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TO: Vaccines for Children (VFC) Providers

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SUBJECT: VFC 2013-14 Seasonal Influenza Vaccine Information

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**SUMMARY**

The 2013-14 summary recommendations of the federal Advisory Committee on Immunization Practices (ACIP) on the *Prevention and Control of Influenza with Vaccines* are posted at <http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm>. The full recommendations will be published in the [Morbidity and Mortality Weekly Report \(MMWR\)](http://www.cdc.gov/mmwr) and posted at <http://www.cdc.gov/vaccines/hcp/acip-recs/>. Routine annual influenza immunization continues to be recommended for all persons 6 months and older, including all adults. VFC vaccine cannot be given to persons older than 18 years of age. Children younger than 9 years of age who have not been previously immunized against influenza need 2 doses of influenza vaccine for optimal protection.

In general, health-care providers should begin offering vaccination soon after vaccine becomes available. All children aged 6 months through 8 years who are recommended for 2 doses should

receive their first dose as soon as possible after vaccine becomes available; these children should receive the second dose 4 weeks or more after the first dose.

### **TRIVALENT AND QUADRIVALENT INFLUENZA VACCINES**

Influenza B viruses are separated into two antigenically distinct genetic lineages (Yamagata and Victoria). Immunization against B virus strains of one lineage provides at best limited cross-protection against strains in the other lineage. Influenza B viruses from both lineages have circulated in most recent influenza seasons; it is difficult to predict with certainty which lineage will be predominant in any given season.

For the 2013-14 influenza season, both trivalent and quadrivalent influenza vaccines will be available. The quadrivalent vaccines will include the same vaccine virus strains as the trivalent influenza vaccines [A(H1N1), A(H3N2), and B virus] plus an additional B virus strain from the other lineage.

### **VACCINE ABBREVIATIONS**

- IIV3 = Inactivated influenza vaccine, trivalent
- IIV4 = Inactivated influenza vaccine, quadrivalent
- LAIV4 = Live-attenuated, intranasal influenza vaccine, quadrivalent—LAIV is expected to be available only as a quadrivalent influenza vaccine for the 2013-14 season.

### **2013-14 INFLUENZA VACCINE COMPOSITION (TRIVALENT AND QUADRIVALENT)**

The 2013-14 vaccine virus strains in this year's influenza vaccines are representative of viruses that are anticipated to circulate in the US during the 2013-14 influenza season. For the 2013-14 influenza season, both trivalent (IIV3) and quadrivalent (IIV4 and LAIV4) influenza vaccines will be available; the 2013-14 influenza vaccines include B strains that were not in the 2012-13 seasonal influenza vaccine.

Trivalent influenza vaccines will contain hemagglutinin (HA) derived from the following:

- A/California/7/2009 (H1N1)-like – same as last season (derived from the 2009 pandemic (H1N1) influenza virus)
- A/Victoria/361/2011 (H3N2)-like – same as last season
- B/Massachusetts/2/2012-like (B/Yamagata lineage) – new for this season

Quadrivalent influenza virus vaccines will contain these three antigens, and:

- B/Brisbane/60/2008-like (B/Victoria lineage) – new for this season

Persons who received influenza vaccine in previous seasons are recommended to be immunized with 2013-14 influenza vaccine 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 2013-14 influenza season, including:

VFC-eligible children ages 6 through 35 months:

- Fluzone<sup>®</sup> PF Pediatric (sanofi pasteur)
  - Trivalent, inactivated [IIV3], intramuscular injection
  - No preservative
  - Available as 0.25mL pre-filled syringes
  - CPT Code: 90655

VFC-eligible children and youth through age 18 years:

- Fluzone<sup>®</sup> (sanofi pasteur)
  - Trivalent, inactivated [IIV3], intramuscular injection
  - Preservative-containing (for use in children and adolescents aged 3 through 18 years)
  - Multi-dose vial
  - CPT Code: 90658
- FluMist<sup>®</sup> Quadrivalent (MedImmune)
  - Quadrivalent, live, attenuated intranasal vaccine [LAIV4]
  - No preservative (for use in only healthy, non-pregnant children and adolescents aged 2 through 18 years of age)
  - 0.2 mL single-use sprayer
  - CPT Code: 90672
- Fluarix<sup>®</sup> Quadrivalent (GlaxoSmithKline)
  - Quadrivalent, inactivated [IIV4], intramuscular injection
  - No preservative (for use in children and youth ages 3 through 18 years and pregnant women who are VFC-eligible)
  - Available as 0.5 mL single-dose pre-filled syringes
  - CPT Code: 90686

Both FluMist<sup>®</sup> Quadrivalent (MedImmune) and Fluarix<sup>®</sup> Quadrivalent (GlaxoSmithKline) are new for the 2013-14 influenza season.

[According to California law](#), pregnant women or children younger than 3 years old may only receive vaccine doses that contain no more than trace levels of 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 exceed the legal limit of mercury content and should not be used in these groups.** Preservative-free influenza VFC vaccine formulations should be used for administration to VFC-eligible children younger than 3 years of age and pregnant teens younger than 19 years of age.

## ELIGIBILITY FOR VFC-SUPPLIED SEASONAL INFLUENZA VACCINE

VFC-supplied seasonal influenza vaccine can only be administered to VFC-eligible children. All VFC-eligible children aged 6 months through 18 years of age in your practice should be vaccinated according to ACIP recommendations.

## DOSAGE AND ADMINISTRATION

### Inactivated Seasonal Influenza Vaccine

Children aged 6 months through 18 years.

- For children 6 through 35 months of age, one dose is 0.25 mL
- For children and youth 36 months of age and older, 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**

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

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.

### **Number of doses**

Children 9 years and older are recommended to receive one dose of 2013-14 seasonal influenza vaccine.

Children 6 months through 8 years of age are recommended to receive two doses of 2013-14 seasonal influenza vaccine (administered a minimum of 4 weeks apart). However, some children in this age group may need only one dose of 2013-2014 seasonal influenza, depending on the number of seasonal influenza doses and monovalent 2009 H1N1 doses received in previous seasons. The ACIP's summary recommendations for the Prevention and Control of Influenza with Vaccines for the 2013-2014 influenza season include two approaches for determining the number of doses required for children aged 6 through 8 years of age.

- The first approach addresses situations in which ascertaining vaccination history before the 2010-2011 season is difficult. See Figure 1 of ACIP's 2013-14 [Summary Recommendations: Prevention and Control of Influenza with Vaccines](#).
- The second approach may be used in situations or settings where adequate vaccination history prior to the 2010-2011 season is available. See vaccine dose considerations in ACIP's 2013-2014 [Summary Recommendations: Prevention and Control of Influenza with Vaccines](#).

### **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. Please see the ACIP's 2013-2014 [Summary Recommendations: Prevention and Control of Influenza with Vaccines](#) for further information.

### **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 "[Influenza Vaccine Identification](#)

[Chart](#)” may help you identify all available influenza vaccines, including formulations 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
- *Cell culture-based influenza vaccine* for persons aged 18 and older
- *Recombinant influenza vaccine* for persons aged 18 through 49 years

It is extremely important that staff review **all** (VFC, non-VFC) influenza vaccine products that you will be administering in your facility this year, including their dosages, age indications, and administration techniques. We strongly encourage yearly competency review of all staff administering any vaccine formulation, including influenza.

Any inactivated influenza products that are exposed to freezing temperatures cannot be used. Aim for a temperature of 40°F in all of your refrigerators that store vaccines. Clinic staff involved in ordering, managing inventory, and administering vaccines are strongly encouraged to complete VFC's EZIZ on-line Vaccine Administration lessons, accessible at [www.eziz.org](http://www.eziz.org). All other lessons, including Vaccine Inventory Management, Storage and Handling, and a VFC Program Overview Lesson (available this fall) are required to be completed by December 31, 2013.

Prior to the receipt of vaccines, an annual influenza preparation meeting can assist your clinic in outlining key strategies for a successful influenza vaccination season at your practice. This will not only help achieve high influenza vaccination coverage rates of your patient population and decrease missed opportunities for vaccination; but also provide an opportunity to:

- review this year's flu products to be used in your practice,
- ensure all unused and expired products have been returned to VFC's national vaccine distributor
- prepare room in your vaccine storage unit to receive initial vaccine shipments
- discuss how the clinic will remind patients to come in for their annual influenza vaccination, and
- discuss mechanisms to track patients that will be due to return to the practice for a second dose.

### **VACCINE INFORMATION STATEMENTS (VISs)**

The appropriate influenza [Vaccine Information Statement \(VIS\) for Inactivated or Live, Attenuated Influenza Vaccine \(LAIV\) for 2013-2014](#) must be provided to a parent or guardian before the child receives each dose of influenza vaccine. Each time a VIS is provided the following information must be included in each patient's permanent medical record:

- (1) Edition date of the current Vaccine Information Statement that was provided
- (2) Date that the VIS was provided.

Copies of the 2013-14 Influenza VISs are attached. Please discard any remaining copies of the Influenza VIS from prior seasons.

### **ORDERING INSTRUCTIONS**

VFC's On-line Order Confirmation System was open for the submission of requests for 2013-14 seasonal flu vaccine from June 25, 2013, through July 26, 2013. All orders confirmed by the

deadline have been reviewed and approved. (The June 2013 provider notice and order confirmation instructions are available at [www.eziz.org](http://www.eziz.org).) Confirmation of final vaccine allocations and approval of brand allocations have been sent electronically to the clinic's provider of record on August 5, 2013.

### **Supplemental Flu Orders**

Providers who did not confirm orders by the July 26 deadline or who wish to order additional doses may submit a supplemental vaccine request. Supplemental ordering information will be sent to providers in mid to late fall, once the on-line site is ready to receive provider orders.

### **Timing of Vaccine Supply**

It is anticipated that up to 50% of expected doses of VFC influenza vaccine will become available by late September, with the remaining balance available by late October.

### **Order Fulfillment and Shipments**

All orders confirmed by the date of this letter will remain in queue until doses become available. Orders will be filled in the order received. Orders will typically be shipped in increments, as the timing and volume of deliveries to the distributor vary for each formulation of influenza vaccine. Order fulfillment information will be posted and updated as necessary on [www.eziz.org](http://www.eziz.org) in the "Order Status" section.

Please ensure that any changes in the clinic's hours of operation are promptly reported to the VFC Program. This is critical to ensure that vaccine orders are delivered within the clinic's reported vaccine delivery times. Failure to report changes in clinic's open hours (hours clinics are able to receive vaccine shipments) will result in delayed delivery of vaccines and can potentially compromise vaccine shipments leading to a negligence vaccine loss.

## **STORAGE AND HANDLING OF INFLUENZA VACCINES**

Prior to receiving your influenza vaccine request, please ensure that:

- You have sufficient space in your vaccine refrigerator(s) to store your influenza vaccine along with all of your other vaccines.
- All supplies of VFC seasonal influenza vaccine from 2012-13 or earlier are removed from your refrigerator and returned to McKesson Specialty Inc. See page 7 for instructions on returning expired vaccine.

Once your vaccines arrive:

All influenza vaccine formulations, including LAIV4, 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. If the monitors indicate the vaccine has been exposed to suboptimal temperatures during transit:
  - Contact the VFC Program **immediately**.
  - Instruct clinic staff to label the vaccines "Do not use."
  - Refrigerate the vaccines until you have received further instructions from the VFC program.
- Verify that the number and type of vaccine doses received matches the information **both** in your shipment's packing slip and in the e-mailed order confirmation. Contact the VFC Program **immediately** to report any discrepancy in your order.

- 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.)

## **PROMOTING FLU VACCINATION IN YOUR OFFICE**

A number of influenza promotion materials are available for you, your staff, and your patients. We encourage you to post them around your office. To see what's available this year, visit the flu resources page on EZIZ.org: <http://eziz.org/resources/flu-promo-materials/>. A sample packet of available materials will be included in your clinic's first vaccine shipment.

## **RETURN OF UNUSED INFLUENZA VACCINE**

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, Inc.

To return vaccine, please submit a completed VFC Return and Transfer Form either:

- Electronically using [MYVFCVaccines](#).
- By faxing to 877-FAXX-VFC (877-329-9832).

A Return/Transfer Form MUST be submitted to VFC prior to sending vaccines to McKesson Specialty, Inc. Please note that if a paper-based form is used, it must be the most current version of the form posted on [www.eziz.org](http://www.eziz.org).

When submitting the Return and Transfer Form, you may request return shipping labels, which should arrive at your office within 10 business days. Please keep the returned doses in their original packaging. Please ship in a container in which you receive your typical vaccine shipments. Clearly label the outside of the shipping container "Non-viable vaccine enclosed."

## **LAIV Replacement Program**

LAIV has a brief expiration date, with some lots expiring as early as November 2013. Providers may request replacement of eligible LAIV up to 15 days prior to the expiration date printed on the sprayer label. Details for this year's LAIV replacement program will be posted on [www.eziz.org](http://www.eziz.org) once available.

## **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.

### **Child Health and Disability Prevention Program (CHDP)**

The CHDP program will reimburse for administration of seasonal influenza vaccine provided by the VFC program.

- If trivalent inactivated seasonal influenza vaccine (IIV3) is provided by the VFC Program and administered to a CHDP patient, continue to use code "53," for administration fee only.
- If quadrivalent inactivated influenza vaccine (IIV4) or LAIV4 is provided by the VFC Program, please await further guidance from the Department of Health Care Services (DHCS), CHDP Program for billing information. CHDP providers with additional questions are advised to contact the Telephone Service Center at 1-800-541-5555.

### **New CPT Codes (Quadrivalent VFC Vaccine) - Please await clarifications for use from Department of Health Care Services before billing Medi-Cal**

| <b>Vaccine</b>        | <b>Presentation</b>        | <b>Licensed Ages</b> | <b>CPT Code</b> |
|-----------------------|----------------------------|----------------------|-----------------|
| Flumist® Quadrivalent | 0.2 mL nasal spray         | 2 through 49 years   | 90672           |
| Fluarix® Quadrivalent | 0.5 mL single-dose syringe | 3 years and older    | 90686           |

A complete list of influenza vaccine products and CPT codes for the 2013-14 influenza season may be found at <http://www.immunize.org/catg.d/p4072.pdf>.

### **QUESTIONS?**

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

Encl: Influenza Vaccine Identification Chart (IMM-859, 8/13)  
Live, Intranasal Influenza Vaccine 2013-14 (7/26/13)  
Inactivated Influenza Vaccine Statement 2013-14 (7/26/13)

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