



**American Hospital
Association**

Quality Advisory

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CDC Issues Guidance on Flu Vaccine Shortage

A Message to America's Hospitals:

The sudden announcement last week that influenza vaccines would be in short supply due to contamination issues at British-based Chiron, one of the major vaccine manufacturers, took Americans and their caregivers by surprise – just as hundreds of flu shot clinics at physician offices, hospitals and community health outreach events across the country were scheduled to take place. This AHA Quality Advisory is designed to provide you with preliminary information from the Centers for Disease and Prevention (CDC) about how to handle the shortage of vaccines this flu season.

The absence of Chiron's scheduled 46-48 million doses leaves just under 56 million doses available for this year's flu season. Aventis Pasteur Inc. will provide approximately 54 million of them and another 1 to 2 million are expected to come from MedImmune's FluMist nasal spray. Both manufacturers have already shipped 33 million doses to vendors, suppliers and health care providers, and you may already have some in stock.

Vaccine Administration

Guidance issued by the CDC suggests that the existing flu vaccine be administered to those at greatest risk from the serious complications that can accompany the flu. These groups include:

- People 65 years and older
- Children 6 months to 23 months
- Adults and children 2 years and older with chronic lung or heart disorders, including heart disease and asthma
- Pregnant women
- Adults and children 2 years and older with chronic metabolic diseases (including diabetes), kidney diseases, blood disorders (such as sickle cell anemia), or weakened immune systems, including HIV/AIDS
- Children and teenagers, 6 months to 18 years, who take aspirin daily
- Residents of nursing homes and other chronic-care facilities
- Household members and out-of-home caregivers of infants under 6 months (Children under 6 months cannot be vaccinated.)
- Health care workers who provide direct, hands-on care to patients

More specific information on priority groups can be found in the attached CDC document, *Interim Influenza Vaccine Recommendations*. The CDC has requested that patients follow these guidelines on a voluntary basis and asked that those not included in the high-risk groups forego or defer vaccination. In a news conference earlier this week, Julie Gerberding, M.D., CDC director, called healthy Americans who voluntarily stepped aside so that higher-risk people could be vaccinated first “health heroes.” Also, the CDC has no intent to prioritize among these high-risk groups as to who should receive vaccinations first.

Vaccine Distribution

On October 12, the CDC and Aventis announced a two-phase plan to allocate the remaining unshipped 22.4 million doses to identified areas of need throughout the country. The CDC notice announcing the plan is attached. During Phase I distribution over the next six to eight weeks, 14.2 million doses will be allocated through Aventis contracts directly to high priority vaccine providers. Phase I distribution includes:

- All doses ordered through the Vaccines for Children (VFC) program
- All Aventis preservative-free doses, licensed for use in children under 3 years of age
- 50 percent of the non-VFC doses ordered by state and local health departments
- Doses ordered from Aventis by providers that care for young children or represent long-term care facilities or hospitals
- Doses ordered from Aventis by the Department of Defense
- Doses ordered from Aventis by the Veteran’s Administration
- Doses ordered from Aventis by the Indian Health Service

Dr. Gerberding said that during Phase II’s allocation of the remaining 8 million doses, the CDC will work with state and local health officials to identify high-priority needs, and map the delivery of flu vaccine at the county level to accurately determine where the vaccine has been sent as well as where flu outbreaks occur. CDC also will use BioSense, a new tool that tracks the sale of over-the-counter flu medications, and where and what laboratory tests are ordered, to determine areas of higher flu activity. This comprehensive picture will enable CDC to target the remaining doses to high-need areas.

The redistribution of vaccine already in the hands of health care providers is permitted under an exception to the Food, Drug and Cosmetic (FDC) Act that allows the Food and Drug Administration (FDA) to intervene for an “emergency medical reason.” The FDA has ruled that this year’s shortage qualifies for the exception, thus allowing hospitals or health care entities to redistribute vaccine supplies. Any hospital or health care entity wishing to redistribute their current vaccine supply to alleviate a shortage elsewhere must comply with the FDA’s current good manufacturing requirements. Information on proper handling, storage and shipping can be found at www.cdc.gov/nip/publications/vac_mgt_book.htm#flu. Hospitals should coordinate all requests for additional vaccines, as well as offers to redistribute surplus doses, with the local health department.

The news media has reported on recent flu vaccination price gouging. If you encounter such activities, contact your state attorney general. The CDC will be keeping tabs on price gouging as well. Forward information to Jim Harrison at the CDC at jharrison@cdc.gov.

CDC will publish additional information on the two-phase distribution plan in an upcoming Mortality and Morbidity Weekly Report, due out within the next week, and available at www.cdc.gov/mmwr. Additional information and guidance is available at www.cdc.gov/flu, or by calling the National Immunization Hotline at (800) 232-2522 (English); (800) 232-0233 (Spanish); or (800) 243-7889 (TTY).

As you prepare for this upcoming flu season, put the following items on your “To Do” list:

- ✓ Share this advisory with your infection control team, pharmacy staff, risk managers, and emergency department and medical staff.
- ✓ Work with your state and local health departments on vaccination plans for your community.
- ✓ Contact your vaccine vendor to determine the status of your supply. Be prepared to provide an estimate of doses needed to vaccinate high-risk populations in your community.
- ✓ Meet with local officials, including public health officials, and keep them up to date about flu vaccination activities and outbreaks. Ask them to help you help your community take steps to ensure the public health and well being of residents.
- ✓ Log onto www.cdc.gov/flu for more information and public materials on flu prevention guidance.

We’ll be working with CDC and others to provide you with the latest information on the flu vaccine.

Sincerely,

Dick Davidson
President

October 14, 2004