

The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
250 Washington Street, Boston, MA 02108-4619

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Determination and Order Pursuant to M.G.L.  
c. 111, s. 5A: Prescribing and Dispensing  
TAMIFLU® for Oral Suspension

Administration of oral suspension of oseltamivir (Tamiflu®) is essential in the interest of public health to reduce morbidity and mortality for individuals needing treatment for Influenza A H1N1 or chemoprophylaxis to prevent illness from suspected exposure to Influenza A H1N1;

An emergency exists by reason of a shortage of this antiviral medication in the normal distribution system.

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.

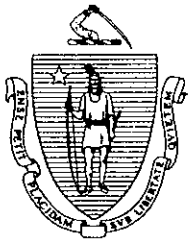
Notwithstanding any other provision of law, licensed pharmacies may compound and dispense oral suspensions of oseltamivir (Tamiflu®) where there is a prescription for oseltamivir (Tamiflu®) oral suspension and such suspension is not readily available to the pharmacy, as follows:

- such compounding and dispensing shall be in accordance with the Tamiflu® package insert and with Guidelines for Prescribing and Dispensing Tamiflu® issued jointly by the Boards of Registration in Medicine, Pharmacy, Nursing and Physician Assistants (Attachment A) as well as any subsequent guidelines, orders, rule and priorities established by the Massachusetts Department of Public Health 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 expressly authorize such compounding.

John Auerbach  
Commissioner  
Massachusetts Department of Public Health

11/5/09

Date



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ATTACHMENT A

To: Massachusetts Prescribers and Pharmacists

From: Board of Registration in Medicine  
Board of Registration in Nursing  
Board of Registration in Pharmacy  
Board of Registration of Physician Assistants

Date: November 6, 2009

Re: **GUIDELINES for Prescribing and Dispensing TAMIFLU®**

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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 (Tamiflu®) 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 Commissioner John Auerbach issued an Order on November 6, 2009, 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 (Tamiflu®) oral suspension utilizing the recipe in the Tamiflu® package insert (p.19).

### IMPORTANT DOSING INFORMATION

- The compounded suspension is a different concentration (15 mg/mL) than the commercially available **Tamiflu® for Oral Suspension**, which has a concentration of 12 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 provided in the Tamiflu® package insert includes:

### Volume of Oral Suspension (15 mg/mL) Needed to be Compounded Based on Patient's Weight

Body Weight (kg)	Body Weight (lbs)	Total Volume to Compound per patient (mL)
≤ 15 kg	≤ 33 lbs	30 mL
16 to 23 kg	34 to 51 lbs	40 mL
24 to 40 kg	52 to 88 lbs	50 mL
≥ 41 kg	≥ 89 lbs	60 mL

### Dosing Chart for Pharmacy-compounded Tamiflu®

Body Weight (kg)	Body Weight (lbs)	Dose (mg)	Volume per Dose (15 mg/mL)	Treatment Dose Required (for 5 days)	Prophylaxis Dose Required (for 10 days)
≤ 15 kg	≤ 33 lbs	30 mg	2 mL	2 mL twice daily	2 mL once daily
16 to 23 kg	34 to 51 lbs	45 mg	3 mL	3 mL twice daily	3 mL once daily
24 to 40 kg	52 to 88 lbs	60 mg	4 mL	4 mL twice daily	4 mL once daily
≥ 41 kg	≥ 89 lbs	75 mg	5 mL	5 mL twice daily	5 mL once daily

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>

### FDA Releases New Guidance for Compounding Multiple Prescriptions of Tamiflu Oral Suspension

To assist pharmacists in meeting demand during shortages of commercially manufactured Tamiflu Oral Suspension, the U.S. Food and Drug Administration (FDA) has released (October

31, 2009) **“Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions”**:

- <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm>

This FDA publication provides instructions for compounding the suspension in advance of receiving prescriptions when demand is high, a practice the FDA considers acceptable if the compounded amount is commensurate with the number of valid prescriptions reasonably anticipated by the pharmacy within 24 hours. The update includes instructions for compounding Tamiflu Oral Suspension in advance, as well as for storing, dispensing, and counseling patients regarding the medication. The FDA has also alerted pharmacists to ensure that the units of measure on the prescription instructions match the dosing device provided with the drug to avoid dosing errors, per **FDA Public Health Alert: Potential Medication Errors with Tamiflu for Oral Suspension** at:

- <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm183649.htm>

**Additional information to Pharmacists regarding FDA AUTHORIZATION on the USE OF EXPIRED TAMIFLU® Products**

Please be advised that the FDA has also issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu® for Oral Suspension in response to the Influenza public health emergency. The authorized lots of Tamiflu® for Oral Suspension (part of the Strategic National Stockpile) are listed on the FDA website ([www.fda.gov](http://www.fda.gov).) The lots have been tested through the federal government's Shelf-Life Extension Program. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless earlier terminated or extended. Pursuant to this EUA, Massachusetts pharmacists are authorized to dispense these products.

Additional information is available on the FDA website:

- Information for Healthcare Professionals - **Authorization of Use of Expired Tamiflu® for Oral Suspension**  
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm184770.htm>
- **FDA authorization letter** to CDC, July 14, 2009  
<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM143872.pdf>

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

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

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