

**New Jersey Dept. of Health and Senior Services**  
**H1N1 Vaccination Program and Clinical FAQs**

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**GLOSSARY OF TERMS**

**H1N1 Vaccine System:** NJDHSS's H1N1 vaccine data tracking system which resides in and uses the format of the New Jersey Immunization Information System (NJIS), the state's immunization registry.

**Provider:** any entity that will receive vaccine and/or administer vaccinations; providers include hospitals, FQHCs, local health departments, LINCS agencies, pharmacies, pharmacists, physicians, and employee health services.

**Provider site:** physical location where vaccine will be received and/or administered.

**Ship-to site:** physical location where vaccine will be received directly from the vaccine distributor (McKesson). Ship-to sites may also administer vaccine. NJ has been allocated 2,353 ship-to sites (per U.S. population-based formula).

**Vaccination-only site:** physical location where vaccine will be administered. Vaccine will be provided by a ship-to site.

**Provider type:** individual authorized to bind a provider site to receive vaccines and/or administer vaccinations; provider types can only be licensed physicians, advanced practice nurses, pharmacies, and pharmacists.

**User:** any authorized individual associated with a provider site who will or has access to the H1N1 Vaccine System in order to administer vaccine-related information (e.g., doses-administered reports, vaccine inventory data); examples of users include physician office managers, data entry clerks, and health care professionals.

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## **H1N1 VACCINE PROGRAM FAQs**

Beginning today, January 7, 2010, the New Jersey Department of Health and Senior Services (NJDHSS) Vaccine Preventable Disease Program is expanding the hours for ordering H1N1 vaccine. Due to an increase in H1N1 vaccine supply and the recommendation to provide vaccination to the general population, ordering will now be available 24 hours a day and 7 days a week until further notice.

Please check your inventory before placing orders to avoid vaccine wastage and to ensure adequate storage capacity for vaccines. Remember to enter vaccine inventory, temperature logs, and doses administered in the H1N1 Vaccine System.

If you have any questions please call the Program's help desk at 609-633-2218. Please note that beginning January 26, 2010 the help desk hours will be 8:30am-4:30pm. We appreciate your cooperation and participation in H1N1 vaccination efforts.

### **BECOMING A PROVIDER**

**NOTE: Provider Registration is open.**

#### **Who should register to be a "ship-to" site?**

Providers who register to be a "ship-to" site should be committed to agreeing to the terms of the program and participating in the H1N1 vaccine program through its completion. NJ has a limited number of ship-to sites and if providers dis-enroll from the program, the state cannot fill that vacant site with another provider. That site will be lost. If you change your mind, when you receive the confirmatory email from your LINC agency with your PIN and access code, please inform them of your decision at that time so that the space for your provider site is not lost.

#### **How does a New Jersey provider site register to receive the H1N1 vaccine?**

It is required that all providers interested in receiving a direct shipment or being a "vaccinator only" site must register online at the H1N1 Vaccine System at <http://nj.gov/health/flu/h1n1.shtml>. Once there, click "H1N1 Vaccine Registration," look to the left side of the webpage and click on "Provider Site Registration." Please complete registration form and Vaccine Provider Agreement below.

#### **Can I fax or send a paper copy to register?**

No. Paper copies will not be accepted. Providers must register electronically online at <http://nj.gov/health/flu/h1n1.shtml>. Once there, click "H1N1 Vaccine Registration," look to the left side of the webpage and click on "Provider Site Registration." Please complete registration form and Vaccine Provider Agreement below.

#### **Must I have a valid email address?**

Yes, an email address must be provided in order to receive a confirmation of your enrollment and the status of your enrollment application. There will be information in the email that you will need to receive Webinar training on the H1N1 Vaccine System for use during the H1N1 influenza season.

**Will I get an account number or provider identification number (PIN)?**

Yes, once a provider is registered, he or she will be assigned a PIN that will be needed to electronically order vaccine, electronically record the vaccines that you administer and electronically record the temperatures of the refrigerator in which the H1N1 vaccine is stored.

**How do commercial facilities or providers request vaccines?**

Any facility interested in receiving the H1N1 vaccine must register as a provider. (Refer to question #3 for the enrollment website.)

**Do individual provider sites need to register if they are not a “ship-to” site but will be receiving vaccine from a parent company?**

Yes, all provider sites, whether direct “ship-to” or “vaccination only” site, must register to receive the vaccines. That is one of the ways that the State will be able to monitor the vaccine administered and transferred from one location to another. Individual staff within those sites do not need to register. Only one individual at the site is required to register in order to serve as the point of contact for the NJDHSS and LHD. If you have further questions regarding this, your parent company should contact the NJ Immunization Program at 609-588-7512 for more guidance.

**I am with a local health department or LINCS agency. Who is eligible to complete and sign the Provider Agreement?**

To be eligible to complete and sign the Provider Agreement, an individual must have a current license as a D.O., M.D., Advanced Practice Nurse, Pharmacist, or Pharmacy in order to legally bind the terms of the Provider Agreement. In the H1N1 Vaccine System, this individual is identified in the “Provider Type” section.

A registered site can designate up to three individuals who will have the ability to order vaccine. An indefinite number of individuals can serve as data entry personnel, responsible for entering data on the doses of vaccine administered.

**Should individual schools register as provider sites?**

This will be a local school district decision, but in general there are two options. First, school districts can register as provider sites which will receive vaccine and forward it to the individual schools within their district. The other option is to have each school register as a provider site and receive the vaccine directly.

**If a site registers and decides afterwards that they no longer wish to receive vaccine, can they dis-enroll?**

Yes. You should contact the LINCS agency in your jurisdiction and inform them of your decision to no longer receive vaccine. That way, you will no longer be selected to be a “ship-to” or “vaccination-only” site. The LINCS agency will contact the NJDHSS VPDP to remove your information from the H1N1 Vaccination Program System. The LINCS agency will contact the VPDP at the VFC email address at [vfc@doh.state.nj.us](mailto:vfc@doh.state.nj.us).

**If a location has more than one National Provider Identifier number (NPI) (i.e., one for the location and one for each provider) which one should be put on the registration form?**

Enter the NPI number for the site that will receive the vaccine. Do not enter the NPI for an individual provider.

**If I am a physician who contracts to give shots for a local school district, but also gives shots at my office to a different age population, what numbers should I enter in the Patient Number Estimate section of the Registration Form?**

You should enter the number of people for any applicable age range of the population for whom you are currently contracted to serve. For instance, if you are a physician with an adult practice, but are still awaiting to be contracted to give shots for a local school district, you should only enter the numbers for the age range of your practice. You can go back into the system at a later date to modify the age ranges and order vaccine to accommodate any additional contracts you might receive.

**If I have multiple sites with one NPI for all sites, how do I register?**

On the Provider Registration Form, enter the NPI for the primary location and click on “NPI used by multiple offices.” That action will include all of your sites that you register under that one NPI number.

**Criteria for Approving Submitted Application as H1N1 Sites**

**Combination Ship-to & Vaccinator Site:**

- **Provider must be licensed or certified to vaccinate in New Jersey.**
- **Provider address must be a business not a home address or PO Box.**
- **Telephone number must be an office number not a cell or mobile #.**
- **Must have internet access.**
- **Provider must have a computer or laptop from which to order vaccine, record vaccine accountability and refrigerator temperatures where the H1N1 vaccine is stored.**
- **Each person that will administer vaccine must register as a user of the H1N1 Vaccine System.**
- **Refrigerator must be a single-door household size (13 cu. ft) or larger no dorm-style or bar-style refrigerators permitted.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**

**Ship-to only Site:**

- **Refrigerator must be a single-door household size (13 cu. ft) or larger.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**
- **Must have internet access.**
- **Provider must have a computer or laptop from which to order vaccine, record vaccine inventory and refrigerator temperatures where the H1N1 vaccine is stored.**

- **Provider address must be a business not a home address or PO Box suitable to accept delivery of large shipments of vaccine for distribution to vaccinator-only sites.**
- **Telephone number must be an office number not a cell or mobile #.**

### **Vaccinator –Only Site**

- **Provider must be licensed or certified to vaccinate in New Jersey.**
- **Provider address must be a business not a home address or PO Box.**
- **Telephone number must be an office number not a cell or mobile #.**
- **Must have internet access.**
- **Provide must have a computer or laptop from which to order vaccine, record vaccine accountability and refrigerator temperatures where the H1N1 vaccine is stored.**
- **Each person that will administer vaccine must register as a user on H1N1 Vaccine System.**
- **Refrigerator must be a single-door household size (13 cu. ft) or larger, no dorm-style or bar-style refrigerators permitted.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**

### **New Jersey Department of Health and Senior Services (NJDHSS) H1N1 Vaccine System Provider Registration in Brief: Health Care Providers**

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for health care providers (e.g., physicians, pharmacists, advanced practice nurses).

#### *Step 1 – Provider Site Registration*

Providers need to register their office or facility as a site for administering H1N1 vaccines. Eligible providers include physicians, pharmacies, hospitals, employee health programs, local health departments and federally qualified health centers. If you have more than one office/location, you will need to register each location separately. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

Once you register in the H1N1 Vaccine System, your information will be approved by the appropriate LINCS agency and/or local health department. Once approved and then verified by NJDHSS, you will receive an email with your PIN and a security access code. If you are not approved, you will receive an email notification, and you can contact the LINCS agency in your jurisdiction to get further information.

You can be approved as a *ship-to site*, where the vaccine will be delivered to your location, or as a *vaccinator only site*, where you will need to pick up the vaccine from a designated site in your jurisdiction such as a local health department or LINCS agency.

**Important –**

- Please provide a valid email address in the provider registration process as all communication is via email.
- Current New Jersey Immunization Information System (NJIIS) providers need to register for participation in the H1N1 Vaccine System.

*Step 2 – User Registration*

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. All users will have the ability to track H1N1 vaccine inventory, complete temperature logs, and update administered doses for each person you vaccinate. In addition, ship-to site users will have the ability to order vaccine online through the H1N1 Vaccine System.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self-training through a user manual and/or series of video clips provided under Documents and Tutorials on the H1N1 Vaccine System main page.

*Step 3 – Vaccine Order (Only for Ship-to Sites)*

After completing the previous two steps, i.e., registering your facility and creating your user account, as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification), you can start ordering H1N1 vaccines by clicking on the “Order Vaccine” tab. Vaccine ordering privileges will be restricted to three users per registered ship-to site. As mentioned above, training is available to help you with your ordering process.

Note: vaccinator only sites will have to place their vaccine orders through the designated ship-to sites in their jurisdiction such as the LINCS agency or local health department.

*Step 4 – Record Patient Vaccination*

Use your user name and password (created in Step 2) to access data entry screens for reporting patient information. If the patient already exists in NJIIS, the state’s immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient’s name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the doses already shipped to you. Any registered user from your facility can enter patient vaccination information.

Current NJIIS users will also be able to document H1N1 vaccines through NJIIS screens.

**New Jersey Department of Health and Senior Services (NJDHSS)  
H1N1 Vaccine System Provider Registration in Brief:  
LINCS Agencies and Local Health Departments (LHDs)**

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for LINCS agencies and LHDs.

*Step 1 – Provider Registration and Approval*

All LINCS agencies and local health departments need to register in the H1N1 Vaccine System if they want to be provider sites for administering H1N1 vaccines. You will receive your approval email from NJDHSS after registration in the H1N1 Vaccine System. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

In addition, two LINCS agency staff will be assigned H1N1 Vaccine System administrative privileges to “approve” ship-to or vaccinator only sites within their jurisdiction (“LINCS H1N1 Vaccine System administrators”). One person per local health department will be assigned H1N1 Vaccine System privileges to view the list of providers enrolling in their county in order to help the LINCS agencies in the approval process. Ship-to sites will receive vaccine shipments at the address indicated in their registration information, while vaccinator only sites will be asked to pick up their vaccine orders from a designated site such as the LINCS agency or local health department. As you have a limited number of ship-to sites in your jurisdiction, please use your judgment in allocating them; NJDHSS has provided some guidance for your consideration as you review provider registration information.

As the LINCS agency, you are requested to work with local health departments in your jurisdiction and to approve providers as *ship-to sites*, where vaccine will be delivered to these locations, or as *vaccinator only sites*, where these sites will need to pick up vaccines from a designated ship-to site such as the local health department or LINCS agency. You will need to check off a flag on the H1N1 Vaccine System approval screen to designate ship-to sites.

Once you approve a site, NJDHSS will verify eligibility and send out an email to the approved providers with their PIN, security access code and training information.

Providers that are not LINCS-approved will be sent an email informing them that their applications have not been approved and that they can contact the designated LINCS H1N1 Vaccine System administrators for further information. The email address of the LINCS H1N1 Vaccine administrators will be included in the email.

*Step 2 – User Registration*

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. Users will have the ability to order vaccine, track vaccine inventory, complete temperature logs, and update administered doses by inputting the information for each person you vaccinate.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self training through a user manual and/or series of video clips provided under Documents and Tutorials on the H1N1 Vaccine System main page.

### *Step 3 – Vaccine Order*

After completing the previous steps, i.e., registering your facility, creating your user ID, and attending the training, you can start ordering the H1N1 vaccines by clicking on the “Order Vaccine” tab as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification). As a LINC agency or LHD, you can also order vaccine for other vaccinator only sites. Only three users per registered facility can be assigned vaccine ordering privileges.

### *Step 4 – Record Patient Vaccination*

Use your user name and password to access data entry screens for reporting patient vaccination information. If the patient already exists in the New Jersey Immunization Information System, the state’s immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient’s name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the ones already shipped to you. Any registered user in your organization can enter patient vaccination information.

## **New Jersey Department of Health and Senior Services (NJDHSS) H1N1 Vaccine System Provider Registration in Brief: Hospitals and Federally Qualified Health Centers (FQHCs)**

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for hospitals and FQHCs.

### *Step 1 – Provider Site Registration*

Hospitals and FQHCs need to register in the H1N1 Vaccine System if they want to be provider sites for administering H1N1 vaccines. If you have more than one location, you will need to register each location separately. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

Once you register in the H1N1 Vaccine System, your information will be approved and verified by NJDHSS. Once approved and verified, you will receive an email with your PIN and a security access code

#### **Important –**

- Please provide a valid email address in the provider registration process as all communication is via email.
- Current New Jersey Immunization Information System (NJIIS) providers need to register for participation in the H1N1 Vaccine System.

### *Step 2 – User Registration*

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. All users will have the ability to track H1N1 vaccine inventory, complete temperature logs, and update administered doses for

each person you vaccinate. In addition, you will have the ability to order vaccine online through the H1N1 Vaccine System.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self-training through a user manual and/or series of video clips provided under Documents and Tutorials on the H1N1 Vaccine System main page.

### *Step 3 – Vaccine Order*

After completing the previous two steps, i.e., registering your facility and creating your user account, as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification), you can start ordering H1N1 vaccines by clicking on the “Order Vaccine” tab. Vaccine ordering privileges will be restricted to three users per registered site. As mentioned above, training is available to help you with your ordering process.

### *Step 4 – Record Patient Vaccination*

Use your user name and password (created in Step 2) to access data entry screens for reporting patient information. If the patient already exists in NJIIS, the state’s immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient’s name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the doses already shipped to you. Any registered user from your facility can enter patient vaccination information.

Current NJIIS users will also be able to document H1N1 vaccines through NJIIS screens.

## **VACCINE ORDERING**

### **I would like to cancel or add to my order. How do I do that?**

You can cancel/add to your order as long as the original order has not been transmitted. To see if your order has been transmitted, go to the ordering page and view your order. Look for the “cancel order” button at the bottom of the ordering page. Click “cancel.” Be sure all items on the initial order are canceled (it should say “canceled” next to each item). Go back into the order page and order the items you need. To add to your order, you need to cancel out the original order and then re-enter the amount of vaccine you need.

**Detailed instructions for Ordering Vaccine are available on-line as a pdf manual and a series of video clips under the Documents & Tutorial page on the H1N1 Vaccine System main page.**

### **What is the minimum dose order for shipments of 2009 H1N1 vaccine?**

For each vaccine formulation (identified by its National Drug Code) the minimum dose order is 100 doses and all orders must be placed in increments of 100 doses. Each ancillary supply kit will contain supplies to support 100 doses of vaccine, with different kits available for prefilled syringe products and for multi-dose vial products.

## REPORTING

### **Are providers required to report each dose administered to an individual?**

Yes, all doses administered must be reported to the New Jersey Department of Health and Senior Services electronically at <http://nj.gov/health/flu/h1n1.shtml> .

### **How do I inform the New Jersey Department of Health and Senior Services of the doses used or administered?**

All enrolled providers will be sent by email the information needed to access a Webinar training on the H1N1 Vaccine System. The 20-minute training will show where all doses administered must be electronically entered and reported in the H1N1 Vaccine System.

### **Is there a way to transfer data to the registry from other electronic systems?**

Yes, the H1N1 Vaccine System is capable of receiving data from various electronic systems. The documentation is available on the NJ Immunization Information System (NJIIS), the state's immunization registry, website at [http://njiis.nj.gov/njiis/html/h1n1\\_forms.html](http://njiis.nj.gov/njiis/html/h1n1_forms.html). Data must include the lot number of the vaccine administered to an individual. This is a CDC requirement. The H1N1 Vaccine System also allows documenting refrigerator temperature logs, and the doses administered.

### **How do I report doses administered if I am getting additional doses from vials or reduced doses from using pediatric syringes?**

Additional doses administered from vial must be accounted for in order to enter patient vaccination records. Doses reduced from using pediatric syringes must be accounted for in order to reflect the current on-hand inventory.

1. Go to website: <http://njiis.nj.gov/njiis/jsp/h1n1home.jsp>
2. Click Record Patient Vaccination tab
3. Enter Username and Password
4. Click Inventory tab
5. Click Management
6. Click Vaccine ID hyperlink for the appropriate vaccine product and lot number that you need to account for the extra or reduced doses
7. Click the Add Transactions tab
8. **For additional doses:** under "Additional Doses Administered from Vial" transaction, enter the number of extra doses in the "Doses" column, transaction date, and comments
9. **For reduced doses:** under "Doses Reduced From Using Ped Syringes" transaction, enter the number of reduced doses in the "Doses" column, transaction date, and comments
10. Click Save

If your "Inventory on Hand" is 0 and you need to account for additional doses:

1. Follow the above mentioned steps 1-5
2. On Display Options drop down choose "All" to display all lots including lots with zero inventory on hand
3. Follow above mentioned steps 6-10

**If one of the two H1N1 doses administered to a patient is invalid, and a third dose is administered, how do I enter the third dose?**

Previously, you had to enter the third dose into NJIIS, because the H1N1 vaccine system would not allow you to record three doses of H1N1. However, in an effort to make the system more user-friendly, the H1N1 Vaccine System has been modified so that you are now able to record the three doses of H1N1.

**FINDING FLU VACCINE - PUBLIC**

**How will the public be able to locate a vaccination location?**

There are multiple sites to which the public can go to be vaccinated. Click on the “Find a Flu Shot” button on the NJDHSS website: <http://nj.gov/health>.

**RECEIVING SITES**

**What kind of providers can be designated as “vaccinator only” site?**

Providers that have the capability to receive, store and administer vaccine, including but not limited to provider offices, occupational health clinics, hospitals, local health departments, community vaccinators and pharmacies.

**How many sites can be designated to be a “ship-to” site?**

There will be a maximum of approximately 90,000 sites to which vaccine can be shipped via centralized distribution. CDC has developed a formula to determine the maximum number of sites within each state. New Jersey has 4069 “ship-to” sites. More information is available on the CDC website.

**What is the difference between direct “ship-to” and “vaccinator site”?**

Direct “ship-to” sites are designated sites to receive the shipment of vaccine from McKesson while “vaccinator sites” will vaccinate only, but not receive the vaccine directly from McKesson. “Vaccinator only” sites need to contact their local LINC agency to obtain the vaccine.

**How many direct “ship-to” sites are in New Jersey?**

New Jersey can have approximately 4069 direct “ship-to” sites.

**SHIPMENTS/RECEIVING SITES/LOGISTICS**

**How is vaccine shipped to New Jersey?**

Vaccine is shipped by CDC’s contractor for centralized distribution, McKesson Specialty, to hospitals, clinics, doctors’ offices, health departments, and other providers of vaccines that have been designated as “ship-to” sites.

**How frequently will vaccine shipments arrive to New Jersey ship-to sites?**

As details of distribution are finalized, CDC will communicate with states about the anticipated time period between placing vaccine orders and receiving shipments.

**How many sites can be designated as “vaccinator only” sites?**

One of the key benefits of using a centralized, third party distributor to support H1N1 vaccine distribution is that it allows distribution of doses to a much larger number of providers sites than would be feasible with direct manufacturer distribution. Thus, we will be able to serve a significantly larger provider base than the original state “ship-to” sites, and are planning to be able to accommodate more providers than are currently served by the VFC program.

**How long will it take for vaccine to arrive once I place my order?**

The shipping timelines for 2009 H1N1 vaccine are currently being established between CDC and McKesson. Information will be provided to state planners as soon as it is available.

**What should states expect with respect to frequency of vaccine shipments?**

Vaccine will be shipped as it becomes available, taking into account state allocations and orders. The process will be modeled after that utilized by immunization programs that order seasonal influenza vaccine off the federal contract, except for the shipment timeline, which is not yet finalized.

**Can a “ship-to” site transfer vaccine to another “ship-to” or “vaccinator site”?**

Yes, as long as the site to which the vaccine is being transferred and the site receiving the vaccine are registered as H1N1 vaccine sites.

**Can a “ship-to” or vaccinator site transfer vaccine to another location?**

Yes, if properly packaged for transport with a thermometer inside to monitor the container temperature in which the vaccine is being moved. Maintaining the cold-chain is very important to protecting the potency of the vaccine.

**Can distribution sites be added over the coming weeks?**

Yes, states can add distribution sites over time, but cannot exceed their total number of site allocations. Please remember that sites receiving vaccine early in the distribution process cannot be switched out for new sites once those sites no longer receive the vaccine.

**VACCINE ADVERSE EVENTS****How do I report adverse events related to the H1N1 vaccine?**

The Vaccine Adverse Event Reporting System (VAERS) is the front-line monitoring system for collecting and analyzing voluntary reports of adverse events following vaccination. There are three ways to report to VAERS which are outlined on the VAERS website at <http://vaers.hhs.gov/esub/index>.

1. Submit the report online via the secure website
2. fax a completed VAERS form to 877-721-0366
3. Mail a completed VAERS form to VAERS, PO Box 1100, Rockville, MD 20849-1100.

If you do not have an internet connection, you can request a VAERS form by sending an email to [info@vaers.org](mailto:info@vaers.org), by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366.

**PRIORITY GROUPS**

**As of December 16, 2009, the State is allowing the general public to receive H1N1 flu vaccine. This is earlier than anticipated due to the receipt of additional shipments of vaccine.**

**Priority groups can get H1N1 vaccine anywhere it is available, regardless of where they live in NJ. The general public can go to health care providers' offices, community health centers, county and local health departments, and retail pharmacies. However, administration of H1N1 vaccine to the general public at clinics sponsored by public health departments may be limited to the residents of the jurisdictions they serve. Additionally,**

providers may schedule clinics/appointments for specific populations to receive H1N1 vaccine. To find a flu shot, go to: <http://nj.gov/health/flu/findflushot.shtml>

#### **Who are considered to be priority groups?**

The groups recommended to receive the 2009 H1N1 influenza vaccine include:

**Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;

**Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants younger than 6 months old might help protect infants by “cocooning” them from the virus.

**Healthcare and emergency medical services personnel** because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity.

#### **All people from 6 months through 24 years of age**

**Children from 6 months through 18 years of age** because cases of 2009 H1N1 influenza have been seen in children who are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and

**Young adults 19 through 24 years of age** because many cases of 2009 H1N1 influenza have been seen in these healthy young adults and they often live, work and study in close proximity, and they are a frequently mobile population; and,

#### **Persons aged 25 through 64 years of age who have underlying health conditions associated with higher risk of medical complications from influenza.**

#### **What are the underlying health conditions?**

The same age and risk groups who are at higher risk for seasonal influenza complications should also be considered at higher risk for swine-origin influenza complications.

Groups at higher risk for seasonal influenza complications include:

- Children and adolescents (less than 18 years of age) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- Adults and children who have chronic pulmonary, cardiovascular, hepatic, hematological, neurologic, neuromuscular, or metabolic disorders;
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV).

**How is the priority group “healthcare and emergency medical services personnel” defined?**

Healthcare personnel are defined as all persons, regardless of age, whose occupational activities involve contact with patients or contaminated material in a healthcare, home healthcare, or clinical laboratory setting. Healthcare personnel are engaged in a range of occupations, many of which include patient contact even though they do not involve direct provision of patient care, such as dietary and housekeeping services. This includes healthcare personnel working in the following settings: acute care hospitals, nursing homes, skilled nursing facilities, physician’s offices (providers licensed by a health-related board), urgent care centers, outpatient clinics, and home healthcare agencies. It also includes those working in clinical settings within non-healthcare institutions, such as school nurses or personnel staffing clinics in correctional facilities.

The term “healthcare personnel” includes not only employees of the organization or agency, but also contractors, clinicians, volunteers, students, trainees, clergy, and others who may come in contact with patients. Outside the clinical and healthcare settings mentioned above, healthcare personnel are defined as all persons who are licensed or certified to provide direct patient care including students or trainees of the same.

This includes emergency medical service (EMS) personnel defined as EMT-Basic and EMT-Paramedic.

[From NJ Administrative Code (N.J.A.C.) Title 8, Chapter 40A: "Emergency Medical Technician-Basic" or "EMT-Basic" means a person trained in basic life support care and validly certified or recognized by the Commissioner in accordance with the standards for Emergency Medical Technician-Basic certification as set forth in this chapter.

"Emergency Medical Technician-Paramedic" or "EMT-Paramedic" means a person trained in advanced life support care and validly certified or recognized by the Commissioner in accordance with the standards for Emergency Medical Technician-Paramedic certification as set forth at N.J.A.C. 8:41A.]

**How will the state determine that vaccine is given to the recommended target groups?**

Each provider that enrolls to be a “ship-to” or “vaccination only” site will sign the Provider Agreement in which they will agree to comply with the ACIP recommendations for the H1N1 vaccine.

**Are there requirements regarding documentation of priority group membership?**

There are no federal requirements or New Jersey requirements for vaccinators to require documentation of priority group status such as a doctor’s note documenting pregnancy or risk status.

**VACCINE AND SUPPLIES**

**Will vaccine be in multi-dose vials?**

The majority of vaccine will be in multi-dose vials, the remainder in single-dose syringes or nasal sprayers. The aim is to have enough vaccine in single-dose syringes (i.e., preservative free) for young children and pregnant women.

**Which ancillary supplies will be provided with vaccine?**

CDC will provide needles, syringes, sharps containers and alcohol swabs.

**How will ancillary supplies be distributed?**

Ancillary supplies will be distributed to the same “ship-to” sites as the vaccine. Plans for ensuring the distribution of these products are currently being developed.

**How will orders of ancillary supplies be transmitted?**

Ancillary supply kits and sharps containers will be included in the vaccine order that is shipped from McKesson to the “ship-to” site.

**Can vaccine be sent to one address and ancillary supply kits to another address?**

No, because of logistical considerations, vaccine and ancillary supply kit orders cannot be shipped to different addresses.

**How can I access the 2009 H1N1 Ancillary Supply Kits Feedback System?**

In order to expedite the system to submit feedback about 2009 H1N1 ancillary supply kits, CDC has established a NEW online feedback system to receive and collect feedback regarding 2009 H1N1 ancillary supply kits. If there are issues with any 2009 H1N1 ancillary supply kit products including needles, syringes, sharps containers, or alcohol swabs, please visit [and provide the requested details](#). The system will REPLACE the need to send an email to [H1N1AncillarySup@cdc.gov](mailto:H1N1AncillarySup@cdc.gov) that was initially set up earlier this week. For those inquiries previously submitted to this email address, CC will ensure they are addressed accordingly.

**What do I do with unused or expired H1N1 Vaccines?**

Continue to properly store any remaining H1N1 vaccines and ancillary supplies until the expiration dates. Although the vaccine may be in little demand at this time, influenza is unpredictable and we do not know the likelihood of a future wave of 2009 H1N1 influenza A. Please remember to enter your inventory, doses administered, and maintain temperature logs to ensure vaccine efficacy and to avoid vaccine wastage.

Any expired vaccines, vaccine delivery devices (needles and syringes), vaccine containers (vials of killed or live/attenuated vaccine), and other associated, potentially contaminated materials must be handled and properly disposed of in accordance with Regulated Medical Waste (RMW) guidelines.

**STATE ALLOTMENTS****Can States request less than their full allocation?**

Yes, States will not be required to accept vaccine they cannot store or administer.

If a State requests less than their full allocation, will they have given up rights to the balance of their allocation?

States will not forfeit the remainder of their allotment if not all is ordered at one time.

**Can States share or exchange allocations of specific products with other States?**

As with seasonal influenza vaccine, CDC will facilitate such exchanges.

**STORAGE****Where can I find the CDC Vaccine Storage and Handling Toolkit?**

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm>

**What is the cold chain?**

Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency, increasing the risk that recipients will not be protected against vaccine-preventable diseases. The system used to distribute and keep vaccines in good condition is called the cold chain.

**What is the size of storage volume for each product type?**

CDC will communicate the corresponding storage volume of 100 dose increments of each product type as soon as that information becomes available.

**What are general requirements for vaccine storage?**

Refrigerators without freezers, and stand-alone freezers, may be better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate external door. Additional information is available at

[http://www2a.cdc.gov/vaccine/ed/shtoolkit/storage\\_equipment.htm#Thermometers](http://www2a.cdc.gov/vaccine/ed/shtoolkit/storage_equipment.htm#Thermometers)

**Can I use a small single-door or bar-style (dormitory-style) unit to store vaccines?**

Small single-door (dormitory-style or bar-style) combined refrigerator-freezer units should not be used for permanent vaccine storage. However, this type of unit may be adequate for temporarily storing small quantities of inactivated vaccines in the refrigerator compartment. Unused vaccine should be removed at the end of the business day and restored in the appropriate size refrigerator.

**What is the recommended temperature to store H1N1?**

Read the vaccine package insert for correct temperature requirements, most inactivated vaccines should be stored between 35° and 46°F (2°C and 8°C). The temperature should never fall below 35°F (2°C) or rise above 46°F (8°C).

**How often should I check the temperature of the refrigerator or freezer?**

The recommended method to ensure that a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day and electronically record the temperatures in the H1N1 Vaccine System. For further information, visit “Check the Internal Temperature” at

[http://www2a.cdc.gov/vaccines/ed/shtoolkit/storage\\_equipment.htm#Thermometers](http://www2a.cdc.gov/vaccines/ed/shtoolkit/storage_equipment.htm#Thermometers)

**What type of thermometers do I use?**

The CDC recommends using only certified calibrated thermometers for measuring vaccine storage unit temperatures. For further information, visit

[http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage\\_equipment.htm#Thermometers](http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_equipment.htm#Thermometers)

**Can refrigerated trucks be used to store H1N1 vaccine?**

For those sites that wish to use refrigerated trucks/trailers for H1N1 vaccine, please ensure that the following criteria are met:

1. Verify and document operating temperature of the truck/trailer (must maintain temperature 35 - 46 degrees F).
2. Vehicle/Trailer must be stored inside a temperature controlled building to prevent freezing of the vaccine.

3. Agency must provide appropriate security.
4. Vehicle/trailer must connect to a land line to ensure uninterrupted power.
5. The vehicle/trailer must conform to all other requirements as outlined in the Provider Agreement for vaccine storage.

If you have questions, please call the Office of Emergency Planning at 609-777-0625.

## VACCINE EXPIRATION

### SHORTENED EXPIRATION DATE FOR 15 LOTS OF MEDIMMUNE INFLUENZA A (H1N1) 2009 MONVALENT VACCINE, LIVE INTRANASAL

MedImmune recently issued a field correction for 15 lots of 2009 H1N1 influenza vaccine in nasal sprayers (FluMist). These lots have a shorter expiration period than indicated on the label. The affected lots **cannot** be used past the revised expiration date of **March 29, 2010**.

### Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Expiration Date Update

Product Code (NDC)	Lot Number	Labeled Expiration Date	Re-assigned Expiration Date
66019-200-05	500850P	3/30/2010	3/29/2010
	500851P	4/2/2010	3/29/2010
	500852P	4/5/2010	3/29/2010
	500854P	3/30/2010	3/29/2010
	500855P	4/1/2010	3/29/2010
	500856P	4/4/2010	3/29/2010
	500857P	4/7/2010	3/29/2010
	500871P	3/31/2010	3/29/2010
	500873P	4/6/2010	3/29/2010
	500874P	4/8/2010	3/29/2010
	500875P	4/10/2010	3/29/2010
	500876P	4/12/2010	3/29/2010
	500890P	4/8/2010	3/29/2010
	500891P	4/11/2010	3/29/2010
	500893P	4/16/2010	3/29/2010

#### Did NJ Providers receive vaccine from these lots?

Yes, 59,800 doses from eight of the 15 lots were shipped to 113 different providers between 12/7/2009 and 3/3/2010.

#### What should providers do with this vaccine?

Providers who directly received H1N1 vaccine from these lots from McKesson should have received a packet with instructions and shipping labels from MedImmune. Providers can also call MedImmune at 877-633-4411 for additional information or to request a packet.

### SHORTENED SHELF LIVE OF SANOFI PASTEUR MONOVALENT 2009 (H1N1) INFLUENZA VACCINE IN PRE-FILLED SYRINGES

Sanofi Pasteur has notified CDC and FDA that some lots of monovalent 2009 (H1N1) influenza vaccine in prefilled syringes will have a shorter expiration period than indicated on the label. The lots of Sanofi Pasteur monovalent 2009 H1N1 influenza vaccine in prefilled syringes should be

used by **February 15, 2010**, as indicated in the table below regardless of the expiration imprinted on the package. This is to ensure that the vaccine is used while it remains within its potency specification. There are no safety concerns with these lots of 2009 H1N1 vaccine. People who received vaccine from the lots listed below with shortened shelf life do not need to take any action.

The 50 lots subject to this change in expiration date include approximately 12 million doses. These lots were shipped to providers between November 2009 and January 2010. Although these lots remain potent, they are losing their potency more rapidly than expected, and therefore the shelf life is being shortened. While most of the doses from these lots are believed to have already been administered, there are almost certainly some doses that have not yet been used.

The change in expiration date described here is specific to the 50 lots of Sanofi Pasteur 2009 H1N1 influenza vaccine in pre-filled syringes listed below. However, a related recall (See <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00306>) was conducted recently, which involved lots from Sanofi Pasteur’s 2009 H1N1 vaccine in 0.25 mL and 0.5 mL pre-filled syringes. These actions do not affect Sanofi Pasteur’s 2009 H1N1 vaccine in multi-dose vials.

Sanofi Pasteur will send a notification to providers who received doses from any of the 50 lots of vaccine described below.

**Lot Information:**

These lots should be used by February 15, 2010, as indicated in the table below regardless of the expiration date imprinted on the package.

All pre-filled syringes that have not been used by February 15, 2010 should be discarded in an appropriate manner, or you may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64<sup>th</sup> Street, Milwaukee, WI 53218

**Influenza A (H1N1) 2009 Monovalent Vaccine in Pre-Filled Syringes  
Expiration Date Change**

Product Code (NDC)	Description	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
49281-650-25	0.25mL syringes in 10-packs	UT014AA	March 4, 2011	February 15, 2010
		UT014BA	March 4, 2011	February 15, 2010
		UT014CA	March 4, 2011	February 15, 2010
		UT014DA	March 4, 2011	February 15, 2010
		UT014FA	March 27, 2011	February 15, 2010
		UT014EA	March 25, 2011	February 15, 2010
		UT029DA	April 7, 2011	February 15, 2010
		UT029BA	April 6, 2011	February 15, 2010
		UT029CA	April 6, 2011	February 15, 2010
		UT029EA	April 8, 2011	February 15, 2010
		UT030EA	April 10, 2011	February 15, 2010
		UT030FA	April 11, 2011	February 15, 2010
		UT033CA	April 12, 2011	February 15, 2010
		UT033DA	April 12, 2011	February 15, 2010

<b>Product Code (NDC)</b>	<b>Description</b>	<b>Lot Number</b>	<b>Labeled Expiration Date</b>	<b>Re-Assigned Expiration Date</b>
49281-650-50	0.5mL syringes in 10-packs	UP033CA	April 16, 2011	February 15, 2010
		UP036CA	April 19, 2011	February 15, 2010
		UP034BB	April 22, 2011	February 15, 2010
		UP036EA	May 3, 2011	February 15, 2010
		UP037CA	April 30, 2011	February 15, 2010
		UP037DA	May 2, 2011	February 15, 2010
		UP048CA	May 6, 2011	February 15, 2010
		UP040CA	May 4, 2011	February 15, 2010
		UP048DA	May 9, 2011	February 15, 2010
		UP049FA	May 16, 2011	February 15, 2010
		UP049CA	May 11, 2011	February 15, 2010
		UP049DA	May 13, 2011	February 15, 2010
		UP035BA	April 15, 2011	February 15, 2010
		UP059DA	May 16, 2011	February 15, 2010
		UP060CA	May 17, 2011	February 15, 2010
		UP060DA	May 19, 2011	February 15, 2010
		UT047BA	May 11, 2011	February 15, 2010
		UP033AB	April 9, 2011	February 15, 2010
		UP041BA	April 30, 2011	February 15, 2010
		UT041AA	April 29, 2011	February 15, 2010
		UT034AA	April 19, 2011	February 15, 2010
		UT045BA	May 5, 2011	February 15, 2010
		UP061DA	May 21, 2011	February 15, 2010
		UP061FA	May 23, 2011	February 15, 2010
		UP035AA	April 12, 2011	February 15, 2010
		UT048BA	May 12, 2011	February 15, 2010
		UT058BA	May 16, 2011	February 15, 2010
		UT059AA	May 18, 2011	February 15, 2010
		UT058AA	May 14, 2011	February 15, 2010
		UT061GA	May 24, 2011	February 15, 2010
UP045EA	June 9, 2011	February 15, 2010		
49281-650-90	0.5mL syringes in 25-packs	UT036DA	April 26, 2011	February 15, 2010
		UT040BA	April 28, 2011	February 15, 2010
		UT047AA	May 9, 2011	February 15, 2010
		UT046BA	May 9, 2011	February 15, 2010
		UT046AA	May 4, 2011	February 15, 2010

## **For More Information:**

- CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, is available 24 hours a day, every day.
- For other inquiries, please contact Sanofi Pasteur Customer Services: 1-800-VACCINE (1-800-822-2463) or visit [www.vaccineshoppe.com](http://www.vaccineshoppe.com)

## **VACCINE RECALLS**

### **NOTICE OF VACCINE RECALL:**

As part of its quality assurance program, Sanofi Pasteur, Inc., performs routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that the vaccine continues to meet required specifications. In recent testing of its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found five distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine and one distributed lot of single-dose pre-filled syringe for older children and adults (0.5 mL) vaccine had potency below pre-specified limits. The manufacturer is conducting a voluntary recall of any unused doses of these affected lots of vaccine. Information will be sent by Sanofi Pasteur to providers who received vaccine from the affected lots. **There is no safety concern with the lots that are being recalled.**

### **Should people who received vaccines from these lots be revaccinated?**

The potency of the affected lots of vaccine is only slightly below the specification limit. Vaccine doses from these lots are still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots.

As is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine is produced in single units that do not contain thimerosal.

Sanofi Pasteur has informed the CDC that it will be submitting a field correction to the FDA to request a change for the expiration date of the company's remaining pediatric and adult pre-filled syringes. CDC will share additional information as soon as it is available.

### **What lots are involved?**

Providers will be asked to return any unused vaccine from the affected lots to the manufacturer. The only vaccine affected by this recall is supplied in pre-filled syringes and is identified by the following lot numbers:

**UT023AA, UT023BA, UT023CA, UT023EA, UT023FA**

**(NDC # 49281-650-25, which also may be recorded as # 49281-0650-25), 0.25 mL syringes in 10-packs**

**UT037AA**

**(NDC # 49281-650-90, which also may be recorded as # 49281-0650-90), 0.5 mL syringes in 25-packs**

These lots were shipped to providers between November 2009 and January 2010. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers.

All vaccines are thoroughly tested prior to release and shipping for safety, purity, and potency. The affected lots met all required specifications at the time of release. CDC and FDA have determined that there are no safety concerns for people who have received these vaccines.

Call CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

**Did NJ Providers receive any of the vaccine that Sanofi Pasteur, Inc. recently recalled?**

Yes, twenty-eight providers received 12,400 doses from the following Lot #s:

**Lot# UT023FA – NJ providers received 9,100 doses of this lot till until 11/11/2009.**

**Lot # UT037AA – NJ providers received 3,300 doses between 1/3 to 1/14/2010.**

**NOTICE OF VACCINE RECALL:**

Vaccine manufacturer, MedImmune announced that it is voluntarily recalling unused doses of 13 *specific lots* of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal due to a slight decrease in potency. **There is no safety concern with the lots that are being recalled.**

Before they were shipped, the lots being recalled passed all quality controls and met all specifications for safety, purity, and potency. As part of its quality assurance program, the manufacturer of the nasal spray monovalent H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of the vaccine during the vaccine's "shelf life", that is after the vaccine has been shipped to providers until its expiration date. Stability testing means measuring the strength (also called potency) of vaccine over time to make sure it does not go down below the pre-specified limit.

On December 18 and 21, MedImmune notified CDC and FDA that the potency of 13 lots of monovalent 2009 (H1N1) nasal spray vaccine had decreased below a pre-specified limit or were at risk of falling below that limit in the next week. This slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. There are no safety concerns with these lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety. However, because their potency is now or might soon be below the specified lower limit, MedImmune will send providers directions for returning any unused vaccine from these lots.

The 13 lots subject to the recall include approximately 4.7 million doses. These doses were shipped to CDC's contract distributor in October and early November. **Most of the doses are believed to have already been administered while fully potent and within specifications.** However, there are almost certainly some doses that have not yet been used.

The potency issue described here is specific to the 13 lots of nasal spray 2009 H1N1 influenza vaccine. Subsequent lots of the vaccine were produced with a slightly higher initial potency to decrease the chance that the potency would fall "below specification" before their expiration dates. Following its routine practice, the manufacturer will continue to monitor the stability of these subsequent lots.

**Should people who received vaccines from these lots be revaccinated?**

No. The vaccine potency is only slightly below what it is supposed to be. The vaccine in these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots.

**What lots are involved?**

MedImmune is sending a notification to providers who received doses from any of the 13 lot of vaccines so that they can return any unused vaccine.

- 500754P
- 500751P
- 500756P
- 500757P
- 500758P
- 500759P
- 500760P
- 500761P
- 500762P
- 500763P
- 500764P
- 500765P
- 500776P

**Did NJ providers receive any of this vaccine?**

Yes, seven of the 13 lot numbers were shipped to NJ, for a total of 182,600 doses. These were shipped between 10/5 to 10/28 to 397 unique providers.

**NOTICE OF VACCINE RECALL:**

This is a voluntary recall by the manufacturer, Sanofi Pasteur. It is not a safety issue. The vaccine being recalled was shipped in November and intended for children 6 through 35 months of age. It was packaged in 0.25 mL pre-filled syringes.

All vaccines are routinely tested for purity, potency and safety prior to release. As part of its quality assurance program, the manufacturer performs routine, ongoing stability testing of the vaccine after has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can go down over time.

During routine testing it was discovered that the strength of four lots (batches) of one particular vaccine had dropped slightly below the manufacturer's specifications for potency. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. This small decrease in strength is not likely to result in a significant reduction in immune response. Therefore, there is no need to re-administer this dose.

### **What do I do if I have vaccine from a lot that has been recalled?**

Providers who have received H1N1 vaccine from the lots in question **directly from McKesson** will receive a packet with instructions from Sanofi Pasteur. Sanofi Pasteur will ship their packets on Wednesday, December 16, 2009 for arrival on Thursday, December 17, 2009. If these providers do not receive a packet on Thursday, December 17, 2009, they can call Sanofi Pasteur's Customer Service Department at 888-241-9288. Providers that are "vaccinator only" sites who did not receive vaccine directly from McKesson should call Sanofi Pasteur's Customer Service Department at 888-241-9288 to request a packet.

### **What lots are involved?**

Vaccine doses with the following lot numbers are included in the recall:

0.25 ml pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):

UT023DA

UT028DA

UT028CB

0.25 ml pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):

UT030CA

### **More information on CDC website**

**[http://www.cdc.gov/h1n1flu/vaccination/syringes\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm)**

### **Did NJ providers receive any of this vaccine?**

Yes. Approximately 18,000 doses were shipped to 100 ship-to sites in NJ.

**NOTICE OF VACCINE RECALL:** There have been news reports regarding a recall of 2009 H1N1 vaccine. The pharmaceutical company GlaxoSmithKline has recalled one batch of 172,000 doses of 2009 H1N1 vaccine after reports that it might have caused more allergic reactions than usual. This one batch of vaccine was distributed in Canada. The 2009 H1N1 vaccine used in the U.S. is not part of this recall.

## **VACCINE ISSUES**

### **It looks like H1N1 is over. Should people still get vaccinated?**

In past flu pandemics, "waves" of activity have been observed over a year or so after a new flu virus appears, with each wave lasting 6-12 weeks. The US experienced its first wave of 2009 H1N1 flu in the spring of 2009 and now the second wave is winding down. Additional waves of H1N1 may occur as well as outbreaks of seasonal flu. Because the timing and spread of flu viruses are unpredictable, the CDC is continuing to recommend vaccination with seasonal flu vaccine and 2009 H1N1 vaccine for those people for whom it is recommended. There is no way to accurately predict the course of influenza epidemics. Right now is a window of opportunity for more people to get vaccinated for 2009 H1N1 flu.

### **When should we stop vaccinating against seasonal influenza?**

It is difficult to decide when to stop vaccinating against seasonal influenza. Flu seasons vary in terms of length and severity. As a result, instead of setting a firm date to stop vaccinating, CDC generally recommends that vaccination efforts continue as long as influenza is circulating in the community. Clinicians should be aware that more than one wave of influenza can occur in communities, and that a decline in influenza illnesses during the fall or winter might be followed by another increase in illness caused by a different influenza virus strain. Clinicians deciding whether to continue vaccination efforts into May may consider accessing state and/or local influenza surveillance information to determine if flu is still circulating in the community.

However, end-of-season vaccination (in April and May) may particularly benefit the following people:

- Persons likely to be traveling to the Southern Hemisphere, where influenza may be circulating before the 2009-10 vaccine is available, and
- Children younger than 9 years of age being vaccinated against influenza for the first time who still have not gotten their second recommended dose of vaccine.

Based on clinical judgment, seasonal influenza vaccine may be given until the expiration date of the vaccine.

### **Are the expiration dates for the 2009 H1N1 vaccine longer than for the expiration dates of the seasonal influenza vaccine?**

Unlike seasonal influenza vaccine which typically expires on June 30th, the 2009 H1N1 monovalent influenza vaccine expiration dates range from February 2010 to early 2011. Sanofi Pasteur multi-dose vials (MDV), specifically, have expiration dates in 2011. Additional 2009 H1N1 influenza activity (i.e. “third wave”) is possible through spring and summer of 2010, or in early fall 2010 when the 2010-11 trivalent influenza vaccine is not yet available. Although the 2010-11 seasonal trivalent influenza vaccine will contain a 2009 H1N1-like influenza A strain, the timing of its production and availability is not yet known. Therefore, unexpired 2009 H1N1 Sanofi Pasteur MDV should not be destroyed and it should be stored in the event there is a resurgence of disease before the 2010-2011 vaccine is available. Distribution of seasonal influenza vaccine by manufacturers will be monitored by CDC and CDC expects to issue a recommendation that stored vaccine no longer needs to be kept once available information indicates a robust supply, in order to minimize confusion about which flu vaccine (2010-11 trivalent vaccine versus 2009 H1N1 monovalent vaccine) should be administered.

### **Should the long-dated 2009 H1N1 influenza vaccine be used instead of 2010-2011 seasonal influenza vaccine?**

The 2010-2011 seasonal vaccine will contain two other strains in addition to the 2009 H1N1 strain. For this reason the 2009 H1N1 monovalent vaccine will not be considered a substitute for the seasonal trivalent vaccine. It would only be used in the event of resurgence in disease before the 2010-2011 seasonal vaccine is widely available.

**What is the spacing between the 2009 H1N1 influenza vaccine and the upcoming 2010-2011 seasonal influenza vaccine?**

The 2010-11 seasonal trivalent influenza vaccine will contain a 2009 H1N1-like influenza A strain, as well as an A/Perth/16/2009 (H3N2)-like virus, and a B/Brisbane/60/2008-like virus. The recommended minimum interval between someone receiving the H1N1 (2009) monovalent vaccine and the 2010 - 2011 seasonal influenza vaccine is four weeks.

**Will two doses of the 2009 H1N1 vaccine be required?**

The U.S. Food and Drug Administration (FDA) has approved the use of one dose of 2009 H1N1 flu vaccine for persons 10 years of age and older. Children under 10 years will need two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines. NOTE: For seasonal flu, children under 9 years of age need two doses.

**Will there be federal requirements to recall persons for their second dose, if a second dose is needed?**

There will be no federal requirement to send out recall notices. Providing information on second dose at the time of the first dose, as well as educating persons about who needs a second dose administered is important if it is needed.

**Should doses of vaccine be held for children who require two doses?**

No, due to the limited supply of vaccine, providers should not hold vaccine to provide a second dose but can give the second dose if it is available at the time a child is due to receive it. With limited supplies of vaccine, providers may target specific groups within the CDC defined priority groups. For instance, providers may target pregnant women or choose to administer only the first shot of a two-dose regimen until vaccine is more available.

**Does the 2009 H1N1 flu shot have an adjuvant or squalene in it?**

Adjuvants are agents that are sometimes added to a vaccine to make it more effective. There are no adjuvants (such as squalene) in either the 2009 H1N1 or seasonal flu shot used in the United States.

**Will the vaccine be administered under EUA (Emergency Use Authorization)?**

EUA will not be used for unadjuvanted vaccine if FDA licenses the vaccine under the current BLA (Biologics License Application) as a strain change.

**How much thimerosal-free vaccine will be available?**

Thimerosal is a preservative. There is no evidence that thimerosal-containing vaccines cause harm; thimerosal-containing vaccine can safely be given to children and pregnant women. It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes and single dose vials will be available for individuals who request it. You can consult your local health agency or health care provider for more information about this.

**How many manufacturers are producing vaccine?**

Five manufacturers are producing vaccine for the U.S.: Sanofi Pasteur, Novartis, GSK, Medimmune and CSL.

**Depending on age, does it matter which manufacturer's vaccine is administered?**

Yes.

### Injectable Vaccines:

Influenza A (H1N1) 2009 Monovalent Vaccine (ID Biomedical) – 18 years of age and older

Influenza A (H1N1) 2009 Monovalent Vaccine (CSL Limited) – *6 months and older*

Note: Both the CSL H1N1 pre-filled syringe and multi-dose vial vaccine formulations should be reserved for individuals aged 3 years and older if alternative products are available for children aged 6-35 months.

### Rationale

Pre-filled syringe presentation: Using the CSL H1N1 pre-filled syringe vaccine in children aged 6-35 months would result in wastage of one dose per syringe. Since children aged 6-35 months would only require a half dose of this vaccine, only half of the contents of the syringe could be used. Transfer of some or all of the contents of one syringe to another syringe is not permissible nor is using the same syringe to administer the latter half dose to another individual. Therefore, the only option is to discard the remaining half dose. With the current limited supply and availability of vaccine nationwide, CDC discourages using a half dose of CSL H1N1 pre-filled syringe vaccine on a child aged 6-35 months and discarding the remaining half dose.

Multi-dose vial presentation: While CSL's H1N1 multi-dose vial vaccine is now licensed for use in individuals aged 6 months and older, CDC is treating this formulation as being for use in individuals aged 3 years and older for the purpose of allocating and ordering vaccine and ancillary supply kits (the multi-dose vial kits used for all H1N1 vaccines contain supplies that are intended for use in children and adults aged 3 years and older). CSL H1N1 multi-dose vial vaccine formulation will continue to be ordered as a 100 dose (0.5mL per dose) minimum order size and CDC will allocate one multi-dose vial ancillary supply kit for each 100 doses of multi-dose vial vaccine. If providers choose to administer half doses of the multi-dose vial formulation to children aged 6-35 months, they will effectively be short half the number of needle/syringe units, alcohol pads, vaccination record cards and sharps containers.

Providers will be required to use their own ancillary supplies to make up the difference and print out additional shot cards from the CDC website ([http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza\\_record\\_card2009.pdf](http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza_record_card2009.pdf)). This situation also applies to the Sanofi Pasteur multi-dose vial vaccine formulation that is licensed for individuals aged 6 months and older.

Influenza A (H1N1) 2009 Monovalent Vaccine (Novartis Vaccines and Diagnostics Limited) - *4 years and older*

Influenza A (H1N1) 2009 Monovalent Vaccine (Sanofi Pasteur, Inc.) - *6 months and older*

### Intranasal Vaccines:

Influenza A (H1N1) 2009 Monovalent Vaccine (MedImmune LLC) – *2-49 years (healthy and not pregnant)*

## **CENTRAL VACCINE RECOVERY PROGRAM**

The U.S. federal government is implementing a central (federally managed) process to assist state and local health departments with the recovery of unused 2009 H1N1 influenza vaccine. The Central Vaccine Recovery Program is voluntary and will allow for pick-up of unused and

expired 2009 H1N1 influenza vaccine directly from providers and from centralized locations, such as a local or state health department.

Unlike seasonal influenza vaccine which typically expires on June 30th, the 2009 H1N1 monovalent influenza vaccine expiration dates range from February 2010 to early 2011; sanofi pasteur multi-dose vials (MDV), specifically, have expiration dates in 2011. The New Jersey Department of Health and Senior Services (NJDHSS) reminds providers that additional 2009 H1N1 influenza activity (i.e., “third wave”) is possible through spring and summer of 2010, or in early fall 2010 when the 2010-11 trivalent influenza vaccine might not yet be available. Although the 2010-11 seasonal trivalent influenza vaccine will contain a 2009 H1N1-like influenza A strain, the timing of its production and availability is not yet known. Therefore, NJDHSS encourages providers that unexpired 2009 H1N1 sanofi pasteur MDV should not be destroyed, and it should be stored in the event there is a resurgence of disease before the 2010-2011 vaccine is available. CDC will monitor the manufacturers’ distribution of seasonal influenza vaccine, and CDC expects to issue a recommendation that stored vaccine no longer needs to be kept once available information indicates a robust seasonal vaccine supply, in order to minimize confusion about which flu vaccine (2010-11 trivalent vaccine versus 2009 H1N1 monovalent vaccine) should be administered.

### **Is participation required?**

Participation in the Central Vaccine Recovery Program is optional. A location may choose to dispose of its unused H1N1 influenza vaccine through the Central Vaccine Recovery Program or according to the NJDHSS **Guidance for Regulated Medical Waste (RMW) During the National Emergency with Respect to the 2009 H1N1 Influenza Pandemic** available at

<http://www.state.nj.us/dep/dshw/Main%20Page/H1N1Guidance.pdf>

### **When will the Central Vaccine Recovery Program start?**

Although there is no definitive start date yet, the objective is to start the program as soon as possible.

### ***[UPDATED] Who can participate in the Central Vaccine Recovery Program?***

*The Central Vaccine Recovery Program will be made available to those providers who signed a Provider Agreement to administer H1N1 vaccine. If a Provider Agreement covered several locations, the vaccine will need to be consolidated across locations. It will be the responsibility of the provider to bring the vaccine to the designated pick-up location. Further information about the designated sites will be made available. Vaccines should **not** be returned to McKesson directly.*

### **What information will be required for participating providers?**

For providers that received vaccine directly from McKesson, CDC already has the following required information:

1. Provider name
2. Provider addresses (where vaccine will be picked-up)
3. A unique identification number (VACMAN PIN)

NJDHSS will provide future guidance for providers who received vaccine through redistribution (vaccination-only site) instead of receiving the vaccine directly from McKesson.

**Can the sanofi pasteur multi-dose vials with 2011 expiration dates be returned using this system?**

Yes, but not immediately. The first phase of the program (spring 2010) is intended to recover and account for the Novartis, CSL and Medimmune vaccines. In fall 2010, CDC expects to issue a recommendation that stored vaccine will no longer need to be kept once available information indicates a robust supply of the 2010 -11 seasonal influenza vaccine (which will contain a H1N1 strain). Once this happens, additional information will be sent to providers to return the long-dated sanofi pasteur MDVs.

**Will grantees who participate in the Central Vaccine Recovery Program incur any costs?**

No. State/local health departments or providers will incur no direct costs to return unused 2009 H1N1 influenza vaccines directly through the Central Vaccine Recovery Program. State/local health departments or providers may incur costs if 2009 H1N1 vaccine is consolidated prior to returning it through the Central Vaccine Recovery Program.

**Will the federal contractor recover unused 2009 H1N1 vaccine distributed through the federal program directly to federal facilities?**

Yes. The federal contractor will work directly with federal agencies to recover unused 2009 H1N1 vaccine at these federal facilities. Since many federal facilities, such as Department of Defense installations, Veterans Administration medical centers and Indian Health Service facilities received vaccine from state and local health departments, grantees are expected to work with federal facilities in their jurisdictions to incorporate them into the state vaccine recovery plan, if appropriate. This may mean that federal agencies use multiple mechanisms and procedures (federal, state, and local) to have vaccine recovered from their facilities.

**Can ancillary supplies be returned through this program?**

No, ancillary supplies cannot be returned through this program. Also, only unused vaccine can be returned. Empty vials, broken vials, syringes with needles cannot be returned.

## **ADMINISTERING VACCINE**

**Can the seasonal vaccine and the 2009 H1N1 flu vaccine be given at the same time? Can flu vaccines be given at the same time as other vaccines?**

The following three tables, located on the NJDHSS website (<http://nj.gov/health/flu/h1n1.shtml>) answer these questions.

*2009 H1N1 Influenza Vaccine - Dose Spacing for Children 6 Months through 9 Years of Age*  
[http://www.state.nj.us/health/flu/documents/dose\\_for\\_children\\_6m\\_to\\_9y.pdf](http://www.state.nj.us/health/flu/documents/dose_for_children_6m_to_9y.pdf)

*2009 H1N1 Influenza Vaccine - Administration with Seasonal Influenza and Other Vaccines*  
[http://www.state.nj.us/health/flu/documents/admin\\_seasonal\\_and\\_other\\_vac.pdf](http://www.state.nj.us/health/flu/documents/admin_seasonal_and_other_vac.pdf)

*2009 H1N1 Influenza Vaccine - Dose Spacing and Administration with Seasonal Influenza and Other Vaccines*  
[http://www.state.nj.us/health/flu/documents/dose\\_seasonal\\_and\\_other\\_vaccines.pdf](http://www.state.nj.us/health/flu/documents/dose_seasonal_and_other_vaccines.pdf)

**2009 H1N1 Influenza Vaccine  
Dose Spacing for Children 6 Months through 9 Years of Age<sup>1</sup>**

	<b>Influenza 2009 H1N1 LAIV Dose 2<sup>1,2</sup></b>	<b>Influenza 2009 H1N1 Inactivated Dose 2<sup>1</sup></b>
<b>Influenza 2009 H1N1 LAIV Dose 1<sup>2</sup></b>	<p>Separate the first and second dose by at least 28 days. Some experts suggest that 14 days* or longer is acceptable.</p> <p>If given 1-13 days apart, repeat the second dose at least 14 days* (preferably 28 days) from the invalid (second) dose.</p>	<p>Using the same type of vaccine for the first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>
<b>Influenza 2009 H1N1 Inactivated Dose 1</b>	<p>Using the same type of vaccine for the first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* or longer is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>	<p>Separate the first and second dose by at least 28 days preferably, but some experts suggest that 21 days* or longer is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>

<sup>1</sup> Persons 10 and older require only one dose of 2009 H1N1 vaccine.

<sup>2</sup> 2009 H1N1 LAIV is recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

\* These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

**2009 H1N1 Influenza Vaccine  
Administration with Seasonal Influenza and Other Vaccines**

	<b>Influenza Seasonal LAIV<sup>2</sup></b>	<b>Influenza Seasonal Inactivated</b>	<b>Other live vaccines (e.g. MMR)</b>	<b>Other inactivated vaccines (e.g. PPV)</b>
<b>Influenza 2009 H1N1 LAIV<sup>1,2</sup></b>	Vaccines should be separated by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the vaccine administered second at least 14 days* (preferably 28 days) from the invalid (second) dose. Administering both doses at the same visit is not recommended but if they are given at the same visit, neither vaccine needs to be repeated.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered at the same visit. If not administered at the same visit, vaccines should be separated by at least 28 days. If administered 1-27 days apart repeat the vaccine administered second at least 28 days* from the invalid (second) vaccine.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.
<b>Influenza 2009 H1N1 Inactivated<sup>1</sup></b>	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.

<sup>1</sup> Persons 10 and older require only one dose of 2009 H1N1 vaccine.

<sup>2</sup> 2009 H1N1 LAIV and seasonal influenza LAIV are recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

\* These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

**2009 H1N1 Influenza Vaccine  
Dose Spacing<sup>1</sup> and Administration with Seasonal Influenza and Other Vaccines**

	<b>Influenza 2009 H1N1 LAIV Dose 2<sup>1,2</sup></b>	<b>Influenza 2009 H1N1 Inactivated Dose 2<sup>1</sup></b>	<b>Influenza Seasonal LAIV<sup>2</sup></b>	<b>Influenza Seasonal Inactivated</b>	<b>Other live vaccines (e.g. MMR)</b>	<b>Other inactivated vaccines</b>
<b>Influenza 2009 H1N1 LAIV Dose 1<sup>1,2</sup></b>	For children 2 years through 9 years, separate the first and second dose by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the second dose at least 14 days* (preferably 28 days) from the invalid (second) dose.	For children 6 months through 9 years, using the same type of vaccine for first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	Vaccines should be separated by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the vaccine administered second at least 14 days* (preferably 28 days) from the invalid (second) dose. Administering both doses at the same visit is not recommended but if they are given at the same visit, neither vaccine needs to be repeated.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered at the same visit. If not administered at the same visit, vaccines should be separated by at least 28 days. If administered 1-27 days apart repeat the vaccine administered second at least 28 days* from the invalid (second) vaccine.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.
<b>Influenza 2009 H1N1 Inactivated Dose 1<sup>1</sup></b>	For children 2 years through 9 years, using the same type of vaccine for first and second dose is preferred. If not feasible, separate first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* or longer is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	For children 6 months through 9 years, separate first and second dose by at least 28 days preferably, but some experts suggest that 21 days* or more is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.

<sup>1</sup> Persons 10 and older require only one dose of 2009 H1N1 vaccine.

<sup>2</sup> 2009 H1N1 LAIV and seasonal influenza LAIV are recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

\* These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

**If a child gets the 2nd dose more than 4 weeks after the 1st one, how does that affect his/her protection against the flu? Is a child protected against the flu with just one dose?**

The span of 4 weeks between doses is a minimum time. With just one dose, a child has some protection against the flu, but for full protection a second dose should be administered. It is recommended that a child obtains the 2nd dose when it becomes available. The level of protective immunity will not be affected by a delay in receiving the 2nd dose.

**If a child is 9 years old when receiving the first administration of the H1N1 vaccine and he/she turns 10 before the second dose is due, is the second one recommended?**

No. The child does not need a second administration after turning 10. Since children age on a continuum, the difference between 9 and 10 does not represent a true change in immune competence. Two vaccinations are only recommended for children under the age of 10.

**Should all providers now be offering 2<sup>nd</sup> doses to children who need them?**

Yes, since there is ample vaccine available, all providers are encouraged to give second doses.

**Will it be necessary for the first and second dose to be given by the same provider?**

No. Patients should be given written documentation of the doses administered that can be presented to any health care provider in the future. Information should be available through the NJ H1N1 Vaccine System.

**If a provider orders H1N1 vaccine for their patients, are they obliged to give it to a person who requests it, even if they're not their patient?**

No, you are not obliged to give the vaccine to people who are not your patients. You are obliged to give it to patients who are in the CDC priority groups, if they request it.

**What types of professionals can actually administer vaccines?**

Health care professionals should check with their licensing board to verify whether they are permitted to administer vaccines. At this time, there is no waiver for the use of vaccine extenders.

**Are any special precautions needed when administering 2009 H1N1 vaccine when compared to seasonal influenza or other vaccines?**

No. The same recommendations as outlined by the CDC apply. These can be found in the Appendix D of the CDC's Pink Book at

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf>

Each facility that administers vaccines should have a protocol, procedures and equipment to provide initial care for emergencies and these should be reviewed periodically. Facility staff should be prepared to recognize and respond appropriately to vaccine-related problems like fainting and allergic reactions. All staff should maintain current CPR certification. Although both fainting and allergic reactions are rare, vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated. Again, this is no different from what should occur with administration of any other vaccine.

**If adult inactivated influenza vaccine is not available, can a high-risk adult or a high-risk child receive the pediatric product (thimerosal preservative-free 0.25 ml dose) as long as they are given 0.5ml?**

If there is not an adequate supply of adult formulation, providers vaccinating high-risk individuals requiring 0.5mL of influenza vaccine when the provider has only the 0.25mL prefilled syringes of pediatric vaccine may choose to give two separate injections of the 0.25mL product to protect the high-risk individual. Providers should never attempt to transfer vaccine from one syringe to another for the purpose of administering only one injection. If an adequate supply of adult formulation is available in the community, CDC does not recommend that providers combine two 0.25mL doses of pediatric influenza vaccine to vaccinate a single individual who requires a 0.5mL dose of vaccine.

**A person 36 months or older mistakenly receives a 0.25mL (pediatric) dose rather than the recommended 0.5mL dose. Should the first dose be repeated?**

If less than an age-appropriate dose of influenza vaccine is administered it should NOT be counted as valid regardless of the route it was given, and should be repeated.

**I have a single-use vial/syringe containing 0.5mL of influenza vaccine appropriate for individuals 36 months and older? Can I split the dose and use it for two children 6-35 months of age requiring the 0.25 mL dose?**

No. Single-use vials are meant for a single patient and should never be re-entered with a needle for use with a second patient. Single-dose syringes are meant for a single patient and should never be used for 2 patients even if needles are changed between patients. Medications should never be transferred from one syringe to another. Left over medications from vials or syringes should never be combined for later use. All of these practices can lead to contamination of the sterile product and transmission of pathogens.

**Since the nasal mist flu vaccine contains a live virus, can the people who receive it infect others?**

Although the package insert states that a person can shed the vaccine virus, shedding alone should not be equated with person-to-person transmission. Studies have found that transmission is very rare. People who receive the nasal mist can have contact with everyone except the more severely immunocompromised (e.g., bone marrow transplant in a protective environment). This includes nasal mist administered in the school setting. Pregnant women, infants under six months of age and individuals of any age with lesser degrees of immunosuppression (diabetes, asthma, cancer on chemotherapy but not needing a protective environment, steroid or other immunosuppressive therapy, HIV/AIDS) may be in contact with people who have received the nasal mist. Pregnant women and individuals with lesser degrees of immunosuppression can work in the vaccination clinics and administer the vaccine even if they themselves are not candidates for this vaccine.

**Can health care workers with direct patient care duties use the 2009 H1N1 nasal mist flu vaccine?**

Most health care workers with direct patient care duties can safely use the nasal mist vaccine. Only the contacts of people with severely weakened immune systems (such as patients with bone marrow transplants who require a protective environment) should not receive the nasal mist vaccine. If they do receive the nasal mist vaccine, they should be restricted from contact with the immunosuppressed individual for 7 days after vaccination. Contact with individuals with lesser degrees of immunosuppression (such as diabetes, cancer on chemotherapy not requiring a

protective environment, HIV infections, elderly, steroid therapy) can receive the **nasal mist and not be restricted.**

**What is the shelf life for Flumist?**

Flumist should never be used after the expiration date on the sprayer. Flumist has a shelf life of approximately 18 weeks.

**How can we prevent Flumist from going to waste due to the limited shelf life?**

In order to prevent wastage of Flumist, we remind providers to check the expiration date of the product you have received and to use Flumist in a timely fashion. Contact your local health departments, LINCS agency, or neighboring providers if you have extra Flumist that could be transferred to an area of need. Also consider using Flumist by scheduling “second vaccination” appointments for healthy children under 10 years of age.

**Information regarding Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Expiration Dating**

Some lots of the MedImmune Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal have a shorter expiration period than that indicated on the label. Refer to the chart below when speaking with a caller:

Product Code (NDC)	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
66019-200-01	500778P	1-29-2010	1-15-2010
66019-200-05	500779P	2-4-2010	1-15-2010
66019-200-10	500780P	2-6-2010	1-15-2010
	500781P	2-10-2010	1-15-2010
	500782P	2-11-2010	1-15-2010
	500783P	2-12-2010	1-15-2010
	500784P	2-14-2010	1-15-2010
	500785P	2-16-2010	1-15-2010
	500796P	2-17-2010	1-15-2010
	500797P	2-19-2010	1-15-2010
	500798P	2-21-2010	1-15-2010
	500799P	2-22-2010	1-15-2010

**If you have any questions regarding this information, please contact MedImmune at 1-877-574-5040.**

**If a patient under the age of 36 months receives their first dose (0.25 ml) and will be over the age of 36 months when due for their second dose, what dosage amount should they receive?**

The patient should receive the dose that would be age appropriate at the time of their second visit. If they will be over age 36 months for their second visit, they should receive the 0.5 ml dose.

**If a patient took antiviral drugs after getting vaccinated, do they need to be revaccinated?**

If a person takes antiviral drugs within two weeks of getting the nasal mist (live) flu vaccine, that person should be revaccinated. (The antiviral drugs will have killed the vaccine viruses that are

supposed to cause the immune response against those viruses.) Antiviral drugs can be taken with the inactivated (killed) flu vaccine.

## **REIMBURSEMENT**

### **Will private health insurance plans reimburse private providers for administration of 2009 H1N1 vaccine?**

This is up to each individual health plan, but the general expectation is that plans will reimburse for vaccine administration. According to America's Health Insurance Plans, a national association representing nearly 1,300 companies that provide health insurance to over 200 million Americans, "Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

- a) Health plans communicate directly with plan sponsors and members about the current Advisory Committee on Immunization Practices (ACIP) recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions.
- b) Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of 2009 H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established.

### **Are private providers allowed to charge a co-pay?**

The administrative cost of providing the vaccine will be covered by Medicare and most, if not all, health insurers, including Medicaid, that insure New Jersey residents. Insurers are covering this cost the way they cover other vaccines, so whatever co-pay you typically have for a vaccine-related doctor's visit will apply here.

### **Will private providers be able to charge patients for vaccine administration if they are uninsured?**

Yes, private providers may charge a fee for the administration of the vaccine to the patient. Should they choose to charge an administration fee, the fee may not exceed the regional Medicare payment rate for seasonal influenza vaccine administration. If the patient is unable to pay, the provider may choose to administer the 2009 H1N1 vaccine for free or for a reduced fee. Providers are encouraged to ensure that cost is not a barrier to vaccination.

### **Can persons be charged for vaccine administration in public health-organized large scale vaccination clinics?**

Per CDC, there will be no administration fee for vaccination in public-health organized large-scale vaccination clinics.

### **Is billing of third party payors/insurers permissible in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of a public health jurisdiction?**

It is permissible to bill third party payors/insurers in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of a public health entity. Public health jurisdictions that do not currently have a robust billing system in place may not use CDC Public Health Emergency Response (PHER) funds to develop billing systems.

**Can public health clinics charge Medicare an administration fee?**

Yes, public health clinics can bill third party payors including Medicare for administration fees. Public health clinics cannot charge these patients a co-pay.

**Is it permissible to charge patients a co-pay or any out-of-pocket charge in public health clinics or mass vaccinations sites/clinics conducted on behalf of a public health entity?**

It is not permissible to charge patients in public health clinics or mass vaccination sites/clinics conducted by or on behalf of a public health entity.

**What is the definition of a “public health clinic?”**

A “public health clinic” is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and received PHER implementation funds to administer H1N1 vaccine in any setting. For example, this may include a commercial community vaccinators (CCV) or other private provider that has a formal agreement with the public health entity.

**Is it permissible to use PHER funds to offset the costs to private providers to vaccinate uninsured or under-insured persons?**

It is permissible to use PHER funds to offset the costs to private providers to vaccinate the uninsured or under-insured population providing that the jurisdiction has systems in place to assure accountability through auditing and/or other means of accountability. Those that do not have current systems in place are encouraged not to use PHER funds to develop systems of accountability.

**OTHER**

**What about the use of antivirals to treat 2009 H1N1 infections?**

Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu by keeping flu viruses from reproducing in your body. If you get sick, antiviral drugs can make your illness milder and make you feel better faster. They may also prevent serious flu complications. This fall, antivirals may be prioritized for persons with severe illness or those at higher risk for flu complications.

**Can TAMIFLU® still be distributed past its expiration date?**

If you have been asked to distribute/dispense TAMIFLU® that is past its expiration date, please be aware that based on scientific review and analysis of available data, FDA has authorized the use of certain lots of expired TAMIFLU® during this public health emergency. Some of these data may have been generated as part of the federal government’s Shelf Life Extension Program (SLEP). Under SLEP, FDA conducts scientific testing to determine if specific lots of TAMIFLU® can be used beyond their expiration dates. If analysis of the available data indicates the product is still acceptable for use, FDA can authorize its use beyond its expiration date. **For any TAMIFLU® that is past its expiration date, you should look up the lot number at the following website to determine if FDA has authorized its use beyond the expiry date:** <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>.

**If the lot number for expired TAMIFLU® appears on this website, you may inform recipients of the expired TAMIFLU that it has been authorized for use beyond its expiration date.**

For more information including patient fact sheets, please see the CDC website at: <http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>.

### **Is pneumococcal vaccination recommended to help prevent secondary infections?**

Yes. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) recommends a single dose of pneumococcal polysaccharide vaccine (PPSV) for all people 65 years of age and older and for persons 2 through 64 years of age with certain high-risk conditions. Among those with high-risk conditions for pneumococcal disease, most are also at high risk for severe complications from influenza. Special emphasis should be placed on vaccinating adults under 65 years of age who have established high-risk conditions for pneumococcal disease: PPSV coverage among this group is low and this group may be more likely to develop secondary bacterial pneumonia after an influenza infection. All children younger than 5 years of age should continue to receive pneumococcal conjugate vaccine (PCV7) according to existing recommendations.

### **Who is responsible to contact and distribute the vaccine to vaccinator-only sites?**

LINCS agencies in collaboration with the Local Health Departments are responsible for sites in their respective jurisdiction.

### **How will information about vaccine-receiving sites be transmitted to McKesson?**

The NJISS Inventory Monitoring Ordering Distribution System (IMODS) will transmit orders to CDC. These orders will be sent to McKesson the morning after they arrive at CDC. CDC is working with McKesson to determine how the vaccine and ancillary supply components of the orders will be handled and the shipment timeline, relative to vaccine orders.

### **Will states be able to determine where specific presentations of vaccine (multi-dose vials, single dose syringes, and nasal sprayers) are directed?**

Providers will select the specific presentation of vaccine when placing their order electronically in NJISS. The NJISS will be able to track the vaccine to know where and what vaccine has been shipped by way of a report that is generated by McKesson.

## ***CLINICAL TEAM FAQs***

### **H1N1 Disease Reporting**

#### **What cases do I need to report to public health authorities?**

You should report any cases meeting the following criteria:

1. Influenza-like illness (i.e., fever  $\geq 37.8^{\circ}\text{C}$  [ $100^{\circ}\text{F}$ ] plus cough and/or sore throat in the absence of another known cause) in an individual who has been admitted to an intensive care unit of an acute care facility, **OR**
2. Influenza encephalopathy (defined as altered mental status or personality changes in patients lasting more than 24 hours and occurring within 5 days of the onset of an acute febrile respiratory illness) in an individual less than 18 years of age, **OR**
3. Any deaths meeting one of the following criteria:
  - o Any death associated with influenza-like illness in which there is a positive influenza test (i.e., rapid influenza diagnostic testing, viral isolation, RT-PCR);
  - o Sudden pediatric death (i.e., death involving an individual less than 18 years of age) from an unknown cause, but thought to be natural;

- A pediatric death from an unknown, febrile respiratory illness;
- Any unexplained death in a person of any age involving a febrile respiratory illness

**To what public health authority should I report cases meeting the above criteria?**

Reports should be made to the local health department where the patient resides.

**How should these cases be reported?**

These cases should be reported immediately by telephone to the local health department where the patient resides.

**How do I find out which local health department to call?**

A directory of local health departments can be found at:

<http://nj.gov/health/lh/directory/lhdselectcounty.shtml>. Local health departments can also be found in the blue pages of your phone book.

**Do I need to report every case of Influenza A to public health authorities?**

No. Only cases that meet the criteria specified above should be reported to public health authorities. Sporadic cases of influenza that are not hospitalized do not need to be reported to public health authorities.

**Testing**

**Why is the NJ Public Health and Environmental Laboratories (PHEL) performing influenza testing only on patients admitted to an ICU or patients who have died?**

The focus of influenza testing performed by PHEL (NJ’s state laboratory) is currently on severe and fatal cases of influenza-like illness so that the New Jersey Department of Health and Senior Services (NJDHSS) can closely monitor the severity of illness caused by influenza this season. Of note, testing is only one of the many influenza surveillance activities that take place in the State. NJ uses many different surveillance systems to track the temporal and geographic spread of influenza viruses. These systems are used along with testing to determine when, where and what type of influenza viruses are circulating.

**FOR MORE DETAILS, PLEASE REFER TO THE SURVEILLANCE AND TESTING GUIDANCE AVAILABLE AT:**

<http://nj.gov/health/flu/forprof.shtml>

**Is diagnostic testing recommended for patients with uncomplicated illness from suspected influenza infection?**

Most patients with a clinical illness consistent with uncomplicated influenza who reside in an area where influenza viruses are known to be circulating do not require diagnostic influenza testing for clinical management. In certain situations, influenza diagnostic tests may provide additional information that is useful for clinical care decisions (see question: “In what situations are influenza diagnostic tests useful for clinical care decisions”). Clinicians should use their judgment in addition to these recommendations to decide whether to test for influenza in patients with uncomplicated illness.

**When should I pursue diagnostic testing for influenza in general?**

In general, diagnostic testing for influenza should be done when the results will affect clinical decision making.

**In what situations are influenza diagnostic tests useful for patients who are not severely ill?**

Influenza diagnostic testing of patients who are not severely ill may help inform decisions regarding clinical care, infection control, or management of close contacts in certain situations. Clinicians should use their judgment to decide when to test for influenza in patients who are not severely ill. In addition, specifically testing for 2009 H1N1 influenza by rRT-PCR may be important for patients with certain conditions, such as pregnancy or severe immunosuppression, to improve their clinical care. However, if flu is suspected in these or other high risk patients, treatment should still be initiated while awaiting test results and should not be delayed since antiviral medications are most beneficial when started within the first 2 days of illness.

More information about these recommendations can be found at:

[http://www.cdc.gov/h1n1flu/guidance/diagnostic\\_tests.htm](http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm)

**When should I pursue confirmatory H1N1 testing for my patient who has symptoms consistent with influenza?**

NJDHSS is focusing its testing efforts on specimens submitted by our network of sentinel providers, patients hospitalized in the ICU and patients with ILI who have died. So unless your patient meets the screening/testing criteria established by NJDHSS, you do not need to make arrangements for H1N1 confirmatory testing. The results of H1N1 testing should have little impact, if any, on the clinical management or public health response related to a case of influenza. Should your patient not meet the criteria established by NJDHSS but you would like to have testing conducted, you can pursue testing via a commercial laboratory. However, appropriate antiviral treatment and infection control measures should not be delayed pending diagnostic testing results. If influenza infection is clinically suspected, early empiric antiviral therapy should be initiated in hospitalized patients because antiviral medications are most effective when administered as early as possible.

**Can the State perform confirmatory testing for H1N1?**

Yes. The NJ Public Health and Environmental Laboratories (PHEL) can perform confirmatory testing for H1N1. The turn-around time (TAT) for results is usually within 72 hours from specimen submission. However, TAT can vary depending on the number of specimens submitted to PHEL during a given time frame.

**How do I interpret the results of H1N1 testing performed on a patient who is receiving antiviral therapy?**

The RT-PCR test used to detect the presence of novel influenza A (H1N1) detects genetic material (i.e., RNA) associated with this virus and not necessarily live virus. A positive result obtained from a specimen collected from a patient who has been treated with an antiviral medication is likely to reflect that the patient is infected with the novel H1N1 virus. However, since the RT-PCR test is dependent upon the presence of sufficient quantities of viral RNA for detection, a negative result from a person who has been given an antiviral medication or has been tested several days after illness onset should be interpreted with this in mind.

**Is NJDHSS confirming the results of H1N1 testing performed by commercial laboratories?**

No. NJDHSS is testing only patients who meet the criteria specified under “What cases do I need to report to public health authorities?” Patients meeting these criteria who test positive for influenza by a commercial laboratory should be reported to public health authorities.

### **What are the different kinds of influenza diagnostic tests?**

Rapid influenza diagnostic tests (RIDTs), viral culture, direct immunofluorescence assays (DFAs) and indirect immunofluorescence assays (IFAs), and real-time reverse transcriptase polymerase chain reaction (rRT-PCR) can all be used to diagnose influenza. Each test varies in the time it takes to perform the test and the sensitivity to detect different influenza viruses.

### **What does a positive/negative rapid influenza diagnostic test (RIDT) test result mean?**

Rapid influenza diagnostic tests (RIDTs) are widely available, commercial diagnostic tests that can detect influenza viruses in 30 minutes or less. Certain RIDTs can be performed outside of the laboratory in an outpatient setting (e.g., doctor's offices or health clinics). These rapid tests differ in whether or not they can distinguish between influenza A and B viruses. These tests also vary in the chance that they will miss an influenza infection. For example, the sensitivity of these tests for detecting 2009 H1N1 varies from 10-70%. Therefore, a negative test does not exclude influenza infection. During an influenza outbreak, a positive test is likely to indicate influenza infection. Depending on which commercially available RIDT is used, the test can either 1) detect and distinguish between influenza A and B viruses; or 2) detect both influenza A and B but not distinguish between influenza A and B viruses. For more information on the sensitivity, specificity and interpretation of RIDT results, see

[http://www.cdc.gov/h1n1flu/guidance/diagnostic\\_tests.htm](http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm)

### **What does a positive/negative rapid influenza diagnostic test (RIDT) test result mean?**

Given the lower sensitivity of RIDT relative to rRT-PCR and viral culture, a negative test result using RIDT does not rule out influenza infection. Patients with a negative RIDT and underlying medical conditions should continue empiric antiviral treatment if influenza infection is clinically suspected. However, treatment with influenza antiviral medications should not be delayed pending test results if influenza is suspected and if treatment is indicated.

A positive RIDT result is informative because the specificity of these tests is high. These tests do not provide information on the influenza A subtype (e.g., 2009 H1N1 vs. seasonal H3N2), but if most circulating influenza A viruses have similar antiviral susceptibilities, influenza A subtype information may not be needed to inform clinical care. Under conditions where the majority of circulating influenza viruses are 2009 H1N1, a positive RIDT result for influenza A virus can be assumed to be 2009 H1N1 influenza.

### **I am concerned my patient has 2009 H1N1 influenza, but I do not have any rapid flu test kits. Should I send my patient to the emergency department for testing?**

No. You should not refer the patient to the emergency department unless there are clinical indications for emergent/urgent care. Besides, rapid tests may or may not be positive if the patient is infected with the 2009 H1N1 virus.

### **If my patient meets the surveillance and testing criteria, which specimens should I send?**

Nasopharyngeal (NP)/oropharyngeal (OP) swab, nasopharyngeal wash/aspirates, nasopharyngeal wash/aspirates, and certain post mortem specimens are acceptable for testing. Only ONE good quality specimen needs to be submitted to PHEL. A specimen of good quality can be obtained by collecting specimens within the first 3 days of illness onset AND following the collection instructions available through the URLs below. Of note, multiple respiratory specimens, especially bronchoalveolar lavage or endotracheal specimens, should be collected from critically ill patients who are past 6-7 days from illness onset. More than one specimen obtained from

multiple sites collected during postmortem examinations will be accepted. Additional information on sample collection can be found at the following websites.  
<http://nj.gov/health/flu/forprof.shtml>, [http://www.cdc.gov/h1n1flu/guidance/diagnostic\\_tests.htm](http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm)

**What options are available for use by clinicians when patients are not responding to either oral or inhaled antivirals?**

On Friday, October 23, 2009, the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the use of the investigational antiviral drug Peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, Peramivir IV is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons:

1. The patient is not responding to either oral or inhaled antiviral therapy, or
2. When drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- is not expected to be dependable or feasible;
3. For adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

There are no FDA-approved intravenously administered antiviral drugs for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

Clinicians considering use of Peramivir IV under EUA must read and understand the content of the FDA-issued Emergency Use Authorization of Peramivir IV: Fact Sheet For Health Care Providers ([www.cdc.gov/h1n1flu/eua](http://www.cdc.gov/h1n1flu/eua)) prior to initiating a request and must agree to comply with terms and conditions of authorized use of Peramivir per the FDA-issued EUA. Clinicians who, after reading the Fact Sheet for Health Care Providers, wish to obtain Peramivir IV for a patient can download the request form (or access an electronic request portal) at [http://www.cdc.gov/H1N1flu/EUA/peramivir\\_recommendations.htm](http://www.cdc.gov/H1N1flu/EUA/peramivir_recommendations.htm)

**If a specimen is sent to PHEL on a Saturday, is there someone there to receive it and start running the test?**

Specimens should only be sent to PHEL Monday -Thursday. There is no one at PHEL to receive specimens on a weekend from commercial carriers.

We run influenza panels everyday Monday-Friday, usually first thing in the morning, and sometimes an afternoon run if necessary. Samples received the day before are usually run the next day with same day results. We run confirmatory testing when we have enough to fill a plate (~20 specimens). Confirmatory testing is usually done every day, sometimes every other day. Approximately 99% of those that are found A unsubtypable (i.e., not a seasonal virus) on the first test go on to get confirmed by the second (novel H1N1 specific test). ALL test results are entered into CDRSS within about an hour of result approval at PHEL. Hard copy labs are only faxed when both seasonal panel and confirmatory testing are complete which may be why your doctors perceive a delay.

**Do you accept H1N1 confirmations on ICU patients even if their swab is negative?**

Absolutely- swabs from rapid tests should not be used to rule out H1N1. Even if swab is B positive and the patient is admitted to the ICU swabs should still be sent. Literature has indicated that these results are only about 40-60% accurate for novel H1N1 specimens. Accuracy for seasonal is a little better depending on the type of kit used.