



Pat Quinn, Governor
Damon T. Arnold, M.D., M.P.H., Director

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To: Local Health Departments, Physicians, Hospitals, and Retail Pharmacies

From: Damon T. Arnold, M.D., M.P.H.
Director

Date: December 22, 2009

Re: H1N1 Antivirals (Tamiflu & Relenza) for Uninsured/Underinsured

The Illinois Department of Public Health (IDPH) will allow local health departments to partner with Federally Qualified Healthcare Centers (FQHCs), private physicians, and retail pharmacies to provide antivirals (Tamiflu & Relenza) for treatment of uninsured or underinsured H1N1 patients as determined by the treating physician. This is an update and a change from previous guidance to local health departments to partner with retail pharmacies for dispensing of antivirals to H1N1-infected patients.

Local health departments may develop memorandums of understanding with partners for the dispensing of antiviral medications within their jurisdiction (template attached). Partnerships may include treatment centers, medical practitioners, and retail pharmacies for dispensing of antiviral medications for use in treating ill patients. If these providers have patients who need treatment based on IDPH guidelines and cannot obtain antivirals, local health departments may supply antivirals from the Strategic National Stockpile (SNS).

Entities receiving SNS supplies need to meet the prescription and dispensing requirements under the Illinois Pharmacy Practice Act (prescription and labeling). In addition, to comply with the Food and Drug Administration (FDA) emergency use authorization for antivirals for treatment of H1N1 infections, the FDA fact sheets for Tamiflu and Relenza must be provided to each patient when the SNS antiviral are dispensed. Although some lot numbers of the antiviral have expiration dates that have passed, these antiviral have been re-tested by the FDA and found to be safe for patient use and meeting all requirements of the federally approved Shelf Life Extension Program.

Entities cannot charge for drugs received through the SNS program. If a provider deems it necessary to charge an administrative fee, the U.S. Department of Health and Human Services/U.S. Centers for Disease Control and Prevention (CDC) recommends that it not exceed the regional Medicaid rate for administrative fees. Entities must dispense antivirals free of charge to individuals unable to pay the administrative fee.

Reporting Adverse Events

Health care professionals should report all serious adverse events after antiviral medication use promptly to MedWatch, the FDA's adverse event reporting program for medications (<http://www.fda.gov/medwatch/report/hcp.htm>).

Local health departments and hospitals should account for all SNS supplies received, dispensed, and distributed using internal procedures for accountability. In the event a state or federal audit occurs, it will be the responsibility of the local health department and hospital to provide documentation of how SNS supplies were utilized. Local health departments and hospitals that provide SNS supplies to community partners should stress that these entities follow similar procedures.

Review the following CDC Web sites for additional information and updated interim recommendations for the use of antiviral medications in the treatment and prevention of influenza for the 2009- 2010 Season:

<http://www.cdc.gov/h1n1flu/recommendations.htm>

2009-2010 Influenza Season: Information for Pharmacists:

http://www.cdc.gov/H1N1flu/pharmacist/pharmacist_info.htm

Emergency Use Authorization (EUA) of Medical Products and Devices:

<http://www.cdc.gov/h1n1flu/eua/>

Emergency Use Authorization of Tamiflu (Oseltamivir):

<http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>

Emergency Use Authorization (EUA) of Relenza (Zanamivir):

<http://www.cdc.gov/h1n1flu/eua/relenza.htm>

Partners should contact their local health department for additional information or the IDPH SNS program coordinator at 217-557-3771.

Madison County Health Department
MEMORANDUM OF UNDERSTANDING

Between Madison County Health Department (LHD) and _____ (“Private health care provider, hospital or treatment center, pharmacy”) referred to as community partner.

This agreement represents a mutual understanding and establishes a partnership for assisting local health departments (LHDs) and other local public health jurisdictions in developing a plan for the delivery of antiviral medications during an outbreak of pandemic influenza. LHDs will pre-identify community partners willing to dispense antiviral medications in the state/federal Strategic National Stockpile for treatment of ill individuals. These medications are in limited supply and providers should use discretion when prescribing and dispensing the SNS antivirals consistent with U.S. Centers for Disease Control and Prevention (CDC) and Illinois Department of Public Health guidelines.

Storage of state/federal stockpiled antiviral medications.

- These products must be stored in a controlled temperature range of 59 to 86 degrees Fahrenheit (°F), preferable at or near 77°F.
- Maintain proper storage temperature and controls. Loss of antiviral medications due to improper storage shall be deemed as negligence.
- Take immediate action if temperature controls are out of range to return medications to proper storage requirements. Report aberrations to the LHD.
- Area must be free of pests/varmints and have controlled humidity, with little or no light except during routine checks or during use.
- Access to the storage area should be limited 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.
- Only authorized personnel may have 24/7 access to the antiviral medication supplies.
- A backup power source is desirable.
- **Security** (provided 24/7) must be in place and the medications must be monitored at all times.
- A local hospital would be an ideal place to store the product, as it will have a Class C pharmacy, security, controlled temperature and humidity, and 24/7 availability. As long as the drug cache is handled under the purview of a practitioner (doctor or

their designee), it can be at some other location that complies with the aforementioned criteria for drug storage, such as a warehouse, pharmacy, or physician's office.

- Inventory and record keeping is essential. The Illinois Department of Public Health requires documentation and chain of custody be maintained through the life cycle of the medication. This is necessary for contract monitoring and auditing purposes.

GENERAL RESPONSIBILITIES OF BOTH PARTIES

The LHD and community partner will work together to develop a community plan for distribution of the Strategic National Stockpile antiviral medications. Both parties understand antiviral medications will be made available through the Illinois Department of Public Health (IDPH) Office of Preparedness and Response, Division of Disaster Planning and Readiness Strategic National Stockpile Program, on a pro-rata basis. Use of the antiviral medications will begin when federal authorities [CDC and the U.S. Department of Health and Human Services (HHS)] and the World Health Organization announce the implementation of distribution of medical countermeasures.

Each party agrees that inventory and asset tracking will be done according to the following requirements:

- Comply with state's requirements to follow the prioritization table as feasible for use of antiviral medications for treatment of H1N1 pandemic influenza.
- Comply with prescribing SNS acquired antivirals according to recommendations of HHS, CDC and IDPH.
- Comply with the prescription and dispensing requirements of the Illinois Pharmacy Practice Act, 225 ILCS 85 (prescription and labeling).
- Comply with Section 33 of the Illinois Medical Practice Act, 225 ILCS 60/33.
- Comply with recommended treatment protocol.
- Not impose a charge for the cost of SNS acquired antiviral medication.
- Keep inventory separate from privately stocked antiviral medication for assurance in record keeping and compliance.
- Maintain all records related to the antiviral medication program, such as inventory, lot number control, and monitoring during storage (temperature logs) for a period of three years after the end of the pandemic period or following the expiration of the medications.
- Make such records available for review to public health officials (IDPH SNS program representatives, CDC or HHS, as requested).

SPECIFIC ROLES AND RESPONSIBILITIES OF EACH PARTY

By entering this agreement, the Prescriber agrees to:

- a) Provide adequate and appropriate space and facilities for antiviral medications storage and distribution according to environmental recommendations aforementioned.
- b) Maintain appropriate state/federal licensing for distribution and dispensing of antiviral medications.
- c) Comply with state and federal recommendations regarding the prioritization for use of antiviral medications for treatment purposes during an influenza pandemic.
- d) Maintain inventory and record keeping according to aforementioned stipulations.
- e) Report all serious adverse events (SAE) after antiviral medication use promptly to MedWatch, the FDA’s adverse event reporting program for medications (<http://www.fda.gov/medwatch/report/hcp.htm>) and by notifying the IDPH/OPR/DPR SNS Program at (217) 557-3771.

Signature: LHD Administrator

Signature: /Community Partner

Printed Name

Printed Name

Title

Title

Date

Date

Bring signed form with you when picking up the antiviral medications.

We must have the signed form to release the antivirals to your custody.

Questions call: 618-296-6059