



# Iowa Department of Public Health

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November 20, 2009

## FACT SHEET

### Guidelines for Distributing and Dispensing Antivirals from the State Stockpile

#### General Information

The IDPH has released antiviral medications from its stockpile of medical resources to local public health agencies. Tamiflu<sup>®</sup> for Oral Suspension is being released due to a national shortage of commercially available suspension. Tamiflu<sup>®</sup> capsules and Relenza<sup>®</sup> is being released for dispensing to underinsured and uninsured patients. IDPH Regional Epidemiologists are available to assist local public health agencies with questions regarding the antiviral medications. (*Memo from Mary Jones to Local Public Health Administrators*, November 19, 2009). Supportive documentation can be found on the HAN at

[https://www.iowahealthalert.org/btrs/documents/fall%202009%20novel%20influenza%20a%20\(h1n1\)/mitigation%20measures/antiviral%20medications/](https://www.iowahealthalert.org/btrs/documents/fall%202009%20novel%20influenza%20a%20(h1n1)/mitigation%20measures/antiviral%20medications/) .

#### Prescribing

Antivirals from the stockpile must be prescribed following the most current recommendations from the CDC. (*Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season*, October 16, 2009 - CDC website

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

#### Dispensing Partners

Local public health will be responsible to identify all dispensing partners within their respective county. Local public health will also be responsible for letting the health care providers within their county know where they can send patients to receive the antiviral medications released from the state stockpile.

#### Dispensing

Antivirals from the state stockpile must be dispensed in accordance with all current federal and state regulations. Antiviral medications from the state stockpile must be dispensed as a prescription medication. Antivirals from the state stockpile cannot be dispensed as “sample” medications.

#### Labeling

Antiviral medications released from the state stockpile must be labeled in accordance with Iowa Administrative Code 657: 6.10(1) (*IAC 657 - Labeling Requirements*).

#### Fees

No fees can be charged for the antiviral medications released from the state stockpile. If a private pharmacy is dispensing the antiviral medications, a dispensing fee not to exceed \$4.00 may be charged to the patient or their insurance provider. If the patient cannot pay the dispensing fee, the fee must be waived.

#### Data Entry

All dispensed antiviral medications released from the state stockpile must be entered into the Immunization Registry Information System (IRIS). If the agency dispensing the antiviral

medications are not IRIS users, the local public health agency will be responsible for entering the required information. Instructions for entering data are available on the HAN and IDPH webpage (*IRIS H1N1 Antiviral Instructions 10-30-09*).

### Tamiflu® for Oral Suspension

Tamiflu® for Oral Suspension released from the state stockpile will have a printed expiration date that has been exceeded. This suspension has received an extended expiration date from the FDA (*Stockpiled Antivirals at or Nearing Expiration*, October 31, 2009 – FDA website <http://www.fda.gov/newsevents/publichealthfocus/ucm15962.htm> ). The extended expiration date will be based on the suspension's lot number. The Iowa Board of Pharmacy (IBP) recommended not to re-label the suspension but to provide a memo from the IDPH and IBP explaining the extended expiration date (*Memo from IDPH and IBP to Recipient of Tamiflu® for Oral Suspension*, Nov 6, 2009). This memo must be provided to each patient the suspension released from the state stockpile is dispensed to. Tamiflu® for Oral Suspension released from the state stockpile should be dispensed to patients 2 years of age or less (*Use of Tamiflu® for Oral Suspension Memo from Dr. Quinlisk* Nov 20, 2009) regardless of their insurance status. Patients older than 2 years of age who cannot swallow a capsule can have a suspension compounded by a pharmacist (*Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions*, Nov 2, 2009 – FDA website <http://www.fda.gov/drugsafety/informationbydrugclass/ucm188629.htm> ) or by mixture Tamiflu® capsules with liquid by a parent or caregiver (*Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules*, Oct 28, 2009 – CDC website [http://www.cdc.gov/h1n1flu/antivirals/mixing\\_tamiflu\\_qa.htm](http://www.cdc.gov/h1n1flu/antivirals/mixing_tamiflu_qa.htm) ). The document titled *Emergency Use Authorization of Tamiflu®: Fact Sheet for Health Care Providers* (July 14, 2009) (CDC website [http://www.cdc.gov/h1n1flu/eua/Tamiflu%20HCP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/Tamiflu%20HCP%2010%2030%2009_FDA%20Authorized.pdf) ) must be provided to each health care provider dispensing Tamiflu® released from the state stockpile. The document titled *Emergency Use Authorization of Tamiflu®: Fact Sheet for Patients and Parents* (July 14, 2009) (CDC website [http://www.cdc.gov/h1n1flu/eua/Tamiflu%20PP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/Tamiflu%20PP%2010%2030%2009_FDA%20Authorized.pdf) ) Spanish version is available at CDC website [http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Tamiflu\\_30Oct2009.pdf](http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Tamiflu_30Oct2009.pdf) ) must be provided to each patient receiving Tamiflu® released from the state stockpile.

### Tamiflu® Capsules (75mg)

Tamiflu® capsules (75mg) released from the state stockpile is for dispensing to underinsured or uninsured patients. Guidance to assist in determining a patient's insurance status can be found in the *Memo from Mary Jones to Local Public Health Administrators*, November 19, 2009. Tamiflu® capsules (75mg) released from the state stockpile is being dispensed for prevention; the bottle of capsules must have a new label placed over the treatment instructions indicating the proper instructions for prevention. Replacement labels for prevention are provided with the Tamiflu® capsules in the manufacture's shipping case. The document titled *Emergency Use Authorization of Tamiflu®: Fact Sheet for Health Care Providers* (July 14, 2009) (CDC website [http://www.cdc.gov/h1n1flu/eua/Tamiflu%20HCP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/Tamiflu%20HCP%2010%2030%2009_FDA%20Authorized.pdf) ) must be provided to each health care provider dispensing Tamiflu® released from the state stockpile. The document titled *Emergency Use Authorization of Tamiflu®: Fact Sheet for Patients and Parents* (July 14, 2009) (CDC website [http://www.cdc.gov/h1n1flu/eua/Tamiflu%20PP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/Tamiflu%20PP%2010%2030%2009_FDA%20Authorized.pdf) ) Spanish version is available at CDC website [http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Tamiflu\\_30Oct2009.pdf](http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Tamiflu_30Oct2009.pdf) ) must be provided to each patient receiving Tamiflu® released from the state stockpile.

Relenza<sup>®</sup>

Relenza<sup>®</sup> released from the state stockpile is for dispensing to underinsured or uninsured patients. Guidance to assist in determining a patient's insurance status can be found in the *Memo from Mary Jones to Local Public Health Administrators*, November 19, 2009. The document titled *Emergency Use Authorization of Relenza<sup>®</sup>: Fact Sheet for Health Care Providers* (October 30, 2009) (CDC website

[http://www.cdc.gov/h1n1flu/eua/RELENZA%20HCP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/RELENZA%20HCP%2010%2030%2009_FDA%20Authorized.pdf) )

must be provided to each health care provider dispensing Relenza<sup>®</sup> released from the state stockpile. The document titled *Emergency Use Authorization of Relenza<sup>®</sup>: Fact Sheet for Patients and Parents/Caregivers* (October 30, 2009) (CDC website

[http://www.cdc.gov/h1n1flu/eua/RELENZA%20PP%2010%2030%2009\\_FDA%20Authorized.pdf](http://www.cdc.gov/h1n1flu/eua/RELENZA%20PP%2010%2030%2009_FDA%20Authorized.pdf)

Spanish version is available at CDC website

[http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Relenza\\_30Oct2009.pdf](http://www.cdc.gov/H1N1flu/EUA/pdf/es/Spanish%20PP%20Fact%20Sheet%20Relenza_30Oct2009.pdf) ) must be provided to each patient receiving Relenza<sup>®</sup> released from the state stockpile.