

H1N1 VACCINE: FREQUENTLY ASKED QUESTIONS

September 15, 2009

What is Virginia's H1N1 Vaccination Plan?

- Public/Private partnership to assure multiple sites of access by the public to H1N1 vaccine with special emphasis on assuring vaccination of priority groups (see below).
- Private providers have the opportunity to vaccinate their usual patients/clients and healthcare workers for whom they are responsible
- Local Health Departments will focus on school immunization programs, vulnerable populations, large immunization clinics and any gaps in vaccination access

What are the H1N1 Vaccination priority groups?

- Pregnant women
- Household contacts and caregivers for infants younger than 6 months of age
- Healthcare and emergency medical services personnel (see definition below)
- Persons 6 months through 24 years of age
- Persons 25 through 64 years of age who have medical conditions associated with higher risk of medical complications from influenza. (i.e., chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus), and immunosuppression (including that caused by medications or HIV))

Who are included as healthcare and emergency medical services personnel?

- All paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces.
- Includes (but is not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP.
- Applies to acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.

What are the different roles that providers/sites can play in this process?

Vaccination sites can:

- Focus on different patient populations according to their site characteristics.
 - Some may be open to the general public (e.g., retail pharmacies)
 - Private healthcare providers may vaccinate:
 - their existing patients,
 - family members of existing patients,
 - healthcare staff, or any combination thereof.

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What is required to become a Vaccination Site?

A provider/facility must:

- Agree to the terms and conditions outlined in the Provider Agreement and the Provider Profile which can be found on the upcoming registration website (<http://www.vdh.virginia.gov/H1N1prereg>)
- Have a prescribing official (e.g. M.D., D.O.) and adequate vaccine storage capacity
- Report vaccine doses administered via the Virginia Immunization Information System (VIIS). If you wish to use your existing electronic medical record instead of VIIS, you may call VDH at (804) 864-8060 to discuss options for exporting your data into VIIS (your data will need to conform to VIIS standards for this to be a viable option).

What steps are required to register as an H1N1 Vaccination Site?

Vaccination providers/sites are expected to:

- Sign an H1N1 Vaccine Provider Agreement
- Complete an H1N1 Vaccine Provider Profile (focuses on your patient demographics and shipping information)
- Sign the VIIS Enrollment Packet forms (if you are already a VIIS user or are using electronic transfer of information into VIIS, you will not need to complete these forms). These forms will be available on the aforementioned website.
 - Additionally, VIIS training will be required prior to using VIIS and will be accessible on the same website. Training consists of completion of a 15-minute online module or participation in one of many webinars.
 - Providers without internet access should contact Virginia Department of Health (VDH) at 804-864-8055.

When will the registration website with the required documents be available?

- Expected availability is September 18, 2009 at: <http://www.vdh.virginia.gov/H1N1prereg> .

How will I order vaccine?

- Registered providers will be notified via email when vaccine is ready to be ordered.
 - The vaccine order form will be available on the website prior to vaccine distribution.

What are the advantages to me from using VIIS?

- Pre-populated data on many patients
- Documents H1N1 vaccine doses administered
- Allows automated sending of reminder notices to patients due for vaccination
- Provides definitive immunization records on your patients
- Allows visualization of your patient's vaccination history, including vaccines that your patient received from other participating providers
- Provides auto-populated patient immunization forms for school and day care enrollment

What timeframe is acceptable between vaccine administration and data entry into VIIS?

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- Five days. Paper forms will be available online for providers who want to delay entry into VIIS.

How will vaccine be allocated and distributed?

- Vaccine will be shipped directly to vaccination sites from a national vaccine distributor.
- Providers will also receive ancillary clinical supplies directly from the distributor.
- VDH expects regular shipments of vaccine. Ultimately, there should be an adequate supply of vaccine for all persons requesting vaccination. If a limited shipment is received initially, VDH will direct vaccine to those providers most likely to vaccinate persons in the priority groups.

How will the vaccine be packaged?

- Vaccine is being produced by five manufacturers
- Will be available in both preservative-free and preservative-containing formulations
- The injectable preservative-containing formulation will be available in multi-dose vials
- Preservative-free formulations will be available in single-dose pre-loaded syringes and as an attenuated live-virus vaccine administered intra-nasally (i.e., Flumist).

What ancillary clinic supplies will be provided?

- A national distributor will provide needles, syringes, alcohol swabs, sharps-containers and personal immunization record cards.
- Vaccination sites will automatically receive these supplies (no additional order is necessary). The amount of supplies will correspond to the amount of vaccine shipped to each provider.
- Providers will receive vaccine and ancillary supplies in separate shipments, not necessarily on the same day.

How many doses of H1N1 vaccine will be required for a patient to be protected?

- The final recommendation on the number of doses required will not be available until clinical trials have been completed in late-September.

Will providers be able to charge for the vaccine and its administration?

- Providers cannot charge for the vaccine but they may charge a fee for the administration of the vaccine to the patient, the patient's health insurance plan or another third-party payor.
- The Virginia Department of Medical Assistance Services (DMAS) and its managed-care organizations will cover the cost of administering H1N1 vaccine at \$11/dose (Medicaid) and \$19.96/dose (Medicare). The process used by providers for reimbursement will not change. Providers with questions should contact the DMAS Helpline (in-state: 1-800-552-8627 or out of state: 804-786-6273).

Will private providers be required to administer vaccine to individuals who are not currently their patients?

- Private providers are not required to vaccinate individuals who are not their patients. Providers should refer these individuals to the local health department or to another facility where vaccine is available.

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Are there special vaccine storage and handling requirements for the H1N1 vaccine?

- The storage and handling requirements for H1N1 vaccine are similar to those for the seasonal influenza vaccine. Complete storage and handling information can be found at <http://www.cdc.gov/vaccines/recs/default.htm#storage>.

What must vaccine providers, particularly those caring for children, do to legally provide vaccine to non-established patients (e.g., parents of a child who is a patient of the practice)?

- A provider must follow current standards of practice including assessment and consent and meet the protocols and procedures of the regulatory board relevant to the provider. A physical examination may not be needed. For more information see Virginia Code § 54.1-3303.

What is the liability protection for providers who vaccinate with H1N1 vaccine or use Tamiflu or Relenza for H1N1 treatment/prophylaxis?

- Protection comes in two basic legal forms: (a) immunity, and (b) liability insurance.
 - Immunity conferred by statute may state that cause of action cannot be maintained against a provider.
 - Immunity is available under the Federal Public Readiness and Emergency Preparedness Act (PREP) for novel H1N1 vaccinators (<http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html>). Additional protections could become available under Virginia law if a state declaration of emergency is issued (none currently in effect).
 - Liability insurance provides a defense and indemnification for damages in the event of a suit.
 - Liability insurance will likely already exist through the provider's employer

Even if immunity or liability coverage is in effect for vaccinators, what is not covered under these provisions?

- Neither immunity nor liability covers willful misconduct or criminal acts.
- These provisions also do not provide Workers' Compensation coverage. Workers' Compensation coverage is provided by the employer for disease or injury sustained within the course and scope of employment.
- The immunity and liability provisions are also unlikely to cover premises liability.