



# The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

250 Washington Street, Boston, MA 02108-4619

DEVAL L. PATRICK  
GOVERNOR

TIMOTHY P. MURRAY  
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD  
SECRETARY

LAUREN A. SMITH, MD, MPH  
INTERIM COMMISSIONER

## **Determination and Order Pursuant to M.G.L. c. 111, s. 5A: Prescribing and Dispensing Oseltamivir Oral Suspension**

Administration of oral oseltamivir (Tamiflu®) is essential in the interest of the public health to reduce morbidity and mortality for individuals needing treatment for influenza or chemoprophylaxis to prevent illness from suspected exposure to influenza. Oseltamivir oral suspension is especially important to treat pediatric patients and certain adults with difficulty swallowing solid oral dosage forms.

An emergency exists by reason of a shortage of oseltamivir oral suspension.

During this emergency, and until this determination is terminated, oseltamivir (Tamiflu®) may be distributed and dispensed pursuant to the following orders and any subsequent written orders, rules, and priorities established by the Massachusetts Department of Public Health (MDPH).

Notwithstanding any other provision of law, licensed pharmacies may compound and dispense oral suspensions of oseltamivir (Tamiflu®) where there is a prescription for oseltamivir (Tamiflu®) oral suspension and such suspension is not readily available to the pharmacy, as follows:

- Such compounding and dispensing shall be in accordance with the Tamiflu® package insert and with the "Guidelines for Prescribing and Dispensing Tamiflu®" issued by MDPH (Attachment A) as well as any subsequent guidelines, orders, rules, and priorities established by MDPH or the U.S. Food and Drug Administration.
- Such compounding shall not require prior consultation with the prescriber in cases where the prescription does not specifically authorize such compounding.

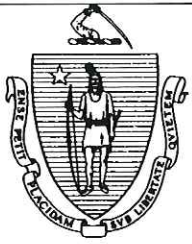
A handwritten signature in blue ink, appearing to read "Lauren A. Smith".

Lauren A. Smith, MD, MPH  
Interim Commissioner

Massachusetts Department of Public Health

1-11-13

Date



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ATTACHMENT A

To: Massachusetts Prescribers and Pharmacists

From: Massachusetts Department of Public Health

Date: January 11, 2013

Re: **GUIDELINES for Prescribing and Dispensing Oseltamivir**

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These guidelines are provided for prescribers and pharmacists related to prescriptions of oseltamivir (Tamiflu®) for influenza treatment. In the event of any shortage of pre-packaged oseltamivir suspension (**Tamiflu® for Oral Suspension**), pharmacists are able to compound suspensions on-site (a non-sterile procedure) from commercially available oseltamivir capsules according to the package insert directions provided by Roche Laboratories Inc.

Based on the shortage of **Tamiflu® for Oral Suspension**, Massachusetts Department of Public Health Interim Commissioner Dr. Lauren Smith issued an Order on January 11, 2013, pursuant to M.G.L.c.111, s.5A, which permits pharmacists to compound suspensions on site to fill prescriptions written for **Tamiflu® for Oral Suspension**.

Prescribers are advised to prescribe this medication in **mg** (milligrams) rather than mL (milligrams) or tsp (teaspoons). Prescribers are also advised to include the following statement on prescriptions for suspensions whenever possible, although such statement is not required for the pharmacist to compound the suspension: "May substitute with compounded suspension."

**PRESCRIPTION CLARIFICATION**

Pharmacists are not required to contact prescribers for additional authorization to compound an oseltamivir oral suspension utilizing the recipe in the Tamiflu® package insert.

**IMPORTANT DOSING INFORMATION**

- The compounded suspension may be a different concentration than the commercially available **Tamiflu® for Oral Suspension**, which has a concentration of 6 mg/mL.
- The pharmacist must convert the appropriate dose **from mg to mL** and dispense any

- compounded suspension of Tamiflu® with a dispensing device that measures volume in mL.
- If the prescription specifies the dose in teaspoons, a syringe calibrated in fractions of a teaspoon should be provided and the instructions adjusted accordingly.
- Specific compounding and dosing information is provided in the Tamiflu® package insert.

Additional TAMIFLU® product information is also available on the Roche Laboratories Inc. website at: <http://www.rocheusa.com/products/tamiflu/pi.pdf> and <http://www.tamiflu.com/hcp/dosing/extprep.aspx>

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**Dispensing** related questions should be directed to the Board of Registration in Pharmacy at 1-800-414-0168 or consult the Pharmacy Board website at [www.mass.gov/dph/boards/pharmacy](http://www.mass.gov/dph/boards/pharmacy).

Inquiries related to **physician prescribing** should be directed to the Board of Registration in Medicine at 1-781-876-8200 or consult [www.massmedboard.org](http://www.massmedboard.org).

Thank you for your attention to this important public health matter.