



# 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*

Wendy E. Saunders  
*Chief of Staff*

August 19, 2008

**TO:** Providers, Hospitals, and Local Health Departments

**FROM:** New York State Department of Health, Bureau of Communicable Disease Control,  
Immunization Program

**HEALTH ADVISORY: 2008-2009 INFLUENZA SEASON VACCINE SUPPLY  
DETERMINATION AS REQUIRED BY PUBLIC HEALTH LAW §2112**

**Please distribute to the Infection Control Department, Emergency Department, Employee  
Health Service, Infectious Disease Department, Director of Nursing, Medical Director,  
Pharmacy Department, Pediatrics, Obstetrics and all primary care providers.**

Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal, a mercury-containing preservative, to children less than 3 years of age and women who know they are pregnant, with certain exceptions. This law requires that the Commissioner of Health make a yearly determination as to whether there exists 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. The Commissioner of Health has determined that, as of August 15, 2008, there appears to be an adequate supply of such influenza vaccine for vaccination of pregnant women. **Therefore, providers who plan to provide influenza vaccine to women who know they are pregnant are required to use influenza vaccine that complies with PHL §2112.** In the event of late failure of vaccine production, it may be necessary for the Commissioner to modify this determination.

In addition, there also appears to be an adequate supply of influenza vaccine that contains not more than 0.625 micrograms of mercury per 0.25 milliliter dose for vaccination of children less than 3 years of age. Providers who plan to provide influenza vaccine to children less than 3 years of age are also required to use influenza vaccine that complies with PHL §2112.

Providers are expected to seek out vaccine that complies with PHL §2112. However, in those instances when providers have in good faith sought out influenza vaccine that complies with PHL §2112 but such vaccine cannot be obtained, vaccination of children under 3 years old and pregnant women is still recommended (with informed consent) because the substantial risk of complications or death from influenza disease in these groups outweighs the unproven risk of vaccination with thimerosal-containing vaccine.

An official notification about PHL §2112 was released on April 23, 2008, in the form of a Health Advisory and can be viewed at:

[https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423\\_0.pdf](https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423_0.pdf).

**Additional Information**

Additional information regarding vaccine safety, including the use of thimerosal in vaccines, can be obtained at the Center for Disease Control and Prevention’s National Immunization Program website at <http://www.cdc.gov/od/science/iso/> and at the website of the U.S. Food and Drug Administration at <http://www.fda.gov/cber/vaccine/thimerosal.htm>.

For further information, please contact your local health department or your regional New York State Department of Health Immunization Program representative at the following:

**Western Regional Office**

Buffalo: 716-847-4385

Rochester: 585-423-8114

**Capital District Regional Office**

Troy: 518-408-5278

Oneonta: 607-432-2890

**Central New York Regional Office**

Syracuse: 315-477-8164

Herkimer: 315-866-6879

**Metropolitan Area Regional Office**

New Rochelle: 914-654-7149

Central Islip: 631-851-3096

For questions about ordering vaccine in New York State (outside of New York City), Vaccines for Children (VFC) providers can call 518-474-2506 during business hours.

Providers and facilities in **New York City** should contact the New York City Department of Health and Mental Hygiene at 212-676-2323. For questions about ordering vaccine in New York City, VFC providers can call 212-447-8175 during business hours.

**New York State Public Health Law §2112**  
**Important Information for Physicians Caring for Children Less Than 3 Years of Age**

**What is Public Health Law §2112?**

Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal, a mercury-containing preservative, to women who know they are pregnant and children less than three years of age, with certain exceptions.

**What is thimerosal?**

Thimerosal is an organic compound containing approximately 49% ethyl mercury and has been used in some vaccines and other products since the 1930s. Since 2001, with the exception of some influenza vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines. In addition, there are thimerosal-free preparations for most vaccines recommended for adults. Multiple scientific studies and an extensive review by the Institutes of Medicine have shown no evidence of adverse health effects due to thimerosal.

**How do you define “trace” amounts of mercury?**

For the purposes of this law, the definition of the term “trace” depends on the type of vaccine. For children less than 3 years old, an influenza vaccine may contain no more than 0.625 micrograms of mercury per 0.25 milliliter dose. All other vaccines may contain no more than 0.5 micrograms of mercury per 0.5 milliliter dose.

**What should I do differently in my practice?**

Plan ahead when ordering vaccines. Order a sufficient supply of thimerosal-free or single-dose preparations of influenza vaccine and other vaccines to adequately immunize your patients less than 3 years old. If you stock both thimerosal-free and thimerosal-containing vaccines to immunize your patients, consider reserving thimerosal-free doses for your patients less than 3 years old to ensure that sufficient doses of vaccine that are compliant with the law are available to vaccinate these individuals.

**What should I do if I have already ordered vaccine that does not comply with PHL §2112?**

If you have already placed your influenza vaccine order for the 2008-2009 season, the vaccine manufacturers have stated that orders can still be changed. Please call the vaccine manufacturer you placed your order with to change your order to vaccine that complies with PHL §2112.

**There have been vaccine shortages in the past. What do I do if I can't get vaccines that comply with PHL §2112?**

If vaccine that complies with the law is not available for distribution in the state, the State Commissioner of Health can authorize the use of other vaccines.

If the State Commissioner of Health has not authorized the use of other vaccines, you are expected to seek out vaccine that complies with PHL §2112. In instances when you have

sought out vaccine with no more than trace amounts of thimerosal but such vaccine cannot be obtained, you must document the attempts that were made to locate and obtain this vaccine, and should contact the New York State Department of Health (NYSDOH) or the New York City Department of Health and Mental Hygiene at the phone numbers provided below to discuss your inability to obtain the vaccine.

**Is there anything special I must do if I need to give vaccines that have more than a trace amount of thimerosal?**

Children less than 3 years of age should still be vaccinated. Before you administer a vaccine that contains more than trace levels of thimerosal, informed consent from the parent/guardian must be obtained. Informed consent should be documented. A consent form may be used, or consent may be documented in a notation in the patient's medical record or on the immunization record.

Federal law requires that you provide the patient's parent/guardian with the most current vaccine information statement (VIS). The VIS for influenza vaccine contains information on thimerosal and mercury used in the vaccine and can be used as background information for the purpose of obtaining informed consent. The information contained in the influenza VIS concerning thimerosal can also be helpful when obtaining informed consent prior to administering other vaccines that contain more than trace amounts of mercury. The influenza VIS can be obtained at [http://www.immunize.org/vis/vis\\_fluinactive.asp](http://www.immunize.org/vis/vis_fluinactive.asp).

**What about disease outbreaks in my community? Will there be enough vaccine?**

The State Commissioner of Health may authorize the use of vaccines containing more than trace amounts of thimerosal, including influenza vaccine, for children less than three years of age when it is necessary to prevent or respond to an outbreak of disease and there are insufficient amounts of vaccine available that contain only trace amounts of thimerosal. During an outbreak, informed consent is not required.

**How do I counsel parents/guardians about the risk of thimerosal?**

It is important to emphasize with parents/guardians that, after multiple scientific studies, there is no evidence that thimerosal causes harm to patients. The real risk of disease from lack of vaccination far outweighs the unproven risk of harm, if any, from thimerosal. For example, the risk of complications due to influenza disease among children less than 3 years old is high. Providers should administer available influenza vaccine to these patients.

**Where can I get more information?**

An official notification about PHL §2112 was released on April 23, 2008, in the form of a Health Advisory and can be viewed at:

[https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423\\_0.pdf](https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423_0.pdf)

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

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

**Western Regional Office**

Buffalo: 716-847-4385

Rochester: 585-423-8114

**Capital District Regional Office**

Troy: 518-408-5278

Oneonta: 607-432-2890

**Central New York Regional Office**

Syracuse: 315-477-8164

Herkimer: 315-866-6879

**Metropolitan Area Regional Office**

New Rochelle: 914-654-7149

Central Islip: 631-851-3096

For questions about ordering vaccine in New York State (outside of New York City), Vaccines for Children (VFC) providers can call 518-474-2506 during business hours.

Providers and facilities in **New York City** should contact the New York City Department of Health and Mental Hygiene at 212-676-2323. For questions about ordering vaccine in New York City, VFC providers can call 212-447-8175 during business hours.

**New York State Public Health Law §2112**  
**Important Information for Physicians Caring for Pregnant Women**

**What is Public Health Law §2112?**

Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal, a mercury-containing preservative, to women who know they are pregnant and children less than three years of age, with certain exceptions.

**What is thimerosal and does it have any risk?**

Thimerosal is an organic compound containing approximately 49% ethyl mercury and has been used in some vaccines and other products since the 1930s. Since 2001, with the exception of some influenza vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines. In addition, there are thimerosal-free preparations for most vaccines recommended for adults. Multiple scientific studies and an extensive review by the Institutes of Medicine have shown no evidence of adverse health effects due to thimerosal.

**How do you define “trace” amounts of mercury?**

For the purposes of this law, the definition of the term “trace” depends on the type of vaccine. For pregnant women, an influenza vaccine may contain no more than 1.25 micrograms of mercury per 0.5 milliliter dose. All other vaccines may contain no more than 0.5 micrograms of mercury per 0.5 milliliter dose.

**What should I do differently in my practice?**

Plan ahead when ordering vaccines. Order a sufficient supply of thimerosal-free or single-dose preparations of influenza vaccine and other vaccines to adequately immunize your pregnant patients. If you stock both thimerosal-free and thimerosal-containing vaccines to immunize your patients, consider reserving thimerosal-free doses for your pregnant patients to ensure that sufficient doses of vaccine that are compliant with the law are available to vaccinate these individuals.

**What should I do if I have already ordered vaccine that does not comply with PHL §2112?**

If you have already placed your influenza vaccine order for the 2008-2009 season, the vaccine manufacturers have stated that orders can still be changed. Please call the vaccine manufacturer you placed your order with to change your order to vaccine that complies with PHL §2112.

**Should I be performing pregnancy tests on all of my patients before giving vaccines?**

No. This law only applies to women who know they are pregnant. It is not necessary to test women for pregnancy before administering influenza vaccine or other vaccines that contain more than a trace amount of mercury.

**There have been vaccine shortages in the past. What do I do if I can't get vaccines that comply with PHL §2112?**

If vaccine that complies with the law is not available for distribution in the state, the State Commissioner of Health can authorize the use of other vaccine. For the influenza vaccine, the Commissioner will make a yearly determination as to whether there is an adequate supply of vaccine that complies with the law.

If the State Commissioner of Health has not authorized the use of other vaccines, or has determined that there is an adequate supply of influenza vaccine that complies with the law, you are expected to seek out vaccine that complies with PHL §2112. In instances when you have sought out vaccine with no more than trace amounts of thimerosal but such vaccine cannot be obtained, you must document the attempts that were made to locate and obtain this vaccine, and should contact the New York State Department of Health (NYSDOH) or the New York City Department of Health and Mental Hygiene at the phone numbers provided below to discuss your inability to obtain the vaccine.

**Is there anything special I must do if I need to give vaccines that have more than a trace amount of thimerosal?**

Pregnant women should still be vaccinated. Before you administer a vaccine that contains more than trace amounts of thimerosal, you must obtain informed consent from the pregnant woman. Informed consent should be documented. A consent form may be used, or consent may be documented in a notation in the patient's medical record or on the immunization record.

Federal law requires that you provide the patient with the most current vaccine information statement (VIS). The VIS for influenza vaccine contains information on thimerosal and mercury used in the vaccine and can be used as background information for the purpose of obtaining informed consent. The information contained in the influenza VIS concerning thimerosal can also be helpful when obtaining informed consent prior to administering other vaccines that contain more than trace amounts of mercury. The influenza VIS can be obtained at [http://www.immunize.org/vis/vis\\_fluinactive.asp](http://www.immunize.org/vis/vis_fluinactive.asp).

**What about disease outbreaks in my community? Will there be enough vaccine?**

The State Commissioner of Health may authorize the use of vaccines containing more than trace amounts of thimerosal, including influenza vaccine, for pregnant women when it is necessary to prevent or respond to an outbreak of disease and there are insufficient amounts of vaccine available that contain only trace amounts of thimerosal. During an outbreak, informed consent is not required.

**How do I counsel my patients about the risk of thimerosal?**

It is important to emphasize with patients that, after multiple scientific studies, there is no evidence that thimerosal causes harm to patients. The real risk of disease from lack of vaccination far outweighs the unproven risk of harm, if any, from thimerosal. For example, the risk of complications due to influenza disease among pregnant women is high. Providers should administer available influenza vaccine to these patients.

**Where can I get more information?**

An official notification about PHL §2112 was released on April 23, 2008, in the form of a Health Advisory and can be viewed at:

[https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423\\_0.pdf](https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423_0.pdf).

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

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

**Western Regional Office**

Buffalo: 716-847-4385

Rochester: 585-423-8114

**Capital District Regional Office**

Troy: 518-408-5278

Oneonta: 607-432-2890

**Central New York Regional Office**

Syracuse: 315-477-8164

Herkimer: 315-866-6879

**Metropolitan Area Regional Office**

New Rochelle: 914-654-7149

Central Islip: 631-851-3096

For questions about ordering vaccine in New York State (outside of New York City), Vaccines for Children (VFC) providers can call 518-474-2506 during business hours.

Providers and facilities in **New York City** should contact the New York City Department of Health and Mental Hygiene at 212-676-2323. For questions about ordering vaccine in New York City, VFC providers can call 212-447-8175 during business hours.