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From: Tim Davis, PharmD, Medical Countermeasures Coordinator

To: North Carolina Local Health Departments

Subject: Guidance for the proper storage, handling, and dispensing of SNS-provided

extended date Tamiflu products for Highly Pathogenic Avian Influenza A (H5N1)

Date: January 23, 2025

Background

Certain lots of Tamiflu (oseltamivir) products held in jurisdictional stockpiles and in the Strategic National Stockpile (SNS) for pandemic use have been <u>extended by the Food and Drug</u>

<u>Administration (FDA) for up to 20 years beyond their original manufacture date</u>. This document provides guidance to NC Local Health Departments (LHDs) related to the storage, handling, and dispensing of these extended date products. This guidance is applicable to all lots of extended Tamiflu products found on this list, that have been distributed to LHDs since 2009.

SNS-provided extended date Tamiflu must only be dispensed in response to current or future novel influenza A virus outbreaks in situations where commercial Tamiflu or generic oseltamivir is not available or accessible.

Storage Requirements

• Store the capsules at 77°F (25°C) (room temperature); excursions permitted to 59° to 86°F (15° to 30°C).

Inventory Management

- Record and track inventory in CDC's Inventory Management & Tracking System (<u>IMATS</u>). (Preferred)
- If IMATS is not used, the LHD should record inventory in their inventory management system being sure to track product by NDC, name, strength, lot number, expiration date, and quantity.
- Note: PHP&R may ask for updated inventory information at any time.

Dispensing

Tamiflu is a prescription only product and therefore must be dispensed in accordance with the NC Pharmacy Practice Act. Antiviral treatment is recommended as soon as possible for outpatients and hospitalized patients who are suspected, probable, or confirmed cases of human infection with novel influenza A viruses associated with severe human disease.

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What is dispensing?

"Dispense" according to the <u>NC Pharmacy Practice Act</u> means preparing and packaging a
prescription drug or device in a container and labeling the container with information
required by State and federal law.

Who can dispense?

- A licensed pharmacist pursuant to a prescription from a medical provider.
- A licensed physician provided the medication is provided at no cost to the patient.
- A dispensing physician, physician assistant, or nurse practitioner registered with the NC Board of Pharmacy. For information on how to register, please visit https://www.ncbop.org/non-pharmacist-dispensers.html.

Note: A registered nurse in a local health department may NOT dispense Tamiflu, as it is not contained in the prescription drug formulary approved by the NC Board of Pharmacy for nurses trained in dispensing.

Dispensing Requirements:

- Products must be labeled in accordance with State and Federal dispensing laws. Details
 from the NC Board of Pharmacy on what information must be included on a prescription
 label can be found at https://www.ncbop.org/faqs/general-pharmacy-faqs.html#faqprescriptionslabeling
- Dispensing physicians, physician assistants, and nurse practitioners may only dispense to their own patients and must perform dispensing activities themselves. Dispensing functions CANNOT be delegated to other staff.
- SNS-provided Tamiflu must be dispensed at no cost to the patient.
- Patients must be provided with a copy of the EUI Fact Sheet for Recipients and Caregivers at the time of dispensing.
- Inventory should be updated in IMATS (or other inventory management system) when dispensing occurs.

Transfers

- Product may be transferred to other LHDs, partner pharmacies, or other dispensing providers, upon notification to PHP&R.
- If a transfer occurs, be sure to maintain proper chain of custody paperwork and update inventory accordingly.
- PHP&R reserves the right to collect and redistribute any remaining product to other local health departments in the state as part of future public health responses.

Disposal

 Once the SNS-provided Tamiflu has surpassed its <u>extended expiration date</u>, it can be disposed of in accordance with local destruction procedures and recordkeeping.

Additional Resources

- Interim Guidance on the Use of Antiviral Medications for Treatment of Human
 Infections with Novel Influenza A Viruses Associated with Severe Human Disease | Bird
 Flu | CDC
- Oseltamivir Emergency Use Instructions (EUI) Fact Sheet for Healthcare Providers
- Oseltamivir Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers
- NC Board of Pharmacy Home

Support

- Contact the PHP&R Medical Countermeasures Team
 - Phpr.nc@dhhs.nc.gov
 - o 1-888-820-0520