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

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TO: Vaccines for Children (VFC) Providers

FROM: Sarah Royce, M.D., M.P.H., Chief, Immunization Branch
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SUBJECT: VFC 2017-18 Seasonal Influenza Vaccine Information

SUMMARY

The 2017-18 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 25, 2017 issue of the Morbidity and Mortality Weekly Report (MMWR).

Routine annual influenza immunization with inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) continues to be recommended for all persons 6 months and older who do not have contraindications. Influenza causes significant illness, medical visits, hospitalizations, and death each year. Influenza vaccines continue to be the best way to prevent influenza.

As in the 2016-17 season, ACIP continues to **not** recommend that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine or Flumist®, be used during the 2017-2018 influenza season. This recommendation reflects data showing low effectiveness of

LAIV against influenza A(H1N1)pdm09 viruses in the United States during the 2013-2014 and 2015-16 influenza seasons, as summarized at http://www.cdc.gov/media/releases/2016/s0622-laiv-flu.html.

Accordingly, LAIV will not be available from the VFC Program for the 2017-2018 influenza season. The VFC Program has replaced doses of LAIV with single-dose syringe doses of different influenza vaccine formulations: Flucelvax® and FluLaval®.

Optimally, vaccination should occur before onset of influenza activity in the community. Vaccination should be offered by end of October, if possible, and for as long as influenza viruses are circulating and unexpired vaccine is available.

Children younger than 9 years of age who have not been previously immunized with at least two doses of influenza vaccine before July 1, 2017 need two doses of influenza vaccine this season for optimal protection. 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.

Recommendations for influenza vaccine for persons with egg allergy are described in this letter; see the ACIP recommendations for full details.

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 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 years of age and older under any circumstance; this may constitute fraud or abuse of VFC-supplied vaccines.
- Doses may be administered to underinsured children ONLY at a Federally Qualified Health Center or Rural Health Center.

VACCINE ABBREVIATIONS

- IIV4 = Inactivated influenza vaccine, quadrivalent
- LAIV=live, attenuated influenza vaccine

2017-18 INFLUENZA VACCINE COMPOSITION AND FORMULATIONS

For the 2017-18 influenza season, the California VFC Program is offering only quadrivalent influenza vaccines representing the following strains:

- A/Michigan/45/2015 (H1N1)pdm09-like virus*
- A/Hong Kong/4801/2014 (H3N2)-like

- B/Brisbane/60/2008-like (B/Victoria lineage)
- B/Phuket/3073/2013-like (B/Yamagata lineage) – [Not in trivalent influenza vaccines].

*change in strain from the 2016-17 formulation

VFC Program options for the 2017-2018 influenza season include:

Ages	Product	Volume Per Dose	Special Notes	Administration	CPT Code
6 - 35 months	Fluzone® PF Pediatric (Sanofi Pasteur), Quadrivalent-inactivated [IIV4], 0.25 mL pre-filled syringes.	0.25 mL	No preservative.	IM injection	90685
	FluLaval® (GlaxoSmithKline), Quadrivalent, inactivated [IIV4], 0.5 mL single-dose pre-filled syringes.	0.5 mL	No preservative. Product now licensed for use in persons 6 months of age and older. FluLaval® dosage is the same, 0.5mL, for both age groups.	IM injection	90686
3 - 18 years	Fluzone® (Sanofi Pasteur), Quadrivalent, inactivated [IIV4], Multi-dose vial.	0.5 mL	Preservative-containing. **DO NOT USE** in children under 3 years of age or pregnant adolescents.	IM injection	90688
	FluLaval® (GlaxoSmithKline), Quadrivalent, inactivated [IIV4], 0.5 mL single-dose pre-filled syringes.	0.5 mL	No preservative. Use for children and youth ages 6 months through 18 years (including pregnant teens).	IM injection	90686
	Flucelvax® (Sequiris), Quadrivalent, cell-culture derived, inactivated [ccIIV4], 0.5 mL single-dose pre-filled syringes.	0.5 mL	Use for children and youth ages 4 through 18 years (including pregnant teens).	IM injection	90674

Note: Unlike Fluzone® products, the dosage for FluLaval® is the same, 0.5 mL, for all ages.

More information on VFC influenza vaccines offered for 2017-18 is available in the Food and Drug Administration (FDA) information and ACIP recommendations.

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.** VFC 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 and youth 36 months of age and older, one dose is 0.50 mL.
- For children 6 through 35 months of age, the dose differs by product:
  - Fluzone: 0.25 mL
  - FluLaval: 0.5 mL
  - Care should be taken to administer the correct dose. Avoid errors by double-checking doses and administering the entire syringe contents of the age-appropriate formulation.

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.

When administering vaccines, keep in mind the following:

- Single-dose vials should not be accessed for more than one dose
- Do Not use half of a 0.5 ml syringe for 6-35 months infants and waste the rest
- Do Not split a 0.5 ml syringe into two 0.25 ml doses for ages 6-35 months
- Do Not combine two doses of 0.25 ml to make a 0.5 ml dose OR administer two doses of 0.25 ml to a patient to make a 0.5 ml dose

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

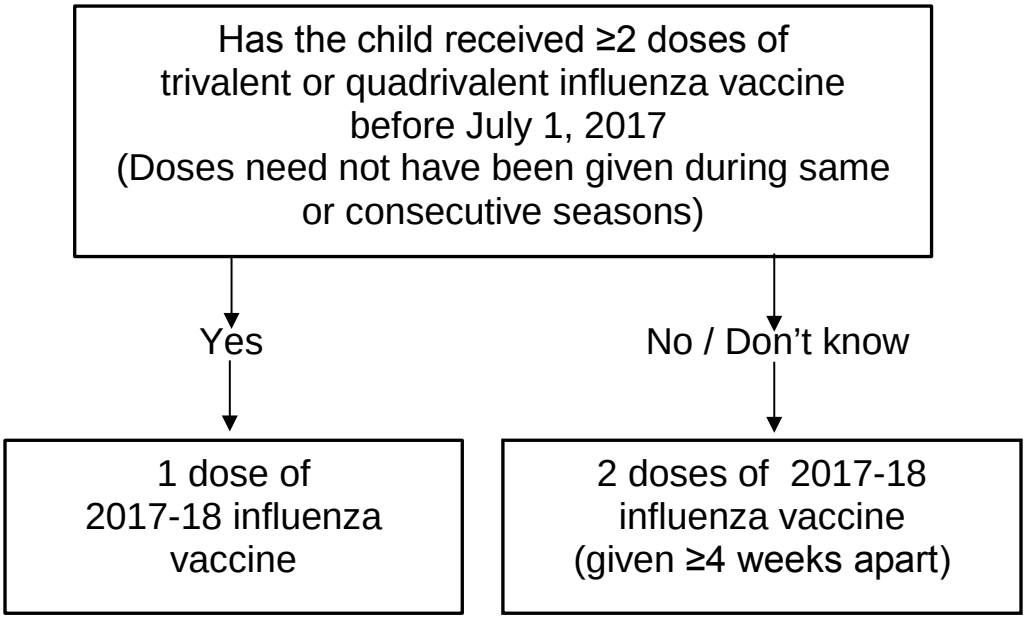
Vaccine Type

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. ACIP did not recommend use of the LAIV for the 2017-18 influenza season. Providers should not delay vaccination to procure a specific vaccine preparation.

Number of doses of 2017-18 seasonal influenza vaccine recommended

Children 9 years and older: One dose.

Children 6 months through 8 years of age:



From: *Prevention and Control of Seasonal Influenza with Vaccines Recommendations of the Advisory Committee on Immunization Practices.* MMWR. Recomm Rep 2017;66(2); 1-20. https://www.cdc.gov/mmwr/volumes/66/rr/pdfs/rr6602.pdf]

Current ACIP Recommendations for Persons with Egg Allergy

- Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury if syncope occurs, per the ACIP General Recommendations on Immunization. (In prior years, egg-allergic recipients were recommended to be observed for possible allergic reactions for 30 minutes postvaccination; this has been revised.)
- Persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives) should be vaccinated with any licensed and recommended influenza vaccine (for the patient's age and health status) in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions.
- Persons with a history of egg allergy who have experienced only hives after egg exposure should continue to receive influenza vaccine (i.e., any age-appropriate IIV or RIV3) that is otherwise appropriate for the recipient's age and health status.
- A previous severe allergic reaction to influenza vaccine, regardless of the component, continues to be a contraindication to future receipt of the vaccine.

For more details, please see ACIP's 2017-2018 *Prevention and Control of Seasonal Influenza with Vaccines*.

Reporting of Suspected Vaccine Reactions or Errors
Providers should report suspected reactions to influenza vaccines or any other vaccine to the Vaccine Adverse Events 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 only half the content of a pre-filled syringe dose administered to a 1 year old, or a vaccine licensed only for adults 65 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 inactivated influenza Vaccine Information Statement 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 latest influenza VISs are attached. There has been no change in the VIS since last season. The current inactivated influenza vaccine VIS version date is 8/7/2015.

VACCINE MANAGEMENT AND TRAINING

Vaccine Storage and Handling

Influenza vaccines must be stored at a temperature range of 35°F to 46°F (2°C to 8°C). Vaccine doses deemed spoiled due to exposure to out-of-range temperatures may not be readily replaced.

Do not freeze or expose vaccines to out-of-range temperatures. Vaccine that has been frozen or deemed non-viable by a vaccine manufacturer may not be used and should be return to the VFC program according to established guidelines. Multiple-dose vials should be returned to recommended storage conditions between uses.

Vaccines should not be used after the expiration date on the label.

Vaccine Shipments

Prior to the receipt of vaccines:

- 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.
- Prepare room in your vaccine storage unit to receive initial vaccine shipments. Pre-designate areas and label them appropriately in order to be ready to receive and readily store doses.
    - Label shelf space or bins according to the two age groups: 6-35 months and 3-18 years.
- Ensure all unused and expired influenza products from the previous season have been removed from the refrigerator and returned to VFC's national vaccine distributor.

All vaccine shipments must be inspected, verified, and stored in the appropriate refrigerator unit immediately upon receipt.

Proper receipt of shipment includes the following steps:

- 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.
    - Practices receiving Flulaval® doses for both age groups (6-35 months and 3-18 years) should refer to the shipment's packing slip, and label doses for each group accordingly in order to assist with inventory levels for each group and facilitate re-ordering.
- 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

Prior to beginning 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. Use the "Influenza Vaccine Identification Chart" to help you identify all available influenza vaccines, including formulations that are not provided by the VFC Program.
- Review VFC eligibility, documentation, and tracking guidelines.
- Implement a yearly competency review of all staff administering any vaccine formulation, including influenza, as well as staff with temperature monitoring responsibilities.

VACCINE ORDERING INSTRUCTIONS AND ACCOUNTABILITY

Ordering Instructions

VFC's Online Order Confirmation System was open for the submission of requests for 2017-2018 seasonal influenza vaccine from August 17 through August 31, 2017. All confirmed orders were reviewed and approved. Notification of final vaccine confirmations have been sent electronically to the clinic's Vaccine Coordinator and Backup Vaccine Coordinator.

During VFC's order confirmation period, providers requested brand allocation changes in the 6-35 month age category beyond available doses received from the Centers for Disease Control and Prevention (CDC). Therefore, your final order confirmation will reflect final approved products and may differ from your submitted request.

For this influenza season, the following two vaccine products are licensed, with ACIP recommendations, and are appropriate for use in children 6 through 35 months of age: Fluzone® Pediatric (0.25 mL dose) and FluLaval® (0.5 mL dose). Any of these 2 available licensed, age-appropriate influenza vaccine products should be used to immunize children in this age range. Vaccination should not be delayed in order to obtain a specific product when an appropriate one is already available. Within these guidelines and approved indications, where more than one type of vaccine is appropriate and available, ACIP has expressed no preferential recommendation for use of any influenza vaccine product over another.

Order Fulfillment
All confirmed orders will remain in queue until doses become available. Be prepared to receive confirmed doses in multiple vaccine shipments (three or four shipments) over the course of the next two months, as the program's vaccine supply arrives at McKesson in multiple shipments as well. Once initial shipments are processed, the remaining order balances for partial shipments are automatically processed and shipped as additional vaccine doses become available.

The VFC program will issue advance notifications with the processing of shipments. In order to prevent any returned shipments due to outdated clinic open hours, make sure clinic hours of operation are current in your MYVFCVaccines account.

Supplemental Influenza Vaccine Orders
Providers who did not confirm orders by the August 31 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 online site is ready to receive provider orders.

Vaccine Accountability
Review vaccine eligibility and tracking procedures with all staff that will be managing and administering vaccines. All VFC-administered doses must be logged in either the VFC Program's 2017-2018 Flu Usage Log, in an Immunization Information System, or your clinic's own system. Your clinic is required to accurately account for all doses of influenza vaccines received through the VFC Program, by age group, with each supplemental vaccine request, or upon request from the VFC Program. Providers will be required to report vaccine inventory and usage with each supplemental vaccine request. Additionally, VFC providers will be required to report the total number of vaccine doses administered at the end of the influenza season, as recorded on the clinic's VFC's 2017-2018 Flu Usage Log, Registry, or similar tracking system.

RETURN OF UNUSED INFLUENZA VACCINE

VFC Providers must return all expired, unused or spoiled seasonal influenza vaccine doses received from VFC to the program during the 2017-2018 influenza season. VFC Returns must be submitted through MYVFCVaccines **prior** to sending vaccines to our national vaccine distributor McKesson Specialty.

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/.

BILLING NOTES

Child Health and Disability Prevention Program (CHDP)
Please refer to relevant CHDP Provider Information Notices on influenza vaccines and any relevant Medi-Cal Bulletin Newsflashes.

In addition, 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 Fee for Service (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 be reimbursed only 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
FluLaval® Quadrivalent	0.5 mL (single-dose syringe)	6 months and older	90686
Fluzone® Quadrivalent	5.0 mL (multi-dose vial)	3 years and older	90688
Flucelvax® Quadrivalent	0.5 mL (single-dose syringe)	4 years and older	90674

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 for the 2017-18 influenza season is posted at: http://www.immunize.org/catg.d/p4072.pdf

QUESTIONS?

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

Resources
AAP Influenza Resources and Recommendations

AAP Influenza Implementation Guidance

ACIP 2017-18 Recommendations: Prevention and Control of Seasonal Influenza with Vaccines

Enclosures

Influenza Vaccine Identification Guide (IMM-859, 8/17)

Flu Usage Log (IMM-1053F, 7/17)

Inactivated Influenza Vaccine VIS (8/7/15)