

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 Information

DATE: October 2, 2009

READ THIS MEMO IN ITS ENTIRITY

The North Dakota Department of Health (NDDoH) Immunization Program is supplying monovalent H1N1 influenza vaccine to providers who signed the H1N1 Influenza Vaccine Agreement and Vaccination Site Registration. These forms are available at www.ndflu.com.

The H1N1 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 H1N1 influenza vaccine is the same vaccine as the seasonal vaccine, but with a different strain of the influenza virus. Adjuvants are not being used in the United States for H1N1 vaccine. The same manufacturers that make seasonal influenza vaccine are manufacturing H1N1 vaccine. These include GlaxoSmithKline, sanofi Pasteur, CSL Biotherapies, Novartis, and MedImmune. **Children ages 9 and younger will need two doses of H1N1 vaccine separated by three or four weeks (unknown at this time). People ages 10 and older only need one dose of H1N1 vaccine.** The vaccine will be available in intranasal and injectable formulations. Multi-dose vials and prefilled syringes will also be available. Prefilled syringes will be prioritized for infants 6 through 35 months and pregnant women. Prefilled syringes and intranasal H1N1 vaccine do not contain thimerosal. Multi-dose vials do contain thimerosal. Thimerosal has been used since the 1930s to prevent contamination of a vaccine and other medical products. Current scientific research shows no evidence of harm caused by small amounts of thimerosal in vaccines. **H1N1 influenza vaccine must be stored in the refrigerator at 35 – 46 degrees Fahrenheit (2 – 8 degrees Celsius).** This is the same temperature as seasonal influenza vaccine. Please see the attached table for more information about the various presentations and age indications for H1N1 influenza vaccine.

H1N1 influenza vaccine may be administered at the same time as other vaccines, including seasonal influenza vaccine, with one exception, 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. If administering multiple vaccines on the same day, it is recommended to use separate injection sites.

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.

If doses of H1N1 influenza vaccine are available after the above priority groups are vaccinated or when demand ceases, then vaccine will be opened up to healthy people 25 through 64 years and then people 65 and older.

H1N1 Vaccine Allocation:

North Dakota will receive an allocation of H1N1 influenza vaccine from the federal government based on its population. North Dakota will receive 0.2078% of the overall federal allotment of H1N1 vaccine. As North Dakota receives its allocation, providers will receive an equitable percentage of that allocation based on the pre-booking information obtained from the H1N1 Vaccination Site Registration. For example, if the NDDoH received requests for 39,000 doses for healthcare workers, but only receives an allocation of 3,900 doses of vaccine that could go to healthcare workers, then every provider would only receive 10% of what was pre-booked for healthcare workers.

The first doses of H1N1 influenza vaccine will be available the first week in October. **Only H1N1 Flumist® will be available at first. The NDDoH has decided to prioritize the first doses of H1N1 Flumist® for healthcare and emergency medical service workers. Long-term care workers will not be receiving the first allocations of H1N1 vaccine for healthcare workers due to the limited amounts available and the fact that the burden of H1N1 illness is less in the 65 and older population.** Long-term care workers can expect later shipments as more vaccine becomes available. North Dakota's first allocation is only 3,900 doses. There are orders for more than 30,000 doses for healthcare workers. The NDDoH encourages providers to prioritize healthcare workers with direct patient contact first and then open vaccine up to all healthcare workers as vaccine becomes available.

As a reminder, Flumist® is only approved for use in people ages 2 through 49 years. Pregnant women and people with chronic medical conditions, such as diabetes, liver, heart, lung, and kidney disease and asthma should not receive Flumist®. The injectable flu vaccine is preferred for people (including healthcare workers, and family members) in close contact with anyone who has a severely weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit). People in close contact with those whose immune systems are less severely weakened

(including those with HIV) may get Flumist®. Other contraindications and precautions are available on the package insert.

Additional doses of H1N1 influenza vaccine will be available each week. Please see the attached spreadsheet for state estimates for how many doses will be available by vaccine type. These are estimates and will change as vaccine becomes available.

H1N1 Vaccine Distribution:

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.** 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. Providers can expect to receive vaccine directly from McKesson and/or from the NDDoH. If receiving vaccine directly from McKesson, ancillary supplies will be shipped the day before vaccine is shipped. If receiving vaccine from the NDDoH, ancillary supplies will be shipped with the vaccine. Depending on how much vaccine is available, providers may receive H1N1 vaccine from McKesson, the NDDoH, or both. For example, if a provider's allocation is 120 doses of a specific H1N1 vaccine, the provider will receive 100 doses from McKesson and 20 doses from the NDDoH. **Providers should check temperature monitors in shipments immediately and notify the NDDoH of any temperature issues at 701.328.3386 or toll-free at 800.472.2180.**

If receiving vaccine from the NDDoH, coolers and temperature monitors must be returned to the NDDoH or providers will be charged. Instructions on how to return items at no charge are included in each shipment. Failure to promptly return shipping materials (coolers and thermometers) from the NDDoH may cause a delay in future vaccine shipments.

The NDDoH will be receiving allocations daily and ordering H1N1 vaccine daily. The NDDoH is unable to estimate what providers will receive in the future as vaccine allocations are based on what is available from the manufacturers. The NDDoH will be posting shipping logs from both McKesson and the NDDoH daily at www.ndflu.com. Shipping logs will not be posted until H1N1 influenza vaccine starts being shipped next week. If providers are interested in obtaining information about how much vaccine they will be receiving and when, they should check this website daily. Shipping information will be posted by provider PIN number, which is the same as the Prevention Partnership Provider and North Dakota Immunization Information System (NDIIS) number. If your provider PIN number is not on any of the shipping logs, then your facility has not yet been shipped vaccine.

As more H1N1 vaccine becomes available, if your facility has adequate supplies and no longer needs vaccine, please contact the NDDoH immediately at 701.328.3386 or toll-free at 800.472.2180.

Reporting of doses administered:

Doses of H1N1 influenza vaccine that are administered must be reported within one week after administration to the NDIIS. If you need access to the NDIIS, please contact the immunization program at 701.328.3386 or toll-free at 800.472.2180. Providers can also register for access to the NDIIS at

<https://www.thor.org/Registration/SysReq.asp>. A webcast about how to enter or scan data into the NDIIS was held on September 23 at 11 am (Central Time). The webcast is archived at www.ndhealth.gov/ET/WebcastCalendar/.

In the near future, providers will have the ability to scan doses administered into the NDIIS. Scanning forms (vaccine administration records) will be supplied to providers as vaccine is shipped. The scanning form is also available at www.ndflu.com under "vaccine info". Until scanning is available, providers must enter doses directly into the NDIIS. For more information about scanning, please see the attached Question and Answers Document. This document will be updated as more information becomes available. The NDDoH will not be scanning on behalf of providers. If for some reason your facility is unable to scan, doses must be manually entered or providers should contact the local public health unit in their area to discuss the possibility of the health unit scanning on a provider's behalf.

Lot numbers for H1N1 vaccine will automatically be located in providers' inventories in NDIIS. H1N1 vaccine must be entered by lot number. If your site is transferring vaccine to another site (i.e., a hospital is transferring vaccine to a satellite clinic), then a transfer must be completed in the NDIIS. If a transfer in the NDIIS is not done, then the H1N1 vaccine lot number will not be in the correct provider inventory.

Vaccine Safety:

H1N1 influenza vaccine safety information is available at www.cdc.gov/h1n1flu/vaccination/.

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.hhs.gov. A VAERS form is also attached to this memo.

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 distributed as vaccine is distributed. VISs will also be posted to the website at www.ndflu.com.

For more information about H1N1 influenza vaccination visit www.ndflu.com or 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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North Dakota Immunization Information System (NDIIS) H1N1 Influenza Vaccine Questions and Answers October 1, 2009

1. How do I know my facility's provider ID?

Your facility's provider ID is the same as your Prevention Partnership Provider Number and is listed at the bottom left hand corner of the NDIIS. If you don't have access to NDIIS or are unsure contact the Immunization Program at 800.472.2180.

2. Our vaccine is being sent to our local public health unit (LPHU), do I use my provider ID on the scanning form or theirs?

When scanning vaccine you'll use your provider ID even if your vaccine is shipped directly to the LPHU. The provider ID field is located on the bottom left hand corner of the scanning form. The provider ID field allows other providers to know where the vaccine was administered.

3. Does our facility have to scan into NDIIS and manually enter immunization data?

No. If your facility is scanning immunization records into NDIIS you **WON'T** have to manually enter the information into NDIIS.

4. What should we do if a lot number isn't in our inventory when we administer a vaccine?

It may take a couple of days for McKesson to send the shipping logs to the NDIIS. After receiving the vaccine, if your facility is scanning immunization records into NDIIS continue to scan the information. If your facility is manually entering vaccine and the lot numbers don't appear in your inventory after a couple of days contact the immunization program at 1-800-472-2180. Providers will not be able to enter vaccine into the NDIIS without a lot number.

5. Do providers need to keep the scanning form after scanning?

Yes, providers will store the scanning form as they would the traditional vaccine administration record.

6. What types of pencils/pens can be used on the scanning form?

The form will scan the best with dark pens. Pencil lead wears off the form and isn't ideal for storage of the form. Do not use red pens.

7. Who will be receiving software for scanning?

The software will be available for all H1N1 vaccine providers. The software will be downloaded from a website that will be sent out in the near future with detailed instructions on scanning.

8. What type of scanner can we use for scanning H1N1 vaccine to NDIIS?

All TWAIN compliant scanners are compatible with the scanning software. See your scanner's specs to determine whether it's TWAIN compliant. Most scanners are TWAIN compliant. These types of scanners are available at most local office supply stores.

9. What should we do if we need to transfer the vaccine to another facility?

If transferring the vaccine to another facility go to the lot distribution tab in NDIIS and select transfer. Mark the lot number that needs to be transferred and the facility the vaccine is being transferred to, print off the packing slip and send a copy of the packing slip with the vaccine. H1N1 vaccine can only be transferred to facilities that have signed the H1N1 provider agreement. Hospitals will need to do this if transferring vaccine to satellite clinics. Local public health units will need to do this if receiving vaccine for clinics in their county.

10. Will the North Dakota Department of Health (NDDoH) scan on behalf of clinics?

No. If unable to conduct scanning, then doses will have to be manually entered into the NDIIS. Private providers may contact the local public health unit in their area to determine whether or not the local public health unit will scan on a provider's behalf.

11. Will the NDDoH purchase scanners for private providers?

No. Most private providers should already have a compatible scanner, if not, the NDDoH will not be purchasing them for private providers.

12. Where can I get copies of the scanning form?

A copy of the scanning form is available at www.ndflu.com. The NDDoH will be printing scanning forms and they will be distributed to providers with H1N1 influenza vaccine. The scanning form should be used as the vaccine administration record.

13. Are providers required to report doses administered of H1N1 influenza vaccine to the NDIIS?

Yes. All doses administered of H1N1 influenza vaccine must be reported to the NDIIS within one week of administration. This can be done by manual data entry or scanning.

14. Do providers need to report doses administered to the NDDoH separately from entering into the NDIIS?

No. Data entry into the NDIIS is sufficient. The NDDoH will be able to determine doses administered from the NDIIS.

2009-2010 H1N1 Influenza Vaccine Dosage Chart (October 1, 2009)

Vaccine	Age Groups	Number of doses*	Dosage
Fluzone® (sanofi pasteur) Preservative Free 0.25 mL prefilled syringes	6 – 35 months	2	0.25 mL
Fluzone® (sanofi pasteur) Multi-dose vials	6 – 35 months	2	0.25 mL
	36 months and older	2 doses for people ages 9 and younger 1 dose for people ages 10 and older	0.5 mL
Fluzone® (sanofi pasteur) Preservative Free 0.5 mL vial and prefilled syringes	36 months and older	2 doses for people ages 9 and younger 1 dose for people ages 10 and older	0.5 mL
Fluvirin® (Novartis) Multi-dose vials	4 years and older	2 doses for people ages 9 and younger 1 dose for people ages 10 and older	0.5 mL
Fluvirin® (Novartis) Trace Preservative 0.5 mL prefilled syringes	4 years and older	2 doses for people ages 9 and younger 1 dose for people ages 10 and older	0.5 mL
Afluria® CSL Limited Preservative Free 0.5 mL prefilled syringes	18 years and older	1	0.5 mL
Afluria® CSL Limited Multi-dose vials	18 years and older	1	0.5 mL
FluLaval® GlaxoSmithKline	Not yet approved by the Food and Drug Administration		
FluMist®** (MedImmune) Preservative Free 0.2 mL Sprayers	2 through 49 years	2 doses for people ages 9 and younger 1 dose for people ages 10 and older	0.2 mL (0.1 mL per nostril)

*Most like three or four weeks apart (unknown as of October 1, 2009)

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For more information about the above H1N1 influenza vaccines, including precautions and contraindications, please read the package insert.

Estimated Availability of H1N1 Vaccine for North Dakota*

This table includes both vaccine expected to be available for ordering, based on the number of doses in each lot scheduled for release, and on production forecasts from manufacturers.

Forecasts are SUBJECT TO CHANGE IN EITHER DIRECTION and are meant for planning purposes only.

updated	sanofi pasteur	sanofi pasteur	sanofi pasteur	Novartis	Novartis	CSL	CSL	GSK	MedImmune	Weekly	Cumulative
9/28/2009	Fluzone	Fluzone	Fluzone	Fluvirin	Fluvirin	Afluria	Afluria	FluLaval	FluMist	Total	Total
Week ending	PFS (7.5mic)	PFS	MDV*	PFS	MDV	PFS	MDV	MDV	Int. Sprayer		
	6 - 35 mo	≥ 3 yr	≥ 6 mo	≥ 4yr	≥ 4yr	≥ 18yr	≥ 18yr	≥ 18yr	2 - 49 yr		
10/02/09	0	0	0	0	0	0	0	0	6,260	6,260	6,260
10/09/09	0	0	3,827	498	0	0	0	0	3,281	7,605	13,866
10/16/09	0	0	15,796	7,786	0	0	0	0	8,472	32,054	45,920
10/23/09	831	0	0	11,942	19,953	0	0	0	3,118	35,844	81,764
10/30/09	5,820	1,039	10,808	4,715	2,078	0	0	0	3,118	27,577	109,341
11/06/09	0	416	0	5,820	2,078	0	0	0	3,118	11,431	120,772
11/13/09	0	0	0	0	3,118	2,078	1,039	0	3,118	9,353	130,125
11/20/09	5,820	3,949	4,365	6,235	0	0	0	0	6,235	26,603	156,728
11/27/09	0	0	0	2,078	6,235	4,157	1,039	0	6,235	19,745	176,473
12/04/09	0	0	0	0	6,235	0	0	15,796	6,235	28,266	204,739
12/11/09	0	0	0	0	8,314	0	0	0	6,235	14,549	219,288
12/18/09	0	11,015	34,086	0	8,314	0	0	0	6,235	59,650	278,938
12/25/09	0	0	0	0	6,235	4,988	1,039	0	6,235	18,498	297,436
01/01/10	0	0	0	0	8,314	0	0	0	6,235	14,549	311,984
01/08/10	0	4,365	59,442		6,235		0	0	6,235	76,277	388,261
Est. Totals	12,470	20,784	128,322	39,074	77,108	11,223	3,118	15,796	80,366	388,261	

*As of October 1, 2009