

# MEMO

**TO:** local public health units, private healthcare providers and hospitals, Indian Health Services, pharmacies, and other immunization providers

**FROM:** Molly Sander, MPH  
Immunization Program Manager

**RE:** H1N1 Influenza Vaccine Provider Agreement and Registration

**DATE:** September 17, 2009

## **READ THIS MEMO IN ITS ENTIRITY**

The North Dakota Department of Health (NDDoH) Immunization Program is supplying monovalent H1N1 influenza vaccine to providers for administration to people who are considered to be at high risk for H1N1. **The vaccine is available free of charge. Providers, with the exception of local public health units, may charge an administration fee for the vaccine. The maximum administration fee that may be charged is \$18.45 per dose (Medicare rate).** The administration fee can be billed directly to the patient or to the insurance company.

### **H1N1 Vaccine:**

The same manufacturers that make seasonal influenza vaccine are manufacturing H1N1 vaccine. These include GlaxoSmithKline, sanofi Pasteur, CSL Biotherapies, Novartis, and MedImmune. The H1N1 influenza vaccine is the same vaccine as the seasonal vaccine, but with a different strain of the influenza virus. The vaccine will be available in intranasal and injectable formulations. Multi-dose vials and prefilled syringes will also be available. **H1N1 influenza vaccine must be stored in the refrigerator at 35 – 46 degrees Fahrenheit.** This is the same temperature as seasonal influenza vaccine.

It is unknown at this time how many doses (one or two) of H1N1 vaccine each person will need. This will be determined after clinical trials are completed. **H1N1 influenza vaccine may be administered at the same time as other vaccines, including seasonal influenza vaccine.** If administering live intranasal influenza vaccine (Flumist®) for both H1N1 and seasonal doses, then the doses may not be administered on the same day, and must be separated by at least four weeks.

### **H1N1 ACIP Recommendations:**

The Advisory Committee on Immunization Practices (ACIP) has recommended five priority groups for vaccination. The groups are as follows (in no particular order):

- People ages 6 months through 24 years, including healthy individuals
- Pregnant women
- Healthcare and emergency medical services personnel
- Household contacts and caregivers of infants less than 6 months of age
- People ages 25 through 64 years who have a chronic health condition that puts them at high risk for influenza related complications

For more specific information about the priority groups, such as the definition of healthcare workers, please see the ACIP recommendations at [www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s\\_cid=rr5810a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s_cid=rr5810a1_e).

**H1N1 Vaccine Distribution:**

The NDDoH will receive an allocation of H1N1 influenza vaccine from the federal government based on its population. H1N1 influenza vaccine will be distributed by a third party distributor (McKesson) at the direction of the NDDoH. **McKesson will also be distributing ancillary supplies (alcohol pads, syringes, needles, and sharps containers) for vaccination.** Ancillary supplies will automatically be shipped with the vaccine; a separate order is not required. Influenza vaccine will be distributed in multiple shipments starting in mid-October and continuing until all vaccine has been distributed. McKesson will only ship in increments of 100 doses per vaccine type. To allow providers to receive less than 100-dose increments per vaccine type, the NDDoH will be shipping orders of less than 100-dose increments directly to providers from a state depot.

**H1N1 Vaccine Provider Agreement:**

Any healthcare provider, who is allowed by law to administer vaccines in North Dakota, may enroll with the NDDoH to receive H1N1 influenza vaccine. **A H1N1 Vaccine Provider Agreement must be completed for all providers who plan to administer H1N1 influenza vaccine.** Providers who are enrolled in the Prevention Partnership Program and already receive vaccine from the NDDoH, must still complete the H1N1 Vaccine Provider Agreement. The Vaccine Provider Agreement will only be available online and must be completed by **Tuesday, September 29**. The agreement is available at [www.ndflu.com/vaccine/H1N1VaccinationProviderAgreement.aspx](http://www.ndflu.com/vaccine/H1N1VaccinationProviderAgreement.aspx). **The provider agreement must be signed by an individual who can bind the organization.** The name and medical license number of the medical director must be provided, whether or not that is the individual that signs the agreement. A health system may sign for all satellite clinics. A district health unit may sign for all counties. The agreement should be shared with all vaccine providers employed by the organization/clinic to ensure that they comply with the requirements spelled out in the agreement.

**H1N1 Vaccination Site Registration Form:**

**The H1N1 Vaccination Site Registration Form must be completed by Tuesday, September 29 for each site that will be administering H1N1 influenza vaccine.** This form is available at [www.ndflu.com/vaccine/H1N1VaccinationProviderPreRegistration.aspx](http://www.ndflu.com/vaccine/H1N1VaccinationProviderPreRegistration.aspx). This form will be used to estimate the number of doses needed by each site and to obtain shipping information. Consider this form a pre-book form for H1N1 influenza vaccine. Vaccine will be distributed to providers based on the estimates of priority groups provided on this form. Facilities that serve out-of-state patients should include these patients in their estimates.

In order to prevent duplication, one form should be completed for each site where vaccine will be administered. A health system may fill out this form on behalf of the satellite clinics, but one form is required per satellite clinic that will be administering H1N1 vaccine. If vaccine is not being shipped directly to your site, then the shipping site information should

be different than the vaccine administration site information (i.e., if a hospital is the shipping site but satellite clinics will be doing the vaccinating).

Organizations should internally communicate to determine who will be completing both the H1N1 Vaccine Provider Agreement and the H1N1 Vaccination Site Registration Form.

**Reporting of doses administered:**

**Doses of H1N1 influenza vaccine that are administered must be reported within one week after administration to the North Dakota Immunization Information System (NDIIS).** If you need access to the NDIIS, please contact the immunization program at 701.328.3386 or toll-free at 800.472.2180. A webcast about how to enter data into the NDIIS will be held on September 23 at 11 am (Central Time). The webcast is available at [www.ndhealth.gov/WebcastHigh.aspx](http://www.ndhealth.gov/WebcastHigh.aspx). The NDDoH is currently assessing the feasibility of scanning immunization data into the NDIIS. More information about this will be available in the near future.

Entering doses administered into the NDIIS is of benefit to providers as many patients will be confused as to which type of influenza vaccine they received (seasonal vs. H1N1); the NDIIS will allow providers to track which type of vaccine was administered, regardless of where the patient was vaccinated. Also, the NDDoH will be conducting reminder/recall for second doses of H1N1 vaccine, if recommended. NDIIS data will be used to do this. If data is not entered into the NDIIS, it will be impossible to remind patients of the need for a second dose.

**Vaccine Adverse Events Reporting:**

Vaccine adverse events should be reported to the NDDoH via the NDIIS or on a VAERS form. VAERS forms are available at [www.vaers.org](http://www.vaers.org).

**Vaccine Information Statements (VIS):**

H1N1 Vaccine Information Statements (VIS) will be available as soon as the Centers for Disease Control and Prevention (CDC) releases them. Copies of the H1N1 VIS will be available to order from the NDDoH. Vaccine Administration Records (VARs) specific to H1N1 influenza vaccine will also be available from the NDDoH in the future.

For more information about H1N1 influenza vaccination visit [www.cdc.gov/h1n1flu/vaccination/](http://www.cdc.gov/h1n1flu/vaccination/).

Please feel free to contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.

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