



Florida's H1N1 Vaccination Program
Healthcare Provider Information FAQs

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The following information provides an overview of Florida's H1N1 vaccination program for healthcare providers practicing in Florida. The objective is to assure that providers have critical information needed to be an effective partner in Florida's H1N1 Influenza Mass Vaccination. Together, we can immunize all Floridians and visitors who choose to be vaccinated.

This information is based on state and federal guidance [e.g. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services and the Florida Department of Health] available **as of October 13, 2009**.

Available H1N1 guidance changes. Utilize the following resources to assure that you have the information you need:

- Your local county health department is a great resource:
<http://www.floridashealth.com>
- The Florida Department of Health's website: <http://www.myflusafety.com>
- The toll free Florida Flu Information Line, 1-877-352-3581, is available 24/7 for recorded messages in English, Spanish and Haitian-Creole. Operators are available 8am to 8pm eastern standard time.
- The Health and Human Services influenza website: <http://www.flu.gov>
- The Centers for Disease Control & Prevention website:
http://www.cdc.gov/h1n1flu/general_info.htm

Table of Contents

Glossary of Terms 3

Administration..... 4

Vaccine Supply vs Demand..... 7

Provider Registration and Orientation..... 9

Ordering & Receiving Vaccine..... 10

Storage..... 12

Costs 13

Safety 17

Reporting Vaccine Adverse Reactions 18

Additional 2009 H1N1 Vaccination Information 18

H1N1 Influenza Disease Management..... 19

Appendix A: Florida SHOTS – H1N1 Enrollment and Registration..... 21

Glossary of Terms

Florida SHOTS: Florida's State Health Online Tracking System. The centralized database for recording and tracking childhood immunizations as authorized by s. 381.003, F.S. This registry addresses all immunizations for all age groups, including the H1N1 immunization.

Organization: An organization may be a single clinic or a group of clinics all registered under a single Florida SHOTS user.

Provider: any entity that will receive vaccine and/or administer vaccinations; providers include hospitals, federally qualified health centers (FQHCs), local health departments, pharmacies, pharmacists, physicians, and employee health services.

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

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.

Administration

Who is recommended to receive H1N1 vaccine?

During the period when vaccine is in limited supply, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that vaccination efforts initially focus on 5 target groups:

- Pregnant women
- People who live with or care for children younger than 6 months of age
- Healthcare and emergency medical services personnel
- Persons between the ages of 6 months through 24 years
- People ages 25 through 64 years who are at higher risk for complications because of chronic health disorders or compromised immune systems (due to medical therapy or disease)

The ACIP also made recommendations regarding which people within the groups listed above should be prioritized if the vaccine is initially available in extremely limited quantities. For more information see the CDC press release [CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1](#).

Once the demand for vaccine for the prioritized groups has been met at the local level, programs and providers should also begin vaccinating everyone from the ages of 25 through 64 years. Once vaccine demand among younger age groups has been met, programs and providers should offer vaccination to people 65 or older (see <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>).

Are there requirements regarding documentation of priority group membership?

There will be no federal requirements for vaccinators to require documentation of priority group status such as a doctor's note documenting pregnancy or risk status.

Is there flexibility in how states implement the recommendations?

The ACIP recommendations leave room for flexibility at the local level depending on the local vaccine supply situation.

How will the State determine that the vaccine can be administered to other priority groups?

Once the demand for vaccine for all prioritized groups has been met at the local level, programs and providers will begin vaccinating everyone.

What forms of the H1N1 vaccines are approved and expected to be available?

The U.S. Food and Drug Administration (FDA) approved supplements to existing vaccine licenses to protect against the pandemic (H1N1) 2009 influenza virus. The Influenza A (H1N1) 2009 Monovalent vaccines contain an A/California/7/09-like virus (see [Information on the Influenza A \(H1N1\)2009 Monovalent Vaccine approvals](#)). Four vaccines have been licensed by the FDA, with a fifth vaccine still pending approval. All currently licensed vaccines for use in the United States are unadjuvanted.

- MedImmune Influenza A (H1N1) 2009 Vaccine Live, Intranasal
 - Live attenuated virus vaccine for healthy individuals 2-49 years of age
 - Should not be administered to individuals with asthma, children <5 years of age with recurrent wheezing, any child < 24 months of age, or children and adolescents on concomitant aspirin therapy
 - Avoid use in immunocompromised individuals, pregnant women, and individuals with underlying medical conditions that predispose them to complications of influenza infection
 - Prefilled single-dose intranasal sprayer containing 0.2 mL suspension; no preservative
- Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine
 - Inactivated virus vaccine for persons 6 months of age and older, given by intramuscular injection
 - Prefilled syringe, 0.25 mL; no preservative
 - Prefilled syringe, 0.5 mL; no preservative
 - Single-dose vial, 0.5 mL; no preservative
 - Multi-dose vial, 5 mL; contains preservative thimerosal
- Novartis Influenza A(H1N1) 2009 Monovalent Vaccine
 - Inactivated virus vaccine for persons 4 years of age and older, given by intramuscular injection
 - Prefilled syringe, 0.5 mL; trace preservative thimerosal (≤ 1 mcg Hg/ 0.5mL dose)
 - Multi-dose vial, 5 mL; contains preservative thimerosal
- CSL Influenza A(H1N1) 2009 Monovalent Vaccine
 - Inactivated virus vaccine for persons 18 years of age and older, given by intramuscular injection.
 - Prefilled syringe, 0.5 mL; no preservative
 - Multi-dose vial, 5 mL; contains preservative thimerosal
- GlaxoSmithKline (GSK) – vaccine not yet licensed by the FDA

Will two doses of vaccine be required?

The FDA approved and preliminary clinical trials data support:

- One dose of 2009 H1N1 flu vaccine for persons 10 years of age and older
- Two doses of 2009 H1N1 flu vaccine for children 3-9 years of age
- Children ages 6 months through 35 months get two doses of 2009 H1N1 flu vaccine that contains one-half the dose used for older children and adults

What is the recommended interval between the first and second dose for children under 10 years of age?

The FDA approved and the vaccine package inserts indicate that a second dose should be administered about one month after the initial dose.

Will it be necessary for the first and second dose to be the same product?

Ideally, first and second doses would be from the same product. However, practical considerations may make this difficult to implement. CDC has been permissive on this issue but prefers that individuals who require a second dose be vaccinated with the same product, if possible. While not preferred, administering one dose as inactivated vaccine and another dose as live vaccine is acceptable.

How will the public be notified 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 using the media to disseminate this message will be the primary means of educating persons about who needs a second dose.

How much Thimerosal-free vaccine will be available?

It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women.

Should the 2009 H1N1 influenza vaccine be given to someone who has had an influenza-like illness since between April and now?

There is no test that can show whether a person had 2009 H1N1 influenza in the past. Many different infections, including influenza, can cause influenza-like symptoms such as cough, sore throat and fever. In addition, infection with one strain of influenza virus will not provide protection against other strains. People for whom influenza vaccine is recommended should receive the 2009 H1N1 vaccine, even if they had an influenza-like illness previously. CDC's recommendation is for persons who were tested for 2009 H1N1 influenza discuss the need for vaccination with their healthcare providers to see if the test they had was either an RT-PCR or a viral culture that showed 2009 H1N1 influenza. There is no harm in being vaccinated if a person had 2009 H1N1 influenza in the past.

Are there some people who should not receive this (H1N1) vaccine?

Anyone who has a severe (life-threatening) allergy to eggs or to any other substance in the vaccine should not get the vaccine. People should always inform their immunization provider if they have any severe allergies, if they've ever had a severe allergic reaction following flu vaccination, or if they have ever had Guillain-Barré Syndrome (GBS).

Vaccine Supply vs Demand

How should I prioritize among the initial target groups recommended by ACIP?

The recommendations are broad and allow for flexibility to accommodate local variability in vaccine needs and demands. At this time Florida has adopted the CDC's ACIP recommendations in total. Providers should vaccinate among the initial target group populations on a first come, first served basis.

How likely is it that recommendations for target groups may change during the immunization period?

Although it is unlikely the ACIP recommendations will change, predicting the behavior of 2009 H1N1 influenza virus is difficult. CDC will continue to monitor the epidemiology of the evolving pandemic very closely. The Advisory Committee on Immunization Practices (ACIP) will be updated frequently on the status of the pandemic, including groups at highest risk of complications, and recommendations will be modified as necessary.

What are some possible approaches a practice might take to administer the 2009 H1N1 vaccine?

Options include holding special clinics, integrating the 2009 H1N1 vaccination into routine practice procedures, providing walk-in immunizations, or coordinating with local public health clinics if unable to administer 2009 H1N1 vaccine themselves. In determining the best option, each practice should consider several factors, including availability of vaccine, practice resources and patient demand.

If my patients are vaccinated outside of my practice, how will that information be available for inclusion in the patient's permanent medical record?

Recipients of the 2009 H1N1 vaccine will be provided with a hand-held card to serve as a record of vaccination and a source of information should a report to the Vaccine Adverse Event Reporting System (VAERS) be needed. Vaccine recipients will be encouraged to bring the hand-held card at their next visit to their primary care provider so that vaccination information can be transcribed into the patient's permanent medical record.

What should a 2009 H1N1 vaccination provider do if there are people requesting 2009 H1N1 vaccine who are not in the initial target groups?

The ACIP recommendations on 2009 H1N1 vaccination are not intended to deny 2009 H1N1 vaccine to anyone who wishes to be vaccinated. The U.S. government has purchased enough 2009 H1N1 influenza vaccine for all those who choose to get vaccinated. The challenge, especially during the first few weeks of the vaccination program, is to try to provide vaccine to people in the highest risk groups, while vaccine supply may not be adequate to meet total demand. It will be key for providers to educate their clients on the initial need for priority groups and that there will be adequate vaccine available within a short time period. The decision regarding who should get vaccinated is one that should be made between the provider and the patient, weighing whether there are enough doses available for those at greatest risk for infection and serious complications as well as the likelihood that patients turned away will come back for vaccine at a later date.

How can providers determine what percentage of their patients plan on getting the 2009 H1N1 vaccine in a physician's office?

It is difficult to predict where individuals will go to receive the 2009 H1N1 vaccine. Providers can use their previous experience with seasonal influenza vaccine usage in their practices as an indicator of how their clients will accept the H1N1 Influenza vaccine.

Provider Registration and Orientation

The following responses to questions regarding provider registration in Florida SHOTS and subsequent vaccine ordering procedures are supplemented by: Florida SHOTS—H1N1 Enrollment and Registration brief (Appendix A) and the Florida SHOTS H1N1 Quick Tips Guide Version 9.3.3.

Who can register to provide H1N1 vaccines?

Generally, entities that provide health care or immunization services either to the public or in defined settings are able to provide H1N1 Influenza vaccines. Examples include private physician practices, urgent care clinics, community health centers, inpatient health care facilities, pharmacies, medical service providers in institutional settings, and county health departments.

How can I register to distribute H1N1 vaccine?

Providers who would like to partner with local health departments can pre-register through the Florida SHOTS system at www.flshots.com

As part of the registration, you will provide a contact name and telephone number in the event that Florida SHOTS personnel have questions regarding the registration.

Additional information can be found on the FLSHOTS website: <https://www.flshots.com/>
Providers can also receive additional information by either calling or e-mailing the Florida SHOTS help desk through the contact information below:

Florida SHOTS Help Desk Hours: Monday – Friday, 8:00 AM – 5:00 PM Eastern
Phone: (877) 888-SHOT (7468)
Fax: (850) 412-5801

E-mail: flshots@doh.state.fl.us

Can I fax or send a paper copy to register?

No. Paper copies are not accepted. Providers must register electronically online at <http://www.flshots.com/enrollment/provider.html> .

How will I know I am registered?

Once your registration has been approved, you will receive information to access the on-line system and will be required to electronically sign the H1N1 Federal Agreement form within the system.

Once I'm registered, how can my staff and I orient to the on-line registration and tracking system?

There are on-line guides available on the FL SHOTS website [<https://www.flshots.com/>] to orient you to the system e.g.:

- User's Guide to Florida SHOTS: Immunization Registry
- Florida SHOTS Quick Tips : http://www.flshots.com/_pdfs/FloridaSHOTSQuickTips.pdf

The FL SHOTS website also provides on-line training modules for registered providers.

How long is my registration valid?

The agreement is effective two years from the date of approval, at which time a renewal agreement is required.

Who in a registered organization will have access to the FL SHOTS information?

Access at each organization will be through the requesting provider's designated user ID and password. Authorized licensed providers may assign staff access to Florida SHOTS and are solely responsible for managing such access.

What are the minimum system specifications for utilizing the on-line Florida SHOTS?

- Windows 2000 operating system (or later) ,
- At least 128MB of RAM
- Internet Explorer 5.5
- Access to the Internet [Faster connections work best. However, dial-up connections can be used for access.]
- Required Browser Settings:
 - Screen Resolution: 800 x 600 (1024 x 768 if supported)
 - Browser: Microsoft Internet Explorer (Version MSIE 5.5 and above)
 - Cookies Enabled: Yes

Ordering & Receiving Vaccine

How do I place orders for vaccine?

Providers may place orders through the FL SHOTS system or receive vaccine directly from their county health department. If you are utilizing the FL SHOTS system for requesting vaccine, providers will need to designate a "ship-to" location and enter requested amount of vaccine. Your county health department will have access to your information and will approve, edit, or deny your order based on current county allocations and total provider requests. A representative will contact you if additional information is needed.

Will vaccine be distributed equitably across providers?

Public health departments will strive to ensure equitable distribution across providers based on each county's allocated amount of vaccine.

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 through FL SHOTS 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. For providers needing less than 100 dose lots, county health departments will work with these providers to make vaccine available.



How is vaccine distributed to providers?

The Federal Government is allocating vaccine to states based on population size. Florida has allocated vaccine to the county level based on population. Vaccine will be distributed in two ways: 1) approved orders placed in FL SHOTS will be shipped directly to your designated "ship-to" site, or 2) orders will be placed with county health departments and distributed based on local procedures.

Which ancillary supplies will be provided with vaccine?

The Federal Government has purchased vaccine and supplies (syringes, alcohol swabs, sharps containers, and vaccination record cards) and distributing these at no cost to participating healthcare providers.

How will ancillary supplies be distributed?

For those providers who request vaccine through FL SHOTS, supplies will be shipped directly to the provider and separately from vaccine with expected arrival before or on the same day as vaccine. Vaccine supplies will be sufficient to support the quantities of ordered vaccine.

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

Delivery to the provider should be approximately 3-5 days from the time CDC receives the approved order.

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 similar to the seasonal influenza vaccine order process that is currently utilized by immunization programs.

Will there be enough vaccine available?

We do not expect that there will be a shortage of H1N1 flu vaccine. However, there will be limited amounts available initially as vaccine production is fully implemented. Florida will receive vaccine each week, as vaccine is manufactured and distributed by our federal partners. Florida is expected to receive 11 million doses by January of 2010.

Storage

How should vaccine be stored?

Vaccine storage and handling recommendations included in the product package inserts should be followed carefully and will provide you with the most up-to-date information. If you have concerns about vaccine that may not have been stored or handled properly, contact your local county health department or contact either the manufacturer's quality control office or the immunization program for guidance. H1N1 vaccine will need to be maintained at 2-8°C.

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#Thermo meters](http://www2a.cdc.gov/vaccine/ed/shtoolkit/storage_equipment.htm#Thermo%20meters)

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?

The vaccine package inserts contain 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_euipment.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

Costs

How will the 2009 H1N1 vaccine be financed?

The federal government has purchased the vaccine and related supplies for distribution to states so providers will not be allowed to bill for the vaccine.

Can vaccination providers charge or bill for administration of the 2009 H1N1 vaccine to patients?

Yes, providers may charge or bill an administration fee for providing the H1N1 vaccination to clients. However, every effort should be made to ensure that cost is not a barrier for patient receipt of vaccine. The administration fee cannot exceed the regional Medicare vaccine administration fee. Public Health-sponsored vaccination clinics will not be charging an administration fee to persons seeking vaccination.

Will 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, has stated:

"Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

- a) Health plans communicate directly with plan sponsors and members on the current 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 a novel (A) 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"

Will Medicaid reimburse H1N1 flu vaccinations?

Florida Medicaid will reimburse Medicaid enrolled practitioners for the vaccine administration to eligible beneficiaries. Practitioners other than federally qualified health centers and county health departments will be reimbursed \$10.00 for vaccines administered by physicians and \$8.00 for vaccines administered by Advanced Registered Nurse Practitioners and Physician Assistants. Additional information is available at the following link:

http://portal.flmmis.com/FLPublic/Provider_ProviderSupport/Provider_ProviderSupport_ProviderAlerts/tabId/43/Default.aspx

What Current Procedural Terminology (CPT) codes are available for submitting a claim for administration of 2009 H1N1 vaccine to a private health insurance plan?

The currently established CPT code for 2009 H1N1 vaccine is 90663 (influenza virus vaccine, pandemic formulation, H1N1). This code may be reported in conjunction with the unique CPT code for H1N1 vaccine administration: 90470, H1N1 immunization administration (intramuscular, intranasal), including counseling when performed. Providers should follow instructions provided by the health plans with whom they contract related to billing for 2009 H1N1 vaccine administration.

Will Medicare Fee for Service (FFS) pay private providers for administration of 2009 H1N1 vaccine?

It is expected that persons aged 10 and over only require one dose of 2009 H1N1 vaccine. However, multiple administration fees will be covered for Medicare beneficiaries requiring multiple doses of H1N1 vaccine.

What type of cost-sharing for 2009 H1N1 vaccine administration will be imposed on Medicare FFS beneficiaries?

For Medicare FFS beneficiaries, co-insurance and deductible requirements are not applied to influenza vaccine administration, including 2009 H1N1.

How much will Medicare FFS pay for administration of 2009 H1N1 vaccine?

Medicare FFS will reimburse the administration of 2009 H1N1 influenza vaccine at the same rate that is paid for administration of seasonal influenza vaccine, for each dose administered.

What codes should be used when submitting a claim for 2009 H1N1 vaccine administration to Medicare FFS?

CMS has established two new Healthcare Common Procedure Coding System (HCPCS) codes for 2009 H1N1 vaccine and vaccine administration: G9141- Influenza A (H1N1) immunization administration (includes the physician counseling the patient/family), and G9142- Influenza A (H1N1) vaccine, any route of administration.

Providers may elect to submit the HCPCS code for the 2009 H1N1 vaccine along with the vaccine administration code. However, since Medicare FFS will not provide payment for the 2009 H1N1 vaccine itself, only the vaccine administration code is required for payment.

What is Medicaid's role in 2009 H1N1 vaccine administration?

CMS recently issued guidance to States outlining existing Medicaid and CHIP authorities available to States for the administration of 2009 H1N1 vaccine. States should consult the guidance at the following link to address concerns that may arise regarding Medicaid and 2009 H1N1 vaccine administration:

<http://www.cms.hhs.gov/SMDL/SHO/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1228935&intNumPerPage=10>

Will screening of children for VFC eligibility be required prior to administration of 2009 H1N1 vaccine?

No.



Will administration of 2009 H1N1 vaccine to eligible tribal members be covered by IHS?

Yes, the IHS will cover administration of the 2009 H1N1 vaccine to tribal members who are eligible for IHS health care benefits. There will be no charge to eligible tribal members for administration of 2009 H1N1 vaccine.

Will the VA cover administration of 2009 H1N1 vaccine for Veterans eligible for VA health care benefits?

Yes, the VA will provide the 2009 H1N1 vaccine to Veterans who are enrolled in the VA health care system. There will be no charge to eligible Veterans for administration of H1N1 vaccine. Veterans seeking the H1N1 vaccine but currently not enrolled in VA health care can apply for enrollment at their closest VA health care facility, or online at: <https://www.1010ez.med.va.gov/sec/vha/1010ez>

Will TRICARE cover administration of 2009 H1N1 vaccine for its beneficiaries?

Yes, TRICARE will cover the 2009 H1N1 vaccine for TRICARE beneficiaries. This coverage applies to beneficiaries served both in Military Treatment Facilities and in private provider offices that are authorized to treat TRICARE beneficiaries.

What type of cost-sharing for 2009 H1N1 vaccine administration will be imposed on TRICARE beneficiaries?

Cost-sharing for 2009 H1N1 vaccine administration will be similar to cost-sharing for other vaccines covered by TRICARE. This cost-sharing may vary depending on what type of TRICARE coverage the beneficiary has. TRICARE beneficiaries should consult their benefits guide for cost-sharing information.

What codes should be used when submitting a claim for administration of 2009 H1N1 vaccine to TRICARE?

The currently established CPT code for 2009 H1N1 vaccine is 90663 (influenza virus vaccine, pandemic formulation, H1N1). This code may be reported in conjunction with the unique CPT code for H1N1 vaccine administration: 90470, H1N1 immunization administration (intramuscular, intranasal), including counseling when performed. Providers should follow instructions provided by the health plans with whom they contract related to billing for 2009 H1N1 vaccine administration.

CMS has established two new HCPCS codes for 2009 H1N1 vaccine and vaccine administration: G9141- Influenza A (H1N1) immunization administration (includes the physician counseling the patient/family), and G9142- Influenza A (H1N1) vaccine, any route of administration.

Are Commercial Community Vaccinators (CCV) who have not contracted with a public health department to provide staff or to run a public health vaccination clinic permitted to administer 2009 H1N1 vaccine?

Yes, a CCV can act as a private provider as long as the CCV has been designated as a 2009 H1N1 vaccinator by the jurisdiction in which it operates. If a CCV organizes a clinic outside of a contract with the public health department to provide staff or to run the vaccination clinic, the CCV may charge patients or bill insurance to recoup the costs of vaccine administration.

Will 2009 H1N1 vaccination in a setting such as a pharmacy or a grocery store be covered by private health insurance plans?


Yes, health insurance plans providing coverage for influenza vaccinations will reimburse the administration of 2009 H1N1 vaccine provided in a setting if the vaccinator/site has an established contract with that insurer. In addition, many CCVs, including urgent care centers, retail-based clinics, and mass vaccinators, already have contracts in place with health insurance plans that can be used for reimbursement purposes. Appropriately licensed and credentialed CCV and pharmacies who seek reimbursement from health insurance plans should work with national, regional, and local insurance plans in anticipation of 2009 H1N1 vaccination.

Who will pay for the administration of 2009 H1N1 vaccine of uninsured or underinsured persons?

Federal funds are being provided to public health authorities to ensure that uninsured or underinsured persons can receive H1N1 vaccine free of charge (see above). Patients without insurance coverage for 2009 H1N1 vaccine may be vaccinated in a private provider's office if they are willing to pay the vaccine administration fee out of pocket, or if the provider chooses to administer the vaccine without charge. Patients who cannot afford to pay a vaccine administration fee are encouraged to seek vaccination through their public health department, mass vaccination clinic, or through a CCV.

Where can persons who are uninsured or underinsured receive 2009 H1N1 vaccine?

Private providers may elect to provide the vaccine to uninsured or underinsured persons without charging an administration fee.

Public health departments and the mass vaccination clinics will be available for the uninsured and underinsured. In addition to these public health sponsored clinics, Federally Qualified Health Centers (FQHCs), also known as Section 330-funded Health Centers (HCs), receive federal funding to provide healthcare to underserved populations, regardless of ability to pay. It is expected that the costs associated with administering 2009 H1N1 vaccine to existing health center patients would be borne by the health centers as part of the general expectations of their grants. As with all services they provide, Health Centers may charge a small fee. For health centers in your area, visit <http://findahealthcenter.hrsa.gov/> .

Safety

Are the H1N1 vaccines safe?

H1N1 flu vaccines are manufactured and tested using the same processes used for the seasonal vaccine. Many millions of doses of seasonal vaccine have been distributed every year for many years, and seasonal vaccines have a well-established safety profile.

What about side effects?

Expected side effects are documented on the Vaccine Information Sheets. Basically, they will be similar to those of the seasonal vaccine, potentially including a mild fever, body aches, and fatigue for a few days after the vaccine, and soreness at the injection site. The most common side effects seen with administration of the nasal vaccine include runny nose or nasal congestion in recipients of all ages; fever more than 100 degrees Fahrenheit in children two to six years of age, and sore throat in adults. Side effects are more common in individuals who have not previously been immunized with influenza vaccines. As with any medical product, serious adverse events may occur.

Is thimerosal safe when used as a preservative in vaccines?

Yes. We are aware of the concerns that some people have regarding thimerosal in vaccines. However, the vast majority of research conducted in the U.S. and around the world does not support an association between thimerosal in vaccines and autism. The Institute of Medicine and the World Health Organization, among other authoritative medical and scientific bodies, have affirmed that the scientific evidence shows no association between vaccines (with or without thimerosal) and autism. Regardless, since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, except for some formulations of influenza vaccine. All formulations in multi-dose vials contain some thimerosal. Please see the following link for additional information:

http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm

Reporting Vaccine Adverse Reactions

What are the minimum vaccine data elements required by CDC?

Minimum data requirements include age group, 1st or 2nd dose, date of vaccination, and state. This data will be extracted from patient data input into Florida SHOTS on a weekly basis. Public health care providers are required to report data to Florida SHOTS and private health care providers are encouraged to report doses administered in Florida SHOTS as well. For those providers who do not report individual patient level information in the Florida SHOTS, they will be required to report aggregate numbers of doses administered each week by age group to their County Health Department.

How do I report vaccine adverse reactions?

Utilize the Vaccine Adverse Event Reporting System (VAERS). The VAERS website is www.vaers.hhs.gov, or you can call 1-800-822-7967.

A report should be submitted even if the reporter is not certain that the vaccine caused the event. Anyone can submit a VAERS report, including healthcare providers, vaccine providers, public health officials, vaccine manufacturers, and persons vaccinated or their caregivers. Reports may be filed securely online, by mail, or by fax. Report forms are available online or can be obtained by calling 1-800-822-7967 to request reporting forms or other assistance.

If I contact VAERS, will they give me medical advice?

VAERS does not provide medical advice.

Additional 2009 H1N1 Vaccination Information

Is the H1N1 vaccine mandatory?

The state is NOT mandating any vaccinations. However, individual healthcare facilities may have their own policy regarding their employees. Healthcare staff will need to check with their human resource/employee health office regarding their specific workplace policy. If you have questions about whether you should get the vaccine, please consult with your healthcare provider.

Does the H1N1 Flu vaccination replace the annual flu vaccine?

No, everyone is encouraged to get both vaccinations as they become available.

Why are the recommendations for who should receive H1N1 Flu vaccine different from annual flu vaccine?

Even though the H1N1 (Swine) Flu is an influenza virus like seasonal flu, it is affecting different groups of people more significantly than seasonal influenza. As with any disease vaccination, experts develop their recommendations by using current disease patterns, identify population groups are most at-risk for severe illness by determining who is getting ill more frequently and having more severe complications such as hospitalization and death, and how much of a vaccine could be available and when.

How can the public locate a H1N1 vaccination site?

- The Florida H1N1 flu vaccine clinic location webpage is live and can be viewed at <http://www.myflusafety.com/myfluclinic.htm>. As clinics are scheduled, the information is included on this website.
- Many media outlets will be advertising local public vaccination clinics.

H1N1 Influenza Disease Management

What is the H1N1 case definition?

The CDC H1N1 case definition can be found at the following website:
<http://www.cdc.gov/h1n1flu/casedef.htm>

The case definition was last updated by CDC on June 1, 2009 12:15 PM ET

Influenza-like-illness (ILI) is defined as fever (temperature of 100°F [37.8°C] or greater) and a cough and/or a sore throat in the absence of a KNOWN cause other than influenza.

A **confirmed case** of H1N1 virus infection is defined as a person **with an influenza-like illness AND laboratory confirmed** novel influenza A H1N1 virus infection by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

A **probable case** of H1N1 virus infection is defined as a person with an influenza-like-illness who is

- positive for influenza A, but negative for human H1 and H3 by influenza RT_PCR

Optional

A **suspected case** of H1N1 virus infection is defined as a person who does not meet the confirmed or probable case definition, and is not novel H1N1 test negative, and is/has:

- a previously healthy person < 65 years hospitalized for ILI

OR

- ILI and resides in a state without confirmed cases, but has traveled to a state or country where there are one or more confirmed or probable cases

OR

- ILI and has an epidemiologic link in the past 7 days to a confirmed case or probable case

For further information please contact the Bureau of Epidemiology at 850-245-4401

How and when should deaths occurring in people with H1N1 infection be reported?

- Report immediately all deaths occurring in individuals **with** confirmed or probable H1N1 infection.
- Please utilize the case definitions when reporting deaths in people with H1N1.
- In the case where a death has occurred in a person who suffered from an illness clinically compatible with influenza and confirmatory laboratory tests for H1N1 are pending, please notify your county health department of the fatal case with suspected infection from H1N1.

- Reports should be made to the appropriate county health department. Reports can also be made to the Florida Department of Health, Bureau of Epidemiology at 850-245-4401. To find a list of county health department epidemiology contacts, please visit the following website: http://www.doh.state.fl.us/disease_ctrl/epi/topics/contact.htm

When do I report cases to the County Health Department?

Call your county health department (CHD) to report people hospitalized with strongly suspected or confirmed H1N1 infection, to report possible influenza outbreaks, and to get advice on testing and management of cases and contacts. The CHD will advise on whether or not specific tests are needed on patients who appear to be part of an outbreak.

How do I know when I have an Influenza-like illness outbreak?

Three or more people who are connected through a group setting, are ill with symptoms suggesting influenza, and are not part of a household cluster.

You can tell if a person is part of such an outbreak by asking the person if they have recently had face to face or close social contact with other people with similar symptoms who share a similar social environment such as a school, workplace, summer camp, or church.

Where can I find the most current influenza activity data for Florida?

http://www.doh.state.fl.us/Disease_ctrl/epi/swineflu/Reports/reports.htm

Additional weekly reports can be found at

http://www.doh.state.fl.us/Disease_ctrl/epi/htopics/flu/2009/index.html

Where can I find the most current recommended guidance and reporting protocols?

Florida Department of Health: <http://www.myflusafety.com/>

Centers for Disease Control and Prevention: <http://www.cdc.gov/h1n1flu/>

What are CDC's current recommendations for antiviral treatment?

As in earlier antiviral recommendations, the priority for use of antiviral medications this season continues to be in people with more severe illness, such as people hospitalized with influenza, and people at increased risk of influenza-related complications. Recommendations have been updated to provide additional clarification on several issues, including the increased risk for complications in young children, particularly children younger than 2 years of age. The CDC Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season are available at <http://www.cdc.gov/H1N1flu/recommendations.htm>

Appendix A: Florida SHOTS – H1N1 Enrollment and Registration

This quick guide is designed to explain how to register to provide H1N1 vaccine by enrolling with and using Florida SHOTS.

First, does your organization currently have access to Florida SHOTS? Some organizations can be quite large and access may already exist even though some staff may not be aware of it. If you are unsure, please contact the Florida SHOTS Helpdesk at 877-888-7468.

If NO, begin at step 1. If yes, begin at step 6.

- 1) Registration to give H1N1 vaccine begins with enrollment in Florida SHOTS. Using your web browser (Internet Explorer only), to begin the enrollment process, navigate to <https://www.flshots.com/flshots/enroll/applicantquestions.html>.
- 2) Read the questions, select your responses, and then click 'Submit'. Florida SHOTS will not work correctly unless using Internet Explorer 5.5 or higher, running on Windows 2000 or later. Only medical professionals licensed under Chapters 458, 459, or 464, F.S. may apply using this method. Pharmacists must contact Florida SHOTS directly using the number above.
- 3) Read the "Authorized Private Provider User Agreement For Access to Florida SHOTS" and click 'Agree' to continue.
- 4) Next, fill in the "Dual Florida SHOTS Application and H1N1 Provider Pre-Registration Form". The "applicant" is the licensed person under whom this organization-level account will be granted. The "contact person" should be the point of contact Florida SHOTS or other providers should use if contact with your organization is necessary. To indicate H1N1 interest, check the box in the "H1N1 Pre-Registration Only" section, enter the estimate of how many doses your organization expects to administer, and select your organization's specialty. Check the box at the bottom of the page to electronically sign the application. Click the 'Click to attach your signature' button to submit the enrollment application.
- 5) After submitting, the completed application form will display, allowing you to print a copy for your records. After you confirm that you have printed a copy, you will see an application confirmation screen and will also receive an application confirmation email. Florida SHOTS Helpdesk staff will process your application and will contact you to complete the enrollment process.
- 6) Once Florida SHOTS access has been granted, to complete the H1N1 registration process, log in to Florida SHOTS, navigate to the "H1N1" section of the main system menu, and click 'H1N1 Registration'.
- 7) Read the "2009 Influenza A(H1N1) monovalent vaccine - Vaccine Provider Agreement". Check the "I have been authorized..." box if you are, or have been authorized to sign the agreement by, the original applicant of your Florida SHOTS organization account and then check the "I electronically sign..." box. If you had pre-registered through the online enrollment process (steps 1-5 above), the dose estimate and specialty you had previously selected will be shown and can be modified. Otherwise, please enter the estimate of the number of doses your organization expects to administer and your organization's specialty. Click 'Submit' to complete the registration.
- 8) After the registration process is complete, organizations may add "ship-to" sites from the "H1N1 Ship-To Sites" menu option.

- 9) After ship-to sites are entered, they must be approved by the local County Health Department.
- 10) After ship-to sites are approved, orders may be created using the “Create Order” menu option.
- 11) After orders are created, they must be approved by the local County Health Department.
- 12) After orders are approved, they are retrieved by the state daily for processing.