



# 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*

September 14, 2009

**TO:** All Medical Providers and Health Care Facilities

**FROM:** NYSDOH Bureau of Immunization

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<p><b>HEALTH ADVISORY: Novel H1N1 Influenza Vaccine Information</b></p> <p><b>Please distribute to the Infection Control Department, Medical Director, Director of Nursing, Emergency Department, Employee Health, and all patient care areas</b></p>
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The purpose of this advisory is to provide information on the novel H1N1 influenza vaccine. Please keep in mind that this information is the best that is known at the 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. Definitions
2. General Information on the Novel H1N1 Influenza Vaccine
3. The Timeline for Development of the Novel H1N1 Influenza Vaccine
4. Target Groups for Novel H1N1 Influenza Vaccine
5. Sites Where the Novel H1N1 Influenza Vaccine Will be Given
6. Methods of Distribution for the Novel H1N1 Influenza Vaccine
7. Insurance Coverage for Administration of the Novel H1N1 Influenza Vaccine
8. How Private Providers, Pharmacists, and Others Located Outside New York City Will Be Able to Register to Receive the Novel H1N1 Influenza Vaccine
9. Advantages of Using NYSIIS
- 10 Reporting Doses Administered
11. How Health Care Facilities will Be Able to Access the Novel H1N1 Influenza Vaccine
12. Vaccine Safety
13. Seasonal Influenza Vaccine
14. Pneumococcal Vaccine
15. New Regulations Requiring Influenza Vaccine in Certain Health Care Facilities
16. Volunteer Opportunities
17. Additional Information and Resources

**1. Definitions**

**Novel H1N1 Influenza:** The new influenza virus that started circulating in the United States in April 2009. Most of the population does not have immunity to this virus. This virus is causing a

worldwide pandemic. It has been called “swine flu” because part of its genetic make up originated in pigs.

**Seasonal Influenza:** The varying influenza viruses that circulate every year and infect up to 20% or more of the population. Seasonal influenza viruses generally circulate during the fall and winter.

**Novel H1N1 Influenza Vaccine:** The vaccine against the novel H1N1 influenza virus that is currently being developed.

**Seasonal Influenza Vaccine:** The influenza vaccine that is developed every year against the 3 influenza virus strains that are expected to cause disease that season.

## **2. General Information on the Novel H1N1 Influenza Vaccine**

Novel H1N1 influenza vaccine is being produced by the same 5 manufacturers that produce seasonal influenza vaccine. This vaccine is expected to:

- Be formulated just like seasonal influenza vaccine but with a change in the influenza strain that is included;
- Contain only the novel H1N1 influenza strain;
- Be a licensed vaccine;
- Be available in both the injectable form and the nasal spray;
- Be available in limited quantities without thimerosal;
- Become available mid to late October, though some doses may be available as early as September;
- Require 1 or 2 doses, 3-4 weeks apart;
- Be provided at no cost by the Federal government;
- Be able to be given at the same time as seasonal influenza vaccine; and
- Be safe and effective.

## **3. The Timeline for the Development of Novel H1N1 Influenza Vaccine**

The novel H1N1 influenza vaccine is currently being manufactured and is simultaneously undergoing clinical trials. The clinical studies will help to address the final dosage of antigen in the vaccine, the number of doses required, the interval between the doses, any safety concerns, antibody responses to the vaccine, and other clinical information. The information from the trials is expected to be available sometime in September.

The vaccine is expected to begin being available in mid October, though some amount of doses may become available in late September or early October. Discussions of which groups would be targeted to receive any doses that become available in September are under way. Though the early doses may be available before the results from the clinical trials are completed, the efficacy and safety profile of the new vaccine is expected to be very similar to seasonal influenza vaccine. The new vaccine is being produced by the same process as seasonal vaccine. Seasonal influenza vaccine already contains an H1N1 strain of the influenza virus. Nevertheless, the safety and efficacy studies that are underway are more extensive than what is usually done with the licensing of seasonal influenza vaccine.

The exact amount of novel H1N1 vaccine that will become available in September or October is not known yet. However, some predictions are being made. The latest information available from the Centers for Disease Control and Prevention says that about 45 million doses will be available first as a “bolus” over several weeks in October. Then vaccine will be produced at a rate of 20 million doses per week.

#### **4. Target Groups for Novel H1N1 Influenza Vaccine**

The Advisory Committee on Immunization Practices (ACIP) met on July 29, 2009, and made recommendations on who should receive the novel H1N1 influenza vaccine and in what order they should receive it.

Here are some of the considerations regarding the epidemiology of novel H1N1 influenza that were used to create the target groups and the order in which they are to be vaccinated:

- Which groups had the most severe illness and risk for complications during the novel H1N1 outbreak earlier this year;
- Which groups had the greatest frequency of illness during the novel H1N1 outbreak;
- Contribution of particular groups to the overall burden of severe illness;
- Protection of healthcare system functions;
- Reduction of societal impact; and
- Potential for indirect protection of more vulnerable contacts.

Phase I: The following groups of people are the first target for the novel H1N1 influenza vaccine:

- Pregnant women;
- Household contacts and caregivers of infants younger than 6 months of age;
- Health care personnel and emergency medical services personnel;
- Children, adolescents, and young adults ages 6 months through 24 years of age; and
- Adults 25 through 64 years of age with a medical condition that makes them at high risk for complications of influenza.

If the initial supply of novel H1N1 influenza vaccine is limited either nationally or on a local basis and there is not enough vaccine to cover the groups above, then the following groups of people will be recommended to receive this vaccine:

- Pregnant women;
- Household contacts and caregivers of infants younger than 6 months of age;
- Health care personnel and emergency medical services personnel who have direct patient contact;
- Children 6 months through 4 years of age; and
- Children and adolescents 5 through 18 years of age with a medical condition that makes them at high risk for complications of influenza;

Phase II: Once it has been shown that there is enough vaccine to immunize the groups above, the next target group is:

- All adults from 25 through 64 years of age.

Phase III: Once it has been shown that there is enough vaccine to immunize the group above, the next target group is:

- All adults 65 years of age and older.

For more information on target groups and to see the rationale behind the recommendations, please visit the ACIP website at: <http://www.cdc.gov/vaccines/recs/provisional/default.htm>.

**Please note: these target groups are somewhat different than those groups that are recommended for seasonal influenza vaccine. For information on recommendations for seasonal influenza vaccine, please see the Prevention and Control of Seasonal Influenza with Vaccines, MMWR July 31, 2009 / 58(RR08);1-52 at: <http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5808a1.htm>.**

### **5. Sites Where the Novel H1N1 Influenza Vaccine Will be Given**

Planning is underway to deliver the novel H1N1 influenza vaccine in the quickest and broadest way possible. It is important to consider the sites where target groups are seen for medical care. Different communities may have different sites available. The following sites may offer the novel H1N1 influenza vaccine:

- Medical provider offices;
- Hospital outpatient clinics and community health centers;
- Local health department clinics (immunization or mass dispensing clinics);
- Pharmacies;
- School-based clinics;
- College and university health centers;
- Health care facilities; and
- Medical practices located in certain occupational sites.

The NYSDOH will be coordinating the sites that will be available in cooperation with each local health department.

### **6. Methods of Distribution for the Novel H1N1 Influenza Vaccine**

Vaccine distribution will occur under the control of the NYSDOH for all counties outside of New York City. Vaccine will be distributed through a central distributor that is under contract with the Centers for Disease Control and Prevention (CDC). The NYSDOH will direct the central distributor, McKesson, to deliver vaccine to sites in New York State. The exact number of sites that will be available to New York State is not known yet, but is expected to be around 3,000. In New York City, the New York City Department of Health and Mental Hygiene will assume responsibility for directing the distribution of vaccine.

### **7. Insurance Coverage for Administration of the Novel H1N1 Influenza Vaccine**

The novel H1N1 influenza vaccine itself and supplies to administer it will be provided without charge by the Federal government. It is expected that the cost of vaccine administration will be covered by most health insurance, and Medicaid and Medicare will cover it. For those who do not have health insurance or whose insurance will not cover the administration fee, the fee may be charged to the patient, unless the provider waives it. In addition, funding is available so that local health departments can work to assure that those who are uninsured can get vaccinated. A provider, pharmacist, or local health department may charge an administration fee. Local health departments cannot turn someone away if he or she cannot afford the administration fee.

Vaccination of school-aged children, under the general direction of local health departments, will most likely occur in schools in many areas of the state, paid for with federal funding. Overall guidance for reimbursement for novel H1N1 vaccination clinics in schools will be forthcoming from both the CDC and the NYSDOH.

#### **8. How Private Providers, Pharmacists, and Others Located Outside New York City Will Be Able to Register to Receive the Novel H1N1 Influenza Vaccine**

Details about receiving vaccine are still being worked out. Vaccine distribution will be managed by the NYSDOH with assistance from a variety of sources. Many providers and pharmacists will be receiving novel H1N1 vaccine directly through CDC's central distributor, McKesson Specialties. Some providers and pharmacists may receive vaccine from their local health department or from the NYSDOH. A website is available for providers and pharmacists to register interest in receiving vaccine (see below). It is not yet clear if all providers who express interest will be able to access vaccine.

To obtain H1N1 vaccine in New York City, contact the NYC Department of Health and Mental Hygiene at <http://www.nyc.gov/html/doh/html/cir/a03c.html> or call 212-676-2323.

#### **Requirements for Receiving Vaccine**

All medical providers and pharmacists that are interested in receiving vaccine must do the following:

- Register your interest in receiving H1N1 vaccine with the NYSDOH vaccine program by going to the registration website at: <https://hcsteamwork1.health.state.ny.us/pub/>.
- Sign a provider agreement that is in the process of development;
- Agree to report weekly all doses administered by age group and
- Agree to report all vaccine inventory to NYSDOH as required.

#### **Providers that Will Vaccinate Patients Less Than 19 Years of Age**

New York State Law requires that all vaccinations of pediatric patients (less than 19 years of age) be entered into the New York State Immunization Information System (NYSIIS), the state's immunization registry. All providers that are interested in receiving novel H1N1 influenza monovalent vaccine for use in pediatric patients (less than 19 years of age) must complete three steps. These can be completed by accessing this website:

<https://hcsteamwork1.health.state.ny.us/pub/>.

##### **1. Establish a NYSDOH Health Commerce System (HCS) account**

- The Health Commerce System (HCS) (also referred to as the Health Provider Network or the HPN) is a secure web-based system designed by the NYSDOH

specifically for electronically exchanging health-related data and information between health care providers and NYSDOH.

- Note: this is the same account that physicians use to order prescription pads and update their Physician Profile; all physicians should have an account.
- Completing the on-line HCS application request form will bring the user to the H1N1 vaccine pre-registration form and the HCS application information will pre-populate appropriate fields to expedite the H1N1 vaccine pre-registration process.

**2. Pre-register interest in receiving H1N1 vaccine with the NYSDOH vaccine program**

- This pre-registration process is designed for you to express interest only and does not obligate you to receive/administer vaccine nor does it guarantee you will receive vaccine if supplies are limited. Users with a current HCS account can use their log in id to pre-populate the vaccine pre-registration form and expedite the process. Once your registration is received and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the formal provider agreement that has been supplied by the Federal government, agreeing to appropriately store and handle the vaccine, to give vaccines only to the CDC targeted groups, and to report vaccine usage.

**3. Establish access in the New York State Immunization Information System (NYSIIS), also known as the immunization registry (see attached fact sheet).**

- NYSIIS participation is required by NYS law for providers who immunize children less than 19 years of age. Participating in training establishes a NYSIIS user account.
- 47 electronic health record/billing vendors are approved to automatically upload immunization information into NYSIIS.
- The website above provides additional information on an online orientation to NYSIIS and training opportunities for new users.

Local Health Departments do not have to register with the NYSDOH to receive vaccine.

## **9. Advantages of Using NYSIIS**

NYSIIS provides a number of advantages for providers of novel H1N1 monovalent influenza vaccine: 1) automatically generates the federally mandated weekly vaccine usage reports, 2) monitors vaccine inventory to enable prompt reordering, 3) generates reminder lists and letters for the second influenza vaccine dose, if required, 4) provides a legal record of the vaccination, 5) enables correct ascertainment of prior influenza vaccine history if patients receive some influenza vaccine doses (seasonal and/or monovalent H1N1) at other provider sites, and 6) enables NYSDOH to more closely monitor possible vaccine adverse events.

## **10. Reporting Doses Administered and Vaccine Inventory**

All vaccinators will be required to report the number of doses administered and their current inventory to the NYSDOH on a weekly basis. The doses administered will be reported according to the age of the recipient. For those vaccinators who are using NYSIIS to record vaccinations given, the report of doses administered and inventory can be generated easily by using reports that are available in NYSIIS. For those who are not using NYSIIS, an alternative method of reporting is being developed by the NYSDOH.

## **11. How Health Care Facilities Will Be Able to Access Novel H1N1 Influenza Vaccine**

All health care personnel and emergency medical service providers are within the initial target groups for vaccination with the novel H1N1 influenza vaccine. All hospitals will receive an allocation of the vaccine for use in the facility. Other health care facilities will also be able to receive vaccine and should follow the procedures outlined above and make sure they have the required accounts set up.

### **12. Vaccine Safety**

Though the novel H1N1 influenza vaccine is manufactured in the same manner as seasonal influenza vaccine, special measures are being taken to ensure its safety. Studies will be conducted by the CDC and vaccine manufacturers to monitor for Guillain Barre Syndrome and any unusual adverse events. New York State will also carefully monitor reports of Guillain Barre Syndrome in the state.

The Vaccine Adverse Events Recording System (VAERS) will be used to accept reports of adverse events after vaccination. The NYSDOH will receive reports from the CDC on any adverse events that occur in New York State on a regular basis. If an adverse event is suspected, it should be reported directly to VAERS by calling 1-800-822-7967 or by going to [www.vaers.hhs.gov](http://www.vaers.hhs.gov)

### **13. Seasonal Influenza Vaccine**

Seasonal influenza vaccine is already becoming available from several manufacturers. Seasonal influenza vaccine should be given to all eligible and interested persons as soon as it becomes available. This is true every year, but, is especially true this influenza season. Seasonal influenza viruses may circulate at the same time as the novel H1N1 influenza virus. Seasonal influenza vaccine use will help to decrease illness and to preserve all important societal functions.

Seasonal influenza disease will probably overlap with novel H1N1 influenza disease, and seasonal influenza vaccination will overlap with novel H1N1 influenza vaccination. To avoid confusion, it is important to keep up-to-date on the latest influenza information and to use communication messages developed by the CDC and the NYSDOH for your health care personnel, patients, and the public.

Some providers may encounter temporary difficulties ordering seasonal influenza vaccine. According to CDC, this is a temporary situation which occurs every year due to double booking of vaccine orders by providers. As vaccine orders start to be filled, double bookings are released and vaccine becomes available. Even with some manufacturing difficulties, the projections are 114-115 million doses of seasonal vaccine this year, which exceeds the amount of 113 million doses last year (when millions of doses went unused).

Providers looking to order additional vaccine should be encouraged to use the supplies that they have now and continue to look for additional flu vaccine for purchase in the coming weeks. To assist providers in finding flu vaccine, the National Influenza Vaccine Summit supports IVATS, the Influenza Vaccine Availability Tracking System, which provides information about vaccine manufacturers and distributors with vaccine available for purchase. IVATS can be found at: <http://www.preventinfluenza.org/ivats/>. The information in IVATS is updated throughout the influenza vaccination season.

For additional information on seasonal influenza vaccine, please see <http://www.cdc.gov/flu/> and [www.health.state.ny.us](http://www.health.state.ny.us)

#### **14. Pneumococcal Vaccine**

Secondary bacterial pneumonia is the most common complication of influenza. For this reason it is important that all those who are recommended to receive the pneumococcal vaccine get immunized as soon as possible. Young infants usually receive all the pneumococcal conjugate vaccine (PCV) doses by the time they are 15 months of age, though children up to 59 months of age can be vaccinated. Persons 2 years of age and up can also receive the pneumococcal polysaccharide vaccine (PPSV) if they have the following:

- Chronic illness,
- Anatomic or functional asplenia
- An immunocompromising condition,
- HIV infection,
- Environments or settings with increased risk,
- Cochlear implant.

In addition, all persons aged 65 years and older should get one PPSV.

For more information on pneumococcal disease please visit the CDC website at <http://www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm>.

#### **15. New Regulations Requiring Influenza Vaccine in Certain Health Care Facilities**

New regulations have been passed by the State Hospital Review and Planning Council (SHRPC) that require all health care personnel in hospitals, diagnostic and treatment centers, long term home health care programs, AIDS home care programs, home care service agencies, and hospices to be immunized against influenza disease each year. Mandating the novel H1N1 influenza vaccine will depend on several factors including whether it is approved as a licensed vaccine, whether there is adequate supply, and any Federal requirements surrounding the vaccine.

It is important that all health care personnel be immunized with both the seasonal influenza vaccine and the novel H1N1 influenza vaccine in order to allow the health care system to function smoothly in the face of increased illness from influenza this fall and winter. The regulation is now available at <http://www.nyhealth.gov/nysdoh/phforum/nycrr10.htm>.

#### **16. Volunteer Opportunities**

The novel H1N1 influenza vaccine campaign will require tremendous resources to assure that every New Yorker has access to vaccination. Volunteers of all sorts, both medical and non-medical will be needed to assist at vaccination sites. If you or your members are interested in

volunteering with a local health department, state health department or Medical Reserve Corp program, please go to [www.nyhealth.gov/ServNY](http://www.nyhealth.gov/ServNY) to enroll.

## **17. Additional Information and Resources**

Additional information and resources on seasonal influenza and novel H1N1 influenza can be found at the following websites:

### **Global, National, State and City Resources**

World Health Organization: Global alert and response, guidance documents, FAQ's etc.  
<http://www.who.int/csr/disease/swineflu/en/index.html>

U.S. Government Swine, Avian and Pandemic Flu Information - One-stop access  
From the U.S. Department of Health and Human Services  
<http://www.flu.gov/>

CDC Novel H1N1: Clinical guidance  
<http://www.cdc.gov/h1n1flu/clinicians/>

CDC Novel H1N1: Vaccination guidance for state, local and territorial health officials  
<http://www.cdc.gov/h1n1flu/vaccination/statelocal/>

**Food and Drug Administration (FDA): Use of Influenza Medicines and Diagnostic Testing Information**  
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>

New York State Department of Health: H1N1 Guidance  
<http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/>

New York State Office of Homeland Security  
<http://www.security.state.ny.us/preparedness/index.html>

New York State Department of Insurance: Information on Vaccine Insurance Requirements  
[http://www.ins.state.ny.us/health/ih\\_hreqimmun.htm](http://www.ins.state.ny.us/health/ih_hreqimmun.htm)

New York City Department of Health and Mental Hygiene  
<http://www.nyc.gov/html/doh/html/cd/cd-h1n1flu.shtml>

### **Clinical Information, Literature Reviews and Updates**

New England Journal of Medicine:  
<http://h1n1.nejm.org/?emp=marcom>

Center for Infectious Disease Research & Policy Academic Health Center -- University of Minnesota  
<http://www.cidrap.umn.edu/>

American Medical Association

<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/infectious-diseases/topics-interest/novel-influenza-a-h1n1.shtml>

American Academy of Pediatrics

<http://www.aap.org/advocacy/releases/may09swineflu.htm>

American Academy of Family Physicians

<http://www.aafp.org/online/en/home/clinical/disasterprep/swine-flu.html>

American College of Obstetricians and Gynecologists: Resource List

[http://www.acog.org/departments/dept\\_notice.cfm?recno=20&bulletin=4866](http://www.acog.org/departments/dept_notice.cfm?recno=20&bulletin=4866)



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Richard F. Daines, M.D.  
*Commissioner*

James W. Clyne, Jr.  
*Executive Deputy Commissioner*

September 14, 2009

Dear Adult Health Care Provider:

This letter provides information about how to pre-register your practice (located outside of New York City\*) for novel influenza A (H1N1) monovalent vaccine to be administered to your adult patients (age 19 years and older) and office staff.

The novel H1N1 influenza virus, in conjunction with regular seasonal influenza viruses, has the potential to cause significant illness, hospitalizations and deaths this flu season starting this fall. Influenza vaccination is the most effective method to prevent influenza infection. A novel influenza A (H1N1) monovalent vaccine is expected to be available by mid-October 2009. In cooperation with the federal government and local health departments, the New York State Department of Health (NYSDOH) will make the monovalent vaccine available to health care providers in New York State (outside New York City). This undertaking will require the active participation of a wide range of immunization providers, but office-based providers will play a key role in delivering influenza vaccine to their targeted patients.

The following populations are recommended by CDC to receive novel influenza A (H1N1) monovalent vaccine as soon as possible:

- Pregnant women
- Household contacts and caregivers for children younger than 6 months of age
- Healthcare and emergency medical services personnel
- All people from 6 months through 24 years of age
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza

The full recommendations are available in the Morbidity and Mortality Weekly Report, August 28, 2009/58 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm>.

Both the vaccine and the supplies required to administer the vaccine will be provided by the Federal government at no charge. Reimbursement for vaccine administration is likely to be covered by most private health insurers and will be covered by public health insurance (Medicaid/Medicare) plans.

Issues regarding the liability and costs associated with administering the H1N1 influenza monovalent vaccine are being addressed. The United States Department of Health and Human Services has issued a Public Readiness and Emergency Preparedness "PREP" Act declaration for novel H1N1 influenza countermeasures. This declaration provides liability protections to providers of H1N1 influenza vaccine.

The allocation and distribution of the vaccine in New York State (outside New York City) will be managed by the NYSDOH in coordination with county health departments. In order to receive novel H1N1 influenza monovalent vaccine, providers must pre-register with NYSDOH. The information you provide will assist in allocating H1N1 vaccine throughout the State, taking into consideration the targeted population groups to receive the H1N1 vaccine.

\*To obtain H1N1 vaccine in New York City, contact the NYC Department of Health and Mental Hygiene at <http://www.nyc.gov/html/doh/html/cir/a03c.html> or call 212-676-2323.

**Pre-registration:** All providers interested in receiving novel H1N1 influenza monovalent vaccine must pre-register at <https://hcsteamwork1.health.state.ny.us/pub/top.html>

- This pre-registration process is designed for you to express interest only and does not obligate you to receive/administer vaccine nor does it guarantee you will receive vaccine if supplies are limited.

**Requirements for receipt of vaccine:**

- In order to receive novel H1N1 influenza monovalent vaccine, providers must sign a federally-mandated Provider Agreement agreeing to appropriately store and handle the vaccine, to give vaccines only to the CDC targeted groups, and to report vaccine usage (see next bullet).
- There is a federal requirement that providers of vaccine to adults (age 19 years and older) report at a minimum, vaccine doses administered by age group on a weekly basis. NYSDOH will set up a mechanism for this reporting.

Once your pre-registration is received and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the federal Provider Agreement and instructed how to order vaccine.

**Option to report vaccinations to the NYS Immunization Information System (NYSIIS).**

NYSIIS, the state immunization registry, provides a number of advantages for providers of H1N1 monovalent vaccine: 1) automatically generates the federally mandated weekly vaccine usage reports, 2) monitors vaccine inventory to enable prompt reordering, 3) generates reminder lists and letters for the second influenza vaccine dose, if required, 4) provides a legal record of the vaccination, 5) enables correct ascertainment of prior influenza vaccine history if patients receive some influenza vaccine doses (seasonal and/or monovalent H1N1) at other provider sites, and 6) enables NYSDOH to more closely monitor possible vaccine adverse events. In addition, 47 electronic health record/billing vendors are approved to automatically upload immunization information into NYSIIS. The website above provides a link to a brief on-line orientation to NYSIIS and details on how to enroll in the system.

If you are not able to provide vaccine you can still contribute by educating and referring your patients and by volunteering at a public health-sponsored clinic. For information on volunteering, please go to [www.nyhealth.gov/ServNY](http://www.nyhealth.gov/ServNY).

Your participation in the H1N1 influenza monovalent vaccine campaign is essential to ensuring that New Yorkers receive the most effective protection against H1N1 influenza. For more information on the novel H1N1 influenza vaccine, please go to the NYSDOH website at: <http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/> or the Centers for Disease Control and Prevention's (CDC) website at: <http://www.cdc.gov/h1n1flu/>. If you have any further questions, please contact the NYSDOH H1N1 hotline at 1-800-808-1987.

Sincerely,



Guthrie S. Birkhead, M.D., M.P.H.  
Deputy Commissioner  
Office of Public Health



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Richard F. Dalnes, M.D.  
*Commissioner*

James W. Clyne, Jr.  
*Executive Deputy Commissioner*

September 14, 2009

Dear Pediatric Health Care Provider:

This letter provides information about how to pre-register your practice (located outside of New York City\*) for novel influenza A (H1N1) monovalent vaccine to be administered to your pediatric patients (less than 19 years of age) and office staff.

The novel H1N1 influenza virus, in conjunction with regular seasonal influenza viruses, has the potential to cause significant illness, hospitalizations and deaths this flu season starting this fall. Influenza vaccination is the most effective method to prevent influenza infection. A novel influenza A (H1N1) monovalent vaccine is expected to be available by mid-October 2009. In cooperation with the federal government and local health departments, the New York State Department of Health (NYSDOH) will make the monovalent vaccine available to health care providers in New York State (outside New York City). This undertaking will require the active participation of a wide range of immunization providers, but office-based providers will play a key role in delivering influenza vaccine to their targeted patients.

The following populations are recommended by CDC to receive novel influenza A (H1N1) monovalent vaccine as soon as possible:

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New York State Law requires that all vaccinations of pediatric patients (less than 19 years of age) be entered into the New York State Immunization Information System (NYSIIS), the state's immunization registry. All providers that are interested in receiving novel H1N1 influenza monovalent vaccine for use in pediatric patients (less than 19 years of age) must complete three steps. These can be completed by accessing this website: <https://hcsteamwork1.health.state.ny.us/pub/top.html>

1. **Establish a NYSDOH Health Commerce System (HCS) account**
  - The Health Commerce System (HCS) (also referred to as the Health Provider Network or the HPN) is a secure web-based system designed by the NYSDOH specifically for electronically exchanging health-related data and information between health care providers and NYSDOH.
  - Note: this is the same account that physicians use to order prescription pads and update their Physician Profile; all physicians should have an account.
  - Completing the on-line HCS application request form will bring the user to the H1N1 vaccine pre-registration form and the HCS application information will pre-populate appropriate fields to expedite the H1N1 vaccine pre-registration process.
2. **Pre-register interest in receiving H1N1 vaccine with the NYSDOH vaccine program**
  - This pre-registration process is designed for you to express interest only and does not obligate you to receive/administer vaccine nor does it guarantee you will receive vaccine if supplies are limited.
  - Users with a current HCS account can use their log in id to pre-populate the vaccine pre-registration form and expedite the process.
  - Once your registration is received and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the formal provider agreement that has been supplied by the Federal government, agreeing to appropriately store and handle the vaccine, to give vaccines only to the CDC targeted groups, and to report vaccine usage.
3. **Establish access in the New York State Immunization Information System (NYSIIS), also known as the immunization registry (see attached fact sheet).**
  - NYSIIS participation is required by NYS law for providers who immunize children less than 19 years of age. Participating in training establishes a NYSIIS user account.
  - 47 electronic health record/billing vendors are approved to automatically upload immunization information into NYSIIS.
  - The website above provides additional information on an online orientation to NYSIIS and training opportunities for new users.

**Reporting to the New York State Immunization Information System (NYSIIS).**

NYSIIS provides a number of advantages for providers of H1N1 monovalent vaccine: 1) automatically generates the federally mandated weekly vaccine usage reports, 2) monitors vaccine inventory to enable prompt reordering, 3) generates reminder lists and letters for the second influenza vaccine dose, if required, 4) provides a legal record of the vaccination, 5) enables correct ascertainment of prior influenza vaccine history if patients receive some influenza vaccine doses (seasonal and/or monovalent H1N1) at other provider sites, and 6) enables NYSDOH to more closely monitor possible vaccine adverse events.

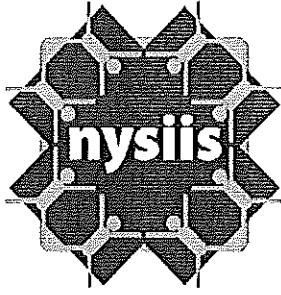
Your participation in the H1N1 influenza monovalent vaccine campaign is essential to ensuring that New Yorkers receive the most effective protection against H1N1 influenza. For more information on the novel H1N1 influenza monovalent vaccine, please go to the NYSDOH website at: <http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/> or the Centers for Disease Control and Prevention's (CDC) website at: <http://www.cdc.gov/h1n1flu/>. If you have any further questions, please contact the NYSDOH H1N1 hotline at 1-800-808-1987.

Sincerely,



Guthrie S. Birkhead, M.D., M.P.H.  
Deputy Commissioner  
Office of Public Health

Attachment – NYSIIS and H1N1 Fact Sheet



## The New York State Immunization Information System (NYSIIS)

### and H1N1 Vaccine

#### **What is NYSIIS?**

The New York State Immunization Information System (NYSIIS) is a confidential, secure, web-based system that maintains one consolidated immunization record for persons of all ages in New York State (outside of New York City). Public Health Law 2168 mandates health care providers report information on vaccinations administered to all persons less than 19 years of age. New York State Department of Health is working to eliminate the requirement for separate written consent for individuals 19 years of age and older.

As of September 2009, NYSIIS contains more than 2.4 million patient records and nearly 28 million immunizations. There are more than 6,800 individual users from 2,200 different health care provider organizations and 1,012 schools across the state.

New York State is not alone in this endeavor. As a nation, we are targeting the Healthy People 2010 goal of having 95% of children less than six years of age with two or more immunizations in an immunization information system. NYS is making great strides toward this goal. We are at 65.7% as of September 2009 – nearly double where we were one year ago.

#### **Why Do We Need NYSIIS?**

For the H1N1 campaign, NYSIIS will be essential for information tracking. The system will allow users to track vaccine inventory and usage on a daily and weekly basis, as required by the Federal government; will provide a key source of information on possible adverse events; will facilitate the generation of reminders for the likely second H1N1 dose by medical practices; will allow review of practice coverage rates, and will serve as a record of the immunization. In addition, by consolidating vaccinations from multiple visits and possible multiple providers into one reliable record, time and paperwork are reduced and accurate immunization histories for providers, patients, schools, camps, day-care centers and colleges will be available.

#### **Will I need to participate in NYSIIS to receive H1N1 vaccine?**

Providers who administer any immunization to persons less than 19 years of age are required by state law to report to NYSIIS. This includes the 2009 influenza A (H1N1) monovalent vaccine. Providers are also strongly encouraged to use NYSIIS to track immunization information for persons 19 years of age and older.

While many providers that immunize children already participate in NYSIIS, most providers that care for adult patients are not yet participating. NYSDOH will provide training, education and technological support to assist new providers.

continued

**How Do I Get Access to NYSIIS?**

NYSIIS is accessed via the Health Commerce System (HCS), designed for the electronic exchange of health related data and information between health care providers and NYSDOH. Licensed health care professionals can apply for an HCS account at:  
<https://hcsteamwork1.health.state.ny.us/pub/top.html>

Once an HCS account has been established, providers must complete NYSIIS training, which authorizes access to NYSIIS. These training opportunities can be found at:  
[https://commerce.health.state.ny.us/hpn/bcdc/immunization/training\\_info.html](https://commerce.health.state.ny.us/hpn/bcdc/immunization/training_info.html).

**How Do I Report Immunizations?**

HINI immunizations can be reported using direct on-line data entry or by batch file transfer from an electronic health record or billing system. The following 47 systems are already approved to submit data to NYSIIS:

- |   |                               |
|---|-------------------------------|
| ACME  | Medical Communication Systems |
| ADS (Medex Premiere) (NEIC)                 | Medical Manager               |
| Allscripts - MYSIS                          | Medisoft/Medinotes            |
| CDS (Contemporary Data Services)            | Meditech                      |
| Cerner System                               | MicroMD                       |
| CMI Medical Systems                         | Mitchell McCormick            |
| EasyBilling                                 | NextGen                       |
| Ecast                                       | Office Practicum              |
| Eclinical Works                             | PerfectCare                   |
| Eclipsys                                    | Physician's Computer Company  |
| EncounterPro                                | Physicians Solution           |
| EPIC  | PMP                           |
| EZImmune                                    | PractiCare                    |
| GE Healthcare -Centricity                   | Practice Made Perfect         |
| Hypocrates                                  | Practice Partner              |
| Iatric                                      | Priority Management Group     |
| McKesson                                    | Pyramid Partner               |
| MD Everywhere                               | Quicksilver Computers         |
| MDOffice                                    | Sage (Medical Manager)        |
| Medallies (working with NextGen)            | SoapWare                      |
| Medcomp                                     | Synamed                       |
| MedData                                     | Virtual Officeware            |
| Medent (Community Computer/Health Sys Tech) | Welligent                     |
| Medfx                                       |                               |

**Where Can I Get More Information?**

Contact NYSIIS Program staff at (518) 473-2839 or [nysiis@health.state.ny.us](mailto:nysiis@health.state.ny.us) for additional information.



Office of the President  
Gerald F. Joseph, Jr., MD, FACOG

Dear Colleague:

**PLEASE TAKE THE TIME TO READ THIS LETTER.**

**The information is important and may save a patient's life. Contained in this letter is material you need to know today concerning influenza and pregnant women. Please take measures to prepare your practice immediately.**

It is expected that cases of H1N1 influenza will rapidly multiply in the U.S. during the fall months. Unlike seasonal flu, the infected people experiencing the highest morbidity and mortality with H1N1 flu are children and young adults. Pregnant women (particularly those in the third trimester) and infants are at very high risk of influenza related complications. A recent report noted that 1/3 of pregnant women with confirmed cases of pandemic H1N1 were hospitalized (mostly with severe respiratory distress) and deaths of otherwise healthy pregnant women are being reported.<sup>i</sup> Additionally, it is quite possible for an individual to experience both seasonal influenza and H1N1 influenza simultaneously or in tandem with serious results. As people gather together for school and other fall activities the likelihood of influenza transmission will increase.

The American College of Obstetricians and Gynecologists has joined with a coalition of prenatal and pediatric health care provider organizations to urge pregnant women to take steps to prevent influenza and to seek early treatment. There are very important steps you should take in your practice.

**What can you do?**

- Educate and inform your patients.
  - Instruct all pregnant women to report the symptoms of influenza or close exposure to persons with influenza to you immediately.
  - Instruct in the use of antipyretics.
  - Caution all pregnant women to use frequent hand washing and to avoid contact with sick individuals.
  - If a family member has flu-like symptoms, instruct pregnant women to try and arrange for another person to care for those who are sick.
- The CDC advises that you do not need to confirm influenza to initiate treatment. If H1N1 is prevalent in your community consider all pregnant women with flu-like symptoms as having H1N1.
- Treat flu exposure with a prophylactic course of oseltamivir (75 mg. once daily. for 10 days). Treat those with flu-like symptoms with a therapeutic course of oseltamivir (75 mg twice daily for 5 days).<sup>ii</sup> Limited data suggest that oseltamivir is not a major human teratogen and it is currently effective for both prevention of H1N1 influenza and the reduction of flu severity if started within 48 hours of the initial symptoms.<sup>ii</sup>
- The Immunization for seasonal flu is available NOW and the Immunization for H1N1 will available in mid- October. We urge you to make provision for all pregnant women to receive both the H1N1 immunization AND immunization for seasonal flu, and to strongly encourage **ALL** pregnant women to be immunized for both. This may require your counseling on the safety of immunization during pregnancy.<sup>iii</sup>

- The Advisory Committee on Immunization Practices and ACOG recommend inactivated flu vaccine for all pregnant women in every trimester<sup>iv</sup>. Please consider immunizing your patients in your office. If you have not already done so, please immediately order your seasonal flu vaccine from an IVATS distributor. IVATS was developed to enable healthcare providers to find influenza vaccine to purchase, especially during the critical vaccination period. (<http://www.preventinfluenza.org/ivats>)
- Contact your health department immediately to obtain the H1N1 vaccine. The H1N1 vaccine is free, however you are able to bill for vaccine administration. Up to date CDC guidance on the H1N1 flu vaccines can be found at <http://www.cdc.gov/h1n1flu/vaccination>.
- Make a plan in your office for how you will inform your pregnant patients, respond to their calls concerning influenza symptoms and exposures, isolate sick women, monitor those you treat, and cover for sick staff.
- Follow the CDC's H1N1 influenza during pregnancy web site (<http://www.cdc.gov/h1n1flu/guidance/obstetric.htm>) and the ACOG web site for up-to-date information
- If you have pregnant health care workers on staff, please also follow CDC guidance at <http://www.cdc.gov/h1n1flu/pregnancy/> and limit their exposure to situations of influenza exposure.

The ACOG Workgroup on Immunization will be mailing you the *Immunization Coding Guide for Obstetricians and Gynecologists*. This coding guide will serve as a ready reference for your practice. It addresses reimbursement for vaccinations, coding for vaccinations, coding examples and other coding resources. Also enclosed in that mailing are two pocket guides on seasonal influenza vaccine developed by the National Influenza Vaccine Summit. For more information or to request additional pocket guides, please visit, [www.immunize.org](http://www.immunize.org)

**The virulence, mutation and distribution patterns of the H1N1 virus are likely to change over time. It is essential that you stay current with this information**

**YOUR ACTION TO PREVENT AND TREAT INFLUENZA IN YOUR PREGNANT PATIENTS IS OF CRITICAL IMPORTANCE.**

Sincerely,



Gerald F. Joseph, Jr., MD, FACOG  
President

<sup>i</sup> Jamieson DJ, et al. H1N1 2009 influenza virus infection during pregnancy in the USA. Lancet early online 7/29/09 downloaded from [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)6134-0/fulltext#article\\_upsell](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)6134-0/fulltext#article_upsell)

<sup>ii</sup> Tanka T, Nakajima K, Murashima A, Garcia-bournissen F, Koren G, Ito S. Safety of neuraminidase inhibitors against novel influenza A (H1N1) in pregnant and breastfeeding women. CMAJ 2009;181:55-58

<sup>iii</sup> Phillippe M. Pandemic Influenza: What obstetricians need to know. Obstet & Gynecol 2009;114:206-8

<sup>iv</sup> Influenza vaccination and treatment during pregnancy. ACOG Committee Opinion No. 305. American College of Obstetricians and Gynecologists. Obstet Gynecol 2004;104:1125-6.