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TO: All Medical Providers and Health Care Facilities

FROM: New York State Department of Health (NYSDOH), Bureau of Immunization

HEALTH ADVISORY: 2009 H1N1 Influenza Vaccine Information #3
Please distribute to the Infection Control Department, Medical Director, Director of Nursing, Emergency Department, Employee Health, and all patient care areas

This is the third 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 in this advisory can change. Updates will be provided when new information becomes available.

Topics covered:

- 1) 2009 H1N1 Influenza Vaccine Ordering
- 2) 2009 H1N1 Influenza Vaccine Allocation
- 3) 2009 H1N1 Influenza Vaccine Substitution
- 4) 2009 H1N1 Influenza Vaccine Storage and Handling
- 5) 2009 H1N1 Influenza Vaccine Information Statements (VIS) Translations
- 6) Subset of Target Groups for 2009 H1N1 Influenza Immunization when Vaccine Supply is Limited
- 7) Reserving 2009 H1N1 Influenza Vaccine 0.5mL Pre-filled Syringes for Pregnant Women
- 8) 2009 H1N1 Influenza Vaccination: Dosing in Pediatric Patients
- 9) The NYSDOH Commissioner Authorizes use of Thimerosal-containing Influenza Vaccines
- 10) 2009 H1N1 Live Attenuated Influenza Vaccine (LAIV) and Cognitive Impairment
- 11) 2009 H1N1 Influenza Vaccine and Latex
- 12) Administering 2009 H1N1 Influenza Vaccine to Patients who Reside Outside of New York State (NYS) or a Given County
- 13) 2009 H1N1 Influenza Vaccine Ancillary Supplies- Syringes
- 14) 2009 H1N1 Influenza Vaccine BD Integra Retractable Needle/Syringe Units
- 15) 2009 H1N1 Influenza Vaccine Usage/Waste Reporting
- 16) 2009 H1N1 Influenza Vaccine Redistribution
- 17) Important Phone Numbers
- 18) Seasonal Influenza Vaccine Supply
- 19) Seasonal Flu Vaccine Redistribution

1) 2009 H1N1 Influenza Vaccine Ordering

The NYSDOH began taking 2009 H1N1 influenza vaccine orders from private providers on October 20th. Vaccine orders are placed 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. Those who have already registered have entered amounts of vaccine that they would like to receive but these requests are not orders. Providers must call on their designated day to place orders. Order placement will be done based on the county in which a provider practice is located. Hospitals, local health departments, federally qualified health centers, retail pharmacies, state agencies, and Veterans Administration facilities will be ordering on Mondays, irrespective of County location (see attached document for more information).

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 until federal supplies arrive.

Providers who want to order vaccine must be pre-registered with the NYSDOH and must sign a provider agreement. The website for pre-registration is <https://hcsteamwork1.health.state.ny.us/pub/top.html>. If you have already registered but have not yet completed the provider agreement, please go back to the website above and do so.

2) 2009 H1N1 Influenza Vaccine Allocation

The New York State Department of Health (NYSDOH) is working to allocate the limited supplies of 2009 H1N1 influenza vaccine in a fair and equitable manner. Vaccine allocation is not determined by the day you call during the week or the time you call on your specified day.

The current vaccine shortage is due to unanticipated delays in manufacturing the vaccine. The NYSDOH has received orders for vaccine far in excess of available vaccine. With larger amounts of vaccine anticipated over the next several weeks, vaccine will become more widely accessible.

The policy guiding the distribution of vaccine in New York State is to get vaccine to all providers who serve vaccine priority groups, ensuring access in all areas of the State and to the largest population. The goal is to mitigate illness in as widespread a manner as possible, using a variety of vaccination locations and types of vaccinators.

Vaccine allocation is guided by the following factors:

- Amount of vaccine available to the state,
- Per capita share of vaccine available for each County,
- Amount of each type of vaccine formulation available for distribution,
- Number of providers requesting vaccine within a given County,
- Provider type,
- Facility type,
- Amount of vaccine previously received,

- Amount of vaccine currently requested, and
- Target population served (we are allocating to providers serving kids and pregnant women first, then adults with underlying risk).

For more information, please visit the NYSDOH website:

<http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/vaccine/update.htm>

3) 2009 H1N1 Influenza Vaccine Substitution

The NYSDOH makes every attempt to fulfill the orders that are placed by providers. With the 2009 H1N1 influenza vaccine in currently limited supply, it is sometimes necessary to make vaccine order substitutions in order to distribute available vaccine to providers who have requested it. We make every attempt to substitute vaccine that can still be utilized by a provider (e.g., if 0.5 pre-filled syringes were ordered for a given population of pregnant women, we substitute with a multi-dose vial but will not substitute with LAIV). If you are unable to utilize the vaccine that is provided to you, please redistribute it to your Local Health Department or another registered 2009 H1N1 influenza vaccine provider. If after receiving an order that contains substitutions, you want to change your original vaccine order, please call the Vaccine ordering Hotline (1-800-KID-SHOT or 1-800-543-7468).

4) 2009 H1N1 Influenza Vaccine Storage and Handling

Failure to adhere to recommended specifications for storage and handling of vaccine can reduce vaccine potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. Vaccine quality is the shared responsibility of all parties, from the time vaccine is manufactured until it is administered. Please review the information contained in the attached document to ensure proper storage and handling of the 2009 H1N1 influenza vaccine.

5) 2009 H1N1 Vaccine Information Statements (VIS) Translations

VIS translations in a number of languages are now available at the following websites:

- 1) Inactivated Vaccine (injectable):
http://www.immunize.org/vis/vis_h1n1inactive.asp
- 2) Live Attenuated Influenza Vaccine (LAIV):
http://www.immunize.org/vis/vis_h1n1live.asp

6) Subset of Target Groups for 2009 H1N1 Influenza Immunization when Vaccine Supply is Limited.

CDC’s Advisory Committee on Immunization Practices (ACIP) initially stated that if the supply of the 2009 H1N1 Influenza vaccine is not adequate to meet demand for vaccination among the five target groups, that the following subset of the initial target groups receive priority for vaccination until vaccine availability increases (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months--4 years, and
- children and adolescents aged 5-18 years who have medical conditions that put them at higher risk for influenza-related complications.

This subset of the five target groups comprises approximately 42 million persons in the United States. Vaccination programs and providers should give priority to this subset of the five target groups only if vaccine availability is too limited to initiate vaccination for all persons in the five initial target groups.

7) Reserving 2009 H1N1 Influenza Vaccine 0.5mL Pre-filled Syringes for Pregnant Women

Efforts should be made to administer vaccine in pre-filled 0.5mL syringes to pregnant women. These syringes contain the appropriate dose of vaccine for pregnant women, and they are thimerosal free. Orders for 0.5 ml pre-filled syringes will be prioritized for those providers who care for pregnant women. All others should place orders for multi-dose vials or the nasal spray vaccine.

8) 2009 H1N1 Influenza Vaccination: Dosing in Pediatric Patients

Patients who are 9 years old and younger should receive 2 doses of the 2009 H1N1 influenza vaccine, and based on current CDC recommendations, they should be given 28 days apart. Children older than 9 years need only 1 dose of the 2009 H1N1 influenza vaccine. The reasoning behind these recommendations stems from currently available data suggesting that children 6 months to 9 years of age have little or no evidence of protective antibodies to the 2009 H1N1 influenza virus (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5819a1.htm>).

Patient age	Number of doses of vaccine needed
6months- 9years	2
>9years	1

Although the 2009 H1N1 influenza vaccine supply is currently limited, children aged 9 years and younger, still need 2 doses. Providers may decide either to give 1 dose of vaccine to all persons

in the target groups before administering a second dose to all applicable patients or to vaccinate patients whenever the opportunity presents, regardless of first/second dose status.

9) Commissioner Authorizes use of Thimerosal-containing Influenza Vaccines

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. The Commissioner of Health is granted the authority to waive this restriction as necessary to respond to inadequate vaccine supplies. Because of the current shortage of both seasonal and 2009 H1N1 influenza vaccines, the Commissioner has authorized the use of both types of influenza vaccines that contain thimerosal for pregnant women and children less than 3 years of age. This authorization will continue until May 1, 2010. For more information, please visit the NYS DOH website:

http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/health_care_providers/guidance/2009-10-29_authorize_use_of_influenza_vaccine_containing_mercury.htm

Consistent with PHL § 2112, the parent/guardian of a person under three years of age or person otherwise authorized to consent on the child's behalf or the pregnant woman must provide informed consent to the administration of vaccine that contains more than trace amounts of thimerosal. Informed consent can either be obtained in writing or verbally. Providers should note verbal informed consent in the medical record.

You can follow the same procedures that you usually do to obtain consent for immunizations. The Vaccine Information Statement (VIS) contains information on thimerosal and can be used to provide information for informed consent.

For more information, please visit the NYS DOH website:

http://www.nyhealth.gov/regulations/public_health_law/section/2112/information_for_physicians/

10) 2009 H1N1 Influenza LAIV and Cognitive Impairment

Vaccination to prevent influenza is particularly important for adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus). These persons are at increased risk for severe complications from influenza, or at higher risk for influenza-related outpatient, emergency department, or hospital visits.

Chronic neurologic and neuromuscular conditions include any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration.

The effectiveness or safety of live attenuated influenza vaccine (LAIV), the nasal spray vaccine, is not known for adults and children who have these chronic conditions; therefore, LAIV is

contraindicated in this population. Since cognitive dysfunction falls under the scope of "neurologic/neuromuscular" disorders, LAIV was therefore considered to be contraindicated in this population. However, physicians should use their clinical judgment in determining whether an individual with cognitive dysfunction (e.g., mental retardation without other dysfunction) can receive LAIV.

11) 2009 H1N1 Influenza Vaccine and Latex

If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction. For latex allergies other than anaphylactic reactions (e.g., a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain natural rubber or rubber latex can be administered.

Providers should note that there is no latex in any of the 2009 H1N1 influenza vaccines, including the nasal spray, or in any components of the final 2009 H1N1 influenza vaccine containers that are *currently* being distributed in the United States by the following manufacturers: CSL Limited, Novartis Vaccines and Diagnostics Limited, Sanofi Pasteur, and MedImmune.

12) Administering 2009 H1N1 Influenza Vaccine to Patients Who Reside Outside of NYS or a Given County

H1N1 vaccine distribution is determined on a State/County per capita basis. We understand that vaccine supply is currently limited, but encourage vaccine providers to administer the vaccine as widely as possible to their target group patients. If a patient in a target group resides outside of NYS or a given county, we hope that providers will vaccinate them. The NYSDOH has contacted our border states to discuss this policy, and all agree that patients should be vaccinated by their own providers whenever possible regardless of their County or State of residency.

13) 2009 H1N1 Influenza Vaccine Ancillary Supplies- Syringes

Some vaccine providers are receiving ancillary kits with 21 gauge needles for use in vaccine administration. CDC has acknowledged that these needles are not ideal for vaccine administration to all vaccinees but that the needles were chosen based on availability at the time of ancillary kit production. CDC notes that while such needles are cumbersome to use in some populations, vaccinators may use their clinical judgment and are free to use other needles appropriate to their patient populations, if available.

Some vaccine providers are also receiving ancillary kits with 20 gauge needles and 5 or 6 cc syringes. These needles and syringes were placed in the kits in case an adjuvant was included with the vaccines. These syringes and needles can be kept, redistributed, or disposed of.

14) 2009 H1N1 Influenza Vaccine BD Integra Retractable Needle/Syringe Units

There has been some discussion regarding how to optimize the performance of the BD Integra retractable needle/syringe units supplied in ancillary kits associated with the 2009 H1N1 vaccine. The following was issued by CDC to address this issue:

To Prevent Vaccine from Leaking

When filling syringes, vaccinators must firmly twist the needle (approximately 1/2 turn) into the hub of the syringe. When removing the cap to draw vaccine from a multi-dose vial, health care providers should tightly hold the end of the cap and pull straight back, being careful not to twist the needle.

If the needle cap has been replaced after drawing up vaccine, be careful not to twist the needle when removing the needle cap prior to vaccinating the patient.

To Activate the Needle Retraction Mechanism

BD Integra retractable needles are safety engineered to retract directly into the barrel of the syringe. If the needle is difficult to retract, withdraw the needle from the patient prior to attempting to retract. Immediately place syringe in sharps container.

15) 2009 H1N1 Influenza Vaccine Usage/Waste Reporting

There are three options available for reporting to the NYSDOH:

New York State Immunization Information System (NYSIIS)

Health care providers are required by Public Health Law 2168 to report all immunizations administered to children less than 19 years of age to NYSIIS. NYSIIS can also be used for reporting doses administered to persons 19 years of age or older, with consent. If vaccination information on an adult is entered into NYSIIS, they do not need to be reported in the Interactive Voice Response (IVR) system as described below. Inventory, including doses wasted, can be tracked using NYSIIS. An on-line tutorial for using the NYSIIS inventory module is available at: <https://commerce.health.state.ny.us/hpn/bcdc/immunization/instantdemo/tutorials.html>.

The Governor has issued an executive order that suspends or modifies several New York State laws due to the existing pandemic emergency. Therefore, if adults are vaccinated in a mass vaccination Point of Dispensing setting (POD), consent is not required to enter those 19 years of age and older into NYSIIS.

Clinic Data Management System (CDMS)

Only Local Health Departments have the ability to use CDMS to assist with managing the information related to the vaccination campaign.

Interactive Voice Response (IVR) System (Telephone Reporting):

1-888-H1N1-VAC (1-888-416-1822)

- Doses administered and vaccine inventory reporting for providers serving adults (19 years and older) can be completed through the IVR system using a touch tone phone.

- Each individual H1N1 PIN # will need to report totals by the CDC mandated age groups. IN addition, the total number of pregnant women vaccinated will be requested in a future release of the phone survey.
- Daily and Weekly Tracking logs are available to assist with compiling the information required for these weekly reports (see attached logs).
- Reporting must be completed by 11:59 p.m. each Monday for the week ending the previous Saturday.
- Reports can be submitted for the current 7 day reporting period and/or the previous reporting periods during the same telephone session.
- Only ONE report per H1N1 PIN# will be saved per weekly reporting period. Subsequent reports for the same 7 day reporting period will OVERWRITE previous reports for the same reporting period.

16) 2009 H1N1 Influenza Vaccine Redistribution

A vaccine provider that receives a shipment of 2009 H1N1 influenza vaccine may consider redistribution in the event that they cannot utilize all vaccine in their possession. However, in some circumstances, vaccine distribution is not permissible (e.g., partially used multi-dose vials, syringes which have been drawn up from multi-dose vials, and redistribution of vaccine to providers who do not have a H1N1 PIN number). Providers are encouraged to contact their local health department if they find that they are unable to use the vaccine allocated to them. Local health departments may have knowledge of other vaccine providers in their area who are in need of vaccine and may be able to facilitate redistribution.

When redistribution occurs, the vaccine provider that is redistributing 2009 H1N1 influenza vaccine should document and maintain, at a minimum, the following information: vaccine brand name, manufacturer, distributor, lot number, number of doses transferred, and the recipient's name and address. All vaccine redistribution **MUST** be reported to the NYSDOH using a Zoomerang survey: <http://www.zoomerang.com/Survey/?p=WEB229T486T6ZP>

The following items MUST be reported on the survey noted above.

- Redistributing vaccine provider name, address, and H1N1 PIN#.
- County in which the redistributing and receiving vaccine providers practice.
- Receiving vaccine provider name, address, and H1N1 PIN#.
- Number of doses being transferred.
- Manufacturer and type of vaccine being transferred.
- National Drug Code (NDC) of vaccine being transferred.
- Lot Number of vaccine being transferred.
- Date of transfer.
- Process used to transfer vaccine (i.e., commercial shipper, personal vehicle, pick-up, etc.)

- If applicable, whether ancillary supplies were also redistributed {NOTE: Ancillary supplies (e.g., syringes for multi-dose vials), if required for vaccine administration, should be redistributed in conjunction with the vaccine}.

Please note: It is the responsibility of the **redistributing** vaccine provider to ensure that these steps are followed.

17) Important Phone Numbers

Vaccine Order Placement: 1-800-KID-SHOT (1-800-543-7468)

- Call the Vaccine Call Center number listed above on your designated order day only. The Vaccine Call Center is open Monday-Friday from 8:30am-4:45pm.

Vaccine Reporting (for those 19 years and older): 1-888-H1N1-VAC (1-888-416-1822)

- Reporting must be completed by 11:59pm each Monday for the week ending the previous Saturday by calling the number noted above. Vaccines given to those under 19 years of age must be reported to the New York State immunization Information system (NYSIIS).

Public Vaccine Hotline (NYS): 1-800-808-1987

- For questions from the general public regarding 2009 H1N1 influenza.

NYC Vaccine Hotline: 1-212-676-2259.

18) Seasonal Influenza Vaccine Supply

The number of doses of seasonal influenza vaccine that will be available is very close (97%) to the planned number and it has been made available earlier this season than ever before. People have been responding to vaccine availability by getting immunized earlier this season.

If the anecdotal reports about increased demand turn out to be correct, the extra demand may not be fully met. Because the total number of doses that will be made this year is approximately the same as the number of doses that were actually administered last year, an increase in demand will outpace supply this season. Manufacturers are not able to produce more seasonal influenza vaccine for this season because their facilities are currently being used for vaccine production.

Some manufacturers fell short of their planned number of doses, and took orders that exceed the number of doses they now expect to make. In addition, some manufacturers have had a delay in the availability of vaccine, and this is resulting in orders that won't be completed until November or December.

Each year, some immunization providers order vaccine from more than one manufacturer or distributor, and then cancel other orders after the earliest vaccine is received. However, we have not seen this so far this season. We are not expecting additional vaccine being released into the market as has been the case in past years.

With orders and availability still being sorted out, CDC recommends that vaccine providers check the National Influenza Summit web site where available vaccine is listed by distributor: <http://www.preventinfluenza.org/>. Providers, who have more vaccine than they anticipate using, are being encouraged to work with their local health department to identify other providers for the vaccine. Providers who do not have vaccine may also advise their patients to check the American Lung Association web site that identifies clinics that have influenza vaccine available: <http://www.flucliniclocator.org/>

19) Seasonal Flu Vaccine Redistribution

It is permissible to redistribute seasonal influenza vaccine in order to alleviate a shortage. Please go to the website below to obtain information from the Centers for Disease Control and Prevention on the definition of a shortage, how seasonal influenza vaccine can be redistributed, and proper documentation. All those who have seasonal influenza vaccine that is not being used are encouraged to redistribute their vaccine to others that can use it. Your local health department may know of other practices that are seeking vaccine.

http://www.cdc.gov/flu/professionals/vaccination/reallocating_influenza.htm.

Ordering Schedule

Orders will be taken Monday through Friday between the hours of **8:15 a.m. and 4:45 p.m.** based upon the schedule below. This process was put in place to ensure fair and equitable distribution of vaccine and to minimize call wait time.

MONDAY		
<ul style="list-style-type: none"> • All Local Health Departments, • Acute Care Hospitals • Federally Qualified Health Centers (FQHCs) 	<ul style="list-style-type: none"> • Retail Pharmacy Chains • State Agencies • Veteran’s Affairs (VA) Facilities • Others to be identified 	
<p>Note: All other vaccine providers can only order vaccine based on the day their respective county is assigned to below.</p>		
TUESDAY		
<ul style="list-style-type: none"> • Columbia • Dutchess • Greene • Madison 	<ul style="list-style-type: none"> • Nassau • Orange • Putnam • Rockland 	<ul style="list-style-type: none"> • Sullivan • Ulster • Wyoming • Yates
WEDNESDAY		
<ul style="list-style-type: none"> • Broome • Cayuga • Chenango • Cortland • Herkimer 	<ul style="list-style-type: none"> • Jefferson • Lewis • Oneida • Onondaga • Oswego 	<ul style="list-style-type: none"> • St. Lawrence • Suffolk • Tioga • Tompkins • Westchester
THURSDAY		
<ul style="list-style-type: none"> • Allegany • Cattaraugus • Chautauqua • Chemung • Erie 	<ul style="list-style-type: none"> • Genesee • Livingston • Niagara • Ontario • Orleans 	<ul style="list-style-type: none"> • Schuyler • Seneca • Steuben • Wayne
FRIDAY		
<ul style="list-style-type: none"> • Albany • Clinton • Delaware • Essex • Franklin • Fulton 	<ul style="list-style-type: none"> • Hamilton • Monroe • Montgomery • Otsego • Rensselaer 	<ul style="list-style-type: none"> • Saratoga • Schenectady • Schoharie • Warren • Washington

Timeline Between Order Placement with the NYSDOH and Vaccine Arrival

Day Provider Places Order with NYSDOH	Day NYSDOH Places Order with CDC	Day Order Expected to Arrive at Provider	Day to Contact Call Center if Order Does Not Arrive
Monday or Tuesday	Thursday	Monday	Thursday
Wednesday, Thursday, or Friday	Tuesday	Thursday	Tuesday

2009 H1N1 Influenza Vaccine Storage and Handling

Requirements and Considerations

General Information

Vaccination efforts have been successful in preventing and eradicating vaccine-preventable diseases in part because of proper vaccine storage and handling practices. Failure to adhere to recommended specifications for storage and handling can reduce vaccine potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. Vaccine quality is the shared responsibility of all parties, from the time vaccine is manufactured until it is administered.

Handling, Storage, and Transporting (Cold Chain)



It is important to keep vaccines at the specified temperature at all times in order to adequately maintain the “cold chain.” Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Furthermore, each time vaccine is exposed to excessive heat or cold, the loss of potency increases and eventually, if the cold chain (35°-46°F) is not correctly maintained, all potency will be lost, and the vaccine becomes useless. Once potency is lost, it can never be restored. It is the provider’s responsibility to ensure appropriate handling of the vaccine after receipt.

During an influenza pandemic, it will be necessary to exert vigilance in maintaining the cold chain. Therefore, it will be essential to have the appropriate equipment, train staff, and develop standard operating procedures outlining protocols to protect the vaccine “cold chain.”

Condition Upon Arrival

In order to maintain the cold chain, upon receipt of the package the following steps should be followed immediately:

- Inspect the package and contents for damage. The vaccine should not appear to have been frozen or exposed to freezing temperatures. Refrigerate immediately.
- If you have questions about the condition of the material at the time of delivery, you should 1) immediately refrigerate the material (mark it as DO NOT USE until the integrity of the vaccine can be determined); and 2) call McKesson Customer Service at 877-836-7123 or your state/local immunization program within 2 hours of receipt of the package.
- If the doses that you have received do not match the packing list, please place in the refrigerator and contact your state/local immunization program right away. The New York State Immunization Program can be reached through the Vaccine Call Center at 1-800-KID-SHOT or 1-800-543-7468.
- If the contents appear to be in satisfactory condition, receive and process the materials according to the following procedures:
 - Count the vials/product and place in monitored refrigerator immediately.
 - Remove the 3M MonitorMark Time Temperature Indicator and check the index. Review the temperature monitor card in the package IMMEDIATELY to determine if the recommended temperatures have been maintained during shipping.

Indicator Color	Usage
0-2	Ready for Use 
3-5	Call 877-TEMP123 or your state/local immunization program right away 

- If multiple boxes are received, segregate the vaccine by box. Annotate box and temperature monitors/indicators to identify which temperature monitors belong to which box of vaccine. The purpose of this is to be able to identify which vials or sprayers were affected if one of the boxes has become compromised in shipment.
- Additionally, it is recommended that the following information be recorded upon arrival:
 - Vaccine name and number of doses received
 - Date the vaccine was received
 - Arrival condition of the vaccine
 - Vaccine manufacturer and lot number
 - Vaccine expiration date

Handling Vaccine

- Maintain a daily temperature log that clearly shows when temperatures are not correct. Examples of recommended temperature logs are attached below; check unit temperature two times per day, once in the morning and once in the evening, and record them on the temperature log posted on the storage unit.
- Monitor inventory monthly.
- Rotate vaccine according to expiration dates; those with shortest expiration dates should be used first.
- Securely close refrigerator doors.
- Lock refrigerator doors at the end of each day.
- Place a warning at the plug and the associated circuit breaker to ensure neither has power removed without first informing appropriate personnel.
- The unit should have a back-up generator power in case of an outage.
- Provide personnel in charge of vaccine with 24-hour access to building and storage location.
- A specific written plan should be available in the case of a power outage; develop standard procedures on how to notify individuals if there is a power outage or problem in the vaccine storage location. You may also reference the Immunization Action Coalition’s Emergency Response Sheet for further guidance as to what to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range
<http://www.immunize.org/catg.d/p3051.pdf>

- Identify a maintenance repair company in the event that the unit breaks down.

Storing Vaccine

- **Vaccine should be stored in a refrigerator unit immediately upon arrival. *It should not be a refrigerator unit that utilizes a freezer tray, such as a dormitory style, as they do not maintain temperature.***
- Store in the original package to protect from light.
- The unit should be capable of maintaining a temperature between 35-46 deg F (2-8 deg C) in the refrigerator section. Do not freeze or expose the vaccine to freezing temperatures.
- Between uses, return the multi-dose vial to the recommended storage conditions 2°-8°C (35.6°-46.4°F).
- A thermometer should be located in the central compartment of the refrigerator .
- An alarm system should be integral to monitor for both temperature and possible tampering.
- Vaccine should be stored in the center of the unit, never in the doors.
- Never store food or beverages in the same unit as vaccine.
- Avoid opening and closing the unit as much as possible in order to maintain a constant temperature.
- Storing bottled water and gel packs in the doors may help in regulating the space temperature and maintaining the temperature during a short power outage.
- Train employees on correct storage of vaccine, acceptable temperature ranges and emergency procedures.
- There should be a plan for an alternate storage location in the event that the vaccine needs to be moved in an emergency (hospitals, fire departments, etc.).

Transporting Vaccine

If vaccine transportation to another site is required, it is critical that the cold chain be maintained throughout the process to ensure the viability of the vaccine. In order to transport vaccine appropriately, it is imperative that the following shipping materials have been purchased: insulated Styrofoam containers, ice packs, temperature monitors, and sheets of bubble or foam wrap. The following procedures should then be followed:

1. Place ice packs on bottom of Styrofoam container.
2. Place bubble wrap or foam wrap on top of ice packs (vaccine should NOT come in direct contact with ice packs.)
3. Place vaccine in container on top of the bubble/foam wrap.
4. Insert temperature monitors near the center of the vaccine.
5. Place more bubble wrap or foam wrap on top of vaccine.
6. Place more ice packs on top of bubble wrap.
7. Ensure vaccine is secure in the container and close and seal the lid.
8. Clearly label the container **“Vaccine- Refrigerate Immediately”** and deliver vaccine to destination without delay.
9. Do NOT transport coolers containing vaccine in the trunk of the vehicle, where the temperature cannot be appropriately regulated.
10. If it needs to be shipped, use **Priority Overnight Mail** on Monday, Tuesday or Wednesday to ensure the product arrives before the weekend. Some shippers require the Styrofoam container to be inside an additional cardboard box for shipping.

Equipment Malfunction

- Move the vaccine to an alternate refrigerator.
- Move the vaccine to an alternate storage location.
- If vaccine reaches temperatures outside of the recommended range, immediately store it in a location at the appropriate temperature and clearly mark and separate it from other vaccines so that it may be checked later. Don't assume that it is spoiled; depending on the recommendations of the manufacturer the vaccine may still be viable.
- Contact the manufacturer for guidance regarding the status of the vaccine.
- Do not discard spoiled or expired vaccine. Contact the NYSDOH and return vaccine accordingly.

Additional Resources and Helpful Links

1. Centers for Disease Control and Prevention: Vaccine Storage and Handling Toolkit
<http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm>
2. CDC H1N1 Flu: Vaccination guidance for state, local, and territorial health officials
<http://www.cdc.gov/h1n1flu/vaccination/statelocal/>
3. Centers for Disease Control and Prevention: Vaccine Storage and Handling FAQs
http://www2a.cdc.gov/vaccines/ed/shtoolkit/resources/Storage_&_Handling_FAQs.htm
4. California Vaccines for Children Program
<http://www.eziz.org/pages/storageandhandling.html>
5. Immunize.org- sample temperature logs, emergency worksheets
http://www.immunize.org/printmaterials/topic_storage.asp
6. U.S. Food & Drug Administration 2009 H1N1 Vaccine Package Inserts
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>

Temperature Log for Vaccines (Fahrenheit)

Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected. 3. **Call the immunization program** at your local health department for further assistance: (____) _____. 4. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																
Room Temp.																
Exact Time																
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	
Too warm*	49°	Take immediate action if temperature is in shaded section*														
	48°															
	47°															
Refrigerator temperature	46°															
	45°															
	44°															
	43°															
	42°															
	41°															
	40°															
	39°															
	38°															
	37°															
	36°															
Too cold*	35°															
	34°	Take immediate action if temperature is in shaded section*														
	33°															
#32°																
Too warm*	Freezer temp	8°	Take immediate action if temperature is in shaded section*													
		7°														
		6°														
		5°														
		4°														
		#3°														

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/catg.d/p3039.pdf • Item #P3039 (1/07)

Temperature Log for Vaccines (Fahrenheit)

Month/Year: _____ Days 16–31

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected. 3. **Call the immunization program** at your local health department for further assistance: (____) _____. 4. **Document the action taken** on the reverse side of this log.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Room Temp.																
Exact Time																
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm*	49°															
	48°				Take immediate action if temperature is in shaded section*											
	47°															
Refrigerator temperature	46°															
	45°															
	44°															
	43°															
	42°															
	41°															
	40°															
	39°															
	38°															
	37°															
Too cold*	36°															
	35°															
	34°				Take immediate action if temperature is in shaded section*											
	33°															
Freezer temp	#32°															
	8°				Take immediate action if temperature is in shaded section*											
	7°															
	6°															
	5°															
Too warm*	4°															
	#3°															

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/catg.d/p3039.pdf • Item #P3039 (1/07)

Name of Facility/Provider:	
*Facility/Provider H1N1 PIN Number:	
**H1N1 Registration Application Number:	
County the Facility/Provider is Located in:	

Age Groups	Number of Doses Administered (///)	TOTAL
19-24yrs		
25-49yrs		
50-64yrs		
≥65yrs		
TOTAL		
***Pregnant Women		

****Total # of Doses Wasted:	
-------------------------------------	--

Public Health Law 2168 mandates that health care providers report information on vaccinations administered to all persons less than 19 years of age into the New York State Immunization Information System (NYSIIS).

* A facility/provider H1N1 PIN# is the identifier given to those who have signed a provider agreement to receive 2009 H1N1 influenza vaccine.

**A H1N1 registration application number is assigned to those who have completed the registration process (can be found on the registration confirmation page).

***Pregnant women should be counted both in their age group category AND in the pregnant women category.

****Total # of doses wasted is the number of doses that are not usable (e.g., temperature irregularities, broken syringe, expired, etc.).

To report 2009 H1N1 influenza vaccine doses administered call **1-888-H1N1 VAC (1-888-416-1822)** by **MONDAY** at 11:59 p.m. weekly.

Name of Facility/Provider:							
*Facility/Provider H1N1 PIN Number:							
**H1N1 Registration Application Number:							
County the Facility/Provider is Located in:							
Reporting Period Start Date (Sunday): MM/DD/YYYY							
Reporting Period End Date (Saturday): MM/DD/YYYY							
Day	Date MM/DD/YYYY	Age Groups				TOTAL	***Pregnant Women
		19-24yrs	25-49yrs	50-64yrs	≥65yrs		
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
TOTAL							
****Total # of Doses Wasted:							

Public Health Law 2168 mandates that health care providers report information on vaccinations administered to all persons less than 19 years of age into the New York State Immunization Information System (NYSIIS).

* A facility/provider H1N1 PIN# is the identifier given to those who have signed a provider agreement to receive 2009 H1N1 influenza vaccine.

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To report 2009 H1N1 influenza vaccine doses administered call **1-888-H1N1 VAC (1-888-416-1822)** by **MONDAY** at 11:59 p.m. weekly.