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TO: Vaccines for Children (VFC) Providers

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SUBJECT: Vaccines for Children (VFC) 2014-15 Seasonal Influenza Vaccine Information

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SUMMARY

The 2014-15 recommendations of the federal Advisory Committee on Immunization Practices (ACIP) on the *Prevention and Control of Seasonal Influenza with Vaccines* are posted at <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html> and published in the August 15, 2014, issue of the *Morbidity and Mortality Weekly Report* (MMWR) at <http://www.cdc.gov/mmwr/pdf/wk/mm6332.pdf> (pp 691-697). Routine annual influenza immunization continues to be recommended for all persons 6 months and older, including all adults. Vaccines for Children (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 two doses of influenza vaccine this season 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 two 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.

VACCINE ABBREVIATIONS

- IIV4 = Inactivated influenza vaccine, quadrivalent
- LAIV4 = Live-attenuated, intranasal influenza vaccine, quadrivalent

2014-15 INFLUENZA VACCINE COMPOSITION (TRIVALENT AND QUADRIVALENT)

The 2014-15 vaccine virus strains in this year's influenza vaccines will contain the same vaccine virus strains as those in the 2013-14 vaccine. For the 2014-15 influenza season, quadrivalent (IIV4 and LAIV4) influenza vaccines will be available from the California VFC Program.

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

- A/California/7/2009 (H1N1)-like
- A/Texas/50/2012 (H3N2)-like
- B/Massachusetts/2/2012-like (B/Yamagata lineage).

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

- B/Brisbane/60/2008-like (B/Victoria lineage).

Persons who received influenza vaccine in last season are recommended to be immunized with 2014-15 influenza vaccine for optimal protection against influenza.

VFC INFLUENZA VACCINE FORMULATIONS

The Vaccines for Children (VFC) Program will make available a variety of licensed quadrivalent influenza vaccines for the 2014-15 influenza season, including:

VFC-eligible children ages 6 through 35 months:

- Fluzone[®] PF Pediatric (sanofi pasteur)
 - Quadrivalent, inactivated [IIV4], intramuscular injection
 - No preservative
 - Available as 0.25mL pre-filled syringes
 - CPT Code: 90685

VFC-eligible children and youth through age 18 years:

- Fluzone[®] (sanofi pasteur)
 - Quadrivalent, inactivated [IIV4], intramuscular injection
 - Preservative-containing (for use in children and adolescents aged 3 through 18 years)
 - Multi-dose vial
 - CPT Code: 90688
- FluMist[®] 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® 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

[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. Older children should be vaccinated in the deltoid muscle.

Live Attenuated Influenza Vaccine (LAIV)

All healthy, non-pregnant children and adolescents 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.

Certain conditions previously considered contraindications to LAIV are now precautions: asthma in children ages 5 years of age and older, and underlying medical conditions that might predispose persons to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)). For additional details on contraindications and precautions, please review the full ACIP recommendations.

Number of doses

Children 9 years and older are recommended to receive one dose of 2014-15 seasonal influenza vaccine.

Children 6 months through 8 years of age are recommended to receive two doses of 2014-15 seasonal influenza vaccine (administered a minimum of 4 weeks apart) in their first season of vaccination.

Since the strains in the 2014-15 seasonal influenza vaccines are identical to those contained in the 2013-14 vaccines, only one dose is required for any child who previously received at least one dose of 2013-14 seasonal influenza vaccine. Two approaches are recommended for determining the number of doses recommended for children aged 6 through 8 years of age.

- The first approach addresses situations in which ascertaining vaccination history before the 2010-2011 influenza season is difficult. See Figure 1 of ACIP's 2014-15 [Prevention and Control of Seasonal Influenza with Vaccines](#) posted at <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>
- The second approach may be used in situations or settings where adequate vaccination history prior to the 2010-2011 season is available. Vaccine dose considerations in ACIP's 2014-2015 [Prevention and Control of Seasonal Influenza with Vaccines](#) are posted at <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>.

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 ACIP's 2014-2015 [Prevention and Control of Seasonal 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.

It is extremely important that prior to the administration of influenza vaccines at your practice, you review the following areas with all staff administering and managing influenza vaccines:

- 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.
- Ensure all unused and expired products from the previous season have been returned to VFC's national vaccine distributor.
- Prepare room in your vaccine storage unit to receive initial vaccine shipments, ensuring that received doses will be labeled appropriately and placed in the pre-designated areas.
- 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.

- PLEASE have clinic staff review your clinic's temperature logs to ensure your vaccine refrigerator has maintained adequate temperatures. Vaccines doses deemed spoiled due to exposure to freezing temperatures may not be readily replaced.
- Ensure all administered doses are logged in either the VFC Program's Influenza Usage Log, in an Immunization Information System, or your clinic's own system. Your clinic will be required to accurately account for all doses of influenza vaccines received through the VFC Program.

We also encourage your practice to discuss and outline key strategies for a successful influenza vaccination season at your practice in order to achieve high influenza vaccination coverage rates of your patients and decrease missed opportunities for vaccination. This may include reminding patients to come in for their annual influenza vaccination, expanding hours for influenza vaccination, allowing influenza vaccine-only visits, and discussing 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 2014-2015](#) 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 2014-15 Influenza VISs are attached. Please discard any remaining copies of the Influenza VIS from prior seasons.

VACCINE ORDERING INSTRUCTIONS AND ACCOUNTABILITY

VFC's On-line Order Confirmation System was open for the submission of requests for 2014-15 seasonal flu vaccine from July 23, 2014 through August 7, 2014. All confirmed orders were reviewed and approved. Notification of final vaccine allocations and approval of brand allocations were sent electronically to the clinic's provider of record.

All confirmed orders will remain in queue until doses become available.

Order Fulfillment and Shipments

Shipment of confirmed orders will begin as soon as adequate inventory of influenza vaccine doses is available at VFC's national distributor, McKesson Specialty Inc. As in previous years, vaccine supply arrives at McKesson in multiple shipments. Therefore, all provider orders are also shipped in increments. The VFC Office will notify providers prior to the processing of each shipment, outlining the expected delivery timeframe and products to be shipped. Order fulfillment information will be posted and updated as necessary on 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.

Supplemental Influenza Vaccine Orders

Providers who did not confirm orders by the August 7, 2014 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.

Vaccine Accountability

As with all other VFC-supplied vaccines, influenza vaccine doses:

- Can only be used for VFC eligible children.
- CANNOT be used for privately insured children or adult patients 19 year of age and older under any circumstance. (This may constitute fraud or abuse of VFC-supplied vaccines.)
- Doses may be administered to under-insured children ONLY at a Federally Qualified Health Center or Rural Health Center.

Vaccine doses administered must be tracked and documented, using a vaccine administration log, immunization registry, or similar system. Doses administered must be reported to the VFC program with each supplemental influenza vaccine order, and total doses administered throughout the season will also be required to be reported at the conclusion of the season.

A sample of VFC's Vaccine Usage log will be included in your clinic's first flu vaccine shipment.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Influenza vaccines must be stored 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.

All influenza vaccine formulations will be shipped to your practice directly from McKesson 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.
- Label vaccine doses as VFC, and place vaccines in the pre-designated VFC Vaccine Supply area of your refrigerator.
- 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.

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

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 once available.

BILLING NOTES

Child Health and Disability Prevention Program (CHDP):

If inactivated, injectable influenza vaccine (IIV4) is provided by the VFC Program and administered to a FFS CHDP patient, please use code "53" for the administration fee on the PM 160 Confidential Screening/Billing Report. If live, attenuated influenza nasal spray vaccine (LAIV4) is provided by the VFC Program and administered to a FFS CHDP patient, please use code "71" for the administration fee on the PM 160 Confidential Screening/Billing Report.

CHDP providers with additional questions are advised to contact their [County CHDP Program](#) at <http://www.dhcs.ca.gov/services/chdp/Pages/CountyOffices.aspx>

Medi-Cal FFS:

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.

Medi-Cal Managed Care:

Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

CPT Codes (Quadrivalent VFC Influenza Vaccine)

Vaccine	Presentation	Ages	CPT Code
Fluzone [®] Quadrivalent	0.25 mL (single dose syringe)	6 through 35 months	90685
Fluzone [®] Quadrivalent	5.0 mL (multi-dose vial)	3 years and older	90688
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 influenza vaccine products and CPT codes may be found at <http://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=cpt>. The Immunization Action Coalition's resource on influenza vaccines and codes is expected to be updated for the 2014-15 season in a few weeks 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.

- Encl: Influenza Vaccine Identification Guide (IMM-859, 7/14)
- Vaccine Usage Log (IMM-1053, 7/14)
- Live, Intranasal Influenza Vaccine (Interim) VIS 2014-15 (8/19/14)
- Inactivated Influenza Vaccine (Interim) VIS 2014-15 (8/19/14)