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TO: Vaccines for Children (VFC) Providers

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SUBJECT: VFC 2015-16 Seasonal Influenza Vaccine Information

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SUMMARY

The 2015-16 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 7, 2015, issue of the [Morbidity and Mortality Weekly Report \(MMWR\)](#). Routine annual influenza immunization continues to be recommended for all persons 6 months and older who do not have contraindications, 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 with at least two doses of influenza vaccine before July 1, 2015, need two doses of influenza vaccine this season for optimal protection.

Optimally, influenza vaccination should occur before onset of influenza activity in the community. Health care providers should begin offering vaccination by October, if possible, and for as long as influenza viruses are circulating. All children aged 6 months through 8 years who are recommended to receive two doses of influenza vaccine 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.

We encourage your practice to implement strategies to achieve high influenza vaccination coverage rates of your patients and decrease missed opportunities for vaccination. This may include plans to remind patients to come in for their annual influenza vaccination and mechanisms to track patients who will be due to return to the practice for a second dose.

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.

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.
- May be administered to under-insured children ONLY at a Federally Qualified Health Center or Rural Health Center.

VACCINE ABBREVIATIONS

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

2015-16 INFLUENZA VACCINE COMPOSITION AND FORMULATIONS

Compared to the 2014-15 influenza vaccine, the 2015-16 influenza vaccines contain different influenza virus strains for the influenza A (H3N2) and influenza B (Yamagata lineage) strains.

For the 2015-16 influenza season, the California VFC Program is offering only quadrivalent (IIV4 and LAIV4) influenza vaccines representing the following strains:

- A/California/7/2009 (H1N1)-like
- A/Switzerland/9715293/2013 (H3N2)-like
- B/Phuket/3073/2013-like (B/Yamagata lineage)
- B/Brisbane/60/2008-like (B/Victoria lineage) – [Not in trivalent influenza vaccines]

See table on next page for product-specific information.

Ages	Product	Special Use Instructions	Administration	CPT Code
VFC-eligible children ages 6 - 35 months	Fluzone [®] PF Pediatric (Sanofi Pasteur), Quadrivalent- inactivated [IIV4], 0.25mL single-dose pre-filled syringes	No preservative.	IM injection	90685
VFC-eligible children and adolescents through 18 years (See additional age restrictions in 3 rd column of this table)	Fluzone [®] (Sanofi Pasteur), Quadrivalent, inactivated [IIV4], Multi-dose vial.	*Preservative-containing. DO NOT USE in children under 3 years of age or pregnant adolescents.	IM injection	90688
	FluMist [®] (MedImmune), Quadrivalent, live, attenuated intranasal vaccine [LAIV4], 0.2 mL single-use sprayer.	No preservative. Use for healthy children and adolescents aged 2 through 18 years of age (non-pregnant)	Intranasal	90672
	Fluarix [®] (GlaxoSmithKline), Quadrivalent, inactivated [IIV4], 0.5 mL single-dose pre-filled syringes	No preservative. Use for children and youth ages 3 through 18 years (including pregnant women)	IM injection	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.

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 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.

For details on LAIV contraindications and precautions, please review the full [ACIP recommendations](#).

Vaccine Type

If more than one type of vaccine is appropriate and available for a specific person, ACIP does not express a preference for use of any particular vaccine product over another. An age-appropriate vaccine formulation should be used. No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate. Providers should not delay vaccination to procure a specific vaccine preparation.

Number of doses

Children 9 years and older are recommended to receive one dose of 2015-16 seasonal influenza vaccine.

Children 6 months through 8 years of age

If they received two or more doses of influenza vaccine before July 1, 2015, only one dose of influenza vaccine is needed for 2015-16. The two previous doses are not required to have been given during the same or consecutive seasons.

If they received less than two doses of influenza vaccine before July 1, 2015, two doses of 2015-16 influenza vaccine are needed. The interval between the two doses should be least 4 weeks apart. See Figure 1 of ACIP's 2015-16 [Prevention and Control of Seasonal Influenza with Vaccines](#) posted at <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>

Egg Allergy

Most persons with a history of egg allergy may receive influenza vaccine in accordance with the algorithm in ACIP's 2015-2016 [Prevention and Control of Seasonal Influenza with Vaccines](#). 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.

Reporting of Suspected Vaccine Reactions or Errors

Providers should report suspected reactions to influenza vaccines or any other vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

Providers should report any vaccine administration error and associated contributing factors to the National Vaccine Errors Reporting Program (VERP) at <http://verp.ismp.org/>. Examples of potential errors include a 0.5 mL influenza vaccine prefilled syringe dose administered to a 1 year old or a vaccine licensed only for adults 18 years and older administered to an 8 year old. As a part of the report, providers can make recommendations for error prevention. This surveillance program aims to prevent future errors by identifying trends, creating targeted education efforts, and making changes to product labeling and design.

VACCINE INFORMATION STATEMENTS (VISs)

The appropriate influenza [Vaccine Information Statement \(VIS\) for Inactivated or Live, Attenuated Influenza Vaccine \(LAIV\) for 2015-2016](#) 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 2015-16 Influenza VISs are attached. Please discard any remaining copies of the Influenza VIS from prior seasons.

VACCINE MANAGEMENT AND TRAINING

Preparations for the Receipt of 2015-2016 Influenza Vaccine Doses

Prepare room in your vaccine storage unit to receive initial vaccine shipments, and ensure that received doses will be labeled appropriately and placed in the pre-designated areas.

Ensure all unused and expired products from the previous season have been returned to VFC's national vaccine distributor.

Clinic staff should review your clinic's temperature logs to ensure your vaccine refrigerator is maintaining adequate temperatures. Any inactivated influenza products that are exposed to freezing temperatures cannot be used.

Storage 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. Vaccines doses deemed spoiled due to exposure to freezing temperatures may not be readily replaced.

All influenza vaccine formulations 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 out-of-range 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.)

Staff 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.

Prior to the administration of this season's influenza vaccines at your practice, providers should 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.
- **Review vaccine eligibility and tracking procedures.** Log all VFC-administered doses 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.

VACCINE ORDERING INSTRUCTIONS AND ACCOUNTABILITY

VFC's On-line Order Confirmation System was open for the submission of requests for 2015-2016 seasonal influenza vaccine from July 17 through August 4, 2015. 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. 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 4th 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

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 influenza vaccine shipment.

PROMOTING INFLUENZA 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 unused or spoiled seasonal influenza vaccine (including vials, syringes, and nasal sprayer packages) received from VFC to the program during the 2014-2015 season.

To return vaccine:

- Submit a completed VFC Return Form through [MYVFCVaccines](#). A Return Form MUST be submitted to VFC prior to sending vaccines to McKesson Specialty.
- Request return shipping labels; these should arrive at your office within 10 business days.
- Keep the returned doses in their original packaging. 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 are 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 Fee For Service (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 2015-16 season 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, 7/15)
Vaccine Usage Log (IMM-1053, 7/15)
Live, Intranasal Influenza Vaccine (Interim) VIS 2015-16 (8/7/15)
Inactivated Influenza Vaccine (Interim) VIS 2015-16 (8/7/15)