State of California—Health and Human Services Agency
California Department of Public Health

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TO: Vaccines for Children (VFC) Providers

FROM: John Talarico, D.O., M.P.H., Chief
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SUBJECT: VFC 2011-12 Seasonal Influenza Vaccine Information

SUMMARY

The recommendations of the federal Advisory Committee on Immunization Practices (ACIP) on the *Prevention and Control of Influenza with Vaccines* were published in the August 18, 2011, issue of *Morbidity and Mortality Weekly Report*. Routine annual influenza immunization continues to be recommended for all children and persons 6 months and older, including all adults. VFC vaccine cannot be given to persons older than 18 years of age. Providers should offer influenza immunization as soon as vaccine is available and throughout the influenza season. On June 27, 2011, providers were sent instructions for confirming their 2011-12 VFC allocations through the Seasonal Influenza On-line Order Confirmation System at www.eziz.org.

2011-2012 INFLUENZA VACCINE COMPOSITION

The 2011-2012 trivalent vaccine virus strains in this year's influenza vaccine, representative of viruses that are anticipated to circulate in the U.S. during the 2011-12 influenza season, are the same strains that were in the 2010-2011 seasonal influenza vaccine:

- A/California/7/2009 (H1N1)-like—(derived from a 2009 pandemic (H1N1) influenza virus)
- A/Perth/16/2009 (H3N2)-like

- B/Brisbane/60/2008-like

Persons that received the influenza vaccine last season are still recommended to be immunized with a dose of 2011-2012 influenza vaccine this season for optimal protection against influenza.

VFC INFLUENZA VACCINE FORMULATIONS
The Vaccines for Children (VFC) Program will make available a variety of licensed influenza vaccines for the 2011-2012 influenza season, including:

VFC-eligible Children ages 6 through 35 months
- Fluzone® PF Pediatric (sanofi pasteur), No preservative, (children 6 through 35 months of age). Available as 0.25mL pre-filled syringes. Intramuscular injection.

VFC-eligible Children and Youth through age 18 years
- Fluzone® (sanofi pasteur), preservative-containing (children and adolescents aged 3 through 18 years). Multi-dose vial. Intramuscular injection.
- FluMist® (MedImmune), preservative free, live, attenuated intranasal vaccine (only healthy, non-pregnant children and adolescents aged 2 through 18 years of age). 0.2 mL single-use sprayer. Intranasal administration.
- Fluarix® (GlaxoSmithKline), no preservative (prioritized for pregnant women who are VFC –eligible, but may also be used in children and youth ages 3 through18 years). Available as 0.5 mL single-dose pre-filled syringes. Intramuscular injection.

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)]. All multi-dose vials of influenza vaccine currently contain levels of mercury that are higher than the legal limit and should not be used in these groups. 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, non-pregnant 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
Children 9 years and older are recommended to receive 1 dose of seasonal influenza vaccine in the 2011-12 season.

For the 2011-2012 influenza season, any child 6 months through 8 years of age is recommended to receive 2 doses of seasonal influenza vaccine unless it is determined that the child received at least 1 dose of 2010-2011 seasonal flu vaccine. The minimum interval between 2 doses of seasonal influenza vaccine is 4 weeks. Recommendations for number of doses in this age group may change for the 2012-13 if the influenza vaccine strains change.

Inactivated Seasonal Influenza Vaccine

- For children 6-35 months of age, one dose is 0.25 mL
- For children ≥36 months of age, one dose is 0.50 mL

The vaccine syringe or vial should be shaken well before administration. Vaccine should be inspected visually for particulate matter and discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

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

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.

Egg Allergy

A history of severe allergic reaction or anaphylaxis to influenza vaccine remains a contraindication to influenza immunization; however, this is not equivalent to history of egg allergy. Influenza immunization has often occurred safely in persons who reported a history of egg allergy. The quantity of egg protein (ovalbumin) in vaccine is low and has been tolerated without serious reactions in studies that reported ovalbumin concentration.

History of severe egg allergy: Persons who have experienced reactions to egg involving angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who required epinephrine or other emergency medical intervention with a short time after egg exposure, are more likely to have a serious systemic or anaphylactic reaction upon re-exposure to egg proteins. These patients should be referred to a physician with expertise in the management of allergic conditions before being administered influenza vaccine.

History of milder egg allergy: Persons who report an allergy to egg but whose medical history is inconsistent with an allergy to eggs (e.g., able to eat scrambled eggs without reaction) are unlikely to be allergic. However, egg-allergic persons may be able to tolerate egg in baked products (e.g., bread or cake); tolerance to such egg-containing baked products does not exclude the possibility of egg allergy. Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus a skin and/or blood test for IgE antibodies to egg proteins.

History of hives (urticaria): Individuals who have experienced hives following exposure to egg can receive influenza vaccine. For such patients:

- TIV (rather than LAIV) should be used.
- Vaccine provider should be familiar with the potential manifestations of egg allergy.

- Patients should be observed for at least 30 minutes for signs of a reaction to the vaccine.

Providers should have an emergency plan and personnel and equipment readily available for rapid recognition and treatment of anaphylactic reactions in any patient.

Vaccine Management and Training
Your office or clinic may receive a variety of influenza vaccine formulations, including privately purchased doses for non-VFC eligible patients The attached "Flu Vial Identification Chart" may help you identify all available flu products, including two newer formulations of inactivated trivalent influenza vaccine that are not provided by the VFC program:

- *intradermal* vaccine for persons aged 18 through 64 years
- *high-dose*, intramuscular influenza vaccine for persons aged 65 years and older.

It is extremely important that staff education include a review of **all** (VFC, non-VFC) trivalent influenza vaccine products, including dosages, age indications, and administration techniques, that you will be administering in your facility this year. We strongly encourage yearly competency review of all staff administering any vaccine formulation, including influenza. All inactivated influenza products cannot be used if exposed to freezing temperatures. The temperature in any vaccine refrigerators should aim for 40°F. Clinic staff involved in ordering, managing vaccine inventory and administering vaccines are strongly encouraged to complete VFC's EZIZ on-line Vaccine Administration and Storage and handling lessons, accessible at www.eziz.org.

VACCINE INFORMATION STATEMENTS (VISs)
The appropriate influenza Vaccine Information Statement (VIS) for Inactivated or Live, Attenuated Influenza Vaccine (LAIV) for 2011-2012, must be provided to a parent or guardian before the child receives each dose of influenza vaccine. Copies of this season's VISs are enclosed.

Please discard any remaining copies of the Influenza VIS from prior seasons.

ORDERING INSTRUCTIONS
On June 27, 2011, VFC announced the availability of VFC's On-line Order Confirmation System for the submission of this year's seasonal flu vaccine requests. Copies of the provider notice and order confirmation instructions are available at www.eziz.org. The deadline for submitting a confirmed request was July 20, 2011.

All provider orders confirmed by the deadline have been reviewed and approved. An e-mail confirmation outlining total influenza doses expected, by brand, was e-mailed to the clinic's provider of record on August 1, 2011.

Supplemental Flu Orders
Providers not able to confirm orders by the deadline and those wishing to receive additional doses will have the opportunity to submit a supplemental vaccine request in late fall. VFC will notify providers and provide additional information about supplemental ordering once this occurs.

Vaccine Supply
Initial vaccine supply for some products has already arrived at VFC's national vaccine distributor. However, multiple shipments are expected over the next 2 months to complete the state's vaccine supply pre-booked for the 2011-2012 influenza season. It is anticipated that up to 50% of expected doses will become available in September, with the remaining balance available in October.

Order Fulfillment and Shipments
All confirmed orders for available products as of the date of this letter will begin to be processed and submitted for fulfillment during the week of August 23, 2011. Orders will be filled in the order received. Order fulfillment information will be posted and updated as necessary on www.eziz.org in the "Order Status" section.
Full supply available:

- Fluarix® (GlaxoSmithKline), no preservative

All confirmed orders will be shipped in full.

Limited supply:

- Fluzone® PF Pediatric (sanofi pasteur), No preservative, 0.25mL pre-filled syringes
- Fluzone® (sanofi pasteur), preservative-containing Multi-dose vials
- FluMist® (MedImmune), preservative free, live, attenuated intranasal vaccine

Partial shipments will be processed. Subsequent shipments will be automatically processed as additional vaccine supplies become available.

STORAGE AND HANDLING OF INFLUENZA VACCINES
Prior to receiving your influenza vaccine request, please ensure that:

- You have sufficient space in your vaccine storage unit to store your flu vaccine along with all other vaccines stored in your refrigerator.
- All expired and unused 2010-11 seasonal influenza vaccine received from VFC is removed from your refrigerator and sent back to VFC's National Distributor, McKesson Specialty Inc.

Once your vaccines arrive:
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 and also match doses reflected on the e-mailed order confirmation.
- 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. If this occurs, 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.
- Refrigerate vaccines at a temperature range of 35°F to 46°F (2°C to 8°C), with a preferred temperature of 40°F. Do not freeze or expose vaccines to freezing temperatures.

- Keep vaccines in their original packaging until they are ready to be administered. (DO NOT take vaccine vials or syringes out of their packaging.)

BILLING NOTES

Medi-Cal:

To bill Medi-Cal for administration of VFC-supplied influenza vaccines, use the appropriate CPT-4 code followed by the "-SL" modifier. Providers will only be reimbursed for the administration fee when using VFC vaccines.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal provider manual on VFC. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

CPT-4 Codes:

- 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

Child Health and Disability Prevention Program (CHDP):

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," administration fee only.
- 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

Seasonal Flu Vaccine Return

All VFC Providers must return all expired or spoiled seasonal influenza vaccine (including vials, syringes, and nasal sprayer packages) received from VFC to the program's national vaccine distributor: McKesson Specialty.

To return vaccine, 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). Enclose the original form in the package with the non-viable or expired vaccines you are returning.

When returning your vaccines, please keep doses in their original packaging and use a container in which you receive your normal vaccine shipments. Clearly label the outside of the

shipping container "Non-viable vaccine enclosed". You may contact VFC to request a return label for your box.

LAIV Replacement Program
Similar to last year, LAIV will have expiration dates as early as December 2011. The manufacturer has a program for replacing doses nearing expiration. Providers may request replacement of eligible LAIV up to 15 days prior to the expiration date printed on the sprayer label. All replacement requests must be made by faxing a request to a toll-free fax number (1-877-633-7375) and must be submitted by January 31, 2012. Information about the program is included. All questions regarding the Replacement Program can be directed to 1-877-633-7375.

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

Encl: Identifying Influenza Vaccine Chart
Live, Intranasal Influenza Vaccine 2011-12 (7/26/11)
Inactivated Influenza Vaccine Statement 2011-12 (7/26/11)

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