

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



EDMUND G. BROWN JR. Governor

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TO: Vaccines for Children (VFC) Providers

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SUBJECT: VFC 2018-19 Seasonal Influenza Vaccine Information

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SUMMARY

The 2018-2019 recommendations of the federal Advisory Committee on Immunization Practices (ACIP) on the <u>Prevention and Control of Seasonal Influenza with Vaccines</u> are posted at <u>http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html.</u>

Routine annual influenza immunization with any licensed, age-appropriate influenza vaccine (inactivated, live, or recombinant) is 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.

ACIP has expressed no preference for any influenza vaccine product for the 2018-2019 season. During two prior influenza seasons, ACIP did not recommend that live attenuated influenza vaccine (LAIV, trade name FluMist[®]) be used because of concerns regarding its effectiveness against influenza A(H1N1)pdm09 viruses in the United States during the 2013-2014 and 2015-16 influenza seasons. After review in 2018 of more recent immunogenicity data, ACIP is again recommending that LAIV be an option for influenza vaccination of persons for whom it is appropriate. Because the California VFC Program had already completed its purchases of influenza vaccine before LAIV became recommended and available for 2018-2019 season, LAIV is not an option for VFC providers this season.

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.

Emphasis should be placed on vaccination of high-risk groups, including children aged 6-59 months, American Indians/Alaska Natives patients, children with chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus); pregnant teens; and children and adolescents (aged 6 months through 18 years) receiving aspirin- or salicylate-containing medications and who might be at risk for Reye syndrome.

Children younger than 9 years of age who have not been previously immunized with at least two doses of influenza vaccine before July 1, 2018 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.

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 may 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:

- May only be used for VFC-eligible children.
- MAY NOT 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

2018-19 INFLUENZA VACCINE COMPOSITION AND FORMULATIONS

For the 2018-2019 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/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus*;
- B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage)*;
- B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage).

*change in strain from the 2017-18 formulation

VFC Program products for the 2018-2019 influenza season include:

Products All Quadrivalent and inactivated	Dose Volume	Ages	СРТ
Fluarix [®] (GlaxoSmithKline) 0.5 mL pre-filled syringes	0.5 mL	6 months of age and older; 0.5mL dose for <u>all ages</u> .	90686
FluLaval [®] (GlaxoSmithKline) 0.5 mL pre-filled syringes	0.5 mL	6 months of age and older; 0.5mL dose for <u>all ages</u> .	90686
Fluzone [®] (Sanofi Pasteur) Multi-dose vial	0.5 mL	Per California law, 3 years and older and not pregnant (contains thimerosal)	90688
Fluzone [®] PF Pediatric (Sanofi Pasteur) 0.25 mL pre-filled syringes (<i>limited supply</i>)	0.25 mL	6 – 35 months	90685
Flucelvax [®] (Sequiris) cell-culture derived, 0.5 mL pre-filled syringes (<i>limited supply</i>)	0.5 mL	4 years and older	90674

More information on VFC influenza vaccines offered for 2018-2019 is available in the Food and Drug Administration (FDA) information and ACIP recommendations.

According to <u>California law</u>, 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)]. **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:
 - o Fluzone: 0.25 mL
 - FluLaval and Fluarix: 0.5 mL
 - <u>Care should be taken to administer the correct dose.</u> Avoid errors by doublechecking doses and administering the entire syringe contents of the ageappropriate 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.

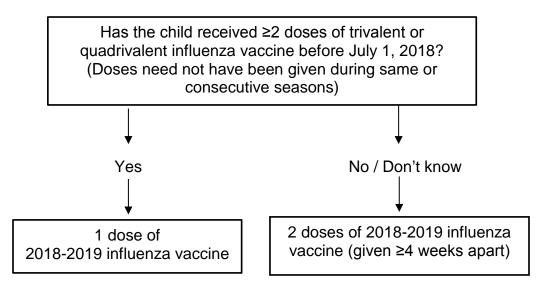
Inactivated influenza vaccine should be administered intramuscularly in the anterolateral aspect of the thigh for infants and young children. Older children and adults should be vaccinated in the deltoid muscle.

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 ageappropriate vaccine formulation should be used. Providers should not delay vaccination to procure a specific vaccine preparation.

Number of doses of 2018-2019 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 2018;67(3); 1-20. https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6703a1-H.pdf]

Although the volume of doses for children 6 to 35 months varies by vaccine formulation, the recommendations for the number of doses do not depend on the formulation; e.g., a child who is 6 months of age this autumn is recommended to receive two doses, regardless of whether the formulation used for the first dose was a volume of 0.25 ml or 0.5 ml.

Current ACIP Recommendations for Persons with Egg Allergy

- Providers should consider observing <u>all patients</u> for 15 minutes after vaccination to decrease the risk for injury if syncope occurs, per the <u>ACIP General Recommendations on</u> <u>Immunization</u>.
- 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 2018-2019 *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 <u>inactivated influenza Vaccine Information Statement</u> 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 36°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 returned to the VFC program according to established guidelines.

Single-dose vials should not be accessed for more than one dose.

Multiple-dose vials should be returned to recommended storage conditions between uses.

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

PROMOTING INFLUENZA VACCINATION IN YOUR OFFICE

Clinicians play a critical role in taking action to patients under their care, their families, and even clinic staff. Every visit with a patient is an opportunity to recommend an influenza vaccine. Work with clinic staff to ensure influenza vaccination status is assessed at every visit from September through March.

According to CDC, a health care professional's strong recommendation is a critical factor that affects whether your patients receive an influenza vaccine. Although most adults believe vaccines are important for them and their children, a reminder from your practice, or offer of a vaccine during the same office visit, will make a difference to get them vaccinated and protected this influenza season.

CDC suggests using the **SHARE** five-part approach to make a strong flu vaccine recommendation to enable patients to make informed decisions about flu vaccination:

- **SHARE** the tailored reasons why the recommended vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors.
- **HIGHLIGHT** positive experiences with vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in vaccination.
- **ADDRESS** patient questions and any concerns about the vaccine, including side effects, safety, and vaccine effectiveness in plain and understandable language.
- **REMIND** patients that vaccines protect them and their loved ones from many common and serious diseases.
- **EXPLAIN** the potential costs of getting the disease, including serious health effects, time lost (such as missing work or family obligations), and financial cost.

Work with clinic staff to ensure email reminders are sent or phone reminders are completed to remind your patients to make an appointment before influenza season. Equally as important is to ensure procedures are in place to follow-up with missed appointments, especially with high-risk patients.

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.

BILLING NOTES

Child Health and Disability Prevention Program (CHDP)

Please refer to relevant <u>CHDP Provider Information Notices</u> on influenza vaccines and any relevant Medi-Cal Bulletin Newsflashes.

In addition, CHDP providers with additional questions are advised to contact their <u>County CHDP</u> <u>Program</u> at <u>http://www.dhcs.ca.gov/services/chdp/Pages/CountyOffices.aspx</u>

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 <u>Medi-Cal provider</u> <u>manual</u> on VFC. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the <u>Telephone Service Center (TSC)</u> 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) – See Table on Page 3

A complete list of influenza vaccine products and CPT codes may be found at <u>http://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=cpt.</u> The Immunization Action Coalition's resource on influenza vaccines for the 2017-18 influenza season is posted at: <u>http://www.immunize.org/catg.d/p4072.pdf</u>

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 <u>www.eziz.org</u>.

Resources

- AAP Influenza Implementation Guidance and links to Resources
- <u>ACIP 2018-2019 Recommendations: Prevention and Control of Seasonal Influenza with Vaccines</u>

Enclosures

- Influenza Vaccine Identification Guide (IMM-859, 9/18)
- Flu Usage Log (IMM-1053F, 8/18)
- Inactivated Influenza Vaccine VIS (8/7/15)