



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 14, 2009

TO: All Medical Providers and Health Care Facilities

FROM: NYSDOH Bureau of Immunization

| **HEALTH ADVISORY: 2009 H1N1 Influenza Vaccine Information #2** |
| **Please distribute to the Infection Control Department, Medical Director, Director of** |
Nursing, Emergency Department, Employee Health, and all patient care areas

This is the second advisory providing information on the 2009 H1N1 influenza vaccine and its purpose is to provide additional information on the vaccine campaign. Please keep in mind that this information is the best that is known at this time. Since this is a rapidly evolving situation, the information provided can change. Updates will be provided when new information is available.

Topics Covered:

1. 2009 H1N1 Influenza Vaccine Has Been Approved and Licensed
2. The Results of Clinical Trials To Date
3. The Timing of Administration of Seasonal Influenza Vaccine and the 2009 H1N1 Influenza Vaccine
4. The First Doses of 2009 H1N1 Influenza Vaccine Are Available the First Week in October
5. How to Order Vaccine
6. The Provider Agreement
8. Planned Vaccine Rollout
9. Reimbursement
10. Reporting Requirements
11. Liability Protection Afforded by the Public Readiness and Emergency Preparedness Act
12. Vaccinating Individuals Who Are Not Established Patients
13. Vaccinating Those Who Have a History of an Influenza-Like Illness.
14. Concern About Giving Seasonal Influenza Too Early and Waning Immunity
15. New York State Department of Health Hotlines Are Available for Questions

1. 2009 H1N1 Influenza Vaccine Has Been Approved and Licensed

In September 2009, the Food and Drug Administration (FDA) licensed four 2009 H1N1 influenza vaccines. This includes the vaccines made by the following manufacturers: CSL Biopharmaceuticals, MedImmune, Novartis, and Sanofi Pasteur. The vaccine being produced by GlaxoSmithKline has not been licensed yet. In general, the vaccine has been licensed for one dose for those 10 years of age and older and two doses, 28 days apart, for those 9 years of age and younger. Some formulations of the vaccine will not be licensed for all ages.

2. The Results of Clinical Trials To Date

Clinical trials on the 2009 H1N1 influenza vaccine are ongoing. So far, the results have shown that one dose creates a robust antibody response in individuals 10 years of age and older. Younger children and infants have a lessened response after one dose and so two doses are required in these age groups. The interval between the two doses is approximately one month or 28 days.

The trials have shown that the safety profile and the observed side effects are similar to the seasonal influenza vaccine. The observed symptoms include redness and swelling at the site of injection, aches, and low grade fever. This is to be expected since the 2009 H1N1 is made exactly like the seasonal influenza except that a different strain is included. Further results of the clinical studies will be forthcoming throughout the influenza season. It is important to note two things: 1) as with most pre-marketing trials, these trials are too small to pick up very rare adverse events and 2) more studies are being conducted on the 2009 H1N1 vaccine than are usually completed each year on the seasonal influenza vaccine.

3. The Timing of Administration of Seasonal Influenza Vaccine and the 2009 H1N1 Influenza Vaccine

Seasonal influenza vaccine can be given at the same time as the 2009 H1N1 vaccine, except that the seasonal live attenuated influenza vaccine (LAIV) and the H1N1 LAIV (nasal spray vaccines) cannot be given at the same time. Either one of the nasal spray vaccines can be given at the same time as one of the injectable vaccines, or, both injectable vaccines can be given at the same time at different sites. When administering both LAIVs to an individual, the interval between the two different LAIVs is approximately one month or 28 days. The interval between the first and the second doses of the 2009 H1N1 influenza vaccine is also about one month or 28 days for those 9 years of age and younger.

4. The First Doses of 2009 H1N1 Influenza Vaccine Are Available the First Week in October

The Centers for Disease Control and Prevention (CDC) have announced that the 2009 H1N1 live attenuated influenza vaccine (LAIV), the nasal spray, will be delivered throughout the nation as a whole during the week of October 5th. The NYSDOH placed the first orders on September 30 for doses to go to hospitals, local health departments, and federally qualified health centers. The second orders placed this week, the week of October 5-9 include more LAIV, pre-filled syringes of 0.5 ml, and multi-dose vials of 10 doses each. These doses of vaccine will go to obstetrical and pediatric practices, along with the same sites that received the vaccine the first week of distribution. Subsequent doses will be delivered to private medical offices, pharmacies, colleges and universities, and other sites as well.

5. How to Order 2009 H1N1 Influenza Vaccine

Vaccine will continue to become available throughout the fall and winter, into 2010. However, not all types and formulations will be available at all times. The NYSDOH will begin taking requests for vaccine from private providers on or after October 19th. Initially, it will not be possible to fill all orders, and requests will be prioritized by county, size of the practice, and the target groups that are served. Providers that are flexible about which type of vaccine they will accept will be able to receive vaccine sooner.

Vaccine orders will be accepted by calling the same phone number that is used by the Vaccines for Children Program (VFC) for receiving vaccine orders: 1-800-KID-SHOT or 1-800-543-7468. The ability to order vaccine will be phased in and those who are pre-registered will be notified when they can begin to place orders. Those who have already registered have specified amounts of vaccine that they would like to receive. These requests are not orders, but may be used to direct some vaccine to practices before the ordering system is operational. However, practices will need to place orders with the NYSDOH and will be directed when it is possible to do so.

Ancillary supplies, needles, syringes, alcohol swabs, and sharps containers will be shipped for use with the vaccine. Ancillary supplies are expected to arrive before or with the vaccine, however, so far some of these supplies have arrived after the vaccine. Please remain flexible about the use of ancillary supplies. You may want to borrow from your own supply rather than wait to give the vaccine for Federal supplies to arrive.

Providers who want to order vaccine in the future must be pre-registered with the NYSDOH and must sign a provider agreement (see number 6 below). The website for pre-registration is <https://hcsteamwork1.health.state.ny.us/pub/top.html>.

6. The Provider Agreement

Each site that wishes to receive and give 2009 H1N1 vaccinations must have a signed provider agreement associated with it. The provider agreement specifies the conditions under which the vaccine must be administered. Any person who is able to bind the facility or practice that will receive and give the vaccine can sign the agreement. A person with a medical license number needs to be entered at the same time that the agreement is signed.

Key points covered in the provider agreement include:

- The 2009 H1N1 influenza vaccine must be administered according to the recommendations of CDC's Advisory Committee on Immunization Practices (ACIP);
- The vaccine must be stored and handled in accordance with the package insert;
- A current Vaccination Information Statement (VIS) must be provided to each individual before vaccination;
- A record of vaccination must be maintained for at least three years;
- All adverse reactions must be reported to the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967 or by going to <http://vaers.hhs.gov/esub/index>;
- A fee cannot be charged to patients or health insurance plans for the vaccine or the supplies that accompany it, nor can they be sold;
- The provider can charge a patient or a health insurance plan for the administration fee;
- The vaccine can be provided for free for those that cannot afford the administration fee;
- The number of doses given and the number of doses expired or wasted must be reported to the NYSDOH;

- The vaccine record card provided by the CDC should be used as an immunization record and be given to the recipient; and
- All doses administered to those 18 years of age and younger must be reported to the New York State Immunization Information System (NYSIIS).

The provider agreement can be accessed by going to the pre-registration website of the NYSDOH at <https://hcsteamwork1.health.state.ny.us/pub/top.html>. If a provider has already pre-registered it is necessary to return to the website and electronically sign the provider agreement by clicking the appropriate button. Information on the shipping address at which the vaccine will be received can also be provided at the website.

7. Vaccine distribution in New York State Outside of New York City

The NYSDOH was able to place the first orders for 90,400 doses of 2009 H1N1 influenza vaccine on September 30 for the State outside of New York City (NYC). NYC was able to order its own vaccine as were all other states. The first doses were all the intra-nasal vaccine. Because of the small number of doses and the short time frame, vaccine was ordered for hospitals, Federally Qualified Health Centers (FQHCs), and local health departments (LHDs). The nasal spray H1N1 vaccine can be used for otherwise healthy persons 2-24 years of age, along with health care workers and caregivers of infants (under 6 months of age) who are ages 25-49 years, not pregnant, and otherwise healthy.

Orders were placed the week of October 5th for doses of the nasal spray vaccine, pre-filled syringes for those 3 years of age and up, and multi-dose vials. These doses will be directed toward obstetric and pediatric practices along with hospitals, FQHCs, and LHDs.

8. Planned vaccine roll out

The CDC has given a tentative schedule for vaccine distribution over the coming weeks. It appears that vaccine will become more widely available the last week in October and early November. Medical practices can expect to receive doses for use in their offices around that time. Distribution will continue thereafter each week into January, if there is demand for it.

All projections for vaccine supply remain tentative, however, and medical practices need to be patient and flexible about receiving vaccine.

The following table shows the approximate amounts that may be available for order for New York State (outside NYC):

Week of Order	Week of Receipt	Pre-filled Syringes: .25cc (7.5 ug)	Pre-filled Syringes: .50cc (15 ug)	10-dose Vials	LAIV Nasal Spray
October 5-9	October 12-16	0	8,400	64,000	56,000
October 12-16	October 19-23	0	131,250	266,000	142,660
October 19-23	October 26-30	14,000	201,000	336,000	52,500
October 26-30	November 2-6	98,000	94,500	217,000	52,500

9. Reimbursement

Vaccine and the supplies needed to give the vaccine, alcohol swabs, syringes, needles, and sharps containers, will be supplied at no cost by the Federal government. The administration fee will be covered in a variety of ways. The administration fee will be covered by Medicare and Medicaid, and is expected to be covered by most private insurances. The New York State Insurance Department and the NYSDOH have issued a joint letter calling for all insurers to cover the administration fee. In addition, practices can charge a patient for an administration fee, however, that fee cannot be more than the regional administration fee reimbursement that Medicare provides. If vaccines are given in a venue that is using funds supplied by the Federal government to cover pandemic influenza expenses, no cash payments of any sort can be charged.

Practices cannot charge or bill more than the regional Medicare rate:

- Long Island \$25.49
- Poughkeepsie \$22.05
- The Rest of NYS \$19.57

Uninsured and underinsured persons can be vaccinated in private practices by either charging an administration fee or providing the vaccine at no cost to the patient. In addition, those who do not have insurance or are underinsured can receive their vaccine from their local health department.

10. Reporting Requirements

Vaccinators must report all doses administered by age and the amounts of vaccine that were wasted to the NYSDOH each week.

- Doses provided to those who are **18 years of age and younger** must be entered into the New York State Immunization Information System (NYSIIS) as required by Public Health Law 2168. All doses administered can be tracked using NYSIIS. No patient consent to report is needed for patients 18 years and younger.
- For doses provided to patients **19 years of age and older**, there are two ways to report. Each dose administered must be reported using one of these methods. Vaccinators may use either or both ways to report from their site:
 - Doses administered can be entered into NYSIIS, but consent must be obtained from each patient to report adult patient information into NYSIIS.
 - Doses can be reported weekly by using a phone reporting system developed by the NYSDOH. The phone number for this system is 1-888-H1N1-VAC (1-888-416-1822). Until the phone number is activated, vaccinators can use a tally sheet that is provided as a template on the H1N1 page of the NYSDOH public website.

Doses administered and the amount of vaccine wasted or expired must be reported by the close of business on Monday for the week ending the Saturday before. The NYSDOH will report the information for the entire state to CDC each Tuesday.

11. Liability Protection Afforded by the Public Readiness and Emergency Preparedness (PREP) Act.

The Prep Act provides liability protection to all those who administer the 2009 H1N1 influenza vaccine. The only exception is for those medical providers or vaccinators that perform willful misconduct. Signing the provider agreement is necessary for protection under the PREP Act. For more information on the PREP Act, please see the documents that are attached at the end of this advisory.

12. Vaccinating Persons Who Are Not Established Patients

The NYSDOH wants to encourage medical providers of all types to consider vaccinating those who present to them who are not established patients. This may include family members of patients, caregivers of patients, or new patients. Any vaccinators with concerns about vaccinating non-patients should consult their own attorneys or insurance carriers.

13. Vaccination of Those Who Have a History of an Influenza-Like Illness (ILI)

Persons who have a history of 2009 H1N1 influenza disease confirmed by a laboratory capable of distinguishing 2009 H1N1 virus (not by rapid testing) do not need to be vaccinated. Those who have a history of ILI but have NOT been confirmed to have 2009 H1N1 disease by such testing still need to be vaccinated.

14. Concern About Giving Seasonal Influenza Too Early and Waning Immunity

Many providers are concerned that giving the seasonal influenza vaccine in September or early October will leave their patients unprotected later in the influenza season. Increasingly research has shown that this shouldn't be a concern. Information contained in "Prevention and Control of Seasonal Influenza Using Vaccine" in the Morbidity and Mortality Weekly Report (MMWR) from July 31, 2009 acknowledges that those 65 years of age and older have a diminished response to influenza vaccination when compared with young healthy adults. However, immunity is still sufficient to extend for one influenza season in those 65 years of age and older and a second dose of influenza vaccine is not recommended. Every year it is recommended to start vaccinating as soon as influenza vaccine is available. This year there is an increased emphasis because seasonal influenza vaccine has become available earlier than it ever has before. To access this article from the MMWR please go to <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm>.

15. NYSDOH Hotlines Are Available for Questions

For questions related to the 2009 H1N1 vaccine please call 1-800-KIDSHOT (1-800-543-7468). Your patients with questions about H1N1 vaccine or disease can call the NYSDOH public hotline at 1-800-808-1987.

FDA Approval of 2009 Novel H1N1 Vaccine: Summary

FDA approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, as well as the package inserts, visit FDA's website at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

Manufacturer	Presentations	Age	Dosage ¹	Type	Package Insert
CSL Limited	-0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial containing 10 doses (with thimerosal)	Adults 18 years of age and older	-Single 0.5 mL dose	Inactivated virus; intramuscular injection	Link
GlaxoSmithKline ²	<i>Awaiting FDA licensure</i>				
Novartis Vaccines and Diagnostics Limited	-0.5 mL prefilled single-dose syringe (trace thimerosal) -5 mL multi-dose vial (with thimerosal)	Persons 4 years of age and older	-Two 0.5 mL doses approx. 1 month apart for children 4 to 9 -Single 0.5 mL dose for children 10-17 -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
Sanofi Pasteur Inc.	-0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod -0.5 mL prefilled single-dose syringe (thimerosal free) -0.5 mL single-dose vial (thimerosal free) -5 mL multi-dose vial (with thimerosal)	Persons 6 months and older	-Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age -Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years -Single 0.5 mL dose for children 10 years and older -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
MedImmune, LLC	-0.2 mL prefilled single-dose intranasal sprayer	Persons aged 2 to 49 years	-Two 0.2 mL doses approx. 1 month apart for children 2 to 9 -Single 0.2 mL dose for persons 10-49	LAIV; Intranasal spray	Link

¹ Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

² The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).

**PREP ACT LIABILITY COVERAGE
FACT SHEET FOR HEALTH CARE PROVIDERS**

Important Note: Providers should always seek legal advice from their own attorneys to discuss application of the PREP Act to their individual facts and circumstances.

What is the PREP Act?

The Public Readiness and Emergency Preparedness (“PREP”) Act (42 U.S.C. § 247d-6d) authorizes the Secretary of Health and Human Services (“Secretary”) to issue a declaration providing broad immunity from tort liability for claims relating to the administration or use of countermeasures to specified health conditions, diseases or threats.

What does “immunity” mean?

Immunity from tort liability means that no legal tort claim (except, as discussed below, claims of willful misconduct) may be pursued in a United States Federal or State court.

Does the PREP Act provide for any compensation for injury?

The PREP Act authorizes an emergency fund to provide compensation for certain eligible individuals. Congress has authorized funds for this purpose – compensation may be available for medical benefits, lost wages and death benefits.

What PREP Act declarations apply to 2009 H1N1 Influenza?

The Secretary has issued four relevant PREP Act declarations, which cover the use of:

- ! Vaccines for pandemic influenza, including 2009 H1N1 Influenza;
- ! Peramivir, for 2009 H1N1 Influenza;
- ! Oral Tamiflu® and Relenza® inhalation powder for 2009 H1N1 Influenza; and
- ! Personal Protective Equipment and respiratory support devices for patients with pandemic influenza.

PREP Act declarations can change at any time. The current declarations are available on the internet at <http://www.hhs.gov/disasters/discussion/planners/prepact/>.

Do these declarations apply to health care providers?

Yes. The PREP Act declarations listed above apply to licensed health professionals or other individuals who are authorized under state law to prescribe, administer, or dispense the covered countermeasures. As a result, the following providers should receive PREP Act protection:

- ! Providers administering 2009 H1N1 vaccine;
- ! Providers dispensing Tamiflu® or Relenza® from the Strategic National Stockpile as long as the guidelines set forth in the applicable Emergency Use Authorizations are followed;¹
- ! Private providers dispensing privately obtained Tamiflu and Relenza for 2009 H1N1 influenza, including off-label uses, as long as reliance on the private providers is part of the state or local emergency response plan.
- ! Providers administering Peramivir for 2009 H1N1 influenza once it is made available, as long as any administration requirements (e.g., EUA guidelines) are met.

Are there any limitations on immunity under the PREP Act?

Yes. Immunity is not available for:

- ! Claims based on activities that fall outside the scope of the declaration (e.g., the effective date or specified geographic area);
- ! Claims of loss that are not based on a causal relationship to the administration or use of the covered countermeasure;
- ! Claims filed under foreign law in courts outside the United States;
- ! Lawsuits other than tort claims (e.g., violations of civil rights laws, ADA laws, labor laws); and
- ! Claims of death or serious physical injury caused by willful misconduct.

Note: Suits based on willful misconduct can be avoided by reporting any injuries caused by the covered product to local or state public health authorities or the Secretary within seven days of learning of the injury.

Has the PREP Act ever been tested in court?

No. The PREP Act is a relatively new statute that has not yet been faced any judicial interpretation.

¹ As you may be aware, the Food and Drug Administration (“FDA”) has issued EUAs for the use of Tamiflu and Relenza for uses and populations that are not covered under the current FDA license for those drugs.