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TO: Vaccines for Children (VFC) Providers

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Center for Infectious Diseases

SUBJECT: VFC 2020-2021 Seasonal Influenza Vaccine Information

Key takeaways from this letter:

- Annual influenza immunization with any licensed, age-appropriate influenza vaccine is recommended for all persons 6 months and older.
- Summary of Advisory Committee on Immunization Practices’ (ACIP) recommendations for the 2020-2021 influenza season.
- Although COVID-19 vaccines are not yet available, you should vaccinate against influenza to prevent comorbidities and to avoid putting a strain on the healthcare system. Resources included in the letter may help in your planning efforts.

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SUMMARY

The California VFC Program has begun shipments of influenza vaccines products received at VFC’s national vaccine distributor. Please begin immunization as soon after you receive vaccine, before onset of influenza activity, and continue to offer vaccine as long as unexpired vaccine is available.
This influenza season coincides with the COVID-19 virus pandemic. Enhanced efforts to immunize all patients in your practice this season will help reduce the:

- Prevalence of influenza disease, thus reducing potential confusion with COVID-19
- Potential impact of influenza on healthcare provider visits
- Stress and impact on hospitals and healthcare systems.

The federal Advisory Committee on Immunization Practices’ (ACIP) recommendations for the 2020-2021 influenza season are posted at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html, and summarized here to assist your practice.

**VACCINATION STRATEGY**

- Annual influenza immunization with any licensed, age-appropriate influenza vaccine is recommended for all persons 6 months and older who do not have contraindications.

- Emphasis should be placed on vaccination of high-risk groups, including children aged 6–59 months; American Indians/Alaska Natives; children with chronic pulmonary conditions (including asthma); cardiovascular disease (excluding isolated hypertension); renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus); pregnant teens; and those 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, 2020 need two doses of influenza vaccine this season for optimal protection.

- Children needing two doses of influenza vaccines should receive their first dose as soon as possible after vaccine becomes available in order to receive the second dose (which must be administered ≥4 weeks later) by the end of October.

- We encourage your practice to implement strategies to achieve high vaccination coverage. This may include plans to remind patients to come in for their annual influenza vaccination and tracking patients due for a second dose. Please refer to the “Flu Action Plan: 3 Habits of Highly Successful VFC Clinics” for additional strategies.

- Influenza vaccination may serve as a catch-up opportunity for other pediatric and adolescent immunizations which may have been delayed due to the impact of the COVID-19 pandemic. Administer all due or overdue vaccines within the same visit.

- In situations which influenza vaccination is delayed, patients should be reminded to return for influenza vaccination once they have recovered from their acute illness.

**ELIGIBILITY FOR VFC-SUPPLIED SEASONAL INFLUENZA VACCINE**

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 from VFC can only be used for VFC-eligible children. Use in privately insured children or adult patients 19 years of age and older may constitute fraud or abuse of VFC-supplied vaccines. Note: Underinsured children may receive VFC supplied vaccines ONLY at a Federally Qualified Health Center or Rural Health Center.
Eligibility screening and documentation of eligibility must occur at every immunization encounter (including special vaccination efforts, such as drive-up flu clinics). In order to meet VFC’s vaccine accountability requirements, make sure you have systems in place to document and track administration of VFC supplied vaccines (i.e. an Immunization Registry, clinic’s Electronic Health Record, or VFC’s usage log). It is required that you submit influenza vaccine usage as part of your routine vaccine ordering, whether or not flu vaccine doses are ordered.

2020-2021 INFLUENZA VACCINE COMPOSITION AND FORMULATIONS

For the 2020-2021 influenza season, the California VFC Program is offering only quadrivalent, inactivated influenza vaccines representing the following strains:

- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus* ^
- A/Hong Kong/2671/2019 (H3N2)-like virus*
- B/Washington/02/2019 (B/Victoria lineage)-like virus*
- B/Phuket/3073/2013-like (Yamagata lineage) virus.

*change in strain from the 2019-20 formulation
^ cell-based vaccine uses instead an A/Hawaii/70/2019 (H1N1)pdm09-like virus

VFC Program products for the 2020-2021 influenza season include:

<table>
<thead>
<tr>
<th>Products</th>
<th>Dose Volume</th>
<th>Minimum Age in California</th>
<th>CPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluarix® pre-filled syringes</td>
<td>0.5 mL at all ages</td>
<td>6 months</td>
<td>90686</td>
</tr>
<tr>
<td>FluLaval® pre-filled syringes</td>
<td>0.5 mL at all ages</td>
<td>6 months</td>
<td>90686</td>
</tr>
<tr>
<td>Fluzone® pre-filled syringes</td>
<td>0.5 mL at all ages</td>
<td>6 months</td>
<td>90686</td>
</tr>
<tr>
<td>Afluria® pre-filled syringes</td>
<td>0.25mL</td>
<td>6 months</td>
<td>90685</td>
</tr>
<tr>
<td>FluMist® pre-filled syringes</td>
<td>0.2 mL</td>
<td>2 years; and not pregnant*</td>
<td>90672</td>
</tr>
<tr>
<td>Fluzone® Multi-dose vial</td>
<td>0.5 mL</td>
<td>3 years; and not pregnant*</td>
<td>90688</td>
</tr>
<tr>
<td>Flucelvax® pre-filled syringes</td>
<td>0.5 mL</td>
<td>4 years</td>
<td>90674</td>
</tr>
</tbody>
</table>

*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)]. 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

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 dosage of most VFC influenza vaccines this season regardless of age is 0.50 mL.
- Exceptions:
  - FluMist®: The dosage for children 2 years of age and older for is 0.20 mL.
  - Fluzone®: is available for private purchase in two options (0.25 mL and 0.50 mL); however, only the 0.50 mL formulation is available from VFC;
Afluria®: The dosage for children 6 to 35 months is 0.25 mL;
• Multi-dose vial Fluzone® formulation (5mL): VFC supply only for children 3 years of age and older in CA.

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:
• DO NOT access more than one dose from a single-dose vial
• DO NOT use half of a 0.5 ml syringe for infants 6-35 months of age 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
• DO NOT 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. Providers should not delay vaccination to procure a specific vaccine preparation.

Number of doses of 2020-2021 seasonal influenza vaccine by age
Children 9 years and older: One dose.
Children 6 months through 8 years of age:

Has the child received ≥2 doses of trivalent or quadrivalent influenza vaccine before July 1, 2020? (Doses need not have been given during same or consecutive seasons)

Yes

No / Don’t know

1 dose of 2020-2021 influenza vaccine

2 doses of 2020-2021 influenza vaccine (given ≥4 weeks apart)

From: https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm

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.
• 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.

- Additional measures for those with a history of severe allergic reaction to egg are needed only if a vaccine other than ccIIV4 or RIV4 is used.

- For more details, please see https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm

ACIP Recommendations for Influenza Vaccination of Persons with COVID-19 Infection

Because SARS-CoV-2 is a novel coronavirus, clinical experience with influenza vaccination of persons with COVID-19 is limited. For those who have acute illness with suspected or laboratory-confirmed COVID-19, clinicians can consider delaying influenza vaccination until the patients are no longer acutely ill. If influenza vaccination is delayed, patients should be reminded to return for influenza vaccination once they have recovered from their acute illness.

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 are encouraged to report any vaccine administration errors to the National Vaccine Errors Reporting Program (VERP) at http://verp.ismp.org/. Examples of potential errors include administering half the content of a pre-filled syringe dose to a 1 year old, or a vaccine licensed only for adults 65 years and older to an 8 year old. In their reports, providers may make recommendations for error prevention. This surveillance program aims to prevent future errors.

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 8/15/2019.

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. “Beyond-use-date” (manufacturer-specified days for use once a multi-dose vial stopper has been punctured) differs for some influenza vaccine products. Please carefully refer to the package insert of any multi-dose vaccine products your clinic may be receiving this reason.
• The 2020-2021 FluMist Quadrivalent Replacement Program will allow for the replacement of unused, expiring FluMist Quadrivalent doses, received through the VFC Program with expiration dates on or before January 31, 2021.

FLU PLANNING
As the influenza season nears, it is imperative to prepare as soon as possible to protect your patients from influenza disease. Although COVID-19 vaccines are not yet available, you should vaccinate against influenza to prevent comorbidities and to avoid putting a strain on the healthcare system. The following resources may help in your planning efforts, including preparing for modified operations for delivery of essential immunization services during the COVID-19 pandemic:
• Use “VFC’s Flu Action Plan: 3 Habits of Highly Successful VFC Clinics” to help your clinical team prepare for the upcoming flu season.
• Discuss strategies with your staff on how you will be administering influenza vaccines while preventing the spread of COVID19.
• Watch VFC’s TEAch webinar on “Updated Guidance for Immunization During COVID-19”
• Refer to the “Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations” from the Centers for Disease Control and Prevention (CDC)
• Refer to CDC’s Guidance for Planning Curbside Vaccination Clinics
• Refer to Immunization Summit Partners ‘Best Practices for Vaccination Clinics held at Satellite, Temporary or Off-site Locations’

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

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.

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 http://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt= cpt.

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 Implementation Guidance and links to Resources
- ACIP 2020-2021 Recommendations: Prevention and Control of Seasonal Influenza with Vaccines
- CDC’s Guidance for Planning Curbside Vaccination Clinics

Enclosures
- Influenza Vaccine Identification Guide (IMM-859, 7/20)
- Flu Usage Log (IMM-1053F, 7/20)
- VFC’s Flu Action Plan: 3 Habits of Highly Successful VFC Clinics (IMM-1274, 9/20)
- Inactivated Influenza Vaccine VIS (8/15/19)
- Live Attenuated Influenza Vaccine VIS (8/15/19)
- FluMist Quadrivalent Replacement Program 2020-21 Season