

Guidance for Retail Pharmacies Participating in Dispensing of Strategic National Stockpile (SNS) Antivirals

1. The Michigan Department of Community Health (MDCH) supports the Center for Disease for Disease Control and Prevention (CDC) guidelines for antiviral treatment or prophylaxis of the 2009 Novel H1N1 disease posted at:
<http://www.cdc.gov/h1n1flu/recommendations.htm>
2. Orders for these products may be presented to the Pharmacy on either a LHD approved Health and History Form, or a traditional prescription blank. It may be requested on that order that you specifically use LHD-SNS provided antivirals. If you are unsure as to whether or not this is expected with a particular order, please contact your LHD representative or the ordering physician.
3. The authority to dispense the SNS provided antivirals to a patient referred by a Local Health Department is granted by the antiviral standing orders signed by that Jurisdictions Medical Director, and held on file by the dispensing Pharmacy and that LHD jurisdiction.¹ This is the same process utilized by Pharmacies operating an influenza vaccination clinic. A traditional prescription could also serve as the Medical Order, in lieu of Standing Orders.
4. Tamiflu® and Relenza® are being provided to you at no charge from your Local Health Department, via the Strategic National Stockpile for use in treatment of active cases of influenza, or prophylaxis of contacts per CDC guidelines posted at
<http://www.cdc.gov/h1n1flu/recommendations.htm>
5. At this time, there can be no charge assessed to the patient(s) for this medication.
6. The dosages for Tamiflu® are weight-based for those patients less than 89 lbs. Compounding directions are listed in the Tamiflu® FDA approved package insert. The final concentration of the compounded formulation is 15mg/ml, which is different than the commercially available 12mg/ml formulation. Make sure to dispense an appropriate oral syringe with the compounded Tamiflu® to insure proper dosing.
7. Pharmacists with access to Tamiflu® oral suspension should be aware that an oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided in the packaging for the manufacturer's product rather than graduations in milliliters (ml) or teaspoons (tsp). There have been cases where the units of measure on the prescription dosing instructions (ml, tsp) do not match the units on the dosing device (mg), which can lead to patient or caregiver confusion and dosing errors. When dispensing commercially manufactured Tamiflu® oral suspension, pharmacists should ensure the units of measure on the dosing instructions match the dosing device provided. If dosing instructions specify administration using ml or tsp the device included in the Tamiflu® product package should be removed and replaced with an appropriate measuring device. When dispensing Tamiflu® oral suspension for children younger than 1 year of age, the oral dosing dispenser that is included in the product package should always be removed and replaced

¹ 133.16215 Michigan Public Health Code

with an appropriate measuring device.
(http://www.cdc.gov/H1N1flu/pharmacist/pharmacist_info.htm)

8. FDA approved Patient Fact Sheets, for both Tamiflu® and Relenza® that have information pertinent to this years outbreak of 2009 Novel H1N1 Influenza are available at; <http://www.fda.gov/cder/drug/antivirals/influenza/default.htm>
Please copy and provide one Patient Fact Sheet with each dispensed prescription
9. It is a requirement by the CDC that SNS assets be tracked to the ultimate user via manufacturer designated lot number. The doses dispensed must either be logged in the Michigan Care Improvement Registry (MCIR) by the Pharmacy, or through a mutually agreed upon arrangement with the LHD. This may involve either LHD provided scan sheets, or log sheets. Please retain all forms of documentation for return to your local LHD Department at a later date.
10. In order to participate in the distribution partnership with a Local Health Department, the pharmacy must be registered in the Michigan Care Improvement Registry (MCIR). The link to begin this process is; <http://www.mcir.org/providercontent.html>
11. If your pharmacy is already registered with MCIR, you do not need a second agreement to report the dispensing of oral antivirals.
12. The actual data entry may be delegated to the LHD, but the Pharmacy site still must be registered as a MCIR site. The decision to delegate this function to the LHD is to be determined between Retail Pharmacy and LHD.
13. In 2005, the Public Health and Emergency Preparedness Act (“PREP Act”) was enacted by Congress. The PREP Act authorizes the Secretary of the Department of Health and Human Services 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 disease, 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, attesting, distribution, administration, and use of such countermeasures.² A PREP Act Declaration has been enacted for the 2009 H1N1 outbreak. More information can be found at:
www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-ga.html
14. The Emergency Management Act 390, states in Section 30.411 (4):
A person licensed to practice medicine or osteopathic medicine and surgery or a licensed hospital, whether licensed in this or another state or by the federal government or a branch of the armed forces of the United States, or an individual listed in subsection (6) who renders services during a state of disaster declared by the governor and at the express or implied request of a state official or agency or county or local coordinator or executive body, is considered an authorized disaster relief worker or facility and is not liable for an injury sustained by a person by reason of those services, regardless of how

² <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>

or under what circumstances or by what cause those injuries are sustained. The immunity granted by this subsection does not apply in the event of an act or omission that is willful or gross negligence. If a civil action for malpractice is filed alleging an act or omission that is willful or gross negligence resulting in injuries, the services rendered that resulted in those injuries shall be judged according the standards required of persons licensed in this state to perform those services.

Section (6) lists both Pharmacists and Pharmacist Interns working under the supervision of a licensed pharmacist.

15. The distribution of this product must still meet all State of Michigan Pharmacy labeling and dispensing laws.

Michigan Required Labeling:
Name and address of location from which drug is dispensed
Prescription Number
Patients Name
Date Dispensed
The Prescribers Name
The Directions for Use
The Name, Strength of Drug
The Quantity Dispensed
Expiration Date

You may wish to utilize your traditional pharmacy dispensing and labeling protocol and procedures to ensure that all labeling and dispensing laws are met.

Local Health Department Name:	
Contact person at Local Health Department:	
Phone:	
Fax Number:	
e-mail address:	