

MAINE HEALTH ALERT NETWORK



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****ADVISORY – Important Information****

2009PHADV047

TO: All schools and health care providers, ambulatory, hospitals, health centers, etc

FROM: Dora Anne Mills, M.D., M.P.H., Public Health Director

SUBJECT: Register to be a H1N1 Flu Vaccine Distribution Site

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Background:

Maine Center for Disease Control and Prevention (Maine CDC)
(Formerly Bureau of Health)

This health alert is to update health care providers on the availability of the ability to order H1N1 vaccine. As you may know, pregnant women, children and young adults are being disproportionately affected by novel H1N1 influenza virus (“swine flu”). We expect to start receiving H1N1 vaccine in Maine by mid-October. If you are a health care provider licensed to administer vaccine, we ask that you consider registering to receive the H1N1 vaccine.

SCHOOL-LOCATED VACCINE CLINICS

We also encourage you to become involved with the initiative to offer all children seasonal and H1N1 vaccines in Maine schools. This will assure all Maine children are offered vaccine as quickly and as efficiently as possible while also not overburdening the health care system. If you are interested in becoming involved, please contact your local schools, or call the Maine CDC at 1-888-257-0990, or check the school-located vaccine website at www.maine flu.gov. Thank you ahead of time for your consideration in this important public health effort to keep our communities and schools healthy!

REGISTRATION TO RECEIVE H1N1 VACCINE

Even if you already receive vaccine from Maine CDC, you need to register separately to receive H1N1 vaccine.

To register, fill out and submit the H1N1 Provider Agreement for H1N1 Vaccine, which can be found at: <http://www.maine.gov/dhhs/boh/maine flu/h1n1/provider-agreement-2009-2010.shtml>

For questions regarding H1N1 influenza vaccine ordering see the FAQ in this document. For other questions:

- **Contact the Maine CDC’s Immunization Program at 287-3746**
- **Email us questions at: flu.questions@maine.gov**
- **More info can be found at www.maine flu.gov**
- **Updated CDC guidance on H1N1 influenza vaccine including vaccine handling can be found at: <http://www.cdc.gov/h1n1flu/vaccination>**

H1N1 vaccine will only be available through state health departments (Maine CDC/DHHS in Maine), and will not be available for private purchase from manufacturers.

Anyone interested in offering H1N1 vaccine must complete and submit the [H1N1 Provider Agreement](#). Even those who are already registered Maine Immunization Program providers and who have already completed paperwork to offer seasonal flu vaccine must submit this form.

There are two important requirements for the receiving end of H1N1 vaccine.

- The vaccine must be placed into a working refrigerator that is dedicated to storing vaccine and can maintain the vaccine’s temperature of 35.6 to 46.4 degrees Fahrenheit (2 to 8 degrees Celsius). The vaccine must NOT be exposed to freezing temperatures. A “dorm” style refrigerator in which the freezer and refrigerator share an exterior door is

not appropriate. For further details on handling: <http://www.cdc.gov/h1n1flu/vaccination>.

- A physician or nurse practitioner with an active Maine license should be on record to be providing oversight for the vaccine.

Completing the H1N1 Provider Agreement is your way of demonstrating interest. Each state is given a limit of the number of distribution sites, so we ask that health care providers consolidate their registrations. For instance, we ask that outpatient practices with multiple health care providers submit one registration form.

Once the designated H1N1 Vaccine Providers are identified, we will take orders for H1N1 vaccine. The H1N1 Vaccine Order Form is currently being developed and will be posted on our web site as soon as it is available. In the mean time, we suggest that you start assessing how many doses you will need so that you are ready to place your order as soon as we have the ordering process in place.

FREQUENTLY ASKED QUESTIONS ON H1N1 VACCINE ORDERING

- **Will I be guaranteed of receiving H1N1 vaccine?** Registering is no guarantee of receiving vaccine. Each state is given a limit of the number of distribution sites, so we ask that health care providers consolidate their orders (while also making sure they can maintain the cold temperature of the vaccine). This will increase the likelihood we can distribute vaccine to the health care providers with whom you work.
- **How will you prioritize distribution?** During the first few weeks we anticipate prioritizing distribution to settings serving high priority populations, such as schools, hospitals (for their health care workforce), clinicians serving pregnant women and/or children. We also anticipate distributing the vaccine to each area of the state based on the population and their readiness to administer vaccine.
- **How should we prepare for and how should we handle the H1N1 vaccine once it arrives?** This website provides the answers to this: <http://www.cdc.gov/h1n1flu/vaccination>.
- **What about vaccinating our staff and other high priority populations?** Feel free to administer the appropriate vaccine to others in the high priority populations when the H1N1 vaccine is first distributed, as well as to any of your staff and others who meet the definition of “health care personnel” for the purpose of H1N1 vaccine priority group (see definition way below). If you do not receive H1N1 vaccine right away and you and your staff want vaccine, contact your local hospital to determine how you and other health care personnel can obtain vaccine.
- **How much will the H1N1 vaccine cost?** The H1N1 vaccine is free, and will come with a kit which will contain needles, syringes, sharps containers and alcohol swabs.

- **May I bill third party payers?** You will be able to bill for vaccine administration (\$5 for MaineCare, and \$14.37 other insurers), but not for the vaccine itself.
- **May I charge patients?** In public health clinic settings, such as schools and community public clinics, no patient can be charged for vaccine administration (though 3rd party payers, including MaineCare, can be billed, and in many instances be roster billed). You can charge a maximum of \$14.37 in the private setting. A ‘public health clinic’ is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and receives federal implementation funds to administer H1N1 vaccine in any setting.
- **What about MaineCare billing?** MaineCare has adopted emergency rules to allow schools to “roster bill” for vaccination clinics. They are also adopting emergency rules to allow home health agencies to similarly “roster bill” for these clinics, as ambulatory care clinics (and not home health agencies). Other health care providers (hospitals, health centers, physician practices) will bill regular claims. However, if they so wish, the school can roster bill and provide a payment to the health care provider to help reimburse them for their costs.
- **How will healthcare providers obtain other supplies necessary for vaccination?** The vaccine will be distributed with a kit which will contain needles, syringes, sharps containers and alcohol swabs.
- **Do all vaccines administered have to be documented in ImmPact2?** ImmPact2 providers may document seasonal flu or H1N1 vaccinations in ImmPact2, if they choose. Vaccination administration must be documented appropriately, but use of ImmPact2 is not required.
- **What reporting requirements are there for H1N1 vaccine?** Some reporting of aggregate information will be required by US CDC, and include information such as the number of doses and age ranges to whom it is administered. Those forms will be posted on www.maineflu.gov as soon as they are available.
- **Will the vaccine have thimerosal?** As with the seasonal influenza vaccines, the 2009 H1N1 vaccines are being produced in formulations that contain thimerosal, a mercury-containing preservative, and in formulations that do not contain thimerosal. We expect to have some thimerosal-free H1N1 vaccine available for pregnant women and very young children.
- **What did the FDA recently approve?** The U.S. Food and Drug Administration (FDA) on September 15th approved vaccines from four manufacturers against the 2009 H1N1 influenza virus (CSL Limited, MedImmune LLC, Novartis Vaccines and Diagnostics Limited, and Sanofi Pasteur, Inc). All four firms manufacture the H1N1 vaccines using the same processes as seasonal flu vaccine, which has a long safety record. The H1N1 vaccines approved by the FDA undergo the same rigorous FDA manufacturing oversight, product quality testing and lot release procedures that apply to seasonal influenza vaccines.

- **What do we know from the clinical studies?** Based on preliminary data from adults participating in multiple clinical studies, the 2009 H1N1 vaccines induce a robust immune response in most healthy adults eight to 10 days after a single dose, as occurs with the seasonal influenza vaccine.
- **What do we expect from clinical studies underway?** Clinical studies under way will provide additional information about the optimal dose in children. The recommendations for dosing will be updated if indicated by findings from those studies. The findings are expected in the near future.
- **What do we know about side effects with the injected vaccine?** People with severe or life-threatening allergies to chicken eggs, or to any other substance in the vaccine, should not be vaccinated. In the ongoing clinical studies, the vaccines have been well tolerated. Potential side effects of the H1N1 vaccines are expected to be similar to those of seasonal flu vaccines. For the injected vaccine, the most common side effect is soreness at the injection site. Other side effects may include mild fever, body aches, and fatigue for a few days after the inoculation.
- **What do we know about side effects with the nasal vaccine?** For the nasal spray vaccine, the most common side effects include runny nose or nasal congestion for all ages, sore throats in adults, and -- in children 2 to 6 years old -- fever.
- **Can you schedule seasonal and H1N1 vaccinations at the same time?**
It is anticipated that vaccine against seasonal flu and vaccine against H1N1 may be administered on the same day. Simultaneous administration of inactivated vaccines against seasonal and H1N1 influenza viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and H1N1 influenza viruses is not recommended, so they should be separated by 1 month.
- **What about the risks of not getting vaccinated?** What we know is that novel H1N1 has spread throughout most of the world and poses a risk to those without immunity. All people under age 25 years old are being more severely affected by novel H1N1 disease than older populations. Children younger than 5 years old or with certain chronic medical conditions are at even higher risk for complications from both seasonal (“regular”) and novel H1N1 influenza. It appears that neurodevelopmental conditions such as developmental delay and cerebral palsy, as well as pulmonary conditions such as asthma are among the chronic medical conditions that put some children at risk for severe complications from H1N1. Studies indicate that one-third of pregnant women with novel H1N1 influenza virus (“swine flu”) are so ill, mostly with severe respiratory distress, that they require hospitalization (Lancet, 7/29/09). Some deaths of otherwise healthy children and pregnant women are being reported. So, the risks of not getting vaccinated are contracting and transmitting the virus to others.

- **What are the H1N1 Vaccine Priority Groups?**

We expect that eventually there will be sufficient supplies of H1N1 vaccine for all who desire it. However, the first few weeks of H1N1 vaccine becoming available, the supply needs to focus on the priority groups. US CDC recommends that the following groups be vaccinated with the H1N1 vaccine (“swine flu vaccine”) when it arrives in October:

- **All people from 6 months through 24 years of age**
 - Children from 6 months through 18 years of age** because we have seen many cases of novel H1N1 influenza in children and they 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 we have seen many cases of novel H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and
 - **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 less than 6 months old might help protect infants by “cocooning” them from the virus;
 - **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;
 - **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;
 - **People aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**
- **What is the definition of health care personnel for the purposes of prioritizing the H1N1 vaccine?** The US CDC defines this as: “Health-care personnel (HCP) include 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. HCP might include (but are 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. The recommendations in this report apply to HCP in 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 medical conditions that confer higher risk for complications from influenza?** Medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) and immunosuppression (including immuno-suppression caused by medications or by human immunodeficiency virus).

SEASONAL VACCINE

Recommend and offer **seasonal influenza vaccine** for your patients, their appropriate family members as well as you and your staff now. To order seasonal influenza vaccine for your patients contact the Immunization Action Coalition's website at <http://www.preventinfluenza.org/ivats>.

KEEP INFORMED

- Clinicians should call Maine CDC (1-800-821-5821) or email disease.reporting@maine.gov to report a patient requiring hospitalization related to H1N1 or any outbreak of H1N1.
- Stay Updated::
 - Check the **Maine CDC H1N1 Website**: www.maineflu.gov
 - **Check the Weekly H1N1 Updates**: Check the Thursday updates on H1N1 in Maine on Maine's H1N1 website: www.maineflu.gov. You can subscribe to these updates via their RSS feed.
 - **Sign Up to Receive Health Advisories**: Sign up to receive urgent updates from Maine CDC's Health Alert Network (HAN). The easiest and quickest way to sign up is through the HAN Alert RSS feed at www.mainepublichealth.gov (midway down the center of the homepage).