

EXHIBIT B – FAQ

Frequently Asked Questions about Ordering and Storing Antiviral Medications for Pandemic Influenza

After reading this information, if you have additional questions regarding the Antiviral Purchase Program, please e-mail them to: stockpile.publichealth@state.or.us and we will respond as soon as possible.

What is Pandemic Influenza?

Pandemic influenza is a global outbreak caused by a new influenza virus to which humans have no immunity. For more information on the difference between pandemic, seasonal and avian influenza, please see <http://www.oregon.gov/DHS/ph/acd/flu/panflu.shtml> . While novel H1N1 influenza, which appeared this spring, has not been classified as a pandemic, it appears to be transmitted readily from person to person and there are low levels of immunity to it, particularly in younger persons.

How are antiviral medicines used?

Influenza antiviral medications are used for *treatment* – to kill infection in people who are ill with influenza, or for *prophylaxis* - to prevent well people from getting ill from influenza. One antiviral treatment course is two pills a day for five days and must be given within 48 hours of symptom onset to be effective. For antiviral prophylaxis, individuals must take one pill a day for the *entire duration of their exposure to influenza* (i.e., during the entire pandemic period).

Who may order antiviral medicines under this program?

Federally recognized tribes and critical infrastructure organizations that are a part of the State's pandemic influenza plan (e.g., healthcare facilities, utilities, emergency services, etc.) may obtain a stockpile of Tamiflu® and/or Relenza®, at a reduced price (subsidized by the Federal Government), by purchasing them through the State of Oregon (subject to State and Federal approval). The drugs may only be used *during a declared influenza pandemic* and in accordance with the Oregon Public Health Plan and Public Health recommendations at the time of the pandemic. Currently, recommendations are for use of these medicines for treatment of ill employees or prophylaxis of critical employees.

To whom can we give the antiviral medicines?

Antiviral medications should be used in accordance with Public Health recommendations. These may change at the time of a pandemic, depending on the epidemiology of the disease. Currently, we recommend that antiviral medications be given for treatment of ill individuals, for instance, if an electrical utility wishes to ensure treatment of all of its employees within 48 hours of symptom onset. These medications may also be used for prophylaxis of critical employees (those whose contributions are necessary to carry out an organization's essential functions as defined in the *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, Section 4.2, page 20)¹.

¹ *Essential functions* are those that are absolutely necessary to keep a business operating during an influenza pandemic, and critical to survival and recovery. Please note: this does not include family members of critical employees.

How much will adult courses of Tamiflu and Relenza cost?

Medications purchased through this program are ordered by the treatment course; multiple treatment courses must be purchased to provide prophylaxis for an individual. Entities ordering Tamiflu will pay between \$14.43 and \$19.24 per treatment course, and entities ordering Relenza will pay between \$16.29 and \$21.72 per treatment course, depending on how much is ordered. There are no freight charges for pandemic antiviral stockpiles purchased through the federal contract.

Planning partners may also wish to purchase antiviral drugs directly from the wholesaler.

Are pediatric antiviral courses available for purchase?

Pediatric Tamiflu courses are now available for purchase under the federal contract; the price for a 45 mg pediatric treatment course is \$9.73; the price for a 30 mg pediatric treatment course is \$6.50. (Dosing depends on child's weight).

How many treatment courses of antiviral medication can I purchase?

Planning partners may purchase enough medication to ensure appropriate treatment and/or *targeted* prophylaxis of their employees and/or community members, as described in the Oregon Public Health Plan. Purchasers should understand that Public Health recommendations at the time of the pandemic should be followed (e.g., if the drugs are less effective, double treatment doses may be required, making it necessary to prioritize treatment).

When can I order the antiviral medication?

The State must submit orders for Tamiflu and Relenza by late August 2009 in order for the reduced price to apply. To allow processing and time to obtain DHHS approval, your application must be received by the State of Oregon on or before June 24, 2009.

How long will the antiviral medication last?

The shelf-life of adult and pediatric Tamiflu has been extended to 7 years. The shelf-life of Relenza is 5 years. There is no indication that Relenza's shelf-life will be extended.

What information must I provide to order antiviral medication?

An application is available to you on the Sate of Oregon's on-line purchasing system ORPIN. Please fill out the application, which includes requests for the following information:

1. A brief statement indicating:
 - a. How, during a pandemic, disruption of your services would negatively affect the health and well-being of Oregon citizens
 - b. How you will meet the storage requirements (requirements described below)

c. Because these medications require a medical provider prescription to be dispensed, please explain how you will provide medical oversight for the proper prescribing and tracking for the medication

2. Total number of employees
3. Total number of critical employees
4. Total number of Tamiflu (specify adult vs. pediatric) and/or Relenza courses needed for:
 - a. Treatment, and/or
 - b. Prophylaxis
5. Ship-to location (including contact name, delivery address, telephone and fax numbers)
6. "Bill to" address

How long will it take to receive the antiviral medication?

The State of Oregon plans to submit purchase orders to the Department of Health and Human Services by July. HHS must then approve the order, which will take an estimated 2-5 business days. Once approved, Roche is contracted to fill Tamiflu orders within 4 months of receipt*, and GlaxoSmithKline (GSK) is contracted to fill Relenza orders "as received".

*NOTE: If a State orders less than a full manufacturing lot of Tamiflu, the drug's delivery may be delayed until Roche has a full lot order (i.e., it may take up to several months after Roche receives the purchase order). HHS reports that actual shipping times have been within 6 weeks.

How must antiviral medications be stored?

These medications must be stored in a facility licensed by the Board of Pharmacy (unless held on Tribal lands), and should be held in a temperature-controlled facility that meets FDA criteria:

- Tamiflu® must be stored at temperatures between 59°F to 86°F (15°C to 30°C).
- Relenza® must be stored in this temperature range, 59°F to 86°F (15°C to 30°C), as well. (Do not puncture any Relenza Rotadisk® blister until taking a dose using the Diskhaler®).
- Antiviral medications should be kept in a locked room with limited access.

How much room is required to store the antiviral medication?

*Tamiflu*²

Tamiflu courses are stored in bottles - one course per bottle. The courses are shipped in cases on pallets:

- Each case contains 48 bottles
- Case Dimensions (L x W x H): 12.875" x 8" x 6.3125"
- Each pallet contains 108 cases, or 5,184 courses
- Pallet dimensions: Length, width, and height = 48" x 42" x 42"

Relenza

Relenza courses come in kits, with 5 rotadisks and 1 diskhaler per kit: one kit equals one course. These kits are also shipped on pallets:

- Each case contains 16 kits
- Case Dimensions (L x W x H): 17" x 6" x 9.25"
- Each pallet contains 60 cases, or 960 courses
- Pallet dimensions: Length, width, and height = 48" x 40" x 48"

² Please note: these dimensions do not apply to antiviral medication bought from wholesalers.