors. *Rev Med Virol*, 2000, 10:45-55.

Last revised: November 8, 2005

**Antiviral Allocation by Priority Group
New York State (Outside of New York City)**

Tier	Priority Group	New York State Population (Outside of New York City)	Estimated # Courses (10 tablets/capsules per course) Needed	Strategy*	# Courses Cumulative	% of group receiving antivirals from current stockpile**	% of group receiving antivirals †
1	Patients admitted to hospital	452,165	339,124	T	339,124	100%	100%
2	HCWs w/ direct patient care and EMS	381,498	100,143	T	481,303	100%	100%
3	Highest Risk Out-patients severely immuno-compromised (pregnant women; cancer; organ recipients; HIV/AIDS)	94,250	24,740	T	506,043	100%	100%
4	Pandemic health responders	5,500	48,988	T	555,031	100%	100%
	Public safety (fire, police, corrections)	179,123					
	Gov't decision makers	2,000					
5	Increased risk outpatients: children 12-23 months	134,389	870,665	T	1,425,696	4.5%	20%
	Increased risk outpatients: adults 65 and older	1,525,632					
	Increased risk outpatients: persons with underlying medical conditions	1,658,800					
6	Outbreak response: nursing homes and other health care residential settings	206,169	206,169	PEP	1,631,865	0%	0%

7	HCWs in EDs, ICUs, dialysis,	20,000	260,000	P	1,891,865	0%	0%
	EMS	45,000					
8	Pandemic societal responders (critical infrastructure)	197,699	101,968	T	1,993,833	0%	0%
	Other HCWs without direct pt care	190,749					
9	Other outpatients (those that develop influenza and do not fall in above groups)	6,786,000	1,781,325	T	3,775,158	0%	0%
10	Highest risk outpatients	173,079	377,000	P	4,152,158	0%	0%
11	Other HCWs with direct patient care	316,498	1,265,992	P	5,418,150	0%	0%

*Strategy: **Treatment (T)** requires one course (2 tablets/capsules per day x 5 days = 10 total). Assumes a 35% attack rate and 75% of those who fall ill will present within 48 hours of symptom onset. **Post-exposure prophylaxis (PEP)** requires one course (1 tablet/capsule per day x 10 days = 10 total). **Prophylaxis (P)** requires 4 courses (1 tablet/capsule a day for 10 days = 40 total) though a longer duration may be needed if community outbreaks last for a longer period.

** Current stockpile includes 1,723,736 courses of antivirals. 598,500 is the allocation of antivirals for New York State outside of New York City.

† Total Stockpile following March, 2007 shipment of antivirals will include 1,277,889 courses of antivirals. 728,396 is the allocation of antivirals for New York State outside of New York City.

Priority Group 1- Calculated using FluSurge 2.0 from the CDC. Assumes 8 week long pandemic with a 35% attack rate. Assumes 75% of those admitted to hospital present within 48 hours of symptom onset. The number of hospitalizations in each county will vary according to population size and the proportion of its population which is at-risk.

Priority Group 2- Estimated using census 2000 calculations- Summary File 3 for social, economic and housing characteristics available at www.census.gov. Like the HHS Pandemic Influenza Plan, assumes 2/3 of all Healthcare Workers have direct patient contact.

Priority Group 3- Estimates NYS population using estimates using the New York State proportion of the HHS pandemic influenza plan estimates. The population of New York State outside of New York City is 3.77% of the United States population.

Priority Group 4- Pandemic responders (5,500) includes NYSDOH and local health department staff as reported to public health responder survey March 2006. Public Safety (179,123) includes Fire and Police Officers and corrections. Police and corrections data from New York State Statistical Yearbook of 2004 (Rockefeller Institute). Firefighters data from the New York Department of State Fire Service Resource Inventory (June 2005). Key government decision makers is estimated at 2,000.

Priority Group 5- High Risk population: 12-23 months or 65 years or older available from 2005 census estimates. Increased risk outpatients- estimates NYS population using estimates using the New York State proportion of the HHS pandemic influenza plan estimates.

Priority Groups 6- Estimates patients in nursing homes and their contacts. Total number of nursing home residents multiplied by 3 to account for patient family visitors and staff. Does not quantify other residential settings such as assisted living facilities.

Priority Group 7- HCWs in these specific settings is estimated to be one half the HHS total number in this category (HCW+EMS) extrapolated to the NYS (outside of NYC) population (3.77% of the U.S. population). EMS counts from NYSDOH, Bureau of EMS.

Priority Group 8- Includes critical infrastructure workers in (utility, transportation, IT and Telecommunication workers, and mortuary workers in vaccine Tier 2B). Other HCWs without direct pt care = 1/3 of total healthcare workers.

Priority Group 9-10 Estimates NYS population using the New York State proportion of the HHS pandemic influenza plan estimates. The population of New York State outside of New York City is 3.77% of the United States population.

Priority Group 11 - Includes healthcare workers with direct patient contact (Priority Group 2) excluding those who have received antiviral prophylaxis as part of Priority Group 7.

Antiviral Medication Priority Group Recommendations

	Group	Estimated population (millions)	Strategy**	# Courses (millions)		Rationale
				For target group	Cumulative	
1	Patients admitted to hospital***	10.0	T	7.5	7.5	Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die.
2	Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers	9.2	T	2.4	9.9	Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.
3	Highest risk outpatients—immunocompromised persons and pregnant women	2.5	T	0.7	10.6	Groups at greatest risk of hospitalization and death; immunocompromised cannot be protected by vaccination.
4	Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers	3.3	T	0.9	11.5	Groups are critical for an effective public health response to a pandemic.
5	Increased risk outpatients— young children 12-23 months old, persons >65 yrs old, and persons with underlying medical conditions	85.5	T	22.4	33.9	Groups are at high risk for hospitalization and death.
6	Outbreak response in nursing homes and other residential settings	NA	PEP	2.0	35.9	Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks; vaccination priorities do not include nursing home residents.

7	HCWs in emergency departments, intensive care units, dialysis centers, and EMS providers	1.2	P	4.8	40.7	These groups are most critical to an effective healthcare response and have limited surge capacity. Prophylaxis will best prevent absenteeism.
8	Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact	10.2	T	2.7	43.4	Infrastructure groups that have impact on maintaining health, implementing a pandemic response, and maintaining societal functions.
9	Other outpatients	180	T	47.3	90.7	Includes others who develop influenza and do not fall within the above groups.
10	Highest risk outpatients	2.5	P	10.0	100.7	Prevents illness in the highest risk groups for hospitalization and death.
11	Other HCWs with direct patient contact	8.0	P	32.0	132.7	Prevention would best reduce absenteeism and preserve optimal function.

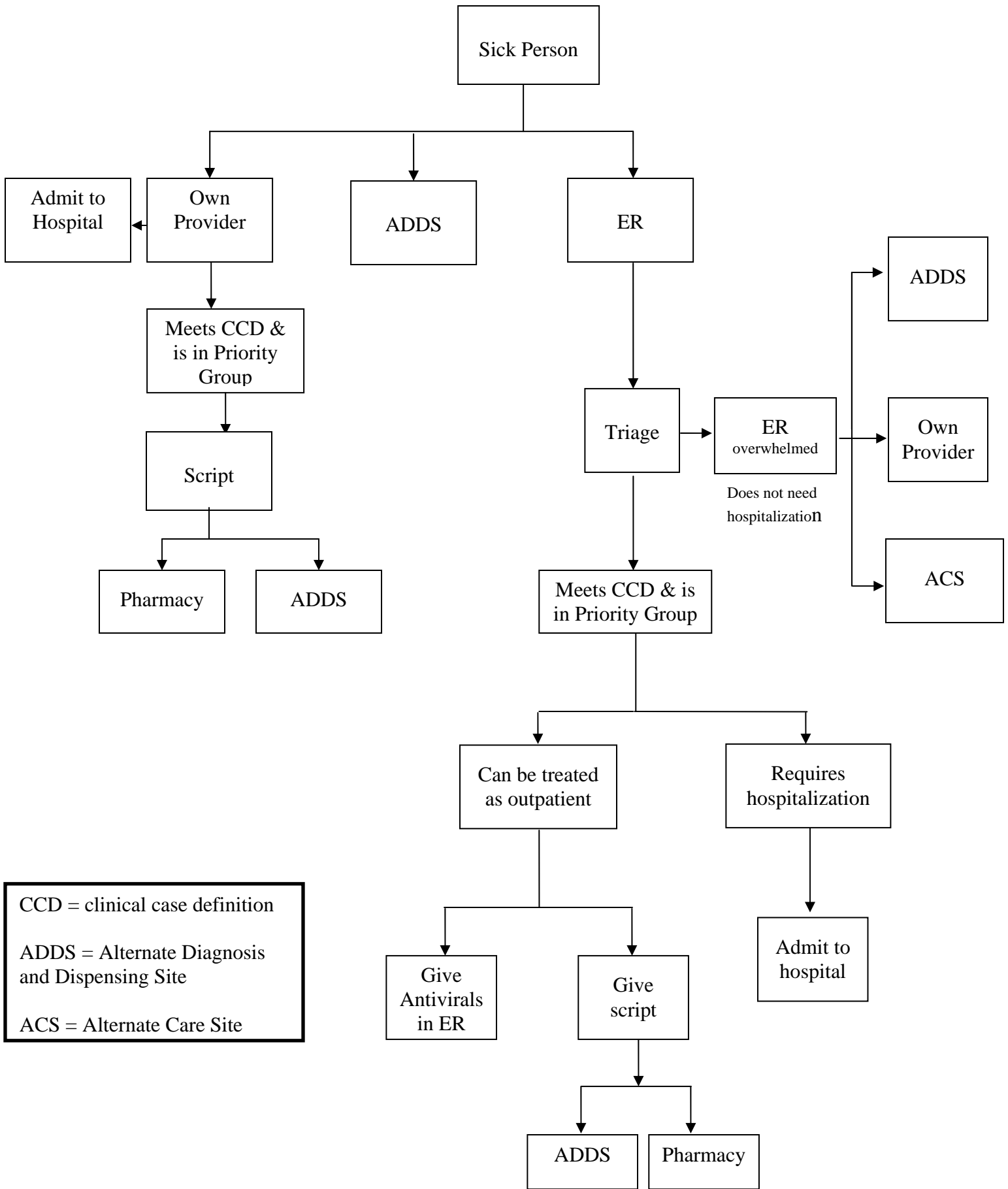
*The committee focused its deliberations on the domestic U.S. civilian population. NVAC recognizes that Department of Defense (DoD) needs should be highly prioritized. A separate DoD antiviral stockpile has been established to meet those needs. Other groups also were not explicitly considered in deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

**Strategy: Treatment (T) requires a total of 10 capsules and is defined as 1 course. Post-exposure prophylaxis (PEP) also requires a single course. Prophylaxis (P) is assumed to require 40 capsules (4 courses) though more may be needed if community outbreaks last for a longer period.

***There are no data on the effectiveness of treatment at hospitalization. If stockpiled antiviral drug supplies are very limited, the priority of this group could be reconsidered based on the epidemiology of the pandemic and any additional data on effectiveness in this population.

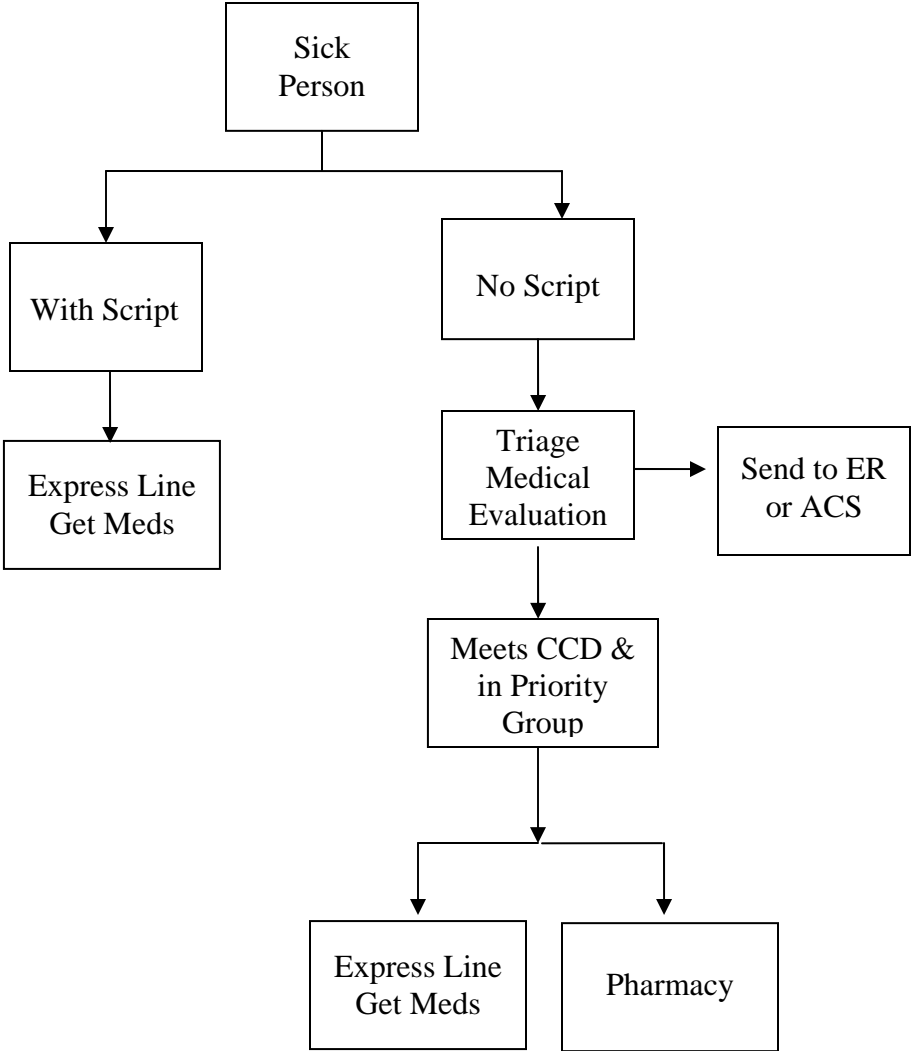
(Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7)

Antiviral Dispensing Scenarios



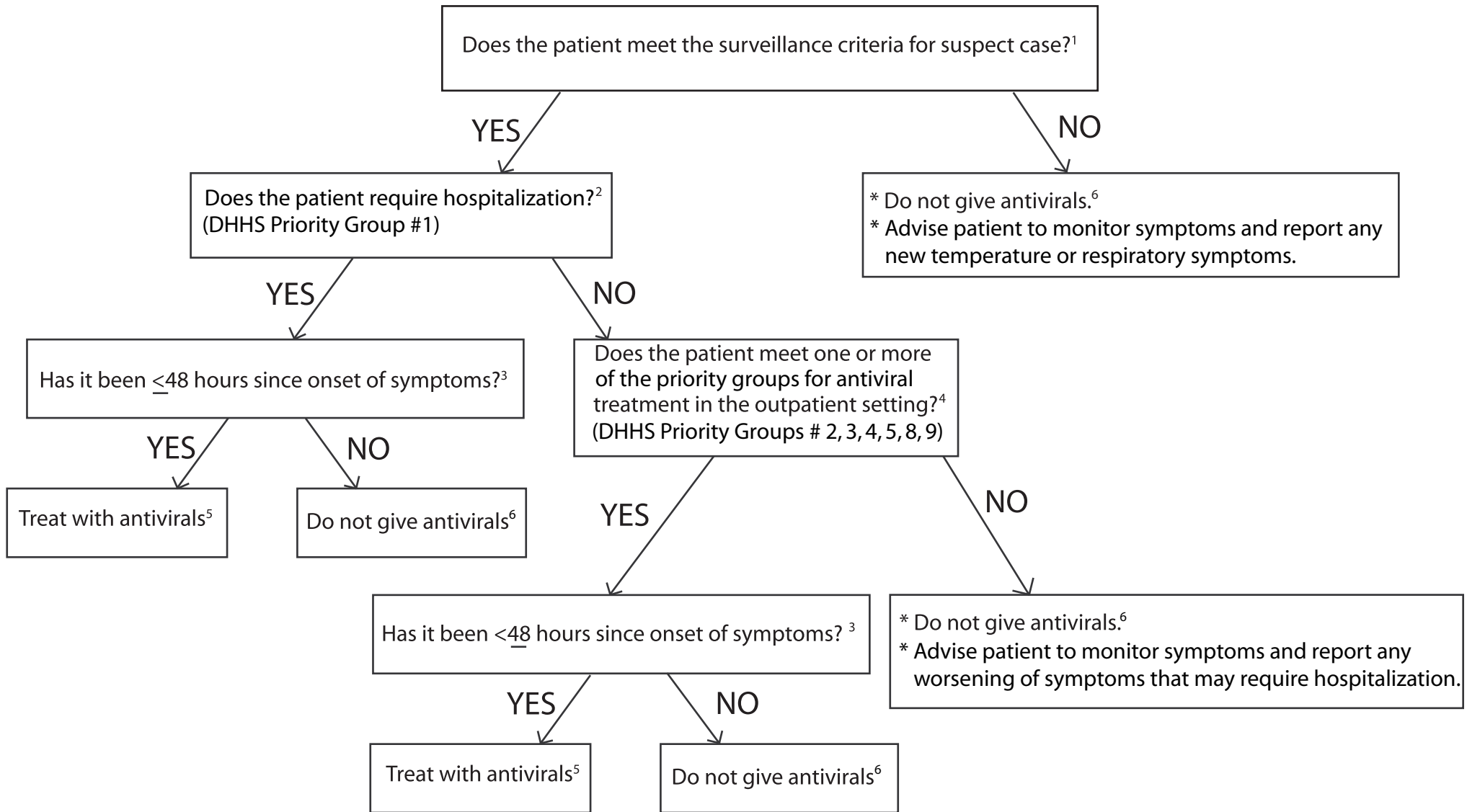
CCD = clinical case definition
 ADDS = Alternate Diagnosis and Dispensing Site
 ACS = Alternate Care Site

Antiviral Dispensing in Alternate Diagnosis and Dispensing Sites (ADDS)



CCD= clinical case definition
ADDS=Alternate Diagnosis and Dispensing Site
ACS = Alternate Care Site

Algorithm for Antiviral Treatment during the Pandemic Period



1. Document temperature >38°C (<100.4°F) and one more respiratory symptom (cough, sore throat, and/or dyspnea).

2. Decision to hospitalize a patient is based upon the clinical assessment.

3. Current data indicate that the effectiveness of antivirals is limited if initiated more than 48 hours after the onset of symptoms.

4. Priority groups for antiviral treatment in the outpatient setting will be determined by the antiviral supply. NYSDOH will allocate enough medication to treat all of those individuals in a priority group during the estimated duration of a pandemic before allocating antivirals to the next priority group. See Appendix 7-C for a list of the DHHS priority groups.

5. See Appendix 7-B for recommended dose. Duration of treatment is 5 days.

6. Treat as clinically indicated with medications other than antivirals.

Pediatric Use of Antiviral Medications

Tamiflu (oseltamivir) is indicated for the treatment of acute influenza in patients 1 year of age and older, who have been symptomatic for 2 days or less. Tamiflu is also indicated for the prophylaxis of influenza in individuals 1 year and older.

None of the available influenza antivirals are currently FDA approved for use among children aged <1 year. In particular, the safety and efficacy of oseltamivir have not been studied in children aged <1 year for either treatment or prophylaxis of influenza (see oseltamivir package insert). The decision by an individual physician to treat children aged <1 year in an emergency setting on a off-label basis with an antiviral must be made on case-by-base basis with full consideration of the potential risks and benefits. Additional human data on the safety of these agents in the treatment of influenza in young children are needed.

Osteltamivir is available as an oral suspension for use in children. This formulation of oseltamivir may not be available in sufficient supply during a pandemic to treat all pediatric patients. If physicians consider opening 75 mg oseltamivir capsules and using the contents in an attempt to deliver a partial, pediatric dose to children, it must be recognized that there are insufficient data on palatability, stability, and dosing consistency to predict the safety or effectiveness of such unapproved use. Additional study of these issues is needed.

The FDA has approved a labeling supplement for Roche Laboratories' Tamiflu (oseltamivir) to include a precaution about neuropsychiatric events. The agency has received postmarketing reports (mostly from Japan) of self-injury and delirium with the use of Tamiflu in patients with influenza. The reports were primarily among pediatric patients. Tamiflu product labeling will include a new statement, in the Precautions section, that individuals with influenza should be closely monitored for signs of abnormal behavior, including self-injury or confusion, immediately after starting Tamiflu. Reports of these events indicate that they occurred after 1-2 doses. The relative contribution of the drug to these events is not known, as stated in the approved labeling.

For more information please visit the FDA website at <http://www.fda.gov/cder/drug/infopage/tamiflu/>.

(Sources: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7, FDA Website: Center for Drug Evaluation and Research, <http://www.fda.gov/cder/drug/infopage/tamiflu/>.)

Vaccine and Antiviral Medication Procurement

Appendix 7-H is intended to serve as an operational guide to the request, receipt, storage, shipment and distribution of pandemic influenza vaccine and antiviral medications. It should be recognized that supplies of both vaccine and antivirals may be limited during a pandemic. Access to these products will be through New York State (NYS) and will be controlled at the local level by county health departments. In all cases, the disposition of these items must be carefully tracked to ensure their appropriate use and efficacy. The allocation and use of both vaccine and antivirals are inter-related. As the amount of vaccine available increases and more individuals become immune to the pandemic strain through vaccination, the amount of antivirals needed will decrease.

Specific details regarding State sites for receiving antivirals, local receiving sites, storage capability, and other planning aspects can be found in the New York State Strategic National Stockpile Operational Appendix to the NYSDOH Comprehensive Emergency Management Plan.

I. Levels of Supply

A public health crisis involving pandemic influenza necessitating the need for distributing vaccine or antiviral medications may be similar to other events that require activation of the NYS Strategic National Stockpile (SNS) plan. Vaccine and antiviral availability will change during the course of a pandemic. Pandemic response strategies will vary with vaccine and antiviral supply. Four vaccine or antiviral supply levels can be defined.

Stage 1: No Vaccine/Antiviral Supply

At the beginning of a pandemic, it is possible that no vaccine will be available. Depending on the particular viral strains that make up the pandemic, there may or may not be a supply of effective antiviral medications available for distribution and use.

Stage 2: Limited Vaccine/Antiviral Supply

When first available, the vaccine/antiviral supply may be less than that required to protect the entire susceptible population. Priority groups for vaccine/antivirals will need to be identified and plans for the distribution of vaccine/antivirals will need to be formulated. Approaches to inform priority groups about the availability of vaccine/antivirals and where to receive them; and to educate the public regarding vaccine/antiviral priorities and their rationale will be needed. Allocation plans for counties that are to receive vaccine/antivirals need to be developed, based on priority populations. Vaccine/antiviral effectiveness and safety need to be monitored. Depending on amounts of vaccine/antivirals available, a State SNS Mobilization Site may be activated. Repackaging may be required.

Stage 3: Adequate Vaccine/Antiviral Supply

Vaccine/antiviral supply will match the need and ability to distribute vaccine/antivirals.

This will allow a shift from priority groups to the wider population. Strategies are developed to assure equitable distribution to special needs populations. The State SNS Plan may be activated to facilitate distribution of the vaccine/antivirals.

Stage 4: Excess Vaccine/Antiviral Supply

Vaccine/antiviral supplies exceed that needed to protect the NYS population. The State SNS Plan may be activated to facilitate distribution of the vaccine/antivirals. With less demand and abundant supply, vaccine/antiviral distribution may return to normal pre-pandemic supply strategies that include the use of private distribution and/or private providers.

II. Operational Assumptions

- Pre-pandemic and pandemic vaccines will be purchased by the Federal Government and distributed to NYS. Antivirals will be purchased by both the Federal Government and the State. NYS maintains a supply of antivirals in the State Medical Emergency Response Cache (MERC). See Appendix 7-C, Antiviral Allocation by Priority Group, for an estimation of the amounts needed by priority group. Pre-pandemic vaccine need is estimated to be 20 million courses for the entire nation.
- Antiviral drug distribution from the CDC will be pro rata (based on population) and will be delivered to the states prior to a request.
- Antivirals are most effective if administered within 48 hours of the onset of symptoms. There is a time-sensitive requirement for rapid distribution and administration of antivirals.
- A planning assumption of 50.4 million manufactured vaccine courses per year or 4.2 million courses per month will be available nationwide once production begins. One course equals 2 doses of vaccine.
- Based upon the planning assumption, NYS will receive sufficient vaccine to immunize 1.5% of its population per month.
- If vaccines with applicable influenza strains are not immediately present during initial stages of the pandemic, vaccine production will take from 4 to 6 months to occur from the time a pandemic strain is selected.
- SNS vaccine/antiviral materiel(s) procured by CDC will arrive at a State Mobilization Site (NYSDOH Vaccine Depot or designated site) after CDC's decision to deploy the vaccine/antivirals. New York State refers to its Receiving, Storing, and Staging (RSS) Sites as State Mobilization Sites. NYS currently has detailed plans for 8 State Mobilization Sites throughout the State. A site, specifically for a pandemic response, has been identified and the information has been shared with the CDC.
- There may be competing requests to the CDC for vaccine/antiviral assets from neighboring states.
- The State will determine allocation of both vaccine and antivirals within its jurisdiction.
- NYS will activate its SNS Plan to facilitate the widespread distribution of vaccines/antivirals.

- Influenza vaccine/antivirals will be distributed rapidly to designated priority groups through partnership arrangements with local health departments (LHDs) and health care facilities.
- Requests for vaccine/antivirals may not be accepted, depending on supply. If requests are permitted, multiple shipments of vaccine/antivirals may be requested and deployed.
- State agency resources and personnel will likely be needed to support local distribution and dispensing efforts.
- The affected locality will be responsible for vaccine/antivirals delivered to it and will have identified suitable locations for storage and distribution.
- The State will adhere to all requirements regarding the use and return of undistributed supplies to the federal authorities.

III. Vaccine and Antiviral Deployment

The goal of deployment is to quickly deliver, in an orderly manner, all needed supplies to local agencies to allow them to immunize, treat or prophylax members of their communities. When appropriate, distribution will be via the State's SNS plan. Receipt and distribution of vaccine/antiviral assets will involve numerous local, State, Federal, volunteer, and private agencies. There are five critical centers that must coordinate actions and ensure a smooth flow of information:

1. State Emergency Operations Center;
2. County Emergency Operations Centers;
3. State Mobilization Site/Vaccine Storage Depot;
4. County Staging Sites; and
5. Points of Dispensing/Alternate Diagnosis and Dispensing Sites.

The deployment of vaccine/antivirals to NYS will be broken down into four distinct phases.

1. Request or Allocation Phase

The request phase includes the local and State analysis of the situation potentially requiring the deployment of vaccine/antivirals and the request itself or the decision to deploy vaccine or antivirals. The NYSDOH will assume the lead role in requesting vaccine or antivirals, if permitted, with support from SEMO. Antivirals and vaccine will most likely not be shipped by the CDC upon request. Instead, when directed, the CDC will allocate pre-determined amounts directly to the states without waiting for a request. Depending on supply, local jurisdictions may be able to request vaccines/antivirals through the County Emergency Operations Center to the State Emergency Operations Center after coordination among appropriate local agencies. Local jurisdictions may be required to accept pre-determined amounts based on population and county-based occupational groups. State Emergency Management Office will coordinate all local requests and allocations with the NYSDOH.

2. Mobilization and Staging Phase

The mobilization phase of distributing vaccine/antiviral assets involves all activities associated with the receipt, off-loading, staging, processing, repackaging, and transportation of materiel. A large state like New York requires rapid distribution to multiple locations throughout a large and diverse geography. NYS agencies, regional agencies, and some counties will be responsible for all activities associated with the mobilization effort. Local resources may also be utilized, where available, to assist with mobilization efforts. Local resources, when utilized, will be integrated into State activities. Counties have planned for the establishment of a county staging site within the county limits that will receive shipments from the State Mobilization Site. This staging site must have the ability to maintain cold chain management of vaccines or proper environmental conditions for storage of antivirals. Certain health care facilities may also be designated to receive vaccine or antivirals directly from the state. These facilities will have the same requirements for management and storage of these assets.

3. Immunization/Dispensing Phase

The immunization/dispensing phase includes those activities associated with the set-up and operation of PODs, alternate diagnosis and dispensing sites, and treatment center facilities, which provide immunization, treatment and/or prophylactic medications to affected members of the public, or provide medications to treatment centers, such as hospitals, clinics, etc. NYSDOH will provide guidance to counties detailing priority groups, duration of prophylaxis, etc.

Collection, storage and transmission of information on individuals who are vaccinated will be undertaken by local public health agencies using the HERDS framework under the supporting architecture of the New York State Commerce System. Information concerning administration of vaccine and tracking of vaccine supplies will be achieved through the use of a countermeasures response system that is integrated with the Clinic Data Management System (CDMS), the New York State Immunization Information System (NYSIIS) and HERDS. A description of this system and the detailed requirements for data collection are included in Section 13 of the New York State Pandemic Influenza Plan, “Public Health Preparedness Informatics.”

The NYSDOH will provide specific guidance on the disposition of vaccine and antiviral medications to local public health authorities to ensure that circumstances surrounding their use and administration are consistent with established priorities. All recipients of State supplied vaccine and antivirals will be required to follow the guidance provided by the NYSDOH.

4. Recovery Phase

The recovery phase includes those activities associated with the returning of unused assets to State control. Local public health agencies will be advised by New York State on how excess supplies will be collected and redistributed (if necessary).

IV. Logistics

1. Facilities

The primary vaccine reception point will be the NYSDOH Vaccine Depot located in Wadsworth Center, Albany, New York. This Albany Vaccine Depot consists of 924 cubic feet of refrigeration space. In addition, 1,000 cubic feet of refrigeration space has been identified for use in Wadsworth Center for a combined total of 1924 cubic feet. Capabilities of the depot to store and distribute vaccine are as follows:

- Current storage capabilities are approximately 1.5 million doses in the Albany Vaccine Depot and an additional 1.5 million doses using the additional storage capacity identified in Wadsworth Center for a total of 3 million doses. Additional vaccine storage capability exists for up to 2-6 million vials additional doses (dependant upon type of vial) in a dedicated refrigerator trailer.
- Vaccine will be distributed through normal commercial carriers up to 150,000 doses per day for a total of 5 days per week assuming security requirements permit. NYSDOH, in cooperation with the New York State Office of General Services, owns and operates a 48-foot refrigerator trailer for the purposes of transporting vaccine.
- Beyond 150,000 doses per day or 3,000,000 doses per month, FedEx custom critical or similar refrigerated vehicles will be used. These vehicles may include or necessitate the use of State identified equipment consistent with assets identified by the State Emergency Management Plan.

The primary storage site for antiviral medications available through the MERC is in Albany and Long Island. However, New York State is in the process of establishing additional MERC storage sites in other areas of the State.

- Antiviral supplies requested by local health authorities may be shipped from the New York State operated storage site closest to the county making the request.
- Locally maintained sites for storage of antivirals should be temperature controlled (not subject to temperature extremes) and be secure against unauthorized access.
- Package inserts for antiviral drugs should be consulted to determine if all Food and Drug Administration (FDA)-established storage criteria have been met.

2. Ground Support

Local transportation resources, supported by State assets as required, will transport bulk and/or repackaged medications and supplies to designated county staging sites. Security will be coordinated by State Police. Specific security duties are the responsibility of the Security Lead (from the New York State Police) identified in the New York State Strategic National Stockpile Plan.

3. Receipt and Sign-off

A designated NYSDOH physician or representative will be dispatched to the mobilization site to meet and sign for assets. The State Health Commissioner may designate a local physician, working under the auspices of the affected LHD, as the SNS receiving physician, also known as the Drug Enforcement Agency (DEA) Registrant.

4. Repackaging

In consultation with local officials, the determination will be made as to where repackaging efforts will be undertaken. Repackaging may be required if short-term prophylaxis of individuals is indicated. Staffing for repackaging efforts will be provided by State agency personnel and/or by local agencies per local plans (if existing), as required. In addition, NYSDOH is currently working on securing an MOU with a private entity to conduct repackaging as needed.

5. Long-term Dispensing Operations

NYSDOH officials will work with local health officials to determine the need for extended or long-term dispensing efforts. Plans will be developed utilizing pharmacies, health care facilities, alternate diagnosis and dispensing sites, and PODs to accomplish these objectives.

V. Activities by WHO Pandemic Period and CDC Interval

Interpandemic Period (*Investigation, Recognition Intervals*)

State Health Department:

- Continue to develop and refine pandemic plan.
- Identify/determine ship-to-sites, up to 100 allowed per state, which will receive shipments on a weekly basis.
- Determine how vaccine/antivirals are transported from ship-to-sites to vaccination or dispensing sites.
- Ensure the availability of sufficient storage at all locations to maintain the cold chain.
- Develop chain of custody procedures.
- Develop/implement a certification process to insure chain of custody procedures and vaccine/antiviral storage and handling, distribution, security and accountability requirements are met.
- Certify vaccine/antiviral ship-to-sites and administration sites.
- Develop/implement a security plan to protect vaccine/antiviral assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.
- Ensure that proper storage requirements exist for the contents of the SNS during storage at the mobilization site and during transport.
- Examine systems requirements for the Vaccine/Antiviral Ordering System to ensure applicable tracking and distribution of influenza vaccine/antivirals.

- Develop, implement and maintain a tracking system for vaccine/antiviral receipts, inventory, point of distribution, and doses administered that captures at a minimum
 - a. Product,
 - b. Manufacturer,
 - c. Lot Number,
 - d. Expiration Date,
 - e. NDC number.
 - f. Depending on product availability some vaccine types, devices, manufacturers, may be targeted to specific populations when warranted.
- Identify overflow storage facilities and make necessary arrangements for use. This may include contracts, memorandums of understanding, etc.
- Identify applicable transportation facilities to distribute vaccine/antiviral. Examples may include UPS and FedEx normal and custom critical.
- Identify applicable supplies needed for standard shipping and monitor availability.
- Identify applicable staff for backup to assist with receiving and distribution of vaccine/antivirals.
- Develop/assemble applicable materials and train/educate staff to meet certification requirements for chain of custody, including storage, handling and distribution.
- Identify backup or alternative distribution facilities to be used if required.
- Identify sources of pneumococcal vaccine.
- Determine proportion of pre-pandemic and pandemic vaccine for each ship-to-site that will/may be allocated to further points of distribution, if applicable.
- Identify any vaccine or antiviral specific roles that are required and develop training materials and a training plan.
- Estimate weekly allocation of vaccine based on CDC-specified criteria and population size.
- Estimate possible weekly allocation of antivirals based on the projected NYS supplies and projected SNS allocation.

Local Health Departments:

- Determine county requirements based upon the guidance received from the NYSDOH/.
- Select/identify primary county staging site(s) where assets may be delivered including vaccine and antiviral distribution end points (administration and ship-to-sites) as a component of the LHD's disaster preparedness plan and according to NYSDOH guidance.
- Assist NYSDOH with certification of all sites expected/anticipated to serve as primary staging sites, ship-to-sites and administration sites.
- Once supplied with project allocation amounts of both vaccine and antivirals, make specific plans for location and use of these assets.

Pandemic Alert Period (*Recognition Interval*)**State Health Department:**

- Continue training staff identified to assist with receiving and distributing vaccine/antivirals.
- Continue the certification of all ship-to-sites to ensure proper storage and handling requirements for vaccine/antivirals.
- Distribute pre-pandemic flu vaccine if applicable (CDC estimates that it will have a stockpile 20 million courses of H5N1 vaccine for early vaccination to persons providing critical infrastructure. The trigger is yet to be determined.)
- Notify NYSDOH partners supporting the breakdown and distribution of antivirals, if needed, and arrange for repackaging, if necessary. This will be coordinated with the NYS Board of Pharmacy.
- Provide staff support, equipment, patient information forms, protocols for receipt, storage and distribution, and adverse event monitoring.
- Ensure the proper storage requirements the vaccine/antivirals at the central mobilization site and during transport.
- Identify and assign technical specialists to support command, operations and planning associated with SNS receipt, repackaging and distribution efforts. Technical specialists may include physicians, pharmacists, logisticians, GIS personnel, etc.
- Assist the locality by providing protocols for distribution, adverse event monitoring, and other support as coordinated or requested.
- Monitor supplies and ensure availability in all areas.
- Monitor backup facility availability and readiness.
- Monitor transportation availability from private contractors.
- Revise allocation numbers and plans for distribution as updated information on the epidemiology of the possible pandemic strain, supply information, and changes in priority group designations are received.

Local Health Departments:

- Assess their local vaccine/antiviral resources.
- Ensure the proper storage of any items received.
- Ensure the security of any items received both at the county staging site and at all POD sites in accordance with the State Education Department Board of Pharmacy standards.
- Ensure adequate staffing at county-designated PODs/ADDS to ensure patient safety, including adequate staffing to screen patients for contraindications, ensure medical consultation on-site, ensure patient education, and immunize and/or dispense medications in accordance with NYSDOH and State Education Department requirements.
- Develop a distribution plan to support local sites such as hospitals, diagnostic and treatment centers, and other healthcare providers.
- Once supplied with updated project allocation amounts of both vaccine and antivirals make any needed modifications to specific plans for location and use of these assets.

- Continue to identify/establish vaccine and antiviral distribution end points (administration and ship-to-sites) and report these sites to the NYSDOH.

Pandemic Period (*Initiation, Acceleration, Peak, Deceleration Intervals*)

State Health Department:

- Obtain guidance from health officials on the level of severity of the pandemic and its impact relative to NYS population.
- Receive and inventory pre-pandemic vaccine/antiviral at Albany Depot.
 - Determine proportion of pre-pandemic vaccine/antivirals that are to be allocated to each ship-to-site
 - Calculate the amount of pre-pandemic vaccine/antivirals for each certified NYSDOH ship-to-site.
 - Determine how pre-pandemic vaccine/antivirals are transported to vaccinating sites.
 - Distribute pre-pandemic vaccine/antivirals to each certified NYSDOH ship-to-site.
 - Implement security plan to protect pre-pandemic vaccine/antiviral assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.
- Revise allocation numbers and plans for distribution as updated information on the epidemiology of the pandemic strain, supply information, and changes in priority group designations are received.
- Work with Disaster Preparedness Unit to assist in delivery of vaccine/antivirals, as needed.
- Work with local health officials to determine the need for extended or long-term dispensing efforts. Plans will be developed utilizing pharmacies, postal service, health care facilities and PODs to accomplish these objectives.)
- If severity is sufficient and vaccine/antiviral supply exists within the SNS program, Managed Inventory (MI) or other CDC-designated location, order vaccine/antivirals to inoculate/treat part/all of affected population within the following existing guidelines:
 - Receive and inventory pandemic vaccine/antivirals at Albany Depot.
 - Calculate the amount of pandemic vaccine/antivirals for each certified NYSDOH ship-to-site.
 - Determine how pandemic vaccine/antivirals are transported to vaccinating sites.
 - Estimate/calculate weekly allocation of pandemic vaccine/antivirals based on vaccine availability and population size.
 - Continue to certify ship-to-sites as needed.
 - Arrange for the shipment of weekly pandemic vaccine/antivirals to the NYSDOH Vaccine/Antiviral Depot located in Wadsworth Center, Albany, New York
 - Receive and inventory pandemic vaccine/antivirals at the Albany Depot.

- Implement security plan to protect vaccine/antiviral assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.
- Distribute pandemic vaccine/antivirals to NYSDOH certified ship-to-sites.
- Communicate plans for distribution and obtain backup resources as needed.

Local Health Department:

- Track dispensing of vaccine/antivirals by lot number and amount.
- Retain responsibility for any undistributed assets until they are returned to the State.
- Assist NYSDOH maintain chain of custody, storage, handling, distribution, accountability and security of vaccine/antiviral assets.

MedWatch

MedWatch is one of two national passive surveillance systems, maintained by the FDA, that monitor the post-marketing safety of medicinal products. Unlike the Vaccine Adverse Events Reporting System (VAERS), this system monitors medical products and devices that are not vaccines and serves both healthcare professionals and the public by:

- Providing information about safety issues involving medical products, including prescription and over-the-counter drugs, cosmetics, biologics, medical and radiation-emitting devices as well as special nutritional products e.g. medical foods, dietary supplements and infant formulas;
- Disseminating medical product safety alerts, recalls, withdrawals, and important labeling changes quickly to the medical community and the general public via <http://www.fda.gov/medwatch/index.html> and the MedWatch e-list;
- Allowing both healthcare professionals and consumers the ability to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Similar to VAERS, MedWatch requires manufacturers, pharmaceutical packers, and facilities that utilize medical devices to report adverse events according to specific reporting requirements. Additionally, while reporting of serious adverse events by healthcare professionals is strongly encouraged it is considered voluntary. It is also recommended that only adverse events that are unexpected and not listed as potential side effects on labeling be reported to MedWatch.

Consumers who wish to report an adverse event are encouraged to take the reporting form to their provider to be completed. However, if the provider is unwilling or unable to complete the form or the consumer does not want to have the form completed by their provider, they may complete the form on-line. Forms can be accessed on-line at <http://www.fda.gov/medwatch/getforms.htm>.

The FDA 3500 Voluntary Form should **not** be used for:

- Events involving vaccines; these should be reported to the Vaccine Adverse Event Reporting System (VAERS.)
- Events involving Investigational New Drugs (IND); these should be reported as required in the study protocol.
- Veterinary medicine product adverse events
- Unlawful sale of medical products on the internet
- Mandatory device reporting, and
- Mandatory drug/biologic reporting

Mandatory medical device and drug/biologic reporting can be accomplished by utilizing the FDA 3500A Form. This form is intended for use by distributors, facilities, importers, manufacturers and applicants for reporting adverse events and product problems and is mandated by the FDA.