

New York State (NYS) Law Restricting Use of Thimerosal-Containing Influenza Vaccines **New York State Department of Health**

Section 2112 of the NYS Public Health Law (PHL), effective July 1, 2008, requires health care providers to use vaccines that do not contain more than trace amounts of thimerosal when vaccinating children less than 3 years of age and pregnant women, with certain exceptions. Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them. PHL § 2112 requires that the Commissioner of Health make a yearly determination that there is an adequate supply of influenza vaccine that contains not more than 1.25 micrograms of mercury per 0.50 milliliter dose for women who know they are pregnant and not more than 0.625 micrograms of mercury per 0.25 milliliter dose for children less than 3 years of age. In the event of late failure of influenza vaccine production, it may be necessary for the Commissioner to modify this determination. Injectable influenza vaccines are the only routinely recommended childhood vaccines whose use is restricted by PHL § 2112.

Health care providers serving patients less than 3 years of age and pregnant women are expected to seek out influenza vaccine, both seasonal influenza vaccine and 2009 H1N1 influenza vaccine, that complies with PHL § 2112. If providers cannot obtain vaccine that complies with PHL § 2112, they must document the attempts that were made to locate and obtain the vaccine. They should also contact their local health department, the New York State Department of Health (NYSDOH) or the New York City Department of Health and Mental Hygiene (NYCDOHMH) at the numbers provided below to discuss their inability to obtain this influenza vaccine.

If providers have in good faith sought out seasonal or 2009 H1N1 influenza vaccine that complies with PHL § 2112, but cannot obtain such vaccine, vaccination of children under 3 years and pregnant women is still recommended. The substantial risk of complications or death from influenza in these groups outweighs the unproven risk of vaccination with thimerosal-containing vaccine. PHL § 2112 requires that the parent/guardian of a person under three years of age or the pregnant woman provide informed consent to the administration of such vaccine. Informed consent can either be obtained in writing or verbally. Providers should note verbal informed consent in the medical record.

The NYSDOH emphasizes that, if thimerosal-free vaccine is not available, pregnant women and the parents and guardians of children less than 3 years of age should not wait for influenza vaccine that complies with PHL § 2112 to immunize themselves or their children. Waiting could allow for exposure to influenza disease and could result in illness, hospitalization and even death.

Providers should remind patients that, after multiple scientific studies and an extensive review by the Institute of Medicine, there is no evidence that thimerosal causes harm. Three leading federal agencies [the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health] have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. There is no scientific evidence of harm caused by the low doses of thimerosal in influenza vaccines. Three independent organizations [The National Academy of Sciences' Institute of Medicine, Advisory Committee on Immunization Practices, and the American Academy of Pediatrics] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines. **The known risk of disease from lack of vaccination far outweighs the risk of harm, if any, from thimerosal. In the 2008-2009 influenza season, the NYSDOH received reports of at least 6 deaths in unvaccinated children caused by influenza.**

Additional information regarding vaccine safety, including the use of thimerosal in vaccines, can be obtained at the CDC's National Center for Immunization and Respiratory Diseases website at: <http://www.cdc.gov/vaccines/> and at the website of the U.S. Food and Drug Administration at <http://www.fda.gov/cber/vaccine/thimerosal.htm>.

Additional information about PHL § 2112 can be found at: http://www.health.state.ny.us/regulations/public_health_law/section/2112/information_for_physicians/

For further information, please contact your local health department or your regional NYSDOH Immunization Program at the following numbers:

Western Regional Office

Buffalo: 716-847-4385

Rochester: 585-423-8014

Central New York Regional Office

Syracuse: 315-477-8164

Herkimer: 315-866-6879

Capital District Regional Office

Troy: 518-408-5278

Oneonta: 607-432-2890

Metropolitan Area Regional Office

New Rochelle: 914-654-7149

Central Islip: 631-851-3096

Providers and facilities in New York City should contact:

The New York City Department of Health and Mental Hygiene: 212-676-2323.