

Immunize NY!

Bureau of Immunization

Welcome to *Immunize NY!* Vaccine Program Edition

In this issue

Vaccine Program Updates

- Change in Thermometer Requirements for VFC Providers
- Provider Profile Update
- 2011-2012 Influenza Season
- HPV for Boys

Storage & Handling Practices

- New Thermometer Logs
- Storage and Handling Webinar
- Frequently Asked Questions
- New Packaging for Varicella

Frequently Used Abbreviations:

- ✓ **ACIP:** Advisory Committee on Immunization Practices
- ✓ **CDC:** U.S. Centers for Disease Control and Prevention
- ✓ **CHPlus:** Child Health Plus
- ✓ **IAC:** Immunization Action Coalition
- ✓ **NYS:** New York State
- ✓ **NYSDOH:** New York State Department of Health
- ✓ **VFC:** Vaccines for Children
- ✓ **VIS:** Vaccine Information Statement

Vaccine Program Updates

Change in Thermometer Requirements for VFC Providers

The CDC require providers enrolled in the VFC program to have calibrated thermometers in all refrigerator and freezer units used for VFC vaccine storage. Each device is to be covered by a Certificate of Traceability and Calibration. The traceability declaration confirms that the measurement standards and instruments used during calibration of the product are traceable to an International Organization of Standardization/International Electrotechnical Commission (ISO/IEC) accredited testing laboratory, to the National Institute of Standards and Technology (NIST), or to another internationally recognized standards agency. A certificate of calibration accompanies thermometers that have undergone this calibration against a reference standard.

VFC providers are required to have calibrated thermometers covered by a Certificate of Traceability and Calibration in all units where publicly funded vaccine is stored. Providers should maintain a valid Certificate of Traceability and Calibration that will be available for NYSDOH regional representatives to review at the time of a site visit.

VFC providers are required to have calibrated and certified thermometers by November 1, 2011.

Maintaining vaccines at the proper storage temperature is the best way to maintain vaccine safety and avoid the possibility of patient re-immunization. Once a vaccine loses potency, it can not be restored. If children have been immunized with nonviable vaccine, the provider will be responsible for revaccination.

Failure to have the appropriate thermometers and documentation will result in suspension of ordering privileges.

On Page 2 is the *New York State Department of Health Bureau of Immunization Thermometer Guide for Storage and Handling of Publicly Purchased Vaccine*. This document will provide guidance in purchasing appropriate thermometers.

New York State Department of Health Bureau of Immunization

Thermometer Guide for Storage and Handling of Publicly Purchased Vaccine

The New York State Department of Health Bureau of Immunization does not recommend or endorse products or manufacturers. The information below is intended to provide guidance in selecting thermometers that meet federal and state requirements of the NYS Vaccine Program, and the needs of individual medical practices.

Thermometers are a critical part of good storage and handling practices. Health care providers enrolled in the NYS Vaccine Program are required to have calibrated thermometers in all refrigerator and freezer compartments used for vaccine storage of publicly funded vaccine by November 1, 2011. All thermometers are calibrated as part of the manufacturing process. This requirement refers to a second calibration process that occurs after manufacturing, but before marketing, and is documented with a certificate that comes with the product.

For measuring vaccine storage unit temperatures, the NYS Vaccine Program requires health care providers to purchase calibrated thermometers with a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are from an International Organization of Standardization (ISO) accredited testing laboratory, from the National Institute of Standards and Technology (NIST), or from another internationally recognized standards agency.

VFC providers will be asked to produce certificates of calibration for each thermometer at the time of a VFC compliance site visit. All thermometers used for monitoring publicly purchased vaccine will require recalibration at least every two years to adhere to manufacturer specifications and guidelines. Recalibration periods should not exceed two years.

Calibrated and certified thermometers are available as digital, bio-safe liquid, continuous graphic, and minimum/maximum thermometers.

Regardless of the type of thermometer used, all VFC providers are required to take temperatures in both freezer and refrigerator units twice daily, record the temperatures on IAC temperature logs, notify the VFC Program if temperatures are out of range, and maintain the logs for three years.

Below is a chart giving a sample list of manufacturers that offer calibrated thermometers with valid documentation (i.e., certificate).

At the time this list was compiled, prices ranged from \$44.95 to \$75.

Company	Website	Possible Models	Phone
Control Company	www.control3.com	4048 or 4127	1-281-482-1714
Fisher Scientific	www.fishersci.com	15-059-148 (freezer) 15-059-147 (refrigerator)	1-800-766-7000
Nova-Tech International, Inc.	www.novatech-usa.com	4605	1-866-433-6682
Taylor Precision Products	www.taylorusa.com		1-866-843-3905

Provider Profile Update

In January, all NYSDOH VFC providers will be required to complete the annual Provider Profile Update, which consists of three parts:

- The *Provider Registration and Profile Form* (DOH-3836) specifies the requirements to which each practice and associated health care provider must agree to participate in the VFC program. By signing the *Provider Registration and Profile Form*, the provider agrees to comply with all program requirements.
- The *Vaccine Storage and Handling Plan* provides an opportunity for everyone in the practice to review and update storage and handling requirements. Vaccines must be properly stored and administered to ensure maximum efficacy and safety.
- Providers are asked to submit a copy of the temperature log for the 30-day period immediately preceding the submission of the renewal application. VFC providers agree to take the temperature in all refrigerator and freezer units twice a day. Providers are required to use logs created by the Immunization Action Coalition (IAC). The IAC logs provide a visual representation of the recommended temperature range, making it very easy for staff to detect temperatures out of range.

To access IAC temperature logs, see the section *New Temperature Logs* on Page 5 of this newsletter.

The Provider Profile Update and a cover letter will be mailed to providers. All three sections need to be returned by the date specified in the cover letter. Failure to submit the *Provider Registration and Profile Form*, the *Vaccine Storage and Handling Plan*, and a 30-day temperature log by the specified due date will result in a suspension of ordering privileges.

2011-2012 Influenza Season

We are now taking orders for the 2011-2012 influenza (flu) season. To place an order, copy the order form on Page 8, and send it to the NYS Bureau of Immunization by fax (518-474-4222) or email (nyvfc@health.state.ny.us). Phone orders for influenza vaccine will not be accepted.

As you complete the form, please note the following:

- Review the number of doses your site ADMINISTERED to VFC/CHPlus eligible children during the 2010-2011 season and use that figure to order accordingly for this season. Orders may be adjusted according to your doses administered reports for the 2010-2011 influenza season. Please do not over-order.
- The NYS Bureau of Immunization will attempt to fill all vaccine requests. Vaccine is received from CDC in increments and partial orders may have to be shipped. Outstanding balances will be shipped as more vaccine becomes available.
- As the season progresses, if you have not received your complete order, and you are finding that you have enough vaccine for the remainder of the season, it is your responsibility to contact the Vaccine Program at 1-800-543-7468 (1-800-KID-SHOT) to cancel any outstanding balances.

VISs should be given to each patient or parent/guardian for all influenza vaccines administered. VISs can be found at: <http://www.immunize.org/vis>.

The CDC, the American Academy of Family Physicians and the American Academy of Pediatrics published a fact sheet titled *Influenza: also known as flu*. It is a provider resource for having conversations with parents on the importance of the influenza vaccine. Visit the CDC site to obtain this resource: www.cdc.gov/vaccines/vpd-vac/flu/downloads/dis-influenza-bw-office.pdf.

The NYSDOH Bureau of Immunization web site also has information related to seasonal influenza. It can be found at: <http://www.health.ny.gov/diseases/communicable/influenza/seasonal>.

(continued on Page 4)

Human Papillomavirus (HPV) Vaccine VIS

On May 3, 2011 CDC published new editions of the VISs for the two human papillomavirus (HPV) vaccines, Gardasil and Cervarix. CDC/ACIP recommendations for the use of HPV vaccine have not changed. To access the VISs go to: <http://www.immunize.org/vis>.

Receive automatic email notification from the CDC when new, or updated, VISs are available! Subscribe to the CDC's free email subscription service.

Go to: <http://www.cdc.gov/vaccines/pubs/vis/default.htm> and click on "Get e-mail updates."

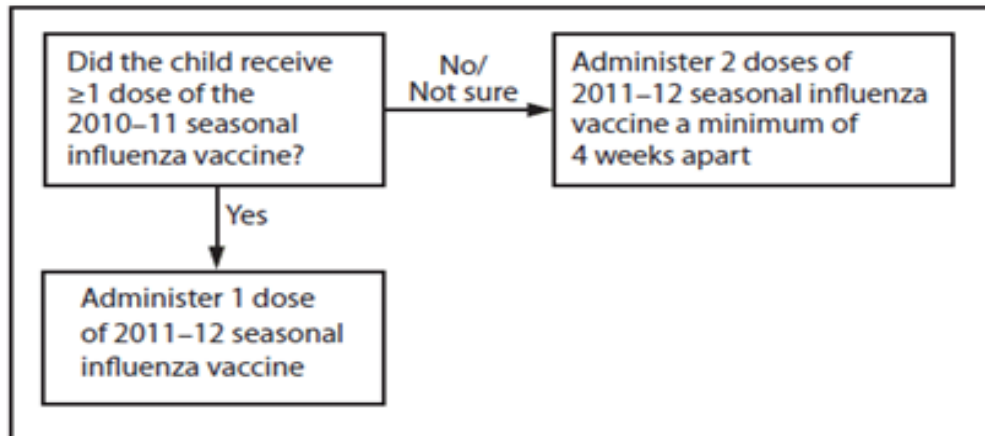
2011-2012 Flu Season

(continued from page 3)

ACIP provides guidance for the use of influenza vaccines given in the United States for the 2011-12 influenza season.

The complete article titled *Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011*, can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a3.htm>.

The following figure is from this article and shows the ACIP influenza vaccine dosing algorithm for children aged 6 months through 8 years for the 2011-12 influenza season. Children aged 6 months through 8 years who did not receive at least one dose of the 2010-11 seasonal influenza vaccine, or for whom it is not certain whether the 2010-11 seasonal vaccine was received, should receive two doses of the 2011-12 seasonal influenza vaccine.



HPV for Boys

On October 21, 2009, ACIP stated that quadrivalent HPV vaccine (HPV4 – Gardasil, Merck & Co., Inc.) may be given to males 9 through 26 years to reduce their likelihood of acquiring genital warts and to prevent anal cancer. CDC allows boys under the age of 19 to receive VFC vaccine in their medical homes if they meet at least one of the following eligibility categories:

- Medicaid
- Uninsured
- Native American/Alaskan

CHPlus will cover HPV4 for boys under the age of 19 in their medical home. In New York State, boys under the age of 19 who are underinsured may receive HPV4 at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). In NYS, HPV4 may be covered by private insurance.

Providers should check with private carriers, prior to administering vaccine, to verify coverage.

Parent Resource

IAC has recently published an information sheet for parents titled: *After the Shots.....What to do if your child has discomfort*. It answers questions many parents have after their children have been vaccinated. It has space for providers to add information.

This resource can be found at: <http://www.immunize.org/catg.d/p4014.pdf>

Storage and Handling Practices

New Temperature Logs

The IAC has revised its temperature logs. The new format continues to have separate forms for Fahrenheit and Celsius, but now has separate log sheets for freezers and refrigerators.

Remember, to ensure vaccine efficacy, VFC providers are required to:

- Take and record temperatures twice daily on IAC logs.
- Immediately report any temperature irregularities to VFC (1-800-543-7468).
- Maintain temperature logs for three years.

If you are required to submit temperature logs, please make sure your VFC PIN number is marked on every page.

The new logs can be found at:

Fahrenheit freezer:

<http://www.immunize.org/catg.d/p3038f.pdf>

Fahrenheit refrigerator:

<http://www.immunize.org/catg.d/p3037f.pdf>

Celsius freezer:

<http://www.immunize.org/catg.d/p3038c.pdf>

Celsius refrigerator:

<http://www.immunize.org/catg.d/p3037c.pdf>

Test Yourself

What is the most common temperature problem associated with refrigerators used for vaccine storage?

- 1) Refrigerator temperatures kept too warm.
- 2) Refrigerator temperatures kept too cold.
- 3) Refrigerator temperatures kept between 2°C and 8°C.
- 4) Refrigerator temperatures kept between 35°F and 46°F.

(The answer is on Page 7.)

Vaccine Storage and Handling Webinar

The NYSDOH Bureau of Immunization hosts *Immunization Update*, a webinar series to update and educate vaccinators across the state on important immunization issues. Each recorded webinar is presented by Bureau of Immunization staff and is now available for viewing at your convenience. In March 2011 a webinar titled *Vaccine Storage and Handling* was presented by three VFC staff: Gary M. Rinaldi, M.B.A., Vaccine Program Manager; Elizabeth Rausch-Phung, M.D., M.P.H., Medical Director; and Patricia M. Moran, R.N., Public Health Representative 4.

You can access this webinar at: http://www.nyhealth.gov/prevention/immunization/providers/webinar_series.htm

Frequently Asked Questions

Question: How long do we need to keep temperature logs on file?

Answer: The NYSDOH Bureau of Immunization requires VFC providers to maintain temperature logs for a minimum of three years. Temperatures should be taken twice daily and recorded on IAC logs.

By keeping temperature logs for at least three years, providers can track recurring temperature problems and determine how long they have been happening. This information allows providers to better define the time frame in question and take appropriate action. A record review can determine how long temperatures have been out of range, which vaccines may have been compromised, and which patients may need to be recalled.

Archived temperature logs also show how well the vaccine storage unit has been working over time, and can be used to determine when a unit may need adjustment, maintenance or replacement. Three years of temperature logs should be available, upon request, at the time of a VFC site visit.

Question: How should we dispose of expired vaccine?

All expired vaccine should be returned through the NYSDOH Bureau of Immunization. There is no cost to the provider to return vaccine and NYSDOH receives an excise tax credit for unused vaccine.

To return expired vaccine, providers need to:

- Complete an Expired/Loss Report as part of your monthly reporting requirements, and fax it to the Vaccine Program at 518-474-4222.
- Wait 7-10 business days for a return label from McKesson Specialty Care Solutions.
- Place expired vaccine in a box, attach the label, and give it to UPS for return. Because the vaccine is expired, it does not need to be packed with cold packs.

Please make sure that whoever opens mail in your practice knows to look for an envelope from McKesson Specialty Care Solutions that will contain a label. On occasion we get calls from providers that are unsure what to look for, or think they have not received a label. Here are reduced size samples of the envelope and label to help identify what you need.



Question: Are there items that cannot be returned to McKesson?

Answer: Yes. Some of the items that are frequently seen on NYSDOH Bureau of Immunization VFC Expired/Loss Report form that cannot be returned are: open multidose vials, diluent and broken vials. For a comprehensive list of what can and cannot be returned to McKesson, follow the link below:

www.cdc.gov/vaccines/programs/vfc/downloads/whatnot-to-return-to-mckesson-v5-508.pdf

Diluent Storage

IAC has recently updated its handout: *Vaccines with Diluents: How to Use Them*. The latest publication includes information on diluent storage environment (refrigerator or room temperature). This is a wonderful resource to display in your vaccine storage area.

The handout can be found at: www.immunize.org/catg.d/p3040.pdf.

New Packaging for Varicella

Merck & Co., Inc. has replaced the use of dry ice with frozen gel packs in the shipping packages for Varicella Virus Vaccine Live (Varivax) and Zoster Vaccine Live (Zostavax). These vaccines are now packed with frozen gel packs that are adequate to maintain proper temperatures for three days from the shipment date. To ensure vaccine efficacy, it is important for all staff to know that the container must be opened immediately and vaccine placed in the freezer. If the shipping container is received more than **three days** from the shipment date located on the packing list, contact Merck immediately for replacement instructions at 1-800-MERCK-RX (1-800-637-2579).

The following link provides more information on packaging for Varivax and Zostavax: https://www.merckvaccines.com/Professional-Resources/Documents/announcements/New_Shipping_Package_for_VARIVAX_and_ZOSTAVAX.pdf

Test Yourself Answer

(from page 5)

The correct answer is #2: Refrigerator temperatures kept too cold.

When it comes to refrigerated vaccine storage, colder is definitely NOT better! Excessive cold exposure is as bad, if not worse than excessive heat exposure for most vaccines. Accidental freezing of refrigerated vaccines can irreparably damage the chemical structure of a vaccine, rendering it ineffective. Once potency is lost, it can never be restored.

The new IAC reference guide *Checklist for Safe Vaccine Storage and Handling* provides valuable information on safeguarding your vaccine supply. You can access this guide at: www.immunize.org/catg.d/p3035.pdf

Important Contact Information

NYSDOH Bureau of Immunization VFC email: nyvfc@health.state.ny.us

VFC Hotline: 1-800-543-7468 (KID-SHOT)

Website: http://www.health.ny.gov/prevention/immunization/vaccines_for_children.htm

For further information, please contact your local health department or your regional NYSDOH Bureau of Immunization:

Western Regional Office
Buffalo: 716-847-4385
Rochester: 585-423-8014

Central New York Regional Office
Syracuse: 315-477-8164

Capital District Regional Office
Troy: 518-408-5278
Oneonta: 607-432-2890

Metropolitan Area Regional Office
New Rochelle: 914-654-7149
Central Islip: 631-851-3096
Monticello: 845-794-5627

VFC providers and facilities in New York City should contact the New York City Immunization Hotline at 347-396-2400.

Email the NYSDOH Bureau of Immunization VFC to receive this e-newsletter directly if you did not.

Prior to completing this form, please review the number of doses your site ADMINISTERD to VFC/CHPlus eligible children during the 2010-11 season and order accordingly for this season.

NEW YORK STATE BUREAU OF IMMUNIZATION –VACCINES FOR CHILDREN (VFC)
AND CHILD HEALTH PLUS (CHPLUS) PROGRAMS
INFLUENZA VACCINE ORDER SHEET FOR THE 2011-2012 SEASON (updated 9/6/11)

(ALL SECTIONS BELOW MUST BE COMPLETED AND SIGNED)

FACILITY/PROVIDER NAME: _____

ADDRESS: _____

NAME OF PERSON ORDERING: _____

PHONE: _____ EMAIL ADDRESS: _____

HOURS OF OPERATION: _____ DATE: _____

SIGNATURE: _____ VFC PIN#: _____ (required)

Please fax the completed form to the NYS Bureau of Immunization at (518) 474-4222

Vaccine Name/ Age for VFC Eligibility	Brand Name (Presentation-Minimum Doses)	Manufacturer	# of Doses requested for the 2011-12 season
LIVE INTRANASAL INFLUENZA	FLUMIST	MedImmune	
FLUARIX (inactivated) (3 years to 18 years)	FLUARIX (10 single dose syringes) (0.5ML)	Glaxo-SmithKline	
INFLUENZA (inactivated) (3 years to 18 years)	FLUZONE PF (10 single dose vials) (0.5 ML)	Sanofi Pasteur	
FLUVIRIN (inactivated) (4 years to 18 years)	FLUVIRIN (10 single dose syringes) (0.5 ML)	Novartis	
INFLUENZA (inactivated)	FLUZONE PF	Sanofi Pasteur	

PLEASE NOTE: The NYS Bureau of Immunization will attempt to fill all vaccine requests but as vaccine is received from CDC in increments **partial orders** may have to be shipped. Outstanding balances will be shipped as more vaccine is made available.

PLEASE NOTE: If you have not received a complete request and no longer require additional flu vaccine, it is your responsibility to contact the Vaccine Program at 1-800-543-7468 to cancel any outstanding balances.

PLEASE DO NOT OVER ORDER. Review the number of doses of each vaccine type administered to VFC/CHPlus eligible children during the 2010-11 season prior to completing the order above and fax your order to (518)474-4222. All orders are subject to approval.

- All children 6 months through 18 years of age should receive annual influenza vaccination
- Vaccinate all children <9 years of age with 2 doses of influenza vaccine, given 4 weeks apart, the first season they are vaccinated (also applies to children who received flu vaccine for the first time last season but received only 1 dose).

KEEP A COPY OF THIS ORDER FOR YOUR RECORDS.