



MARK B HORTON, MD, MSPH  
*Director*

State of California—Health and Human Services Agency  
California Department of Public Health



ARNOLD SCHWARZENEGGER  
*Governor*

May 3, 2009

**INTERIM GUIDANCE ON DISTRIBUTION AND DISPENSING  
OF STATE AND FEDERAL ANTIVIRAL MEDICATIONS**

This guidance is intended to advise local health departments on antivirals provided from State and federal stockpiles. CDPH will continue to update this guidance as new information about the severity and geographic distribution of the virus is available.

The guidance that follows is based on the following assumptions:

- Antivirals will be available through normal wholesale and retail markets.
- State and federal antivirals are intended to be used as a last resort, when patients are not able to obtain them through third-party reimbursement. However, if there is a temporary local shortage of antivirals, any person needed antivirals should be served.
- It is the responsibility of local health departments to assess the needs of their community healthcare partners. When antivirals are not available, local health departments should assure that their community healthcare partners receive State and federally allocated antivirals to meet the needs of those patients that need them.

**ISSUE:** The supply of antivirals available through the State and federal stockpiles will not be sufficient to meet the needs during a pandemic, particularly if it extends over a prolonged period. Therefore, it is important to control the supply and use of influenza antiviral medications.

**BACKGROUND**

In an influenza pandemic, appropriate use of influenza antiviral medications may reduce morbidity and mortality and diminish the overwhelming demands that will be placed on the healthcare system.

California has access to 9 million courses of antivirals supplied by the State and federal governments, which would provide treatment for approximately 25 percent of Californians:

- CDPH has 3.7 million courses of the antiviral medications Tamiflu (oseltamivir) and Relenza (zanamivir) allocated for local health department proportionally, based on county population. When requested, CDPH has shipped these antivirals to local health departments.
- The federal government has 5.3 million treatment courses reserved for California. Twenty five percent has been shipped to California.

## **Interim Guidance on Distribution and Dispensing of State and Federal Antivirals**

Page 2

May 3, 2009

### **AVAILABILITY OF ANTIVIRAL MEDICATIONS THROUGH RETAIL SUPPLY**

This guidance assumes that Tamiflu and Relenza are available in adequate supply through the wholesale and retail markets. If antivirals are not available, local health departments should use their State and federal allocated antivirals to ensure that those who need antivirals receive them.

CDPH has talked to the Roche, the manufacturer of Tamiflu, and three major pharmaceutical wholesalers (Amerisource Bergen, McKesson and Cardinal Health) about the availability of antivirals. All companies reported the availability of adequate supplies to meet current needs and that availability is expected to increase in the next few weeks. They recommend that retail pharmacists/hospitals continue to contact their representatives for supplies. CDPH is requesting that local health departments notify CDPH if antivirals are not available in their jurisdiction.

The one exception to this appears to be pediatric oral suspension of Tamiflu, which is also in short supply in the State and federal stockpiles. The attached *Tamiflu Prescribing Information* provides detailed information on compounding liquid formulations of Tamiflu.

### **DISTRIBUTION OF ANTIVIRALS**

CDPH is responsible for distribution of the State and federal stockpiles of antivirals to local health departments. Local health departments, in turn, maintain and control the State and federal antiviral supply distributed to them and are responsible for distributing these products to local dispensing sites. Each local health department should use its antiviral distribution plan, developed as part of its pandemic planning, as needed for the current H1N1 outbreak to distribute antivirals to community partners.

Specific recommendations for distribution of antivirals are:

1. Community partners likely to be serving the populations unable to obtain antivirals through third party reimbursement:
  - Community healthcare clinics
  - Hospitals
  - Pharmacies
  - Tribal entities and Indian Health clinics
  - Military bases
2. If the county maintains inpatient and/or outpatient healthcare facilities, antivirals should be dispensed by those facilities.
3. If the county has a contract or agreement with specific providers, antivirals should be dispensed by that facility. (Many local Hospital Preparedness Program entities have existing agreements with healthcare facilities.)

## Interim Guidance on Distribution and Dispensing of State and Federal Antivirals

Page 3

May 3, 2009

4. Needs of State institutions, including State hospitals and correctional facilities, must be supported by State and federal antivirals.

### DISPENSING ANTIVIRALS

Clinical use of antivirals is addressed in separate guidance. (See [www.cdph.ca.gov](http://www.cdph.ca.gov) and <http://cdc.gov/h1n1flu/recommendations.htm>)

A prescription is required for either Tamiflu or Relenza. There are no waivers at this time relative to usual and customary prescribing and dispensing practices as required by state and federal laws and regulations.

State and federal antiviral drugs are intended to be dispensed when local stockpiles and commercially obtained supplies are not readily available. In order to ensure that antivirals are dispensed under appropriate controls, each local health department should ensure that the dispensing plan for its jurisdiction is adhered to at all prescribers and dispensing sites. This plan must recognize the need to dispense these antiviral medications without delay to those who may not be able to obtain them through other means (e.g., direct payment or use of the third-party reimbursed healthcare delivery system). Agreements with key providers to carry out this function are highly encouraged.

The attached prescribing information and patient information sheets should accompany each dispensed prescription.

### ADDITIONAL INFORMATION

1. Inventory control must be maintained by the local health department for all antivirals distributed to dispensing sites. Since these medications are being utilized under an approved EUA, local health departments are instructed to record lot numbers of antivirals distributed to each dispensing site. Dispensing sites should record the lot numbers dispensed each day.
2. Emergency Use Authorizations (EUAs) involving Tamiflu and Relenza were issued by the Food and Drug Administration (FDA) on April 27, 2009 and are attached. LHD SNS Coordinators should direct all questions related to EUAs to the following FDA email address: [EUA.OCET@fda.hhs.gov](mailto:EUA.OCET@fda.hhs.gov).

Adverse reactions should be reported through the voluntary U.S. Food and Drug Administration MedWatch System: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>