



**Texas Department of State Health Services**  
Antiviral Allocation, Distribution, and Storage  
Guidelines

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**Update**

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## OVERVIEW

### Introduction

During the last two years, much emphasis has been placed on the use of antivirals to treat and prevent pandemic influenza. So much so that we run the risk of people equating them to antibiotics as a cure and believing they are the “silver bullet” for pandemic influenza control. The Texas Department of State Health Services (DSHS) considers antivirals as one component of a comprehensive containment and treatment plan, not the primary component. As such, DSHS advocates a multifaceted approach to pandemic influenza containment that begins with a strong seasonal influenza program that increases vaccination rates, improves surveillance, provides education, and develops treatment best practices.

These guidelines seek to delineate state and local roles and responsibilities in antiviral allocation, distribution, and storage. The information provided is guidance for decision making at the local level. While we encourage local communities to follow these recommendations for state-provided caches, we recognize their right to make decisions appropriate to their community’s unique needs. Local purchases are the responsibility of the purchaser.

### Factors Affecting Risk and Antiviral Planning for Pandemic Influenza in Texas

Geography and population have an impact on the ability to provide timely containment and intervention for pandemic influenza in the state. Size, population densities, availability of health care and services, and unique risk factors all affect the Texas response to pandemic influenza and allocation, distribution, and storage planning for antivirals.

Texas equals the 14 smallest states in total square miles. It has three of the 10 largest cities and three of the five least populated counties in the United States (U.S. Census Bureau, 2002). Texas’ 254 counties have 63 local health departments or districts (LHD) that provide a full complement of public health services. In addition, 81 local health units provide a more limited array of public health services. The remaining counties are mostly rural. Public health services in those parts of the state without a LHD are served by Health Service Regions (HSR) which are part of DSHS. The HSRs also assist counties with LHDs.

Of the 254 Texas counties, 116 (46%) are considered full primary care health professional shortage areas, 64 (25%) have no hospital, 178 (70%) qualify as fully medically underserved areas and 46 (18%) as partially medically underserved areas; additionally, approximately 25% of all Texans and 40% of Texans of Hispanic origin are uninsured (Nelson, Banning, Kroll, & Bailey, 2006). Texas leads the nation with nine of the 25 poorest counties based on per capita income and at 16.5% is fourth in percent of population living in poverty (U.S. Census Bureau, 2005).

The risk for importing a human case of avian influenza into Texas is increased by a number of factors. The state shares approximately 1,250 miles of border with Mexico. There are between 1.4 million and 1.6 million undocumented people living in Texas (Strayhorn, 2006) who, by federal law, must be considered for communicable disease treatment. Two of the 16 international airports in Texas rank in the top 10 for passenger counts and serve as major hubs

for national travel. Texas has six seaports, two of which serve the cruise ship industry and provide additional risk for exposure to pandemic influenza.

## **FOUNDATION FOR THE TEXAS ANTIVIRAL ALLOCATION, DISTRIBUTION, AND STORAGE GUIDELINES**

### **Scientific Support**

While a vaccine—specific for the pandemic strain—is generally considered the best countermeasure for a pandemic, one will not likely be available for the first wave of disease. However, other measures to slow disease spread are available. Close examination of historical records of the 1918 pandemic has shown the tremendous efficacy of social distancing and other community containment measures if begun early in a pandemic. Mathematical modeling of a future pandemic has demonstrated that community interventions, when applied in combination with antiviral drugs, may have an impact on reducing the spread of disease and disease attack rates, delaying the peak of the wave, and reducing the burden on hospitals and critical infrastructure (ASTHO, 2006; Ferguson, Cummings, & Cauchemez, 2005; Germann, Kadau, Longini, & Macken, 2006; Longini, Nizam, & Xu, 2005).

### **The Use of Antivirals**

Although vaccine, when developed, will be the primary strategy for preventing pandemic influenza virus infection and its complications, antiviral medications combined with community based mitigation strategies can be effective for the prevention and treatment of influenza. When used correctly, antivirals may reduce the duration of symptoms and some influenza complications. Four licensed influenza antiviral agents are currently available in the United States: amantadine (Symmetrel®), rimantadine (Flumadine®), zanamivir (Relenza®), and oseltamivir (Tamiflu®), and new antivirals are being developed. However, resistance to these antivirals and side effects can be complicating factors in their use. All antiviral medications are different in terms of side effects, who can take them, how they are given, and dosage based on age or medical conditions (see [Appendix A](#)). On November 13, 2006, a new precaution about Tamiflu® (oseltamivir) was added. The precaution warns that people with the flu, mostly children, may be at an increased risk of self-injury or confusion shortly after taking Tamiflu® and should be closely monitored for signs of unusual behavior.

### **Guiding Principle**

Antiviral drug countermeasures are one tool of a multi-faceted containment response. Planning activities for antivirals include identifying target groups to receive antiviral drugs, allocating and delivering the antiviral drugs, communicating critical information, and monitoring the effects of the antiviral drugs in the population. Seasonal influenza prevention and treatment activities are the backbone for the successful prevention and control of pandemic influenza. Flu vaccinations, surveillance, education, social distancing, hand washing, and respiratory hygiene play major roles in the containment of flu and are critical to minimize the burden of disease and control of both seasonal and pandemic influenza.

## Ethical Principles

- Respect: All life is precious and deemed important.
- Equity: Reduce significant differences in influenza-related mortality.
- Protect the public from harm: Minimize long-term social disruption and economic impact.
- Reciprocity: Protect those with disproportionate burden in protecting the public good.
- Stewardship: Those entrusted with governance roles must demonstrate ethical behavior and good decision making.

## Goals

Texas has adopted the goals for pandemic influenza planning developed by the United States Department of Health and Human Services (HHS). These are:

- Prevent morbidity and mortality,
- Minimize social disruption, and
- Minimize economic effects.

In addition, Texas goals include:

- Prevent or delay spread geographically.
- Prevent significant compromise of basic health care, public health and public emergency infrastructures.
- Ensure the integrity of the healthcare and public health infrastructures to allow for an adequate response.
- Allocate scarce antiviral resources efficiently and effectively.
- Consider antiviral priorities and use in the context of all prevention and control activities.

## Assumptions

- Demand for significant resources will be regional, and treatment and prevention strategies will be tailored to unique state, regional, and local circumstances.
- Current societal expectations about access to health care will have to change in light of a public health crisis of major proportions.
- Resources and supplies, present in inadequate amounts, will be prioritized based on epidemiology and response.
- Employers, healthcare partners, and local/state government will identify in advance those serving in essential response functions.
- Response roles will determine target group placement rather than job category.
- Target groups for antivirals may change over time as disease epidemiology changes in various areas of the state.
- As immunity for pandemic influenza is developed, the demand for antiviral post-exposure [prophylaxis](#) will decrease.
- The private healthcare sector will continue to treat ill persons during an influenza pandemic including prescribing antivirals, since 50% of Texans have a [medical home](#).
- Military officials will coordinate with DSHS to request antiviral medications for the military staff and their families should the Department of Defense supply of antivirals be exhausted.

## Case Definition

- The Centers for Disease Control and Prevention (CDC) case definitions in place at the beginning of a pandemic response will be used. DSHS may revise case definitions depending on the epidemiology of the disease and character of the virus as the pandemic unfolds.

## ANTIVIRAL TARGET GROUPS

### Texas Antiviral Allocation Model

The Texas Antiviral Allocation Model ([Appendix B](#)) reflects the conceptual underpinning for the DSHS Antiviral Allocation, Distribution, and Storage (AADS) Guidelines. Decisions are based on the latest science and input from participants on two expert panels convened by DSHS in 2006. Participants included personnel from HSRs and LHDs, academicians, attorneys, community advocates, epidemiologists, ethicists, faith community representatives, hospital representatives, influenza experts, pharmacists, nurses, and practicing physicians. While Texas has adopted the HHS planning goals for pandemic influenza planning, the approach is somewhat different.

### Antiviral Target Group Guidelines

The DSHS Target Group Guidelines ([Appendix C](#)) list the three recommended tiers for antiviral allocation: 1) Outbreak Control, 2) Infrastructure, and 3) Risk for Complications. Outbreak control will always be the first containment strategy early in a pandemic. At some point, outbreak control demands might outstrip resources. At such time, outbreak control will cease to be a priority in the general population although it might continue in aggregate settings. Within Tiers 2 and 3, subgroups are listed in general order of emphasis. Consideration of that hierarchy in allocation and distribution will be invoked if the demand for antivirals exceeds availability. If supply and demand are balanced in Tier 2, leveling will not need to occur. Depending again on supply and demand, there may or may not be leveling between Tiers 2 and 3 or within Tier 3.

Two caveats exist with the Antiviral Target Group Guidelines. First, the guidelines can be adjusted by the local health authority in the context of the local pandemic influenza decision-making process to reflect local infrastructure needs, variations in epidemiology or both. Adjustments may be made at a variety of decision making points, including, but not limited to, target group priority tiers, parameters of criteria for receipt of post-exposure [prophylaxis](#), etc. If adjustments are made, LHDs will notify the appropriate Regional Medical Director. Second, while much of the discussion on the use of antivirals during a pandemic has focused on the public health supply, the majority of antiviral drugs (both supply and use) will be in community healthcare settings through normal distribution pathways. The antivirals under DSHS control should not supplant the normal private pharmacological distribution system, but augment it as necessary where shortages might exist. To be comprehensive and effective in preparedness planning, public health and healthcare sector roles, responsibilities, and assets should be considered.

The role of the healthcare sector (private and public) is to assure the provision of treatment and prevention services to individual patients. In the context of a pandemic and the use of antivirals, the responsibility of the healthcare sector is to provide treatment, including antivirals, as medically necessary, for those who become ill, and to provide post exposure prophylaxis for their critical workforce members, i.e. the healthcare workforce.

Public health's normal role during a contagious disease event is outbreak control, focusing on the general population and overall community protection. This includes post-exposure

prophylaxis for first responders (other than those working within the Healthcare Delivery System) and critical public infrastructure needs, as well as serving the uninsured and under-insured populations. These functions are population-focused and serve to protect the community at large versus the individual patient healthcare services referenced above.

[Appendix D](#) (Examples of Special Focus Guidelines) includes two examples of sector-focused charts. These examples are based on the DSHS overarching target guidelines described in [Appendix C](#) and may be developed by healthcare system providers for other settings such as home health care, outpatient clinics, etc.

Table 2 (Public Health Response—Outbreak Control and Post-Exposure Prophylaxis Chart) provides guidance for outbreak control and post-exposure prophylaxis for critical public infrastructure and emergency service workers (other than the patient healthcare workforce). HSRs and LHDs are strongly encouraged to dispense antivirals in accordance with these guidelines. The antivirals in the DSHS Cache and Texas General Revenue Stockpile will be distributed according to the purposes and populations outlined in this chart.

Table 3 (The Patient Care Sector—Outpatient and Inpatient Chart) provides guidelines for the use of antivirals in illness treatment of patients and post-exposure prophylaxis for critical healthcare workers. The patient care sector providers are strongly encouraged to stockpile and dispense antivirals in accordance with these guidelines.

## **SUMMARY OF DSHS AND LOCAL HEALTH DEPARTMENT ROLES AND RESPONSIBILITIES FOR ANTIVIRAL DISTRIBUTION AND USE**

### ***INTERPANDEMIC AND PANDEMIC ALERT PERIODS: WHO PHASES 1–5***

Texas is a local control state, and many decisions about pandemic influenza response will be made at the local government level. These guidelines were developed with local input to provide a simple, flexible process adaptable for state, regional, and local jurisdiction use. The World Health Organization (WHO) and the federal government have developed response stages for pandemic influenza. [Appendix E](#) shows the relationship between the WHO Phases and U.S. Response Stages. The following roles and responsibilities are outlined to match these phases and stages.

### **Department of State Health Services Responsibilities**

#### **Procurement**

1. Acquire and maintain state-purchased stockpiles of antiviral drugs. Three supplies fall into this category:
  - DSHS cache  
DSHS purchased 144,622 courses of antiviral medications, 90% of which DSHS possessed as of 3/1/07.
  - Texas General Revenue (GR) cache  
The Texas GR supply will be antivirals purchased using general revenue funds. The 80<sup>th</sup> Texas Legislature appropriated \$10 million in general revenue funds in 2007 to purchase additional antivirals for the state supply under the federal contract. This allocation will purchase about 675,000 courses. About 1.5 million courses remain available to Texas for purchase at the federally subsidized price. This remaining

amount has been offered to eligible local entities to purchase at the federally subsidized price.

- [Strategic National Stockpile \(SNS\)](#)  
Texas' allocation is 3,293,899 courses. CDC will place antivirals from the SNS after the WHO declares the beginning of Phase 4.
2. Assist LHDs and other government entities in acquiring a local stockpile (CDC, October 19, 2006).

### **Receipt, Storage and Allocation**

1. DSHS cache
  - a. This cache will be the first used. It is earmarked by DSHS for outbreak control and preventive treatment of first responders. It will/can be:
    - Divided equally (one-ninth) among the eight DSHS Health Service Regions (HSRs) and DSHS Austin Office.
    - Moved easily among DSHS HSRs and the DSHS Austin Office as the pandemic unfolds and antiviral needs change.
    - Stored in the eight DSHS HSR offices and DSHS Austin Pharmacy for release when extra supplies are required.
2. Texas General Revenue (GR) cache
  - This supply will be stored centrally, in a state-owned facility, until CDC places the SNS supply following WHO declaration of Phase 4.
  - When CDC declares Phase 4, the Texas GR cache will be allocated per capita by DSHS HSR population and placed in the eight HSRs either within the HSR facility or at identified locations that meet storage requirements. HSRs are responsible for signing any memorandum of understanding with storage facility owners.
3. Strategic National Stockpile
  - When the WHO declares Phase 4, SNS antivirals will be sent to Texas.
  - Antivirals will be received and stored in Austin at the state-owned facility that held the GR supply.
  - DSHS will operate the Receiving, Staging, and Storage (RSS) site according to the Texas SNS Plan and CDC requirements.
    - The RSS management team, staff, volunteers, and management/staff back-up personnel in place for all-hazards SNS will be activated to receive antivirals from the SNS using the 24/7 operations call-down roster.
    - Staff will verify that volunteers are appropriately credentialed and ready to carry out assigned duties. Job action sheets and just-in-time training materials will be on-site for volunteers.
4. DSHS has developed guidance for use of antivirals during a pandemic, including identification of target groups for antiviral drug treatment and preventive measures (Appendices B and C).
  - SNS antivirals will be allocated according to target group population.
  - SNS antivirals will be distributed when community supplies are nearly exhausted and/or when manufacturers cannot fill orders per federal requirements.
5. Storage locations are subject to change.

### **Monitor supplies and use of state and federally purchased antiviral caches**

1. Ensure all antivirals that the state possesses are stored in an appropriate environment. [Appendix F](#) lists antiviral storage requirements.

2. The Public Health Information Network (PHIN)-compliant [Texas Inventory Management System](#) (TIMS), or its back-up, the [Pharmacy Inventory Control System](#) (PICS), will be used to monitor and track location and use of antivirals and other material placed according to the Texas SNS plan.
3. Ensure staff identified to run TIMS have reviewed procedures.

### Distribution

1. Continue planning for the distribution of antivirals and other supplies in the Strategic National Stockpile.
  - DSHS cache
    - Upon receipt of total order, the antivirals will be divided equally among the DSHS HSRs and DSHS Austin Office.
    - Antivirals will be shipped through regular DSHS pharmacy processes to regional offices for long-term storage in previously identified sites.
  - Texas GR cache
    - Distribute to DSHS regional sites through regular DSHS pharmacy processes if delivery is not time sensitive and additional security is not needed.
    - Distribute according to the Texas SNS plan if delivery is time sensitive or additional security is required.
  - SNS
    - Upon release for use by CDC and based on need, distribute to local jurisdictions according to the Texas SNS Plan.

### Systems

1. Laws/rules/policies/procedures
  - Review all laws related to the powers of the Commissioner and local health authorities during [public health disasters](#) to determine if legal authorities are in place to support public interventions. Identify gaps and determine how changes can be made.
  - Develop a Standard Delegation Order template to be signed by the DSHS Commissioner, regional director, or local health department medical director delegating authority to qualified personnel to dispense antivirals to Target Groups if no physician is available.
  - Maintain Investigational New Drug Emergency Use Authorization (EUA) procedure to allow use of new antiviral medications not licensed by the FDA if they become available (see Texas SNS Program Manual, available through PHIN August 2007). Review workers' compensation laws to determine how they apply to healthcare and other essential workers required to use antivirals in their workplace.
2. Implement the [Texas Inventory Management System](#) (TIMS) for distributing antivirals, equipment, and supplies.
3. Track people receiving antivirals for antiviral effectiveness and adverse reactions.
  - Healthcare providers are encouraged to report adverse reactions to [MedWatch](#) (<http://www.fda.gov/medwatch/>) or any system required by the FDA or CDC.
  - Expand ImmTrac childhood vaccination registry to include adults during public health disasters.
  - Coordinate surveillance and planning with other states and Mexico border states to prevent and contain illnesses.
  - The DSHS Drug and Medical Devices Group (DMDG) (see <http://www.dshs.state.tx.us/dmd/default.shtm>) within the Division for Regulatory

Services, Environmental and Consumer Safety Section monitors adverse reactions through the MedWatch reporting system.

- DMDG currently conduct investigations using reports either submitted to DSHS or directly to MedWatch.
4. Attempt to detect with CDC the emergence of drug-resistant variants of a pandemic influenza strain.
    - CDC is developing a process to detect the emergence of drug-resistant strains. DSHS will review the epidemiology of outbreaks and provide CDC with any data on the effectiveness of antiviral treatment, preventive measures and development of antiviral resistance.
  5. Develop public health guidelines to encourage drug-use practices that help minimize development of drug resistance.
  6. Develop and distribute public information materials about the use of antivirals during a pandemic.
  7. Outline decision-making process for determining local need for antivirals based on Target Populations.

## **Local Health Department Responsibilities**

### **Planning**

1. Develop local antiviral plans.

### **Procurement and Storage**

1. Contact the DSHS Health Service Region for the GR cache.
2. Follow Texas SNS plan to get antivirals from the SNS.
3. Follow the Texas SNS plan for security and develop local storage safety plans.
4. Provide technical assistance to local entities that purchased antivirals under the federal HHS contract ([Appendix H](#))..
  - Ordering agency is responsible for storage
  - Physician is required to order for dispensing.

### **Allocation and Distribution**

1. Develop and update local plans for distribution and use of antiviral drugs during a pandemic to include priority groups.
2. Determine decision-making process for requesting and allocating scarce resources.
3. Determine numbers in target groups in jurisdiction for antivirals and provide data to DSHS HSR. [Appendix G](#) contains state-level target group information.
4. Plan how antivirals will reach target populations through distribution sites (e.g., local hospitals, fever clinics, private health clinics, or nontraditional sites such as fire stations).
5. If delegating administration to other sources, ensure any memorandum of understanding is signed and maintain appropriate documentation including location, contact information, logistics, and storage.
6. Distribute antivirals locally based on need and target populations according to local SNS and antiviral allocation and distribution guidelines.
7. Keep accurate allocation and distribution records using TIMS or its back-up (PICS).
8. Submit adverse reaction complaints received by the local health department to the FDA through [MedWatch](http://www.fda.gov/medwatch/) (<http://www.fda.gov/medwatch/>) or any other system FDA chooses.

9. For antiviral prescriptions given through the private sector, educate community and hospital-based pharmacists about target groups, rationale for order, and expected procedures including adverse reaction reporting through MedWatch.
  - Determine if pharmacists understand how to get additional antivirals.
10. Require standard delegation orders for antivirals given through systems without an on-site physician.
11. Develop and distribute public information materials about the use of antivirals during a pandemic.
12. Provide DSHS with aggregate data as requested.

### ***PANDEMIC PERIOD: WHO PHASE 6***

Recommendations for antiviral use may be updated throughout the course of an influenza pandemic to reflect epidemiology, laboratory data, and the availability of an effective influenza vaccine.

### ***Federal Government Response Stage 3***

*Widespread human outbreaks in multiple locations overseas*

### **Department of State Health Services Responsibilities**

1. Review the state antiviral drug [distribution](#) guidelines with local partners and stakeholders. DSHS and local partners will:
  - Modify the distribution guidelines to reflect updated recommendations on target groups and updated information on projected antiviral supplies.
  - Notify medical community about the status of the guidelines and antiviral drug availability.
  - Provide public health guidelines that encourage drug-use practices to help minimize development of drug resistance.
2. Prepare to dispense Texas GR antiviral medications to DSHS HSR sites. Establish and plan to meet security requirements.
  - If the public shows no interest in antiviral movement, move the antivirals through normal drug and vaccine distribution channels.
  - If public interest is high (i.e. heavy media coverage), move antivirals according to the Texas SNS plan.
3. Use the DSHS Austin Office portion of the DSHS supply of antiviral drugs to supplement local health department management of pandemic influenza outbreaks and post-exposure preventive treatment of first responders.
4. Review plans with local partners to provide post-exposure antiviral preventive treatment to people based on identified target groups.
5. Provide public information on use of community mitigation strategies and antiviral drugs during an influenza pandemic.
6. Prepare to work with federal partners to monitor the safety and effectiveness of drugs.

### **Local Health Department Responsibilities**

1. Prepare to activate local plans for distributing and administering antivirals to people in target groups.
2. Review modifications, if any, to interim recommendations on antiviral preventive treatment in selected groups or circumstances.
3. Accelerate training on appropriate use of antiviral drugs among public health staff and healthcare partners.
4. Work with other local governmental entities and non-governmental organizations to ensure effective public health communications about community mitigation strategies.

#### ***Federal Government Response Stage 4***

##### *First human case in North America*

When there is limited transmission of pandemic influenza, the goal of antiviral use will be outbreak control.

When a vaccine becomes available, antiviral drugs may be used to protect people who have an inadequate vaccine response (e.g., the elderly and those with compromised immune systems) and people who cannot take the vaccination, such as those with anaphylactic hypersensitivity to eggs or other vaccine components.

#### **Department of State Health Services Responsibilities**

1. Coordinate with the Texas Department of Criminal Justice, the primary agency for Transportation Emergency Support Function, to deliver:
  - DSHS GR antiviral supplies, as appropriate, to predetermined local sites.
  - SNS antiviral supplies to designated locations.
2. Retain one-ninth of the Texas GR cache and the SNS cache centrally for [distribution](#) to affected areas as needed.
3. Use TIMS to track antiviral distribution.
4. Activate DSHS Antiviral Target Group Guidelines for antiviral drugs to reach groups for preventive use and treatment.
5. Continue to work with local partners to ensure appropriate use of antivirals in managing early cases and contacts.
6. Work with federal partners to monitor antiviral drug safety and effectiveness.
7. Analyze current epidemiology and recommend changes in strategy.

#### **Local Health Department Responsibilities**

1. Distribute antiviral caches to sites serving Target Groups for post-exposure preventive treatment, working with the local emergency operations center to provide any needed security.
2. Encourage use of private healthcare system if people have a [medical home](#) and pharmaceutical benefits or personal funds for both treatment and post-exposure preventive treatment.
3. Encourage use of antivirals within recommended limits.
  - DSHS small cache is restricted for outbreak management and first responder post-exposure preventive measures
  - DSHS GR cache is restricted for use according to Target Group Guidelines.

- As of 9/4/07, the SNS antiviral cache is restricted for illness use only.
- 4. Use ImmTrac to track antiviral dispensing and TIMS to track delivery of antivirals, supplies, and equipment to end users.
- 5. Train and assist providers in using ImmTrac.
- 6. Monitor community disease patterns and adjust implementation of guidelines as needed.

### ***Federal Government Response Stage 5***

#### *Spread throughout United States*

When pandemic flu transmission is widespread, the top goals of antiviral use will be to treat those at highest risk of severe morbidity and mortality and to preserve the delivery of healthcare and other essential critical services through early treatment and limited preventive measures.

When a vaccine becomes available, antiviral drugs may be used to protect people who have an inadequate vaccine response (e.g., the elderly and those with compromised immune systems) and people who cannot take the vaccination, such as those with anaphylactic hypersensitivity to eggs or other vaccine components.

### **Department of State Health Services Responsibilities**

1. Monitor and track use of stockpiles and help DSHS HSRs move antivirals as necessary.
2. Distribute centrally-held antivirals to areas most in need.
3. Monitor effectiveness of antivirals and encourage appropriate drug-use practices that help minimize development of drug resistance.
4. Analyze the emergent epidemiology and make recommendations for changes in strategy.
5. Begin distributing pre-pandemic vaccine, if available (see Vaccine Allocation, [Distribution](#) and Storage [VADS] Guidelines).

### **Local Health Department Responsibilities**

1. Provide antivirals to target populations according to the Antiviral Target Group Guidelines and recommendations on use of supplies.
2. Maintain dispensing records.
3. Provide technical advice to local non-health department entities with antiviral supplies as requested.
4. Collect morbidity and mortality data; analyze and determine changes in strategy as needed.
5. Monitor and report adverse reactions to [MedWatch](http://www.fda.gov/medwatch/) (<http://www.fda.gov/medwatch/>).
6. Monitor for potential drug resistance by getting specimens from people who develop influenza while on preventive medications or who progress to severe disease despite treatment.
7. Begin giving pre-pandemic vaccine if available (VADS guidelines). Continue antiviral administration for those who have an inadequate vaccine response.

### ***Federal Government Response Stage 6***

#### *Recovery and preparation for subsequent waves*

While a pandemic may affect the United States for several months to more than a year, any community can expect to be affected by a particular pandemic wave for at least 6 to 8 weeks. Because several waves of illness have occurred in previous pandemics, communities will need to revitalize as soon as possible to lessen the impact of the continuing outbreak.

### **Department of State Health Services Responsibilities**

1. Evaluate usefulness of the AADS guidelines in reaching Target Groups and distributing antivirals to local agencies. Adjust as needed.
2. Evaluate Texas SNS Plan successes and lessons learned. Adjust as needed.
3. Inventory remaining supplies and restock if possible.
4. Evaluate disease epidemiology to determine age groups with the highest morbidity and mortality. Adjust antiviral Target Groups to reflect current information.
5. Watch for return of disease in the community to begin drug intervention for new wave of illnesses.
6. Provide community updates about antiviral status and any changes in distribution.
7. Continue use of any remaining pre-pandemic vaccine.
8. Begin plans for pandemic vaccine distribution and administration and changes in use of antivirals resulting from pandemic vaccine availability.
9. Evaluate ImmTrac. Adjust as needed.
10. Provide CDC with requested aggregate data of antiviral distribution.

### **Local Health Department Responsibilities**

1. Evaluate usefulness of local AADS guidelines and adjust preparations for next wave related to:
  - Reaching Target Groups
  - Determining administration sites
  - Distributing to sites that give antivirals to Target Groups.
2. Evaluate experiences of agencies that purchased caches and assist in adjusting their plans as needed.
3. Inventory supplies and restock if possible.
4. Review vaccine plans and prepare for pandemic vaccine delivery and changes in antiviral use.
5. Complete adding data to ImmTrac.
6. Evaluate use of ImmTrac and recommend improvement to DSHS.

## **STRATEGIES FOR ANTIVIRAL USE IN PANDEMIC INFLUENZA TREATMENT AND PROPHYLAXIS**

### **Strategies for Treatment**

Treatment strategies for optimizing the use of limited stocks of antiviral drugs will vary depending upon the phase of the pandemic. The following interim guidance will be updated as more information becomes available. Strategies for consideration include:

### 1. At all stages of a pandemic

- Target therapy to influenza patients admitted to a hospital who present within 48 hours of symptom onset.
- Hospitals should use routine procedures for obtaining antivirals through regular routine mechanisms.
  - If supplies of antivirals are scarce, prioritize according to tiers or to levels within tiers, if necessary, as described in the Antiviral Target Group Guidelines in [Appendix C](#).
  - SNS antivirals should be used only when routine methods are unavailable due to shortage in the private sector or the patient's inability to pay for them.
- Implement mechanisms to detect the emergence of drug-resistant variants of a pandemic influenza strain (e.g., obtaining specimens from persons who develop influenza while on prophylaxis or who progress to severe disease despite treatment).

### 2. During the earliest stages of a pandemic in the United States

- Base treatment decisions on laboratory-confirmed subtype identification of the pandemic strain by viral isolation, [RT-PCR](#), or other means recommended by CDC. A positive rapid antigen test for influenza A would be sufficient grounds for initiating treatment, with a confirmatory, definitive laboratory test required for continuation of treatment.
- Interpret negative results of influenza testing as permitting termination of treatment, given the overall low rate of infection in a particular community.
- Consider targeted use of antivirals to contain small, well-defined disease clusters, to possibly delay or reduce spread to other communities.

### 3. When there is increasing disease activity in the United States

- Base treatment decisions on:
  - Laboratory-confirmed identification of the pandemic subtype by viral isolation and subtyping, [RT-PCR](#), or other means recommended by CDC, or
  - Influenza A detection by rapid antigen test, or
  - Epidemiologic and clinical characteristics.
- Permit initiation of antiviral treatment before results from viral isolation, [IFA](#), [RT-PCR](#) assays, or rapid antigen tests become available, since early treatment is more likely to be effective.

Once infection becomes more common, negative rapid antigen test results are more likely to represent false negatives; therefore, treatment should continue while awaiting results from confirmatory testing.

### 4. When the pandemic is widespread in the United States

- Base treatment decisions on clinical features and epidemiologic risk factors, account for updated knowledge of the epidemiology of the pandemic virus.

As the pandemic progresses, strategies for antiviral treatment may be revised as new information is obtained about the pandemic strain.

### **Strategies for Prophylaxis**

Strategies for use of antivirals for prophylaxis will vary according to stages of the pandemic and availability of vaccine.

1. Targeting prophylaxis to priority groups throughout the first wave of the pandemic. Data from 20th century influenza pandemics suggest that the first wave of these pandemics lasted approximately six to eight weeks in a community.
2. Using post-exposure prophylaxis (generally for 10 days) to:
  - Control small, well-defined disease clusters, and
  - Protect individuals with a known recent exposure to a pandemic virus.
3. When a vaccine becomes available, post-exposure prophylaxis may also be used to protect key personnel during the period between vaccination and the development of immunity (usually 10 days to 2 weeks).
4. Strategies for antiviral prophylaxis may be revised as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain, and on when a vaccine becomes available.

### **Strategies for Combined Treatment, Prophylaxis, and Community Mitigation Strategies**

1. During the Pandemic Alert and early Pandemic Periods, antiviral treatment for ill persons, and targeted post-exposure prophylaxis of contacts, combined with community mitigation interventions such as school closures and social distancing should be considered in attempts to contain small disease clusters.
2. The administration of oseltamivir does not interfere with the development of antibodies to influenza viruses after administration of trivalent inactivated influenza vaccine. Therefore, persons receiving prophylaxis can continue to receive oseltamivir during the period between vaccination and the development of immunity. Whether oseltamivir can interfere with the immune response elicited by a live-attenuated pandemic vaccine is unknown.

### **Pediatric Use**

1. 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 an off-label basis with an antiviral must be made on a case-by-case 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.

2. Oseltamivir 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.

## **APPENDICES**

## Appendix A

### A.1: Recommended Daily Dosage of Antivirals For Treatment and Preventive Care

(From *Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices [ACIP], July 2005*)

**Table 1. Dosage of antiviral agents**

Antiviral Agent	Age Groups (years)				
	1–6	7–9	10–12	13–64	≥65
<b>Amantadine<sup>a</sup></b> Symmetrel					
Treatment, influenza A	5 mg/kg body weight/day up to 150 mg in two divided doses <sup>b</sup>	5 mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>	100 mg twice daily <sup>c</sup>	100 mg twice daily <sup>c</sup>	≤100 mg/day
Prophylaxis, influenza A	5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>	5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>	100 mg twice daily <sup>c</sup>	100 mg twice daily <sup>c</sup>	≤100 mg/day
<b>Rimantadine<sup>d</sup></b> Flumadine					
Treatment, <sup>e</sup> influenza A	NA <sup>f</sup>	NA	NA	100 mg twice daily <sup>c,9</sup>	100 mg/day
Prophylaxis, influenza A	5 m/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>	5 mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>	100 mg twice daily <sup>c</sup>	100 mg twice daily <sup>c</sup>	100 mg/day <sup>h</sup>
<b>Zanamivir<sup>i,j</sup></b> Relenza					
Treatment, influenza A and B	NA	10 mg twice daily	10 mg twice daily	10 mg twice daily	10 mg twice daily
Prophylaxis, influenza A	<b>Ages 1–4</b> NA	<b>Ages 5–9</b> 10 mg once daily for 10 days	10 mg once daily	10 mg once daily	10 mg once daily
<b>Oseltamivir</b> Tamiflu					
Treatment, <sup>k</sup> influenza A and B	dose varies by child's weight <sup>l</sup>	dose varies by child's weight <sup>l</sup>	dose varies by child's weight <sup>l</sup>	75 mg twice daily	75 mg twice daily
Prophylaxis, influenza A and B	dose varies by child's weight <sup>l</sup>	dose varies by child's weight <sup>l</sup>	dose varies by child's weight <sup>l</sup>	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](http://www.fda.gov), accessed 3/30/2005.

<sup>a</sup> Consult the drug package insert for dosage recommendations for administering amantadine to people with creatinine clearance  $\leq 50$  ml/min/1.73m<sup>2</sup>.

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

<sup>c</sup> Children aged  $\geq 10$  years who weigh  $< 40$  kg should be administered amantadine or rimantadine at a dosage of 5 mg/kg body weight /day.

<sup>d</sup> 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.

<sup>e</sup> Approved by FDA only for treatment among adults.

<sup>f</sup> Not applicable.

<sup>g</sup> Rimantadine is approved by FDA for treatment among adults. However, some experts in influenza management consider it appropriate for treatment among children. (See American Academy of Pediatrics, 2003 Red Book.)

<sup>h</sup> Older nursing-home residents should be given only 100 mg/day of rimantadine. A reduction in dosage to 100 mg/day should be considered for all persons aged  $\geq 65$  years if they experience possible side effects when taking 200 mg/day.

<sup>i</sup> Zanamivir is 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.

<sup>j</sup> Zanamivir is not approved for preventive treatment.

<sup>k</sup> A reduction in the dose of oseltamivir is recommended for people with creatinine clearance  $< 30$  ml/min.

<sup>l</sup> See [Appendix A.2](#) for dosages and mixing instructions converting capsules into suspension.

On November 13, 2006, a new precaution about Tamiflu® was added. The precaution warns that people with the flu, mostly children, may be at an increased risk of self-injury or confusion shortly after taking Tamiflu® and should be closely monitored. (Obtained 8/1/07 from package insert available at: <http://www.rocheusa.com/products/tamiflu/pi.pdf>)

## A.2: Emergency Compounding of an Oral Suspension from TAMIFLU Capsules (Final Concentration 15 mg/mL)\*

The following directions are provided for use only during emergency situations. These directions are intended to be used ONLY if the FDA-approved, commercially manufactured TAMIFLU for Oral Suspension is NOT available. This is the case with Tamiflu purchased through the government. Compounding an oral suspension with the following procedure will provide one patient with enough medication for a 5-day course of treatment or a 10-day course of prophylaxis.

Commercially manufactured TAMIFLU for Oral Suspension (12 mg/mL) is the preferred product for pediatric and adult patients who have difficulty swallowing capsules or where lower doses are needed. In the event that TAMIFLU for Oral Suspension is not available, the pharmacist may compound a suspension (15 mg/mL) from TAMIFLU (oseltamivir phosphate) Capsules 75 mg using either of two vehicles: Cherry Syrup (Humco®) or Ora-Sweet SF (sugar-free) (Paddock Laboratories). Other vehicles have not been studied. **This compounded suspension should not be used for convenience or when the FDA-approved TAMIFLU for Oral Suspension is commercially available.**

**First**, calculate the Total Volume of an oral suspension needed to be compounded and dispensed for each patient. The Total Volume required is determined by the weight of each patient. Refer to Table 2.

**Table 2. Volume of an Oral Suspension (15 mg/mL) Compounded Based upon the Patient's Weight**

Body Weight (kg)	Body Weight (lbs)	Total Volume to Compound per patient (mL)
≤15 kg	≤33 lbs	30 mL
16 to 23 kg	34 to 51 lbs	40 mL
24 to 40 kg	52 to 88 lbs	50 mL
≥41 kg	≥89 lbs	60 mL

**Second**, determine the number of capsules and the amount of vehicle (Cherry Syrup or Ora-Sweet SF) that are needed to prepare the Total Volume (calculated from Table 2: 30 mL, 40 mL, 50 mL, or 60 mL) of compounded oral suspension (15 mg/mL). Refer to Table 3.

**Table 3. Amount of TAMIFLU 75 mg Capsules and Vehicle Needed to Prepare the Total Volume of a Compounded Oral Suspension (15 mg/mL)**

Total volume needed	30 mL	40 mL	50 mL	60 mL
Required number of TAMIFLU 75 mg Capsules	6 capsules (450 mg oseltamivir)	8 capsules (600 mg oseltamivir)	10 capsules (750 mg oseltamivir)	12 capsules (900 mg oseltamivir)
Required volume of Cherry Syrup (Humco) OR Ora-Sweet SF (Paddock Laboratories)	29 mL	38.5 mL	48 mL	57 mL

**Third**, follow the procedure below for compounding the oral suspension (15 mg/mL) from TAMIFLU Capsules 75 mg

1. Carefully separate the capsule body and cap and transfer the contents of the required number of TAMIFLU 75 mg Capsules into a clean mortar.
2. Triturate the granules to a fine powder.
3. Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a uniform suspension is achieved.
4. Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET) bottle. A funnel may be used to eliminate any spillage.
5. Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar by a triturating motion and transfer the vehicle into the bottle.
6. Repeat the rinsing (Step 5) with the remainder of the vehicle.
7. Close the bottle using a child-resistant cap.
8. Shake well to completely dissolve the active drug and to ensure homogeneous distribution of the dissolved drug in the resulting suspension. (Note: The active drug, oseltamivir, phosphate, readily dissolves in the specified vehicles. The suspension is caused by some of the inert ingredients of TAMIFLU Capsules which are insoluble in these vehicles.)
9. Put an ancillary label on the bottle indicating "Shake Gently before Use". [This compounded suspension should be gently shaken prior to administration to minimize the tendency for air entrapment, particularly with the Ora-Sweet SF preparation.]
10. Instruct the parent or guardian that any remaining material following completion of therapy must be discarded by either affixing an ancillary label to the bottle or adding a statement to the pharmacy label instructions.
11. Place an appropriate expiration date label according to storage condition (see below).

#### STORAGE OF THE PHARMACY-COMPOUNDED SUSPENSION:

**Refrigeration:** Stable for 5 weeks (35 days) when stored in a refrigerator at 2° to 8°X (36° to 46°F).

**Room Temperature:** Stable for five days (5 days) when stored at room temperature, 25°C (77°F).

Note: The storage conditions are based on stability studies of compounded oral suspensions, using the above mentioned vehicles, which were placed in amber glass and amber polyethyleneterephthalate (PET) bottles. Stability studies have not been conducted with other vehicles or bottle types.

Place a pharmacy label on the bottle that includes the patient's name, dosing instructions, and drug name and any other required information to be in compliance with all State and Federal Pharmacy Regulations. **Refer to Table 4 for the proper dosing instructions.**

**Note: This compounding procedure results in a 15 mg/mL suspension, which is different from the commercially available TAMIFLU for Oral Suspension, which has a concentration of 12 mg/mL.**

**Table 4. Dosing for Compounded Suspension from Tamiflu Capsules 75mg**

<b>Body Weight (kg)</b>	<b>Body Weight (lbs)</b>	<b>Dose (mg)</b>	<b>Volume per Dose 15 mg/mL</b>	<b>Treatment dose (for 5 days)</b>	<b>Prophylaxis Dose (for 10 days)</b>
≤15 kg	≤33 lbs	30 mg	2 mL	2 mL two times a day	2 mL once daily
16 to 23 kg	34 to 51 lbs	45 mg	3 mL	3 mL two times a day	3 mL once daily
24 to 40 kg	52 to 88 lbs	60 mg	4 mL	4 mL two times a day	4 mL once daily
≥41 kg	≥89 lbs	75 mg	5 mL	5 mL two times a day	5 mL once daily

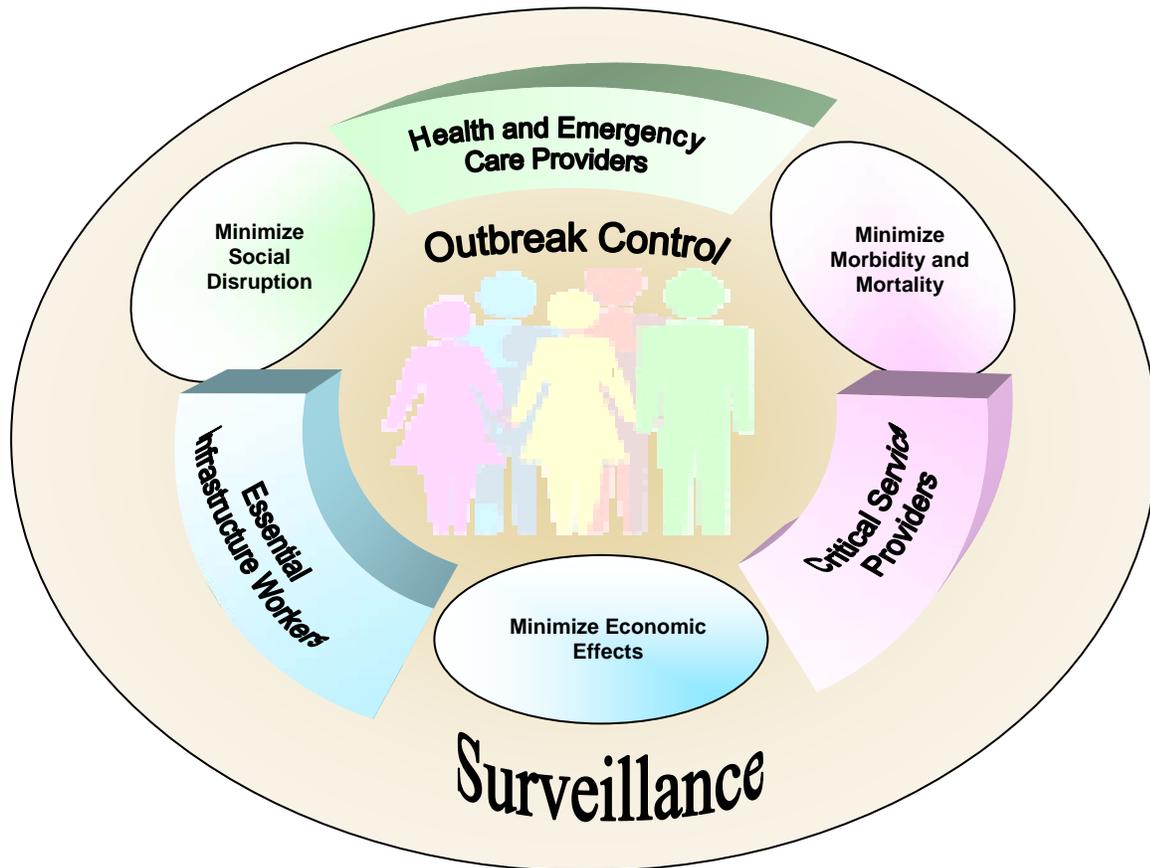
***Consider dispensing the suspension with a graduated oral syringe for measuring small amounts of suspension. If possible, mark or highlight the graduation corresponding to the appropriate dose (2 mL, 3 mL, 4 mL, or 5 mL) on the oral syringe for each patient. The dosing device dispensed with the commercially available TAMIFLU for Oral Suspension should NOT be used with the compounded suspension since they have different concentrations.***

\* Obtained 8/1/07 from package insert available at: <http://www.rocheusa.com/products/tamiflu/pi.pdf>

**Appendix B**

**The Texas Antiviral Allocation Model**

**Figure 1: Texas Antiviral Allocation Model**



***The Texas Antiviral Allocation Model***

The Texas Antiviral Allocation Model reflects the conceptual underpinning for the Texas Department of State Health Services (DSHS) antiviral allocation, distribution, and storage (AADS) guidelines. Decisions are based on the latest science and input from participants in two Expert Panels convened by DSHS. Participants included academicians, attorneys, community advocates, epidemiologists, ethicists, faith community representatives, hospital representatives, influenza experts, pharmacists, nurses, and practicing physicians.

The model rests on a foundation of surveillance. Careful observation and analysis of influenza-like illness (ILI) patterns in the population and vigilance in watching potential points of entry will promote early identification and intervention to limit outbreaks.

## Goals

### Prevent morbidity and mortality

In an effort to prevent or delay widespread infection, outbreak control is of highest priority. Research indicates that with a moderately transmissible virus, the use of targeted antiviral prophylaxis to family and social (school or work) contacts of 60% of diagnosed cases will have the greatest impact on reducing attack rates, surpassed only by adding school closures and social distancing to the mix (Germann, Kadau, Longini, & Macken, 2006). Antivirals must be started within 48 hours of initial symptoms. Patients sick enough for hospitalization may be beyond the window of opportunity. To maximize the potential for timely outbreak management and treatment initiation, health and emergency care providers must stay healthy. The nature of the virus may change these and other treatment and prophylaxis recommendations.

Healthcare providers. The federal Health and Human Services Pandemic Influenza Implementation Plan assumptions include a 30% attack rate during a pandemic. Of these, HHS assumes that half will be cared for in hospitals. Under normal circumstances, health care staffing in hospitals is insufficient. Nurses and other direct care staff are required to work overtime. Hospitals in Texas report that seasonal influenza hospitalizations challenge facilities and staffing. We can ill afford a loss of 30% of staff.

Given the high likelihood of pandemic influenza introduction into Texas and challenges to provide care for those living in the 224 of Texas' 254 counties considered rural and underserved (Nelson, Banning, Kroll, & Bailey, 2006), it is imperative that healthcare providers are high priority for treatment and post-exposure prophylaxis.

### Minimize social disruption

Maslow's hierarchy of human needs lists physical survival needs (food, water, warmth, health) and need for safety and security (physical safety, economic security) as the foundation of human development. These are needs that are rarely thought about if met, yet cause the most anxiety if not met and are the greatest motivators for action to alleviate the need. Supporting community structures that maintain physical and social environments is imperative. It will be difficult to care for the sick without maintenance of infrastructure.

Critical emergency responders. Critical service providers will have more demands on their time. In addition to regular duties for protection of the public in emergency situations, there will be the added duties related to responsibilities in emergency management and more demands for services in the community from locating patients and transport, to increased crime as shops and homes are left empty. If anarchy occurs, it will not be possible to limit morbidity and mortality in the general population.

Essential infrastructure service providers. If essential services such as power, natural gas, and safe drinking water are not available, other illnesses will occur and treatment of those with influenza will be compromised. In rural Texas communities, there is little, if any, excess staff to manage these services. Despite cross training, the loss of one worker could compromise systems.

### Minimize economic effects

Targeting the aforementioned groups would limit morbidity and mortality while limiting hospitalizations and maintaining the social system as best as possible. The Expert Panel that

convened in May 2006 supported the use of antivirals if the science supported it. If so, they recommended placing the aforementioned as priority groups with the caveat that if the epidemiology indicated the need for a different approach strategies would change.

**Appendix C**  
**Target Group Guidelines**

**Table 5. DSHS Target Group Guidelines**

TIER	TARGET GROUP	ILLNESS TREATMENT <sup>2, 3</sup>	POST-EXPOSURE PROPHYLAXIS
<b>Outbreak Control</b>		Outbreak response—treatment of ill; post-exposure prophylaxis of contacts and response personnel <b>Rationale</b> <ul style="list-style-type: none"> <li>• Outbreak control may prevent, postpone, or control spread in conjunction with good personal health practices and implementation of social distancing strategies.</li> <li>▪ Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks.</li> </ul>	
<b>Infrastructure</b>	<b>Health</b>	Healthcare, Emergency Medical Service (EMS), and Public Health workers with patient care or outbreak response duties. <b>Rationale</b> <ul style="list-style-type: none"> <li>▪ Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.</li> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> </ul>	Healthcare, Emergency Medical Service (EMS), and Public Health workers with patient care or outbreak response duties. <b>Rationale</b> <ul style="list-style-type: none"> <li>▪ Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.</li> <li>▪ Prevention would best reduce absenteeism and preserve optimal function.</li> <li>▪ The need for prophylaxis may diminish as the pandemic is recognized and more stringent respiratory protection measures are put into place.</li> </ul>

TIER	TARGET GROUP	ILLNESS TREATMENT <sup>2, 3</sup>	POST-EXPOSURE PROPHYLAXIS
	Emergency	<p>Critical community emergency responders such as</p> <ul style="list-style-type: none"> <li>▪ Law enforcement, firefighters, Texas Military Forces (National Guard); and mortuary services workers.</li> <li>▪ Public Health workers with planned pandemic response roles.</li> <li>▪ Key government officials and essential personnel responsible for the continuity of emergency operations for the State of Texas.</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ Public safety personnel are critical to maintaining public safety and health. Security of vaccine and antivirals along with crowd control must be maintained.</li> <li>▪ Licensed funeral directors, morticians, and their staffs are critical to dispose of remains and prevent disease.</li> <li>▪ Public Health workers are necessary for disease investigation and outbreak control to limit morbidity and mortality.</li> <li>▪ Government officials are needed for decision making related to population, community, and state well-being.</li> </ul>	<p>Critical community emergency responders such as:</p> <ul style="list-style-type: none"> <li>▪ Law enforcement, firefighters, Texas Military Forces (National Guard), and mortuary services workers.</li> <li>▪ Public Health workers with planned pandemic response roles.</li> <li>▪ Key government officials and essential personnel responsible for the continuity of emergency operations for the State of Texas.</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ These groups are critical to maintaining public safety and health. Security of vaccine and antivirals along with crowd control must be maintained.</li> <li>▪ Licensed funeral directors, morticians, and their staffs are critical to dispose of remains and prevent disease.</li> <li>▪ Public Health workers are necessary for disease investigation and outbreak control to limit morbidity and mortality.</li> <li>▪ Government officials are needed for decision making related to population, community, and state well-being.</li> </ul>
	Services	<p>Essential infrastructure service workers <sup>4</sup> such as</p> <ul style="list-style-type: none"> <li>▪ Utility workers responsible for maintenance of critical functions, such as clean water, electricity, and sewage system functioning</li> <li>▪ Transportation workers transporting water, fuel, and food</li> <li>▪ Telecommunications/IT for essential network operations and maintenance</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ These groups are critical to maintaining community services.</li> </ul>	<p>Essential infrastructure service workers <sup>4</sup> such as:</p> <ul style="list-style-type: none"> <li>▪ Utility workers responsible for maintenance of critical functions, such as clean water, electricity, and sewage system functioning</li> <li>▪ Transportation workers transporting water, fuel, and food</li> <li>▪ Telecommunications / IT for essential network operations and maintenance</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ These groups are critical to maintaining community services.</li> </ul>

TIER	TARGET GROUP	ILLNESS TREATMENT <sup>2, 3</sup>	POST-EXPOSURE PROPHYLAXIS
Risk for complications	Severity	<p>Other persons requiring hospitalization for influenza who are within 48 hour of symptom onset.</p> <p><b>Rationale</b> Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die and may benefit from the treatment.</p>	<p>Persons with high risk for complications who are exposed.</p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ Prevents illness in the highest risk groups for hospitalization and death as determined by disease epidemiology demonstrating greater than expected death rates (excess deaths) that may or may not be those in seasonal flu priority groups.</li> <li>▪ Immunocompromised who cannot be protected by vaccination.</li> </ul>
	Co-morbidity	<p>Other high-risk persons not requiring hospitalization for influenza.</p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ Groups at greatest risk for complications and death as determined by disease epidemiology demonstrating greater than expected death rates (excess deaths) that may or may not be those in seasonal flu priority groups.</li> <li>▪ Immunocompromised who cannot be protected by vaccination.</li> </ul>	
	Illness	<p>Other ill patients not requiring hospitalization.</p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ Includes others who develop influenza and do not fall within the aforementioned groups and are not considered high risk as evidenced by disease epidemiology.</li> </ul>	

1. Priority may change related to pandemic spread or epidemiology.
2. Treatment must begin within 48 hours of symptom onset to affect severity and/or duration of illness.
3. Applies to inpatient and outpatient care.
4. Any or all of these groups will become a higher priority if the pandemic appears to be severe enough that basic critical functions are at risk.

Appendix D

Examples of Special Focus Guidelines

Table 6. Public Health Response Example

TIER	TARGET GROUP	<p><b>Example of Special Focus Guidelines: Public Health Response — Outbreak Control and Post Exposure Prophylaxis <sup>1</sup></b></p>
Outbreak Control	General Public	<p>Outbreak response—post-exposure prophylaxis of contacts and response personnel</p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ Outbreak control may prevent, postpone, or control spread in conjunction with good personal health practices and implementation of social distancing strategies.</li> <li>▪ Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks</li> </ul>
Infrastructure	Emergency	<p>Critical community emergency responders such as</p> <ul style="list-style-type: none"> <li>▪ Emergency Medical Service (EMS) and Public Health workers with patient care responsibilities.</li> <li>▪ Law enforcement, firefighters, and Texas Military Forces and mortuary services workers</li> <li>▪ Public Health workers with planned pandemic response roles.</li> <li>▪ Key government officials</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ These groups are critical to maintaining public safety and health. Security of vaccine and antivirals along with crowd control must be maintained.</li> <li>▪ Licensed funeral directors, morticians, and their staffs are critical to dispose of remains and prevent disease.</li> <li>▪ Public Health workers are necessary for disease investigation and outbreak control to limit morbidity and mortality.</li> <li>▪ Government officials are needed for decision making related to population, community, and state well-being.</li> </ul>
	Services	<p>Essential infrastructure service workers <sup>4</sup> such as:</p> <ul style="list-style-type: none"> <li>▪ Utility workers responsible for maintenance of critical functions, such as clean water, electricity, and sewage system functioning</li> <li>▪ Transportation workers transporting water, fuel, and food</li> <li>▪ Telecommunications/IT for essential network operations and maintenance</li> </ul> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ These groups are critical to maintaining community services.</li> </ul>
Risk for complications		<p>Persons with high risk for complications who are exposed.</p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>▪ Prevents illness in the highest risk groups for hospitalization and death as determined by disease epidemiology demonstrating greater than expected death rates (excess deaths) that may or may not be those in seasonal flu priority groups.</li> <li>▪ Immunocompromised who cannot be protected by vaccination.</li> </ul>

<sup>1</sup> Priority may change related to pandemic spread or epidemiology.

<sup>2</sup> Treatment must begin within 48 hours of symptom onset to affect severity and/or duration of illness.

<sup>3</sup> Applies to inpatient and outpatient care.

<sup>4</sup> Any or all of these groups will become a higher priority if the pandemic appears to be severe enough that basic critical functions are at risk

**Table 7. Patient Sector Example**

TIER	TARGET GROUP	<b>Example of Special Focus Guidelines: Patient Care Sector — Outpatient and Inpatient <sup>1,2,3</sup></b>	
<b>Infrastructure</b>	<b>Health</b>	<b>ILLNESS CARE</b>  Healthcare, Emergency Medical Service, and Public Health workers with patient care or outbreak response responsibilities who are ill. <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.</li> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> </ul>	<b>POST-EXPOSURE PROPHYLAXIS</b>  Healthcare workers employed by the facility. <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.</li> <li>▪ Prevention would best reduce absenteeism and preserve optimal function.</li> <li>▪ The need for prophylaxis may diminish as the pandemic is recognized and more stringent respiratory protection measures are put into place.</li> </ul>
	<b>Emergency</b>	Critical community emergency responders who are ill; providers such as: <ul style="list-style-type: none"> <li>▪ Law enforcement, firefighters, and Texas Military Forces and mortuary services workers</li> <li>▪ Public Health workers with planned pandemic response roles.</li> <li>▪ Key government officials</li> </ul> <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ Public safety personnel are critical to maintaining public safety and health. Security of vaccine and antivirals along with crowd control must be maintained.</li> <li>▪ Licensed funeral directors, morticians, and their staffs are critical to dispose of remains and prevent disease.</li> <li>▪ Public Health workers are necessary for disease investigation and outbreak control to limit morbidity and mortality.</li> <li>▪ Government officials are needed for decision making related to population, community, and state well-being.</li> </ul>	
	<b>Services</b>	Essential infrastructure service workers <sup>4</sup> who are ill; providers such as: <ul style="list-style-type: none"> <li>▪ Utility workers responsible for maintenance of critical functions, such as clean water, electricity, and sewage system functioning</li> <li>▪ Transportation workers transporting water, fuel, and food</li> <li>▪ Telecommunications/IT for essential network operations and maintenance</li> </ul> <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</li> <li>▪ These groups are critical to maintaining community services.</li> </ul>	
<b>Risk for complications</b>	<b>Severity</b>	Other persons requiring hospitalization for influenza who are within 48 hours of symptom onset. <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die and may benefit from the treatment.</li> </ul>	
	<b>Co-morbidity</b>	Other high-risk persons who are ill with influenza but do not require hospitalization. <u><b>Rationale</b></u> <ul style="list-style-type: none"> <li>▪ Groups at greatest risk for complications and death as determined by disease epidemiology demonstrating greater than expected death rates (excess deaths) that may or may not be those in seasonal flu priority groups.</li> <li>▪ Persons who are immunocompromised who cannot be protected by vaccination.</li> </ul>	
	<b>Illness</b>	Other patients who are ill with influenza but do not require hospitalization.  Includes others who develop influenza and do not fall within the aforementioned groups and are not considered high risk as evidenced by disease epidemiology.	

<sup>1</sup> Priority may change related to pandemic spread or epidemiology.  
<sup>2</sup> Treatment must begin within 48 hours of symptom onset to affect severity and/or duration of illness.  
<sup>3</sup> Applies to inpatient and outpatient care.  
<sup>4</sup> Any or all of these groups will become a higher priority if the pandemic appears to be severe enough that basic critical functions are at risk.

**Appendix E**

**WHO Phases and Federal Government Response Stages**

**Table 8: WHO Phases and Federal Government Response Stages**

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

## Appendix F

### Antiviral Storage Information

#### Environment

- These products must be stored in a controlled temperature range of 59 to 86 degrees Fahrenheit (°F), preferable at or near 77°F.
- Area must be free of pests/varmints and have controlled humidity, with little or no light except during routine checks or during use.
- Storage area should have limited access to authorized individuals only, with location in compliance with state and federal requirements for prescription drug products. Location would include a licensed pharmacy or other site under the authority of a licensed health practitioner or his/her agent.
- Authorized personnel must have 24/7 access.
- A backup power source is desirable.

#### Amantadine

- 12 bottles of 500 mg–100 mg tablets or 600 courses per case

Each DSHS HSR will receive 6,900 courses or 11.5 cases. Each case is 9”L x 7”W x 51/2”H. Each case has a 0.44 square foot footprint resulting in a total space requirement of 2.5 cubic feet (cu ft). A single stack would be 5.5 feet high.

#### Tamiflu (oseltamivir)<sup>1</sup>

- Unit of use bottles of 10 capsules (one bottle equals one regimen)
- 48 bottles per case
- 90 cases per pallet
- 4,320 regimens per pallet
- Case dimensions: 13” wide x 8” long x 6” high
- Case weight: 3 lbs.
- Pallet is 4’ X 4’ X 6’ high

#### Example 500 cases

Tamiflu pallets can be doubled stacked to reduce the overall space required to store the product. To avoid product damage, careful consideration should be made when planning to double stack pallets.

#### Relenza (zanamivir)<sup>1</sup>

- 1 kit = 1 regimen, (5 Rotadisks and 1 Diskhaler)
- 16 kits per case
- 60 cases per pallet
- 960 regimens per pallet
- Case dimensions: 17” wide x 6” long x 9” high
- Case weight: 4 lbs.

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<sup>1</sup> Please note that the products Project Areas receive from the manufacturers (for Project Area procured antiviral stockpiles) may vary in dimension and configuration. All federally procured products will be specially packaged in unit of use containers.

Relenza pallets can be doubled stacked to reduce the overall space required to store the product. To avoid product damage, careful consideration should be made when planning to double stack pallets.

### **Personal Protective Equipment (PPE):**

Currently, the SNS includes the following PPE items:

- N-95 respirators
- Surgical masks

Additional procurements in the future will include face shields, gowns, and gloves.

There are multiple types of N-95 respirators and surgical masks on hand in the SNS. Depending on the particular model and manufacturer, the number of items per pallet may vary. The following information is provided for planning purposes.

#### N-95 Respirators:

One pallet is comprised of at least 4,800 N-95 respirators; 1 million N-95 respirators would be delivered on approximately 209 pallets. It would require approximately 3,344 square feet to store 209 single stacked pallets. N-95 mask pallets cannot be double stacked.

#### Surgical Masks:

One pallet is comprised of at least 18,000 surgical masks; 1 million surgical masks would be delivered on approximately 56 pallets. It would require approximately 896 square feet to store 56 single stacked pallets. Pallets of surgical masks can be double stacked to reduce the overall space required to store the product. To avoid product damage, careful consideration should be made when planning to double stack product.

#### **Ventilators:**

Current guidelines state that up to 90% of SNS ventilators will be distributed to Project Areas *pro rata* during a Pandemic Influenza response. Please note that this is subject to change. It is expected that Project Areas will receive ventilators in either standard SNS “short” containers or on standard 40” x 48” pallets. Each SNS “short” container is 56.5” wide x 42” long x 58.5” high and has a volume of 80.3 cubic feet.

It is important to note that the SNS ventilators and “short” containers must be returned after a pandemic response. Project Areas are responsible for maintaining the equipment and coordinating with DSNS for the recovery of property.

Currently the SNS includes 2 models of ventilators:

- Puritan Bennett LP10. 10 ventilators are shipped in each container. Quantities less than 10 will probably be shipped on a single pallet.
- Impact Uni-Vent Eagle 754. 28 ventilators are shipped in each container. Quantities less than 28 will probably be shipped on a single pallet.

#### Pandemic Influenza Response Warehouse Example

The following example provides **estimated** warehouse space requirements for 1 million antiviral drug regimens, 1 million N-95 respirators, and 1 million masks. Project Areas should estimate their space needs by applying these figures to their situation. Note that other PPE items and ventilators are not included in this example.

**Table 9. Storage Requirements of SNS Cache**

<b>Item</b>	<b>Pallets</b>	<b>SQFT/pallet</b>	<b>Space (SQFT)</b>
Tamiflu (80%)	186	16	2,976
Relenza (20%)	209	16	3,344
N-95 Masks	209	16	3,344
Surgical Masks	56	16	896
Subtotal	660	N/A	10,560
<b>Additional Space</b>	<b>Subtotal</b>	<b>Additional working space required*</b>	<b>Additional Space Required (SQFT)*</b>
Aisle Space	10,560	23%	2,429
Loading Dock Space	10,560	15%	1,584
Office space	10,560	5%	528
Misc Space	10,560	3%	317
Subtotal	N/A	N/A	4,858
<b>Total Space</b>	<b>SQFT</b>		
Single Stacked Pallets Space	10,560		
Additional Space	4,858		
<b>Minimum Total of Needed Warehouse Space for this example</b>	<b>15,418</b>		

\*Please note: For a warehouse to be operational, working space must be provided in addition to storage space. The above planning percentages provide a way to estimate the amount of space needed for aisles, loading, etc. The needs for these spaces grow proportionally as the total storage spaces increases. The planning percentages illustrated in the chart above provide a way to estimate increasing space needs.

\*Excerpts from *The SNS Medical Countermeasure Distribution Guidelines* (January 2007)

## Appendix G

## Sources of Target Group Data\*

## Licensed Professional Providers\*\*

Table 10. Licensed Professional Providers

Profession	Number	Possibly Non-duplicated	Source****	Priority	Priority Possibly Non-duplicated
Physicians — MD	39,388	39,388	TMB	1	39,388
Physicians — DO	2,634	2,634	TMB	1	2,634
Medical Students MD/DO	5,326	5,326	TMA	1	5,326
Residents MD/DO***	6,548		TMA	1	
Physician Assistants***	2,937		TMB	1	
Advanced Practice Nurses***	10,404		BNE	1	
Registered Nurses***	172,627		BNE	1	
Licensed Practical Nurses***	74,847		BNE	1	
Nursing Assistants***	113,540		DADS	1	
Medication Aids***	9,105		DADS	1	
Medical Radiological Technologists***	20,972		DSHS-PLCU		
Dentists	8,213	8,213	TSDBE	1	8,213
Dental Hygienists	8,548	8,548	TSDBE	1	8,548
Respiratory Care Practitioners***	11,768		DSHS-PLCU	1	
Emergency Medical Services Personnel	50,291	50,291	DSHS-BEM	1	50,291
Occupational Therapists & Assistants***	7,225		ECPTOTE		
Physical Therapists & Assistants***	12,328		ECPTOTE		
Pharmacists***	16,944		TSBP	1	
Optometrists	2,577	2,577	TOB		
Podiatrist	814	814	TSBPME		
Chiropractor	4,091	4,091	TBCE		
Acupuncturists	657	657	TSBAE		
<b>TOTAL</b>	<b>581,784</b>	<b>122,539</b>		<b>524,015</b>	<b>114,400</b>

\* Replace if/when better data is available from State Demographer.

\*\* Might or might not be practicing

\*\*\* Probably counted as employees under Health care in "Texas Employment Totals" (see Table 5, Appendix D) in part or totally.

\*\*\*\* Source:

**BNE** — Board of Nurse Examiners;

**DADS** — Department of Aging and Disability Services;

**DSHS-BEM** — Department of State Health Services-Bureau of Emergency Management;

**DSHS-PLCU** — Department of State Health Services— Professional Licensing and Certification Unit;

**ECPTOTE** — Executive Council of Physical Therapy and Occupational Therapy Examiners;

**TBCE** — Texas Board of Chiropractic Examiners;

**TMA** — Texas Medical Association;

**TMB** — Texas Medical Board;

**TOB** — Texas Optometry Board;

**TSBAE** — Texas State Board of Acupuncture Examiners;

**TSBP** — Texas State Board of Pharmacy;

**TSBPME** — Texas Board of Podiatric Medical Examiners;

**TSDBE** — Texas State Board Of Dental Examiners;

Table 11 Texas Employment Totals and Links to Sector Definitions

<b>Texas Employment Totals for Services Potentially Defined as Critical</b>			
Infrastructure Service	Private Sector*	Public Sector**	Select Services (most critical)
<b>Utilities</b>			
<a href="#">Electric power generation, transmission, &amp; distribution</a>	38,583	8,050	
<a href="#">Natural gas distribution</a>	8,705	1,379	
<a href="#">Water, sewage, &amp; other systems</a> including solid waste	4,684	29,665	
<b>TOTAL</b>		<b>91,066</b>	
<b>Transportation</b>			
<a href="#">Water transportation</a>	4,730	955	
<a href="#">General freight trucking</a>	67,756		
<a href="#">Hazardous materials trucking (except waste), local</a>	2,410		
<a href="#">Hazardous materials trucking (except waste), long-distance</a>	2,415		
<a href="#">Agricultural products trucking without storage, local</a>	1,657		
<a href="#">Agricultural products trucking, long-distance</a>	1,950		
<a href="#">Urban transit systems</a>	4,022	10,762	
<a href="#">Interurban &amp; rural bus transportation</a>	2,581		
<a href="#">School &amp; employee bus transportation</a>	3,400		
<a href="#">Pipeline transportation</a>	10,777		
<a href="#">Scheduled air transportation</a>	982	4,968	
<a href="#">Nonscheduled chartered freight air transportation</a>	503		
<b>TOTAL</b>		<b>119,868</b>	
<b>Support activities for transportation</b>			
<a href="#">Support activities for air transportation</a>	14,544		
<a href="#">Support activities for water transportation</a>	7,736		
<a href="#">Freight transportation arrangement</a>	21,057		
<a href="#">Other support activities for transportation</a>	6,379		
<b>TOTAL</b>		<b>49,716</b>	
<b>Warehousing and storage</b>			
<a href="#">Refrigerated warehousing &amp; storage</a>	2,343		
<a href="#">Farm product warehousing &amp; storage</a>	1,525		
<b>TOTAL</b>		<b>3,868</b>	
<b>Healthcare Professionals not "employed" ***</b>	114,400		
<b>Healthcare</b>		34,349	
<b>Hospitals</b>		78,434	
<a href="#">General medical &amp; surgical hospitals</a>	297,112		
<a href="#">Psychiatric &amp; substance abuse hospitals</a>	11,122		
<a href="#">Specialty (except psychiatric &amp; substance abuse) hospitals</a>	27,318		
<b>Nursing and residential care facilities</b>			
<a href="#">Nursing care facilities</a>	85,104		

<a href="#">Residential mental retardation/health &amp; substance abuse facility</a>	19,659		
<a href="#">Community care facilities for the elderly</a>	23,252		
<a href="#">Other residential care facilities</a>	6,374		
<b>Ambulatory care facilities</b>			
<a href="#">Offices of physicians</a>	136,255		
<a href="#">Offices of mental health practitioners (except physicians)</a>	3,691		
<a href="#">Outpatient care centers</a>	31,093		
<a href="#">Home health</a>	124,962		
<a href="#">Medical &amp; diagnostic laboratories</a>	15,467		
<a href="#">Ambulance services</a>	7,409		
<b>TOTAL</b>		<b>1,016,001</b>	
<b>Selected social services</b>			
<a href="#">Services for the elderly &amp; persons with disabilities</a>	25,364		
<a href="#">Community food &amp; housing/emergency &amp; other relief services</a>	7,100		
<b>TOTAL</b>		<b>32,464</b>	
<b>Government leaders</b>			
Judicial and legal		24,269	
Financial administration		23,745	
Other government administration		16,077	
<b>TOTAL</b>		<b>64,091</b>	
<b>Death care services</b>			
<a href="#">Death care services</a>	10,954		
<b>TOTAL</b>		<b>10,954</b>	
<b>Manufacturing</b>			
<a href="#">Food mfg</a>	85,157		
<a href="#">Petroleum refineries</a>	16,926		
<a href="#">Pharmaceutical &amp; medicine mfg</a>	5,029		
<b>TOTAL</b>		<b>107,112</b>	
<b>Retail stores</b>			
<a href="#">Grocery stores</a>	169,025		
<a href="#">Pharmacies &amp; drug stores</a>	44,983		
<b>TOTAL</b>		<b>214,008</b>	
<b>Public Safety</b>			
Police Officers		45,765	
Police Others		15,769	
Firefighters		22,204	
Fire Other		1,720	
Corrections		68,371	
<b>TOTAL</b>		<b>153,829</b>	
<b>Emergency response workers—other</b>			
TXDOT		14,400	
<a href="#">Texas Army National Guard — 7.7% x 333,177</a>		25,655	
<b>TOTAL</b>		<b>40,055</b>	
<b>TOTAL</b>		<b>1,903,032</b>	

\* [2002 Economic Census, Texas. U.S. Census Bureau](#)

\*\* [2005 Public Employment Data, State and Local Governments, Texas. U.S. Census Bureau](#)

\*\*\* See "Licensed Professional Providers" A24 (some numbers that might overlap were deleted since previously accounted for by employer (e.g. RNs are employed by hospitals; physicians tend to be independent))

**Appendix H:**

**Government Funded Antivirals: Source, Use, and Ordering**

Element	Government Purchase			Government Subsidized—Privately Purchased		
	DSHS Cache	Texas General Revenue Cache	Strategic National Stockpile	Local Health Departments	Eligible Entities <sup>1</sup>	
					Hospitals	Others
<b>Funding Amount</b>	\$1 Million	\$10 Million	No Cost to State	Variable	Variable <sup>2</sup>	Variable
<b>Funding<sup>3</sup> Source</b>	Carry Forward PHEP <sup>4</sup> Funds	Texas General Revenue Funds <sup>5</sup>	Federal Funds	<ul style="list-style-type: none"> <li>○ PHEP Grant</li> <li>○ Other local funding</li> </ul>	<ul style="list-style-type: none"> <li>○ Hospital preparedness program funding<sup>6</sup> dollars</li> <li>○ Other private funds</li> </ul>	Eligible Entity Funds
<b>Method of Purchase</b>	Federal Contract	Federal Contract	N/A	Federal Contract	Federal Contract <sup>7</sup>	Federal Contract
<b>Available Number of Courses</b>	<ul style="list-style-type: none"> <li>○ 169,000 total</li> <li>○ 18,750 per HSR and DSHS Austin</li> </ul>	~675,000	~3.3 Million	Decided by LHD	Decided by Hospital	Decided by Eligible Entity

<sup>1</sup> To be an eligible entity, employers must meet the following two criteria: 1) parties in the regular distribution plan identified and directed in the entity's state-wide pandemic influenza preparedness or all-hazards plan [generic term to imply specific title of codified, signed plan at the state level] and 2) active participants in preparedness planning activities.

<sup>2</sup>Number of antivirals purchased through DSHS should be based on agency size and need for target populations; if the agency wants to provide antivirals for nonessential personnel and families, private purchase is necessary.

<sup>3</sup> The federal government restricts use of antivirals purchased with federal funds to priority groups. While the purchase is not with government funds, the subsidy is federal funds and the contract is federal.

<sup>4</sup> Public Health Emergency Preparedness Grant through Centers for Disease Control and Prevention

<sup>5</sup> The Texas State Legislature appropriated these dollars for antiviral purchase during the 2007 Legislative Session.

<sup>6</sup> Health Resource and Service Administration is an agency of the U.S. Department of Health and Human Services and is responsible for improving access to health care services for people who are uninsured, isolated, or medically vulnerable.

<sup>7</sup> Hospitals should rely on traditional pharmaceutical supply chains for the majority of their antiviral medication supply.

Element	Government Purchase			Government Subsidized—Privately Purchased		
	DSHS Cache	Texas General Revenue Cache	Strategic National Stockpile	Local Health Departments	Eligible Entities <sup>1</sup>	
					Hospitals	Others
<b>Location of Cache<sup>8</sup></b>	<ul style="list-style-type: none"> <li>○ HSRs</li> <li>○ DSHS Austin<sup>9</sup></li> </ul>	<ul style="list-style-type: none"> <li>○ Central Location</li> <li>○ Shipped to predetermined locations prior to receipt of the SNS</li> <li>○</li> </ul>	<ul style="list-style-type: none"> <li>○ SNS<sup>10</sup> Storage, CDC<sup>11</sup></li> <li>○ Moved to State (WHO Phase 4)</li> <li>○ Central Location</li> </ul>	Stored locally by LHD	Stored locally at facility	<ul style="list-style-type: none"> <li>○ Received by licensed person</li> <li>○ Stored locally in appropriate facility</li> </ul>
<b>Recommended Use</b>	<ul style="list-style-type: none"> <li>○ Approved for                             <ul style="list-style-type: none"> <li>● Outbreak Control</li> <li>● Illness</li> <li>● Post-exposure prophylaxis</li> <li>● To back-fill for LHDs if needed</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Approved for                             <ul style="list-style-type: none"> <li>● Outbreak Control</li> <li>● First Responder</li> <li>● Post-exposure prophylaxis</li> <li>● Safety Net<sup>12</sup></li> <li>● To back-fill for LHDs if needed</li> </ul> </li> </ul>	Treatment of Illness Only	<ul style="list-style-type: none"> <li>○ Outbreak Control</li> <li>○ First Responder</li> <li>○ Post-Exposure prophylaxis</li> <li>○ Safety Net</li> </ul>	<ul style="list-style-type: none"> <li>○ Hospital preparedness program funding                             <ul style="list-style-type: none"> <li>● Staff</li> <li>● Families</li> </ul> </li> <li>○ Federal Contract                             <ul style="list-style-type: none"> <li>● Critical infrastructure workers</li> <li>● Uninsured ill</li> </ul> </li> </ul>	As determined by eligible entity, workers who are: <ul style="list-style-type: none"> <li>○ Critical to continue the organization's mission</li> <li>○ Critical to maintaining organization' viability</li> <li>○ Involved in emergency response</li> </ul>
<b>Restrictions for Use</b>	<ul style="list-style-type: none"> <li>○ Limited to those designated above</li> <li>○ Stock cannot be rotated</li> </ul>	<ul style="list-style-type: none"> <li>○ Limited to those above</li> <li>○ Stock cannot be rotated</li> </ul>	<ul style="list-style-type: none"> <li>○ Used only after other assets are exhausted</li> <li>○ Only available to treat ill patients</li> <li>○ Stock cannot be rotated</li> </ul>	<ul style="list-style-type: none"> <li>○ Stock cannot be rotated</li> </ul>	<ul style="list-style-type: none"> <li>○ If purchased with Hospital preparedness program funding, must be used for staff and their families.</li> <li>○ If purchased under federal contract, stock cannot be rotated</li> </ul>	<ul style="list-style-type: none"> <li>○ Standing order by MD, nurse practitioner, physician assistant to distribute by licensed person</li> <li>○ Cannot be rotated</li> <li>○ Use for family members is unclear<sup>13</sup></li> </ul>

<sup>8</sup> Antivirals must be placed in safe, climate-controlled room with limited access and adequate security.

<sup>9</sup> The Department of State Health Services (DSHS) Central Office is located in Austin, Texas. In addition, DSHS has divided Texas into 11 Health Service Regions (HSR) and has placed 8 DSHS HSR Region Offices (HSR 1, 2/3, 4/5 North, 6/5 South, 7, 8, 9/10, and 11) within those regions.

<sup>10</sup> Strategic National Stockpile is federally operated and will forward place available medical assets in states requesting them during a crisis. The SNS will be forward-placed during an influenza pandemic when the World Health Organization declares Phase 4—small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the pandemic influenza virus is not well adapted to humans.

<sup>11</sup> Centers for Disease Control and Prevention

<sup>12</sup> This group of individuals includes individuals identified for illness treatment and post-exposure preventive treatment. This may include individuals requiring hospitalization, individuals with other conditions that might make their illness from pandemic influenza even worse, and possibly other ill or exposed persons who do not require hospitalization. Safety net individuals likely would be uninsured, isolated, or medically vulnerable.

<sup>13</sup> State law also has limitations related to the purchase for family members. § 607.004. PREVENTATIVE IMMUNIZATIONS AND VACCINATIONS is very specific regarding family members and vaccination/immunization. While not specifically dealing with antivirals for prophylaxis, it should serve as a guide to legislative intent regarding family protection. Providing antivirals to family members should be examined by your legal counsel.

Element	Government Purchase			Government Subsidized—Privately Purchased		
	DSHS Cache	Texas General Revenue Cache	Strategic National Stockpile	Local Health Departments	Eligible Entities <sup>1</sup>	
					Hospitals	Others
<b>Allocation</b>	Evenly divided between 8 HSRs and DSHS Austin.	Based on Assessment of Number of Critical Infrastructure Target Group Members	Based on need and population	N/A	N/A	N/A
<b>Target Population</b>	<ul style="list-style-type: none"> <li>○ Outbreak Control                             <ul style="list-style-type: none"> <li>● Identified Cases</li> <li>● Household/social contacts of identified cases</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Outbreak Control                             <ul style="list-style-type: none"> <li>● Identified Cases</li> <li>● Household/social contacts</li> </ul> </li> <li>○ Critical Infrastructure                             <ul style="list-style-type: none"> <li>● Health</li> <li>● Emergency</li> <li>● Service</li> </ul> </li> <li>○ Safety Net</li> </ul>	Persons diagnosed as having pandemic influenza, who are identified within 48 hours of symptom onset.	<ul style="list-style-type: none"> <li>○ Outbreak Control                             <ul style="list-style-type: none"> <li>● Identified Cases</li> <li>● Household/social contacts</li> </ul> </li> <li>○ Critical Infrastructure                             <ul style="list-style-type: none"> <li>● Health</li> <li>● Emergency</li> <li>● Service</li> </ul> </li> <li>○ Safety Net</li> </ul>	<ul style="list-style-type: none"> <li>○ HRSA                             <ul style="list-style-type: none"> <li>● Staff</li> <li>● Families</li> </ul> </li> <li>○ Federal Contract                             <ul style="list-style-type: none"> <li>● Critical infrastructure workers</li> <li>● Uninsured ill</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Workers critical to the entity's ability to:                             <ul style="list-style-type: none"> <li>● Carry out its mission</li> <li>● Maintain its viability</li> </ul> </li> </ul> Participate in emergency response
<b>Procurement Procedures</b>	<ul style="list-style-type: none"> <li>○ Currently placed in HSRs</li> <li>○ Request through appropriate ICS<sup>14</sup> channels</li> <li>○ Request must include:                             <ul style="list-style-type: none"> <li>● Number of people requiring post-exposure prophylaxis</li> <li>● Whether or not each is on the agency list as a critical service provider or critical to agency function</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Request through appropriate ICS channels</li> <li>○ Request must include:                             <ul style="list-style-type: none"> <li>● Number of people requiring post-exposure prophylaxis</li> <li>● Whether or not each is on the agency list as a critical service provider or critical to agency function</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Shipped based on availability, local supply, and target populations needs from central RSS<sup>15</sup></li> <li>○ Request through proper ICS channels</li> <li>○ Request must include:                             <ul style="list-style-type: none"> <li>● The requesting facility and amount per location</li> </ul> </li> </ul>	Antivirals purchased through this contract will be sent directly to LHD from the manufacturer.	Antivirals purchased through this contract will be sent directly to the hospital from the manufacturer.	Antivirals purchased through this contract will be sent directly from the manufacturer to the agency's licensed professional (pharmacist or MD) who agreed to receive and take responsibility for them <sup>16</sup> .

<sup>14</sup> Incident Command System (ICS) is an accepted method for managing large or small emergency incidents, possibly involving multiple agencies or organizations.

<sup>15</sup> Receiving Storage and Shipping Sites (RSS): Sites designed to receive medical assets including antiviral drugs from the Strategic National Stockpile

<sup>16</sup> Procedures may be different for Austin-based State agencies.

## GLOSSARY

**Distribution:** The process of delivering SNS assets from a receiving, staging, and storing (RSS) warehouse facility to [points of dispensing](#), treatment centers, and/or other locations.

**IFA:** Serologic evaluations are conducted by using the indirect immunofluorescence assay (IFA). Antibodies in the serum bind to the organisms on a slide and are detected by a fluorescein-labeled conjugate.

**Medical home:** Medical care that is accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally effective. It should be delivered or directed by well-trained physicians who provide primary care and help to manage and facilitate essentially all aspects of health care.

**MedWatch:** The FDA Safety Information and Adverse Reactions Reporting Program, that provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products.

**Pharmacy Inventory Control System:** The primary purposes of this inventory control system are to provide the state with “real-time” inventories, maximum stock levels for each antigen, automate vaccine orders, improve vaccine administrative data, inventory control and recall/quarantine measures, and reduce emergency orders.

**Points of Dispensing:** Sites within a community where target populations receive antiviral prophylaxis intended for individuals who may have been exposed to a novel influenza virus, but are not yet exhibiting symptoms of disease. Individuals who are exhibiting symptoms or appear to be ill should be directed to treatment centers to receive appropriate care.

**Prophylaxis:** Prevention or protection: giving a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.

**Public Health Disaster:** A declaration by the Governor of a state of disaster and a determination by the Commissioner of Health that there exists an immediate threat from a communicable disease that poses a high risk of death or serious long-term disability to a large number of people and creates a substantial risk of public exposure because of the disease’s high level of contagion or the method by which the disease is transmitted.

**Strategic National Stockpile (SNS):** A federal resource for medical supplies that will be available to the State during catastrophic events that deplete local and state resources.

**RT-PCR:** The exponential amplification via reverse transcription polymerase chain reaction provides for a highly sensitive technique, where a very low copy number of RNA molecules can be detected.

**Texas Inventory Management System (TIMS):** The Texas Inventory Management System is used to manage and track Strategic National Stockpile (SNS) materials at all levels, terminal foci.

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