



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

October 29, 2009

Dear Health Care Provider:

This letter is to inform you that pursuant to Public Health Law (PHL) § 2112(4), I hereby authorize the use of influenza vaccines containing more than the mercury levels described in PHL § 2112 (2) and (3), due to insufficient amounts of vaccine containing the mercury levels described in said sections, as is necessary to respond to a disease outbreak. This authorization shall continue until May 1, 2010. All vaccinations should be given with the informed consent of the patient or the patient's parent or person otherwise authorized to consent..

New York State is currently experiencing a resurgence of the 2009 H1N1 influenza pandemic. The State's influenza activity level has been at "widespread," the highest category, for the past two weeks. Indicators of influenza activity including hospitalizations for confirmed influenza, emergency department visits for influenza-like-illness (ILI), sentinel provider reports of the proportion of patients with ILI, and laboratory reporting of positive influenza results are elevated in many areas of the state, greatly exceeding normal levels for this time of year. Most influenza identified by laboratories is the H1N1 strain, but some isolates of seasonal influenza are also being identified. High rates of school absenteeism are being reported in some communities and outbreaks on college campuses have been reported, with one death of a college student. There have been several other deaths reported due to influenza, including the death of a pregnant woman. This level of influenza activity is very unusual for this time of year and indicates that the H1N1 pandemic is not lessening and may be accelerating in New York State.

Young children and pregnant women are documented to be at greater risk of severe disease outcomes from influenza in general, and H1N1 influenza in particular. The epidemiology of H1N1 infections in New York State last spring showed that children under age five years had rates of confirmed H1N1 infection of about five per 100,000, which was almost twice the infection rate in persons age five to 24 years, and five times the rate for persons 25 years of age and older. Children under age five years had rates of hospitalization more than eight times that for persons age five to 24 years of age and 14-20 times higher than for older persons. Nine deaths were reported in the spring in children under age 18 years. According to the federal Centers for Disease Control and Prevention (CDC), pregnant women are at increased risk of complications and death from H1N1 influenza. Pregnant women have experienced a four-fold higher rate of hospitalization and a six-fold higher death rate than the general population due to H1N1 infection.

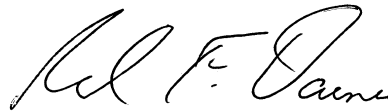
Supplies of both the 2009 seasonal trivalent and 2009 H1N1 monovalent vaccines are inadequate to meet the immediate need to vaccinate all persons who seek vaccination including young children and pregnant women. On October 14, 2009, the CDC issued an update on the

availability of the 2009 trivalent seasonal influenza vaccine. The CDC update stated that, "Because the total number of doses that will be made this year is approximately the same as the number of doses that were actually administered last year, an increase in demand cannot be met this season." The New York State Department of Health (DOH) has received numerous calls from hospitals, other regulated facilities, county health departments, and members of the public about difficulty in obtaining seasonal influenza vaccine.

Supplies of monovalent 2009 H1N1 influenza vaccine have become available from the federal government in the last three weeks. According to CDC, only six million doses of thimerosal-free influenza vaccine for children under three years of age will be available nationally. New York State's per capita share of these doses is approximately 378,000 doses. This is only enough to vaccinate 26 percent of the estimated 723,851 children in this age group (2007 data) with the recommended two doses. In addition, CDC indicates that substantial supplies of the pediatric thimerosal-free formulation will not start to be available until mid- to late November, while H1N1 disease is accelerating in the state now.

For these reasons, I have determined that there will be insufficient supplies of 2009 seasonal trivalent and 2009 H1N1 monovalent vaccines that contain the mercury levels set forth in PHL §2112 (2) related to children under three years of age and (3) related to pregnant women. Therefore, the authorization for the use of vaccine containing more than the mercury levels set forth in said sections is necessary to protect the public health.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard F. Daines".

Richard F. Daines, M.D.
Commissioner of Health

Enclosure (PHL § 2112)