

# 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:** Week 4: H1N1 Influenza Vaccine

**DATE:** October 21, 2009

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

**There is no minimum interval between doses of seasonal influenza vaccine and H1N1 vaccine. The only exception to this is when administering both seasonal Flumist® and H1N1 Flumist®, they can't be administered on the same day and because they are live vaccines, they must be separated by four weeks.**

### Examples:

- If someone receives seasonal inactivated influenza vaccine, they could get H1N1 inactivated vaccine or Flumist® that same day, next day, or whenever possible. There is no minimum interval.
- If someone receives seasonal Flumist®, they could get H1N1 inactivated vaccine that same day, the next day, or whenever possible. There is no minimum interval.
- If someone receives H1N1 inactivated influenza vaccine, they could get seasonal inactivated vaccine or Flumist® that same day, the next day, or whenever possible. There is no minimum interval.
- If someone receives H1N1 Flumist®, they could get seasonal inactivated vaccine that same day, the next day or whenever possible. There is no minimum interval.
- If someone receives seasonal Flumist®, they cannot get H1N1 Flumist® on the same day. The H1N1 Flumist® must not be administered until four weeks after the seasonal Flumist®.
- If someone receives H1N1 Flumist®, they cannot get seasonal Flumist® on the same day. The seasonal Flumist® must not be administered until four weeks after the H1N1 Flumist®.

### **H1N1 Allocations:**

- Sanofi pasteur H1N1 Fluzone® multi-dose vials will again be allocated this week for children ages 6 months through 18 years and healthcare workers. Children ages 6 months through 9 years will need two doses, separated by about 4 weeks.
- Novartis H1N1 Fluvirin® pre-filled syringes will again be allocated for pregnant women. Pregnant women may be vaccinated at any time during their pregnancy.
- H1N1 Flumist® will be allocated to providers for administration to healthy children ages 2 through 18 years. Children ages 2 through 9 years will need two doses of H1N1 Flumist®, separated by four weeks.
  - As a reminder seasonal and H1N1 Flumist® cannot be administered on the same day.

- This week, minimal doses of sanofi pasteur H1N1 Fluzone® 0.25mL pre-filled syringes will be allocated to the state. These doses will be allocated to providers for infants ages 6 through 35 months.
- This week, minimal doses of Novartis H1N1 Fluvirin® multi-dose vials will be allocated to the state. This vaccine is approved for use in people 4 and older. These doses will be allocated to healthcare workers.

The above allocations describe how the North Dakota Department of Health (NDDoH) is allocating vaccine to providers. **If necessary, providers may choose to use any of the above vaccine types (except the 0.25mL Fluzone® syringes) on either: healthcare workers, pregnant women, and/or children.** Sanofi pasteur is the only manufacturer of H1N1 influenza vaccine for people 6 months and older, which is why the NDDoH is recommending its use for children. The NDDoH does not recommend vaccinating additional priority groups at this time. It is the provider's responsibility to decide how many healthcare workers vs. children vs. pregnant women to vaccinate. Providers should make every effort to vaccinate children, pregnant women, or healthcare workers in contact with people at highest risk of complications. Providers may choose to prioritize children (by age or chronic medical condition) for vaccination if necessary based on the availability of vaccine locally. If vaccine supplies are limited, the Advisory Committee on Immunization Practices (ACIP) recommends that children ages 6 months through 4 years and children 5 through 18 years of age with a chronic medical condition be the highest priority for vaccination.

**Providers who received Sanofi pasteur H1N1 Fluzone® multi-dose vials or Novartis H1N1 Fluvirin® pre-filled syringes in shipments with frozen (red) indicators, will be prioritized for reimbursement of lost doses before allocations are made to other providers this week.**

H1N1 allocations by provider and/or county are posted as available at [www.ndflu.com](http://www.ndflu.com).

The federal government revised the estimates for H1N1 vaccine availability again. The new estimates show even smaller quantities of vaccine arriving in the state each week, with some vaccine arriving later than expected.

**Update about frozen indicators from the October 14<sup>th</sup> shipment:**

On Oct. 14, 2009, the North Dakota Department of Health shipped orders of Fluvirin and Fluzone vaccine to North Dakota providers. On October 15, we received several calls from providers reporting that the freeze indicator showed temperatures outside of safe shipping and storage range. Preliminary investigations revealed that many of these indicators may have been incorrectly placed in the package (i.e., directly next to the ice packs).

Because we cannot know for sure why some of the temperature monitors went out of range, we are recommending that health-care providers do not use the injectable vaccine they received Oct. 15, 2009, from the NDDoH warehouse if a temperature indicator in the vaccine shipment showed frozen temperatures (the freeze indicator turned red). This vaccine may be discarded and does not need to be returned to the NDDoH. In addition, those people who received this vaccine should be contacted for revaccination as soon as vaccine is available. **There is no interval needed between the dose of non-viable vaccine and the revaccination dose.** The non-viable vaccine poses no greater safety

issue than vaccine kept within the correct temperature range. However, the ability of the non-viable vaccine to illicit an immune response may be diminished.

As of October 20, 30 providers were affected and 1,100 doses in multi-dose vials and 70 doses in pre-filled syringes had to be discarded due to this issue.

**H1N1 Vaccine Shipping:**

Starting this week, the NDDoH will not be shipping vaccine, but will be driving vaccine to provider offices once a week. This week's vaccine delivery will be for last week's October 13<sup>th</sup> and part of the October 15<sup>th</sup> allocation. Driving vaccine to provider offices may occur for the next few weeks until new shipping supplies are available at the NDDoH. This may slightly delay the time period from when vaccine is allocated to when vaccine is delivered. Providers should allow at least 10 days to two weeks for delivery.

McKesson will continue to ship vaccine and ancillary supplies when allocations are in 100-dose increments.

**Vaccine Administration Records and Vaccine Information Statements:**

If your facility needs additional copies of the Vaccine Administration Record (scanning form), the Inactivated H1N1 Influenza Vaccine Information Statement (VIS), or the Live H1N1 Influenza VIS they may be ordered online at <http://hanassets.nd.gov/>. Click on the "forms" link. Please pay special attention to how many forms are in each package. Each package of vaccine administration records contains 50 forms. Each package of VISs contains 100 forms. So if your facility needs 500 VISs, you would order 5 packages.

**These forms will no longer be shipped along with H1N1 influenza vaccine, so providers must order them.**

**Ancillary Supplies:**

CDC has established a new e-mail box to receive and address issues associated with the H1N1 ancillary supply kits. If there are issues with any H1N1 ancillary supply kit products including needles, syringes, sharps containers, or alcohol swabs, please send an e-mail to [H1N1AncillarySup@cdc.gov](mailto:H1N1AncillarySup@cdc.gov). Please include specific details on the issue at-hand including the following:

1. Specific product description
2. Manufacturer
3. Expiration date
4. Lot number
5. Details related to the specific issue

**Weekly H1N1 Provider Updates:**

Each week, until further notice, the NDDoH will be holding a H1N1 provider update on Fridays at 9 am (CT). You can participate via videoconference, teleconference, or webcast. Videoconferences will mainly be held at the local public health units and some hospitals. Interested providers may contact the closest local public health unit to check for availability and make reservation. To participate by teleconference, call 866.888.3385. To participate via webcast (watch from your computer):

1. Step 1. Prior to the first time viewing a Department of Health web cast, please check that your computer has the necessary software installed. Follow the link <http://www.ndhealth.gov/webcasthtml/preflight> for a test.

2. Follow the link <http://www.ndhealth.gov/WebcastHigh.aspx> to view the webcast. The feed will start 30 minutes prior to the scheduled time.

For technical support call 866.716.1274 (beginning at 8:30 am)

If you are unable to attend these sessions, they will be archived at <http://www.ndhealth.gov/ET/WebcastCalendar/Default.aspx> search "H1N1" or dropdown box topic "H1N1 Influenza".

### **NDIIS:**

The scanning system for the NDIIS is being piloted by a couple clinics this week. A memo about the ability to scan and written instructions will be distributed. A second demonstration webcast will also be scheduled. H1N1 doses administered must be reported either by scanning or data entry to the NDIIS within seven days of administration. If a provider is scanning doses into the NDIIS, then the provider does not need to manually enter doses into the NDIIS.

### **H1N1 Billing Update:**

The federal government purchased all of the H1N1 influenza vaccine and is supplying it at no charge to providers, so providers are unable to charge or bill for the cost of the vaccine. The H1N1 provider agreement states that the provider "may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee." This means that the provider may not request out-of-pocket payment from a patient that is greater than the amount that Medicare reimburses for influenza vaccine administration in that jurisdiction (\$18.45 for North Dakota). "Charge" refers to collecting an out-of-pocket payment from the patient.

However, the provider agreement does not dictate the level of reimbursement for vaccine administration that is provided by an insurance plan or payer. **Providers should bill payers and insurance plans at their regular agreed-upon rates, and may accept whatever level of reimbursement is provided by a plan or payer for H1N1 vaccine administration.** Providers participating with Blue Cross Blue Shield of North Dakota (BCBSND) will need to charge BCBSND members the same rate for administration of the H1N1 vaccine as those patients paying out of pocket to comply with their contracts. Thus, BCBSND will use the Medicare Regional Fee Cap (\$18.45) as the fee schedule amount for the administration of H1N1 influenza vaccine.

Local public health units may not charge for the administration of H1N1 influenza vaccine.

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.

## Estimated Availability of H1N1 Vaccine for Ordering by States/Territories

UPDATED: October 20, 2009

This table shows number of doses expected to be available for ordering based on lots scheduled for release and on production forecasts from manufacturers for the next 8 weeks.

Forecasts are SUBJECT TO CHANGE IN EITHER DIRECTION and are meant for planning purposes only. Actual allocation will differ from these projections. NOT FOR FURTHER DISTRIBUTION

Updated	sanofi pasteur	sanofi pasteur	sanofi pasteur	Novartis	Novartis	CSL	CSL	GSK	Medimmune	Weekly	Cumulative
10/19/2009	Fluzone	Fluzone	Fluzone	Fluvirin	Fluvirin	Afluria	Afluria	FluLaval	FluMist	Total	Total 10/19
By end of	PFS (7.5 µg)	PFS	MDV*	PFS	MDV	PFS	MDV	MDV	Int. Sprayer		
week of:	6 - 35 mo	≥ 3 yr	≥ 6 mo	≥ 4 yr	≥ 4 yr	≥ 18 yr	≥ 18 yr	≥ 18 yr	2 - 49 yr		
10/02/09	0	0	0	0	0	0	0	0	4,949	4,949	4,949
10/09/09	0	0	6,548	382	0	0	0	0	4,239	11,169	16,118
10/16/09	0	0	6,088	699	0	0	0	0	2,810	9,597	25,715
10/23/09	769	0	4,781	2,201	105	0	0	0	2,862	10,719	36,434
10/30/09	1,933	0	10,811	4,909	0	642	0	0	2,911	21,206	57,639
11/06/09	0	0	0	6,130	5,733	967	0	0	2,911	15,740	73,379
11/13/09	2,807	0	0	5,821	2,994	967	665	0	2,911	16,164	89,543
11/20/09	2,807	1,871	4,366	4,158	8,524	322	0	0	6,237	28,285	117,828
11/27/09	0	2,495	0	4,158	6,237	0	0	0	6,237	19,127	136,955
12/04/09	1,247	2,495	17,048	4,158	8,316	4,158	1,040	0	6,237	44,699	181,653
12/11/09	1,247	2,495	8,524	0	8,316	644	0	0	6,237	27,464	209,117
<b>Est. Totals</b>	<b>10,811</b>	<b>9,356</b>	<b>58,165</b>	<b>32,617</b>	<b>40,224</b>	<b>7,700</b>	<b>1,705</b>	<b>0</b>	<b>48,540</b>	<b>209,117</b>	
12/18/09	1,663	2,495	8,524	0	8,316	0	0	0	6,237	27,235	236,352
12/25/09	0	4,366	19,819	0	4,158	644	1,559	0	6,237	36,784	273,136
01/01/10	0	4,574	19,819	0	8,316	0	0	0	6,237	38,946	312,081
01/08/10	0	0	19,821	0	6,237	1,289	0	0	6,237	33,584	345,666
<b>Est. Totals *</b>	<b>12,474</b>	<b>20,790</b>	<b>126,148</b>	<b>32,617</b>	<b>67,251</b>	<b>9,633</b>	<b>3,264</b>	<b>0</b>	<b>73,488</b>	<b>345,666</b>	