

Pandemic Influenza Plan – Antiviral Medication Distribution and Dispensing

For more information contact Sebastian Gely at sebastian.gely@sema.dps.mo.gov or 573-522-5637

INTRODUCTION

The use of antiviral medications for management of influenza is an important component of a multi-faceted response to an influenza pandemic. Treatment with a class of agents called neuraminidase inhibitors has been shown to decrease severe complications of influenza, such as pneumonia, and to reduce hospitalizations. Antiviral usage may be particularly important before vaccine is available and for those for whom vaccination may be medically contraindicated. The effect of antiviral medications is usually immediate and does not interfere with the response to inactivated influenza vaccines. It is also essential to avoid inappropriate use of antiviral medications because that may lead to influenza virus developing resistance to these medications. Ultimately, vaccination against the pandemic influenza virus is likely to provide the most durable protection against the illness, but pandemic vaccine may not be available in a timely manner.

Antiviral medications for treatment of influenza included in the Strategic National Stockpile (SNS) include the neuraminidase inhibitors, oseltamivir (Tamiflu[®]) and zanamivir (Relenza[®]). The Centers for Disease Control and Prevention (CDC) also has added some additional medications. Peramivir is approved for intravenous administration for patients who have severe, complicated, or progressive illness; are hospitalized; or who are unable to take oral medication or in whom oral medication appears to be ineffective. Baloxavir Marboxil (Xofluza[®]) has been approved for early treatment of uncomplicated influenza for people five to twelve years old. Adamantanes (Amantadine and Rimantadine), while not recommended for use in the US due to concerns about antiviral resistance, has also been approved in narrow circumstances.

OBJECTIVES

- Describe plan for allocation, distribution, and administration of antiviral medications.
- Monitor antiviral medication use and safety during a pandemic.

PLANNING ASSUMPTIONS

- The Missouri Department of Health and Senior Services/State Emergency Management Agency (DHSS/SEMA) will continue to follow the guidance issued by CDC regarding the use of antiviral medications. (Please see specific references in the resources section at the end of this annex.)
- Treatment with a neuraminidase inhibitor (oseltamivir [Tamiflu[®]] or zanamivir [Relenza[®]]) will be effective in decreasing risk of pneumonia, will decrease hospitalization by about half (as shown for interpandemic influenza), and will also decrease mortality.
- The effectiveness of antiviral medications against a new pandemic influenza strain cannot be completely predicted.
- The choice of particular antiviral medications will depend on what is known about the viral resistance pattern at the time of the pandemic, and on the availability of a particular drug.
- Antiviral resistance to the adamantanes (amantadine and rimantadine) may limit their use during a pandemic.
- Early treatment is a more efficient use of antiviral medications than prophylaxis.

- Early treatment after the onset of disease is most effective in decreasing the risk of complications and shortening illness duration. Generally, treatment should be given within the first 48 hours.
- Antiviral use will be most important during the time when vaccine is not yet available, when the supply of the new vaccine is limited, and while immunity from the vaccine is being developed.
- Within local communities, private providers, health care facilities, industry, and others may have purchased antiviral medication caches for protection of their workers.

EMERGENCY USE AUTHORIZATION (EUA)

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), amended by the Project BioShield Act of 2004, permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.

Should a pandemic occur, Missouri would follow the guidance and requirements issued by the federal government related to use of antiviral medications. It is anticipated the Secretary would declare a public health emergency; therefore the U.S. Food and Drug Administration (FDA) would have authority to issue an Emergency Use Authorization (EUA) for emergency use of Tamiflu[®] (oseltamivir) and Relenza[®] (zanamivir). More information on the EUA can be found at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>.

In addition to the medical countermeasures supplied by the SNS, Tamiflu[®] and Relenza[®] that may be supplied via state and local governments are also covered by the EUA, if the terms and conditions of the EUA are met.

PUBLIC READINESS AND EMERGENCY PREPAREDNESS (PREP) ACT

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration and use of such countermeasures.

WHAT THE LAW DOES

Liability Protection

The PREP Act confers immunity from liability on specified persons for certain activities related to covered countermeasures:

- **Persons Covered**—The PREP Act covers individual persons and entities. Covered persons may, at the secretary’s discretion, include manufacturers, distributors, program planners (i.e., individuals and entities involved in planning and administering programs for the distribution of countermeasures), and qualified persons who prescribe, administer, or dispense

countermeasures (i.e., healthcare and other providers). The United State officials, agents, and employees of any of these entities or persons are also covered persons.

- **Activities Covered**—Immunity applies to the development, manufacture, testing, distribution, administration, and use of countermeasures.
- **Countermeasures Covered**—Countermeasures can include vaccines, drugs, or medical devices to be used against chemical, biological, radiological, and nuclear (CBRN) agents of terrorism, epidemics, and pandemics.
- **Claims Covered**—The act provides immunity from tort liability except for willful misconduct. PREP Act immunity covers death and physical, mental, or emotional injury, illness, or disability, and the fear of these conditions. Liability protections also extend to claims made for medical monitoring as well as loss or damage to property, including business interruption. Claims that have a causal relationship to the development, distribution, administration, or use of the covered countermeasure are potentially included within the scope of PREP Act liability protections.

Compensation Fund

The PREP Act authorizes an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the secretary’s declaration. The Countermeasures Injury Compensation Program (CICP) is administered by the Health Resources and Services Administration (HRSA). For more information on CICP, go to:

<https://www.astho.org/advocacy/state-health-policy/legal-preparedness-series/emergency-authority-immunity-toolkit/>

What the Law Does Not Do

A PREP Act declaration by the U. S. Department of Health and Human Services secretary only provides immunity from liability for the persons, activities, and countermeasures specified in the declaration; it does not automatically protect everyone involved in any kind of medical response to an emergency. The act’s liability protections do not apply where the liability arose from willful misconduct. It also does not protect individuals who violate a person’s civil rights or who violate the Americans with Disabilities Act, among other exceptions stated in the act. The PREP Act does not confer any other immunities or liability protections. A PREP Act declaration is different from, and independent of, other federal emergency declarations. A separate public health emergency determination under Public Health Service Act Section 319 or another statute is not required to enable the PREP Act or for its immunities to take effect. See:

<https://www.astho.org/advocacy/state-health-policy/legal-preparedness-series/emergency-use-authorization-toolkit/>

How the Law Works

Before issuing a PREP Act declaration, the secretary must determine that a disease, condition, or threat to health constitutes a public health emergency or a credible risk of a future public health emergency and find that the development of a countermeasure is desirable. The secretary then issues a PREP Act declaration that specifies, among other things:

- The countermeasures covered by the declaration.

- The category of diseases, health conditions, or health threats determined by the secretary to constitute a present or credible risk of a future public health emergency for which administration and use of the countermeasures is recommended.
- The effective time period of the declaration.
- The population of individuals receiving the countermeasure.
- Limitations, if any, on the geographic area for which immunity is in effect.
- Limitations, if any, on the means of distribution of the countermeasure.

Any additional persons identified by the secretary as qualified to prescribe, dispense, or administer the countermeasures.

DISTRIBUTION OF ANTIVIRAL MEDICATIONS IN MISSOURI

- Antiviral medications purchased with publicly funded monies through the SNS are to be used for **treatment only**.
- The model of delivery will vary in local communities depending on each jurisdiction's dispensing plan and resources.
- In general, local public health agencies (LPHA's) will be required to pick up the antiviral medications from the designated Receiving Staging and Storage site.
- The amounts antivirals needed will be determined by the community's population size or numbers of persons at risk.
- DHSS/SEMA will continue to work closely with LPHAs to enhance specific distribution plans for these assets for communities utilizing available health care providers and resources.

LPHAs will utilize the SNS WebEOC system, or other system(s) as specified, for ordering antiviral medications from the SNS stockpile. LPHA's will work closely with community partners to integrate plans for antiviral distribution into existing pandemic influenza plans and identify the best method of distribution and dispensing for their population.

LPHA's will identify community partners who can prescribe antiviral medications for treatment and who would be willing to dispense this medication and comply with other stipulations set forth by DHSS/SEMA and CDC regarding the dispensing of subsidized medications.

Community partners could include hospital pharmacies, retail pharmacies, health care providers, Federally Qualified Health Centers, and other facilities with appropriate storage facilities, hours of operation, and staff to dispense the medication.

USING ANTIVIRAL MEDICATIONS TO TREAT HIGH-RISK INDIVIDUALS

CDC is strongly encouraging state health departments to use assets provided by the states and the SNS for treatment of high-risk individuals. These individuals may not have routine access to medications through commercial pharmacy distribution systems and may be unable to purchase antiviral medications prescribed to them. High-risk individuals are defined as having increased risk of developing severe disease or complications from influenza. The high-risk groups include:

- Pregnant women.
- Individuals with chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus).
- Individuals with immunosuppression, including that caused by medications or by HIV.
- People younger than 19 years of age who are receiving long-term aspirin therapy.

- Children younger than 5 years old. The risk of severe complications from influenza is highest among children younger than 2 years old.
- Adults 65 years of age or older.

It is likely that current antiviral usage guidelines, including high risk groups and prioritization recommendations, will change when epidemiologic data on a specific pandemic virus becomes available or when supplies of antiviral medications are greatly increased.

Many communities have hospitals or clinic pharmacies that provide direct dispensing of medications or onsite prescription assistance programs for treatment of high-risk individuals that may not otherwise have affordable access. A broad, forward deployment of antiviral medications to these locations can help ensure that **underinsured or uninsured high-risk individuals with influenza** will be able to receive antiviral medications for treatment.

A forward deployment also can help ensure rapid dispensing of medication to those who might otherwise have limited or no access for obtaining medications through commercial pharmacies.

ANTIVIRAL MEDICATIONS ADVERSE EVENTS

For information on recognizing adverse events (side effects) related to the use of each medical countermeasure, please refer to the respective EUA fact sheets for that product. Health care professionals and consumers may report serious adverse events (side effects) associated with the use of these products, or product quality problems, to the FDA's MedWatch Adverse Event Reporting program at <https://www.accessdata.fda.gov/scripts/medwatch/>.

Additionally, questions related to adverse reactions may be directed to DHSS' Emergency Response Center (ERC) by calling 800-392-0272.

RESOURCES

Department of Health and Human Services. *Pandemic Influenza Plan – 2017 Update*
<https://www.cdc.gov/pandemic-flu/media/pan-flu-report-2017v2.pdf>

FDA. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>

CDC. Information for Health Care Professionals: Antiviral Drugs
<https://www.cdc.gov/flu/professionals/antivirals/index.htm>

DHSS. Pandemic Influenza - Medical & Public Health Professionals
<https://health.mo.gov/emergencies/panflu/panflu.php>