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TO: Vaccines for Children (VFC) Providers
FROM: Robert Schechter, MD, Interim Chief *RS* *JS*
Immunization Branch
SUBJECT: Seasonal Influenza Vaccine Availability for VFC Children; and
2009-2010 VFC Vaccine Ordering Instructions

This memo is divided into sections to enable you to quickly access the information you need:

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SUMMARY

The federal Advisory Committee on Immunization Practices (**ACIP**) recently published its annual **Influenza Recommendations (MMWR, July 31, 2009 / 58(RR-8);1-52)**, available at <http://www.cdc.gov/mmwr/pdf/rr/rr5808a1.htm> . The VFC Influenza Resolution can also be found online at: <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0208influenza.pdf>.

The 2009 recommendations for pediatric influenza vaccination include the recommendation that annual vaccination of all children aged 6 months through 18 years against influenza begin as soon as the vaccine is available. However, annual vaccination of all children aged 6 months through 4 years (59 months) and older children with conditions that place them at increased risk for complications from influenza should continue to be a primary focus of vaccination efforts as providers and programs transition to routinely vaccinating all children.

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The California VFC Program will begin accepting seasonal influenza vaccine requests for the 2009-2010 influenza season in early September 2009. VFC is streamlining the ordering process for seasonal influenza vaccine to expedite delivery. Providers will be able to submit their vaccine request electronically to VFC through an on-line ordering system. Providers will receive a pre-allocated supply of vaccine that is an increase of last year's VFC utilization, anticipating higher immunization coverage in children. Please note that the total approved doses will arrive in multiple shipments reflecting partial shipments to the VFC distributor. However, unlike previous years, there will be no need to submit supplemental requests, as vaccines will be shipped automatically to you as supply becomes available.

The 2009-2010 Influenza Season Vaccine On-line Order system is accessible to all VFC providers through VFC's website, at www.eziz.org. You will be able to log-in the site in the same manner as your yearly re-certification, using your PIN and your clinic's zip code.

Sites MUST log in, verify their request, and submit orders to VFC in order to receive vaccines.

An initial supply of flu vaccine is expected from vaccine manufacturers by mid- to late September, with multiple subsequent shipments expected in October. The VFC Program will notify providers via FAX and e-mail when products are received at VFC's vaccine distributor, and delivery of approved orders begins.

2009-2010 INFLUENZA VACCINE COMPOSITION

The 2009-2010 trivalent vaccine virus strains in this year's influenza vaccine, representative of viruses that are anticipated to circulate in the US during the 2009-10 influenza season, are:

- A/Brisbane/59/2007 (H1N1)-like;
- A/Brisbane/10/2007 (H3N2)-like; and
- B/Brisbane/60/2008-like antigens.

Both inactivated and live-attenuated influenza vaccines are grown in eggs.

VFC INFLUENZA VACCINE FORMULATIONS

The Vaccines for Children (VFC) Program will make available a variety of licensed influenza vaccines for the 2009-2010 influenza season, including:

Children ages 6--35 months

- Fluzone[®] (sanofi), No Preservative, Pediatric Dose (children 6 through 35 months of age)

Children ages 3 years — 18 years

- Fluzone[®] (sanofi), Preservative-containing (children and adolescents aged 3 through 18 years)
- Fluvirin[®] (Novartis), Preservative-containing (children and adolescents aged 4 through 18 years)
- FluMist[®] (MedImmune), Preservative free, live, attenuated intranasal vaccine (healthy children and adolescents aged 2 through 18 years of age **only**)

Pregnant women 18 years of age and younger

- Fluzone[®] (sanofi), No Preservative (Pregnant women, 18 years of age and younger)

According to California law, pregnant women or children younger than three years old may only receive vaccine doses that contain trace levels or no mercury. [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)]. Due to a limited supply of preservative-free influenza formulation, preservative-free vaccines should be prioritized for administration to VFC-eligible children younger than three years of age and pregnant teens 18 years of age and younger.

ELIGIBILITY FOR VFC-SUPPLIED SEASONAL INFLUENZA VACCINE

VFC-supplied seasonal influenza vaccine may be used for all VFC-eligible children in the ACIP recommended groups using appropriate indications for the specific vaccine:

Eligible Groups for Inactivated Seasonal Influenza Vaccine

- All children aged 6 months through 18 years.

Eligible Groups for Live Attenuated Seasonal Influenza Vaccine (LAIV)

- All healthy children and adolescents (those who do not have an underlying medical condition that predisposes them to influenza complications) aged 2 years through 18 years.

DOSAGE AND ADMINISTRATION

Inactivated Seasonal Influenza Vaccine

Children under 9 years of age, receiving inactivated influenza vaccine for the first time, require two doses, 4 weeks apart.

- For children 6-35 months of age, one dose is 0.25 mL.
- For children \geq 36 months of age, one dose is 0.5 mL

Children under 9 years who received only their first dose of influenza vaccine during last season are recommended to receive **2** doses this season.

Children under 3 years of age should receive preservative-free influenza products.

Inactivated influenza vaccine should be administered intramuscularly in the anterolateral aspect of the thigh for infants and young children. Adults and older children should be vaccinated in the deltoid muscle.

LAIV

Children aged 2 through 8 years previously unvaccinated with influenza vaccine or who received only 1 dose of any influenza vaccine in their first year of vaccination are recommended to receive 2 doses the following year, separated by at least 4 weeks.

LAIV is only administered intranasally. The vaccine is supplied in pre-filled, single-use sprayers containing 0.2 mL of vaccine. One half of the sprayer's contents (0.1 mL) should be sprayed into each nostril while the patient is in an upright position. Do not repeat a dose if the patient sneezes after administration of the dose.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Prior to placing this year's influenza vaccine request for your practice, please ensure that:

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- You have sufficient space in your vaccine storage unit to store your flu vaccine request along with any doses of H1N1 flu vaccine your clinic may be requesting and all other pediatric vaccines routinely stored in your refrigerator.
- Vaccines may not be stored in drawers or deli/vegetable bins, and must be kept in their original packaging until they are ready to be administered. (DO NOT take vaccine vials or syringes out of their packaging.)
- All expired and unused flu vaccine for the 2008-2009 flu season is removed from your refrigerator and sent back to VFC's National Distributor, McKesson Specialty Inc.

All influenza vaccine formulations, including LAIV, will be shipped to your practice directly from McKesson Specialty Inc., in insulated containers maintaining a constant temperature between 35° to 46°F (2° to 8°C).

Immediately upon receipt:

- Check the temperature monitors included in your shipment to verify that the temperature has been maintained while shipment was in transit to your practice.
- Verify that the vaccine doses received match the doses reflected in your shipment's packing slip.
- Refrigerate vaccines at a temperature range of 35° to 46°F (2° to 8°C), with a preferred temperature of 40°F. Do not freeze or expose vaccines to freezing temperatures
- Contact the VFC Program **immediately** to report any discrepancy in your order or if the vaccine shipment's monitor indicates the vaccine has been exposed to suboptimal temperatures. Please instruct clinic staff to label the vaccines "Do not use" and refrigerate the vaccines until you have received further instructions from the VFC program.

ORDERING INSTRUCTIONS

During the 2009-2010 VFC Influenza season, VFC will be launching an on-line influenza ordering system, easily accessible through VFC's website, www.eziz.org. VFC providers will be able to submit their vaccine request electronically to VFC, by logging on to the site in the same manner as yearly recertification, using the provider's PIN and corresponding clinic ZIP code.

Upon log-in, providers will be able to view their clinic's pre-allocated 2009-2010 supply of vaccine for their practice, verify the request, and submit the order electronically to VFC. Pre-allocated doses are based on doses received during the preceding season, and are inclusive of an increase doses in anticipation of higher immunization coverage in children ages 5-18 years of age. Upon review of allocated doses, clinics will have the ability to reduce the number of doses allocated if needed, and /or request doses for products not ordered in previous season. Providers will **not** be able to increase vaccine request beyond the capped allocation. However, VFC will notify providers in winter months about supplemental flu orders, depending on influenza vaccine supply and availability.

Important: Sites **MUST** log in, verify their request, and submit orders to VFC in order to receive vaccines. We encourage printing a copy of the submitted request for your records. If you are unable to use the electronic ordering system, please contact our VFC Customer Service Center for assistance.

Initial vaccine supplies are expected to arrive at VFC's national vaccine distributor by late September, with multiple subsequent shipments expected in October. Therefore, it is likely that providers will also receive allocated vaccine supplies in multiple shipments. Unlike previous seasons, there will be no need to submit supplemental vaccine request to VFC for the remaining

balance in your allocation. VFC will automatically ship doses to your practice as vaccine supplies become available.

The VFC Program will notify providers via FAX and e-mail when products are received at VFC's vaccine distributor and delivery of approved orders begins.

BILLING NOTES

Medi-Cal: To bill Medi-Cal for vaccines and administration of influenza vaccines, use only CPT-4 codes 90655, 90656, 90658, and 90660 (LAIV). If VFC vaccine is used, the provider will only be reimbursed for the administration fee. The "-SL" modifier should be used for administration of VFC seasonal influenza vaccine. Medi-Cal Program providers who are unable to obtain influenza vaccine from the VFC Program for their Medi-Cal beneficiaries should purchase it privately and bill Medi-Cal using the appropriate CPT-4 codes.

For more information, please refer to the Medi-Cal provider manual on VFC

http://files.medi-cal.ca.gov/pubsdoco/publications/masters-tp/part2/vaccine_m00o03o04o11.doc

- **90655** Influenza virus vaccine, **split virus, no preservative**, for children 6-35 months of age, for intramuscular use
- 90656 Influenza virus vaccine, **split virus, no preservative**, for use in individuals 3 years of age and above, for intramuscular use
- 90658 Influenza virus vaccine, **split virus**, for use in individuals 3 years of age and above, for intramuscular use
- 90660 Influenza virus vaccine, **live**, for intranasal use

The CHDP program will reimburse for seasonal influenza vaccine and its administration.

- If seasonal influenza vaccine is provided by the VFC Program use code "53."
- If seasonal influenza vaccine is purchased because the vaccine is not available through VFC use code "54" for children 36 months through 20 years, 11 months and code 80 (preservative free) for children 6 months through 35 months.
- If Live Attenuated Influenza Vaccine (LAIV), intranasally administered is provided by the VFC Program use code "71."
- Code 71 is payable for ages two years through 18 years, 11 months, administration fee only.

RETURN OF UNUSED VIALS OF INFLUENZA VACCINE

All VFC Providers must return all expired or spoiled influenza vaccine (including vials, syringes, and nasal sprayer packages) to VFC's national vaccine distributor: McKesson Specialty, 3775 Seaport Blvd, West Sacramento CA 95691.

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Complete a VFC Return and Transfer Form and make a copy for your records. Fax a copy to the VFC Program at 877-FAXX-VFC (877-329-9832) and enclose the original copy of the form in the package with the non-viable or expired vaccines you are returning to the VFC Program.

When returning your vaccines, please use a container in which you receive your normal vaccine shipments, and clearly label the outside of the shipping container "Non-viable vaccine enclosed". You may contact VFC to request a return label for your box.

FluMist Replacement Program

LAIV products received early in the flu season will have an earlier expiration date. Doses with an expiration date on or before January 31, 2010 are eligible for the FluMist Replacement Program. The program allows for the replacement of short-dated doses with the doses that have a later expiration date. Replacement requests must be submitted by January 29, 2010. Providers will have from 15 days prior to the expiration date stamped on the sprayer until January 29, 2010 to request replacement doses. All requests should be placed with McKesson Specialty by calling 1-877-633-7375.

VIS STATEMENTS

Copies of the current interim Vaccine Information Statement (VIS) for the Inactivated Influenza Vaccine and the Live, Attenuated Influenza Vaccine (LAIV), dated 8/11/09, are included in this mailing and are also at <http://www.cdc.gov/vaccines/pubs/vis/default.htm#flu>. Federal regulation requires that you provide the VIS to a parent or guardian before the child receives influenza vaccine.

HELPFUL RESOURCES

To help you remind parents about new pediatric flu shots recommendations, we are enclosing a copy of the **"Guess Who Needs a Flu Shot" (IMM-782)** self-adhering cling-on flyer and a copy of **"Babies Need You"** Parents and Caregivers poster (IMM-823E/S). These pieces are suitable for posting in a medical office waiting room or patient exam room and require no tape or thumb tacks. In addition, a sample **"Guess Who Needs a Flu Shot" (IMM-781)** reminder postcard and a "Flu Vaccine Identification Guide" (IMM-859) are also enclosed. To order additional copies of these materials, VFC providers should contact their local health department. Listings are at <http://www.cdph.ca.gov/programs/immunize/Pages/CaliforniaLocalHealthDepartments.aspx>.

QUESTIONS?

If you have any questions, please call your VFC Field Representative or the VFC Program at: 877-243-8832 (877-2GET-VFC). You can also visit our website at www.eziz.org

Enclosures: Inactivated Influenza Vaccine Information Statement (8/11/09)
Live Intranasal Influenza Vaccine Information Statement (8/11/09)
"Guess Who Needs a Flu Shot" postcard (IMM-781)
"Guess Who Needs a Flu Shot" cling-on flyers (IMM-782)
"Babies Need You" Parents and Caregivers poster (IMM-823E/S)
"Flu Vaccine Identification Guide" (IMM-859)
2009-2010 Seasonal Flu Ordering Instructions"

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