



## Immunization Program Update

This has been a busy year in the Immunization Program with many changes yet to come. This summer, the North Dakota Department of Health (NDDoH) Immunization Program will transition to a centralized national vaccine inventory and distribution system. This is a national effort led by the Centers for Disease Control and Prevention (CDC) to improve our nation's vaccine delivery system. Through the Vaccine Management Business Improvement Project (VMBIP), CDC has selected a national vaccine distributor, McKesson Specialty Ltd., which will be responsible for the distribution of vaccines to providers enrolled to receive vaccine from state immunization programs.

Beginning the week of **August 13, 2007**, state-supplied vaccines (with the exception of the varicella and the measles, mumps, rubella, varicella [MMRV] vaccines) will be distributed by McKesson Specialty Ltd. Vaccine will no longer be shipped directly to providers from the NDDoH.

### **Background**

VMBIP is a multifaceted approach that has been in development over several years in order to improve vaccine management processes at the federal, state and local levels. Among the project's goals are improving efficiency of vaccine delivery systems; reducing the lead time between vaccine orders and delivery; centralizing vaccine distribution for all states; and enhancing the nation's ability to respond to public health crises through the development of a centralized vaccine stockpile system.

The first phase of this project is the implementation of a centralized vaccine distribution system. With this system, vaccines will be shipped directly to all public and private provider sites. The second phase, still in development, will consist of the implementation of a web-based vaccine ordering system at a national level. The NDDoH currently is discussing the possibility of using the North Dakota Immunization Information System (NDIIS) for ordering vaccines for providers. A decision has not yet been made. More information will be sent about this issue as it becomes available.

### **National Distributor**

McKesson Specialty Ltd., a division of McKesson, is a large-scale distributor with experience in distribution to wholesalers and hospitals across the United States. Its main distribution center, located in Memphis, Tenn., has more than 8,000 square footage of refrigerated space. McKesson Specialty Ltd. will distribute vaccines for all immunization programs across the United States.

### **Order Frequency**

The frequency of placing orders for providers will change with the transition to the national vaccine distribution system. The frequency for placing vaccine orders will be dictated by the volume of vaccines received during the previous year, as follows:

- Large providers ( $\geq 2,000$  doses/year): order monthly

- Medium-size providers (500 to 1,999 doses/year): order bimonthly
- Small providers (100 to 499 doses/year): order quarterly
- Very low providers (<100 doses/year): order as needed

### **Vaccine Shipments**

Vaccine orders will be processed by McKesson Specialty Ltd. within three to five business days and will be shipped via commercial carrier. Although FedEx is its primary carrier, alternative carriers such as UPS may also be utilized when vaccine delivery through FedEx is not possible.

McKesson Specialty Ltd. is an environmentally-friendly company. As such, vaccines will be shipped in recyclable insulated containers able to maintain proper temperatures for up to 72 hours. These containers will come with postage-paid labeling to facilitate their return via United States Postal Service. We recommend that you keep one to two boxes on hand to use for any vaccine returns and encourage you to return the remainder to McKesson Specialty Ltd. Each container will include easy-to-read temperature monitors to ensure that appropriate vaccine temperature is maintained during shipment, as well as a vaccine shipment packing slip outlining the vaccines received in the shipment.

**Please note that varicella and MMRV vaccines will continue to be shipped directly from the manufacturer, Merck & Co., in insulated containers containing dry-ice.**

### **Vaccine Deliveries**

McKesson Specialty Ltd. is able to process vaccine orders Mondays, Tuesdays and Wednesdays. Therefore, providers should expect vaccine deliveries Tuesdays through Fridays. Provider orders with unrestricted

delivery information (able to accept vaccine shipments during normal business hours, Monday through Friday) will be processed immediately. Orders with special handling instructions or limited delivery times will be carefully reviewed to ensure that vaccines are delivered within the specified window of time.

### **Provider Choice and VMBIP**

Due to a decrease in federal funding and increasing vaccine prices and new vaccines, the NDDoH is moving to the Provider Choice Program. With this program, the NDDoH will broker vaccines at a reduced rate for providers. Providers will order Vaccines For Children vaccines (for those who are Medicaid-eligible, uninsured, Native American, or underinsured) as usual, but for children with health insurance that covers vaccines, vaccines will be ordered separately, and providers will be required to submit a payment to the NDDoH for these vaccines at the time of the order. Providers will then bill insurance for the cost of the vaccine and administration. A task force has been established for Provider Choice implementation and includes members of public and private health, as well as other stakeholders. The task force will be responsible for setting a time for implementation, which will likely be between September and December 2007, and also will determine how Provider Choice and VMBIP will work together. Updates will be provided via the newsletter on a regular basis.

The NDDoH Immunization Program anticipates a smooth transition to VMBIP. Please contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.

## **Case on Autism and Vaccinations Heard in Federal Vaccines Court**

The federal vaccines court began hearing arguments on June 11, 2007, in the first of many test cases regarding the claims of close to 5,000 parents who say their children are autistic due to thimerosal, a preservative used in vaccines until 2001. The judges said the concerns of each family will be considered carefully; however, it is uncertain whether they will be awarded money from the government because no connection between vaccines and autism has been found. Autism rates nationwide have not declined in the years since thimerosal was eliminated from vaccines because of concerns about mercury exposure. Hearings for the first test case will continue through June and into July, with hearings for the second test case beginning in 2008.

*New York Times (06/12/07) P. A1; Harris, Gardiner*

For more information about vaccine safety, visit [www.cdc.gov/vaccines/vac-gen/safety/default.htm](http://www.cdc.gov/vaccines/vac-gen/safety/default.htm).



## **August Is National Immunization Awareness Month**

August is recognized as National Immunization Awareness Month (NIAM). The goal of NIAM is to increase awareness about immunizations across the life span, from infants to the elderly.

August is the perfect time to remind family, friends, coworkers, and those in the community to catch up on their vaccinations. Parents are enrolling their children in school, students are entering college, and health-care workers are preparing for the upcoming flu season.

For more information about NIAM, visit [www.cdc.gov/vaccines/events/niam/default.htm](http://www.cdc.gov/vaccines/events/niam/default.htm)



## **FDA Approves an Accelerated Dosing Schedule for Twinrix®**

On April 2, 2007, GlaxoSmithKline (GSK) announced that the FDA approved Twinrix® for an accelerated dosing schedule that consists of three doses given within three weeks followed by a booster dose at 12 months. The approval means Twinrix®, the only hepatitis A and hepatitis B combination vaccine available in the United States, is now available on a dosing schedule at 0, 7, and 21 to 30 days, followed by a booster dose at 12 months. The vaccine was first approved by the FDA for adults older than 18 in May 2001 on a 0-, 1- and 6-month dosing schedule.

The accelerated schedule could benefit individuals traveling to high-risk areas; emergency responders, especially those being deployed to disaster areas overseas; and others who are at risk for hepatitis A and B infection.

For more information about Twinrix®, visit [www.gskvaccines.com](http://www.gskvaccines.com).

## **ACIP's Varicella Recommendations Published in MMWR**

The ACIP's varicella recommendations were published in the June 22, 2007, MMWR. To view the html version, visit [www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm).



## **MMWR Early Release Issued for ACIP's 2007-2008 Influenza Recommendations**

On June 29, 2007, an MMWR early release was issued for the ACIP's *Prevention and Control of Influenza*, which includes six major changes/updates. To view the MMWR, visit [www.cdc.gov/mmwr/preview/mmwrhtml/rr56e629a1.htm?s\\_cid=rr56e629a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e629a1.htm?s_cid=rr56e629a1_e).

## **FDA Approves the First Avian Influenza Vaccine**

On April 17, 2007, the Food and Drug Administration (FDA) announced the first U.S. approval of a vaccine against the H5N1 virus, commonly known as avian influenza.

The vaccine, manufactured by sanofi pasteur, is intended for people ages 18 through 64, and is given as two intramuscular injections one month apart. Efficacy is estimated to be approximately 45 percent. The vaccine will not be available commercially but will be purchased by the U.S. government for inclusion in the Strategic National Stockpile.

For more information, visit [www.cdc.gov/flu/avian/](http://www.cdc.gov/flu/avian/).

## **ACIP Urges Meningitis Vaccination for Ages 11 through 18**

From the June 27-28 ACIP meeting comes new recommendations that all children ages 11 through 18 should receive meningococcal vaccine.

According to the ACIP, earlier guidance for vaccinating only those children ages 11 and

12, adolescents entering high school and college freshmen was due to the shortage of Menactra. Now that the vaccine supply issues have been resolved, physicians should offer Menactra to all children ages 11 through 18. The ACIP is not recommending recalls or a catch-up schedule at this time.

## **CDC Launches New Immunization Website**

The National Center for Immunization and Respiratory Diseases (NCIRD) unveiled its new website June 11, 2007. Visit the website at [www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/).

## **GlaxoSmithKline's Hepatitis B Vaccine Now Provided by the NDDOH**

The North Dakota Department of Health will now be providing GlaxoSmithKline's hepatitis B vaccine (Engerix-B) instead of Merck's hepatitis B vaccine (Recombivax HB). This is a result of an increase in the price of Merck's product on the federal contract.

The vaccines are equally effective and interchangeable, even though the antigen content of each vaccine differs. The hepatitis B series can be started with one brand and finished with another brand.

Dose differences:

- Engerix-B (GSK)
  - 10 mcg/0.5ml
  
- Recombivax HB (Merck)
  - 5 mcg/0.5ml

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 if you have questions.

## Shipping Instructions for Vaccine Management Business Improvement Project (VMBIP)

On May 25, 2007, a memo was sent asking providers to complete a "Vaccine Delivery Information Form." It was later discovered that the directions had to be limited to 50 characters or less. Therefore, basic delivery information was entered, and other information, such as specific seasonal hours, was omitted. Consequently, after August 13, 2007, when your facility has a change in acceptable delivery days/times, you must contact the NDDoH Immunization Program immediately so that the distributor can be notified. This applies to any significant changes that could affect the ability of the distributor to deliver your vaccine in a timely and accurate manner.

If you have any questions, please contact the NDDoH Immunization Program at 800.472.2180 or 328.3386.



## Prevention Partnership Agreement Update

The 2007 Prevention Partnership Enrollments were sent out February 2007 and were to be returned to the NDDoH by April 1, 2007. A signed Prevention Partnership Enrollment is required annually for providers to receive Vaccines For Children vaccine from the NDDoH. Therefore, the NDDoH will not fill vaccine orders for providers who have not returned their signed 2007 Prevention Partnership Enrollment forms. Orders will resume to be filled upon receipt of a signed enrollment.

Please contact the NDDoH Immunization Program with any questions at 701.328.3386 or 800.472.2180.

## MMRV Shortage Update

In February 2007, Merck & Co. Inc. notified the Centers for Disease Control and Prevention (CDC) that the amounts of varicella-zoster virus (VZV) from recently manufactured bulk vaccine were lower than expected. To conserve existing bulk vaccine, Merck & Co. has prioritized continued production of varicella (Varivax<sup>®</sup>) and zoster (Zostavax<sup>®</sup>) vaccine over MMRV (ProQuad<sup>®</sup>).

Initially, Merck & Co. projected current supplies of MMRV to be depleted in the fourth quarter of 2007. However; Merck & Co. currently projects that MMRV will be unavailable beginning July 2007, depending on market demand. After depletion, ProQuad<sup>®</sup> is not expected to be available for the remainder of 2007.

At this time, Merck & Co. is requesting that providers begin using MMR and Varivax<sup>®</sup> in place of MMRV. **Therefore the NDDoH will no longer be accepting orders for MMRV. Providers should order MMR and varicella separately to compensate for the lack of MMRV.** Merck & Co. expects to be able to continue to meet demands for MMR and varicella vaccine to fully implement the recommended immunization schedule.

An important safety reminder: MMR and varicella vaccines **cannot** be mixed to create MMRV. The antigen contents are not the same. Please make sure all staff giving immunizations are aware of this.

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



## **Loss Policy Reminder**

Please remember to carefully review the North Dakota Immunization Vaccine Loss Policy. Providers will be requested to reimburse for state-supplied vaccine that is wasted due to the provider's failure to properly store, handle or rotate vaccine inventory. This includes vaccine that is allowed to expire that is of a value of \$500 or greater.

If you have any questions on the Vaccine Loss Policy, please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.

## **Immunization Program Survey Sent to Providers**

A provider satisfaction survey has been sent to all providers from the NDDoH Immunization Program. This anonymous survey will be used to make program improvements that will allow the Immunization Program to better serve providers and the children of North Dakota.

If you have any questions, please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.



### **Did You Know?**

The *Immunization Newsletter* can be viewed on the NDDoH Immunization website. Visit [www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize) and click on the "Newsletter" tab to read current and past issues.

## **Updating Demographic Information in NDIIS**

As the ability of the North Dakota Immunization Information System (NDIIS) to generate reminder/recall and billing systems gets closer, it is important for providers to update patients' demographic information in NDIIS at each immunization visit. This will ensure not only that insurance information is correct, but also that the most current address is on file.

If you have any questions, please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.

## **NDIIS Forecaster**

The addition of the forecaster to the immunization registry is a great resource for providers to help ensure children receive all vaccines they are eligible for during their visit. However, please keep in mind that the forecaster should be used as a guide only and not the primary method for determining which immunizations are needed. The immunization schedule is very complicated, and errors do occur with the forecaster. One way to help reduce forecaster errors is for providers to report all errors encountered to the NDDoH so they can be corrected.

For questions regarding the forecaster, please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.

## **Wanted: Influenza Vaccine**

Just a reminder to providers to send back last season's state influenza vaccine to the NDDoH. When returning the vaccine, please be sure to include a completed Vaccine Return Form. Thank you!



## Memorandums of Understanding Signed

In April 2007, Memorandums of Understanding (MOU) were sent from the NDDoH to all public health units and private providers delegating authority to the providers to vaccinate underinsured children with Vaccines For Children (VFC) vaccine on the behalf of Coal Country Community Clinic, a Federally Qualified Health Center. This delegation of authority allows children to maintain their medical home.

To date, the NDDoH has received 111 MOUs, with 16 yet to be returned. Once the MOUs have been signed by the provider and Coal Country Community Clinic, the NDDoH returns them to the providers so they can begin to immunize underinsured children with VFC vaccine.

If you have not yet returned your signed MOU, please do so as soon as possible.

Please contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180 with any questions.

### Welcome New Providers!

The NDDoH would like to welcome these new VFC providers:

- Great Plains Women’s Health Center – Williston
- Valley Community Health Center – Larimore
- Community Action Partnership Family Planning – Dickinson



## Meningococcal and Second-Dose Varicella Vaccine Available Universally July 15, 2007

The 2007 North Dakota Legislature appropriated funding for the North Dakota Immunization Program to provide MCV-4 (Menactra®) universally and the second dose of varicella vaccine to all children in the state. Previously, state-supplied MCV-4 and second dose varicella vaccine could only be given to Vaccines for Children (VFC) eligible children (those who are Medicaid-eligible, uninsured, underinsured or Native American) only. This funding is available only until Dec. 31, 2007.

As of **July 15, 2007**, providers may order MCV-4 and second dose varicella vaccine for all children, including those with health insurance that covers vaccinations. Existing supplies of varicella and MCV-4 may also be used for children with health insurance.

Since this funding is only available through Dec. 31, 2007, the North Dakota Immunization Program encourages all providers to vaccinate as many children as possible during this time period. After Jan. 1, 2008, providers will have to start purchasing all childhood vaccines for administration to children with health insurance that covers vaccinations. The North Dakota Immunization Program will continue to supply VFC vaccine after Jan. 1, 2008.

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



**2006-2007 School Immunization Rates**

The results for 2006-2007 North Dakota School Immunization Survey are in.

The survey showed that children entering kindergarten had the following rates:

Vaccine	Immunization Rate
Polio	94.3%
DTP/DTaP/DT	93.7%
MMR	93.2%
Hepatitis B	97.3%
Varicella*	94.4%

\*Includes immunity from vaccination or disease

The survey also showed that 11 kindergartners had vaccination exemptions due to medical reasons, 11 due to religious reasons, 46 due to philosophical reasons and 16 due to moral reasons.

Immunization rates for DTP/DTaP/DT, MMR and varicella have increased, polio rates remained steady and hepatitis B rates have dropped from those reported in the 2005-2006 school survey. It is unknown if these changes are due to changes in immunizations or because of the number of schools that reported

The survey showed that adolescents in seventh and eighth grades had the following rates:

Vaccine	Immunization Rate
Polio	95.0%
DTP/DTaP/DT	94.9%
MMR	94.1%
Hepatitis B	71.9%**
Varicella*	29.4%**
TD	29.6%**

\*Includes immunity from vaccination or disease

\*\*Not required for school entry for this age group

The survey also showed that 11 seventh and eighth graders had vaccination exemptions due to medical reasons, 15 due to religious reasons, 31 due to philosophical reasons and 11 due to moral reasons.

If you have questions regarding the school immunization survey, contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.

**Administrative Rules Update**

On June 12, 2007, the State Health Council gave approval to the NDDoH to proceed with public comments regarding proposed changes to the administrative rules, including day-care and school immunization requirements and an increase in the vaccine administration fee.

The day-care requirements would be expanded to include age-appropriate vaccination against rotavirus, hepatitis A and pneumococcal disease. School requirements would include second-dose varicella for kindergarten entry and age-appropriate vaccination with meningococcal vaccine and Tdap.

The proposed vaccine administration fee for vaccines received at no charge from the state would be \$13.90, the Medicaid regional fee cap. For vaccines purchased by providers, no vaccine administration fee was set. Providers would be able to bill insurance for what it costs them to administer vaccines. Insurance companies will then set their own administration fee reimbursement rates.

A public hearing has been set for August 1, 2007.

## **How Well Do You Know Your New ACIP Influenza Recommendations?**

There are new ACIP recommendations for the 2007-2008 influenza season. Children ages 6 months through 8 years who do not receive two doses of influenza vaccine in their first vaccination year will be required to receive 2 doses in their second vaccination year. What does this mean exactly? Here are two common scenarios.

### **Scenario #1**

A child comes to your clinic and receives one dose of influenza vaccine in her first vaccination year and doesn't return for her second dose. Three years later the child returns to your clinic for a flu shot. The child has not received any influenza vaccine since the last time you saw her three years ago. How many shots does she receive this year?

**Answer:** The child should receive two shots. The key concept is not how many years have passed, but that it is the child's second vaccination year.

### **Scenario #2**

A child comes to your clinic and receives one dose of influenza vaccine in his first vaccination year and does not return for the second dose. The child returns the following year, and, again, receives only one dose of flu vaccine. When the child returns in his third vaccination year, how many shots should the child receive?

**Answer:** The child should receive one shot. Again, the key concept is that two doses should be given in the second vaccination year. Once the child is beyond the second vaccination year, the recommendation returns to one dose of influenza vaccine.

For questions regarding the new influenza recommendations, contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.



## **What Is the North Dakota Immunization Advisory Committee?**

The North Dakota Immunization Advisory Committee (formerly the Immunization Task Force) is made up of representatives of public health, private providers, Blue Cross Blue Shield, pharmacists and the North Dakota Department of Health (NDDoH). The Advisory Committee's responsibilities include advising the NDDoH on various immunization and vaccine-preventable disease issues, selection of vaccines provided by the NDDoH, determining use of 317 and state funds, and receiving and providing feedback and advice on provider level issues.

The Advisory Committee is an integral part of the decision-making processes of the NDDoH. A summary of the activities of the Advisory Committee will be included in future newsletters.

For more information or to become a member of the Advisory Committee, contact the NDDoH Immunization Program at 701.328.3386 or 800.472.2180.

### **New HPV Vaccine Q&A Sheet**

A new question and answer (Q&A) sheet geared towards health-care professionals is now available at [www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm](http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm)



## Hepatitis B Vaccine Q & A

**Q: Who should receive hepatitis B vaccine?**

A: Hepatitis B vaccine should be given to all babies at birth, children ages birth to 18 who have not been vaccinated and adults of any age who are at risk for hepatitis B infection or who are requesting to be vaccinated.

**Q: What is the schedule for hepatitis B?**

A: Hepatitis B vaccine is given by three intramuscular injections. The second dose must be administered at least one month after the first dose, and the third dose must be given at least eight weeks after the second dose and 16 weeks after the first dose. For infants, the last dose must be administered at or after age 24 weeks.

**Q: Are booster doses of hepatitis B vaccine needed?**

A: No, booster doses of hepatitis B vaccine are not recommended routinely for people who are not immunocompromised. Even though vaccine-induced antibody levels may decline over time, immune competent people are still protected against clinical illness and chronic illness.

**Q: Can hepatitis B vaccine from different manufacturers be used interchangeably in the series?**

A: Yes. The immune response when one or two doses of a vaccine produced by one manufacturer are followed by subsequent doses from a different

manufacturer has been shown to be comparable with that resulting from a full series of vaccination from one manufacturer.

**Q: If the hepatitis B series is interrupted, should it be restarted?**

A: No, the series should not be restarted. The second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least two months. If only the third dose is delayed, it can be given at any time.

**Q: Can hepatitis B vaccine be given to women who are pregnant or breastfeeding?**

A: Yes. Neither pregnancy nor breastfeeding are contraindications to vaccinating women.

**Q: Who should not receive the hepatitis B vaccine?**

A: People who have had a serious allergic reaction to a prior dose of hepatitis B vaccine or a vaccine component should not receive the vaccine. The recombinant vaccines licensed for use in the United States contain yeast; therefore, people allergic to yeast should not be vaccinated with vaccines containing yeast.

If you have questions about hepatitis B vaccine, please contact the NDDoH at 701.328.3386 or 800.472.2180.



## Upcoming Events

- Immunization Update satellite broadcast: **August 9, 2007; 8 a.m.-10:30 a.m CST (re-broadcast at 11 a.m.-1:30 p.m. CST)**
- VMBIP Implementation: **August 13, 2007**
- National Adult Immunization Awareness Week: **September 23-29, 2007**



**NORTH DAKOTA**  
DEPARTMENT of HEALTH

Molly Sander  
Immunization Program Manager  
[msander@nd.gov](mailto:msander@nd.gov)

Stacy Lovelace  
Immunization Surveillance Coordinator  
[slovelace@nd.gov](mailto:slovelace@nd.gov)

Darcey Tysver, RN  
VFC/AFIX Coordinator  
[dtysver@nd.gov](mailto:dtysver@nd.gov)

Kristin Hertz, RN  
AFIX Coordinator  
[krhertz@nd.gov](mailto:krhertz@nd.gov)

Teri Arso  
Administrative Assistant  
[tarso@nd.gov](mailto:tarso@nd.gov)

**The *Immunization Newsletter* is a quarterly publication distributed to Prevention Partnership Providers.**

---

Terry Dwelle, MD, MPHTM  
State Health Officer

Craig Lambrecht, MD, MPH  
Chief, Medical Services Section

Kirby Kruger  
Director, Disease Control

Molly Sander  
Immunization Program Manager

Published by the North Dakota Department of Health, Division of Disease Control, 600 E. Boulevard Ave. Dept. 301, Bismarck, N.D. 58505  
Phone 701.328.2378 or in N.D. 800.472.2180.

Publication is available in alternative forms; for more information, contact Darcey Tysver, editor, *Immunization Newsletter*.

**EQUAL OPPORTUNITY EMPLOYER**