



MARK B HORTON, MD, MSPH
Director

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



ARNOLD SCHWARZENEGGER
Governor

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TO: Vaccines for Children (VFC) Providers

FROM: John Talarico, D.O., M.P.H., Chief *John Talarico, D.O.*
Center for Infectious Diseases
Division of Communicable Disease Control, Immunization Branch

SUBJECT: VFC 2010-11 Seasonal Influenza Vaccine Information

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SUMMARY

The [federal Advisory Committee on Immunization Practices \(ACIP\) recently published its 2010 Influenza Recommendations](#), consistent with the [2010 VFC Influenza Vaccine Resolution](#).

All children and persons 6 months and older, including all adults, are recommended for immunization against influenza beginning as soon as the vaccine is available (although VFC vaccine cannot be used in persons older than 18 years of age). Protection of persons at higher risk for influenza-related complications should continue to be a focus of vaccination efforts as providers transition to universal vaccination.

Providers were previously sent instructions for confirming 2010-11 seasonal influenza vaccine doses allocated to their practices through California’s VFC Seasonal Influenza On-line Order Confirmation System, available at www.eziz.org. The system was launched on July 26, 2010 and allowed providers a number of weeks to log-in, review, edit and confirm doses allocated to their practices.

2010-2011 INFLUENZA VACCINE COMPOSITION

The 2010-2011 trivalent vaccine virus strains in this year's influenza vaccine, representative of viruses that are anticipated to circulate in the U.S. during the 2010-11 influenza season, are:

- A/California/7/2009 (H1N1)-like--*Note: the same strain is in the 2009-10 pandemic influenza A(H1N1) monovalent vaccine.*
- A/Perth/16/2009 (H3N2)-like
- B/Brisbane/60/2008-like

Both inactivated and live-attenuated influenza vaccines are grown in eggs.

VFC INFLUENZA VACCINE FORMULATIONS

The Vaccines for Children (VFC) Program will make available a variety of licensed influenza vaccines for the 2010-2011 influenza season, including:

Children ages 6 through 35 months

- Fluzone[®] (sanofi), No Preservative, Pediatric Dose (children 6 through 35 months of age). Available as 0.25mL pre-filled syringes.

Children ages 3 years through 18 years

- Fluzone[®] (sanofi), Preservative-containing (children and adolescents aged 3 through 18 years). Multi-dose vial.
- FluMist[®] (MedImmune), Preservative free, live, attenuated intranasal vaccine (only healthy, non-pregnant children and adolescents aged 2 through 18 years of age). 0.2 mL single-use sprayer.

Pregnant women 18 years of age and younger

- Fluzone[®] (sanofi), No Preservative (Pregnant women, 18 years of age and younger). Available as 0.5 mL single-dose vials and 0.5mL pre-filled syringes.

[According to California law](#), pregnant women or children younger than three years old may only receive vaccine doses that contain trace levels or no mercury. [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)]. Due to a limited supply of preservative-free influenza formulation, preservative-free vaccines should be prioritized for administration to VFC-eligible children younger than three years of age and pregnant teens 18 years of age and younger.

ELIGIBILITY FOR VFC-SUPPLIED SEASONAL INFLUENZA VACCINE

VFC-supplied seasonal influenza vaccine may be used for all VFC-eligible children in the ACIP recommended groups using appropriate indications for the specific vaccine:

Eligible Groups for Inactivated Seasonal Influenza Vaccine

- All children aged 6 months through 18 years.

Eligible Groups for Live Attenuated Seasonal Influenza Vaccine (LAIV)

- All healthy children and adolescents (those who do not have an underlying medical condition that predisposes them to influenza complications) aged 2 years through 18 years.

DOSAGE AND ADMINISTRATION

Children 9 years and older are recommended to receive 1 dose of seasonal influenza vaccine in the 2010-11 season.

Any child 6 months through 8 years of age is recommended to receive 2 doses of seasonal influenza vaccine in the 2010-11 season *unless* it is determined that the child received at least 1 dose of:

- a) H1N1 vaccine in 2009-10 **AND** seasonal flu vaccine before 2009-10
OR
- b) 2 doses of seasonal vaccine in 2009-10

The minimum interval between 2 doses of seasonal influenza vaccine is 4 weeks.

Inactivated Seasonal Influenza Vaccine

- For children 6-35 months of age, one dose is 0.25 mL
- For children ≥36 months of age, one dose is 0.50 mL

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.

Important note about CSL's influenza vaccine, Afluria®: This product is not available through the VFC program for the 2010-11 influenza season. However, if you have privately purchased this product for immunization of non-VFC-eligible patients in your practice, please note that [on August 5, 2010 ACIP recommended that Afluria® not be used in children 6 months through 8 years of age due to the increased incidence of febrile reactions](#), particularly in children <5 years of age. For children 5 through 8 years of age who are at high risk of complications from influenza due to a medical condition, providers may choose to immunize these patients with Afluria® if there is no other alternative influenza vaccine available after discussion of the benefits and risks of influenza vaccination with Afluria®.

LAIV

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.

ORDERING INSTRUCTIONS

On July 26, 2010, VFC announced the availability of VFC's On-line Order Confirmation System for the submission of this year's seasonal flu vaccine requests. Copies of the provider notice and order confirmation instructions are available at www.eziz.org. The deadline for submitting a confirmed request was August 18, 2010.

Vaccine Supply

An initial supply of Sanofi's Fluzone® multi-dose vials (for use in the 3-18 age group categories) and MedImmune's FluMist® (for use in the Healthy 2-18 age group category) has already arrived at VFC's national vaccine distributor. However, multiple subsequent shipments are expected over the next months to complete the state's vaccine supply pre-booked for the 2010-2011 influenza season. The VFC Program will notify providers via FAX and e-mail as confirmed orders for available products are submitted for fulfillment.

Order Fulfillment and Shipments

All confirmed orders in the “3-18 age group category” (Sanofi Fluzone multi-dose vials) and in the “Healthy 2-18 age group category” (MedImmune’s FluMist®) will begin to be processed and submitted for fulfillment during the week of August 23rd 2010. Orders will be filled as follows:

- Confirmed orders of 100 doses or less will be shipped in full.
- Providers confirming orders over 100 doses for these products can expect a partial shipment, consisting of 25 % of their total order. Subsequent shipments will be automatically processed as additional vaccine supplies become available.

Shipments of pediatric and PF formulations will begin as soon as we receive inventory of these products.

Supplemental Flu Orders

Providers not able to confirm orders by the deadline, or those wishing to receive additional doses, will have the opportunity to submit a supplemental vaccine request once Supplemental Flu Ordering is opened up to all providers later in the flu season. VFC will notify providers once this occurs.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Prior to receiving your influenza vaccine request, please ensure that:

- You have sufficient space in your vaccine storage unit to store your flu vaccine along with all other vaccines stored in your refrigerator.
- All expired and unused 2009-10 seasonal influenza vaccine is removed from your refrigerator and sent back to VFC’s National Distributor, McKesson Specialty Inc.
- After September 15, 2010, any unused Monovalent 2009 H1N1 influenza vaccine be disposed of locally or returned via the [Federal H1N1 Influenza Vaccine Central Recovery Program](#). For more information, please call the Health and Human Services Supply Center at 1-800-642-0263 (4:00 am – 4:00 pm PST).

Once your vaccines arrive:

All influenza vaccine formulations, including LAIV, 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 to verify that the temperature has been maintained while shipment was in transit to your practice.
- Verify that the vaccine doses received match the doses reflected in your shipment’s packing slip and also match doses reflected on the e-mailed order confirmation.
- Contact the VFC Program **immediately** to report any discrepancy in your order or if the vaccine shipment’s monitor indicates the vaccine has been exposed to suboptimal temperatures. Please instruct clinic staff to label the vaccines “Do not use” and refrigerate the vaccines until you have received further instructions from the VFC program.
- Refrigerate vaccines 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

- Keep vaccines in their original packaging until they are ready to be administered. (DO NOT take vaccine vials or syringes out of their packaging.)

BILLING NOTES

Medi-Cal: To bill Medi-Cal for vaccines and administration of influenza vaccines, use only CPT-4 codes 90655, 90656, 90658, and 90660 (LAIV). If VFC vaccine is used, the provider will only be reimbursed for the administration fee. The “-SL” modifier should be use for administration of VFC seasonal influenza vaccine. Medi-Cal Program providers who are unable to obtain influenza vaccine from the VFC Program for their Medi-Cal beneficiaries should purchase it privately and bill Medi-Cal using the appropriate CPT-4 codes.

For more information, please refer to the Medi-Cal provider manual on VFC

http://files.medi-cal.ca.gov/pubsdoco/Manuals_menu.asp

- **90655** Influenza virus vaccine, **split virus, no preservative**, for children 6-35 months of age, for intramuscular use
- 90656 Influenza virus vaccine, **split virus, no preservative**, for use in individuals 3 years of age and above, for intramuscular use
- 90658 Influenza virus vaccine, **split virus**, for use in individuals 3 years of age and above, for intramuscular use
- 90660 Influenza virus vaccine, **live**, for intranasal use

The CHDP program will reimburse for seasonal influenza vaccine and its administration.

- If seasonal influenza vaccine is provided by the VFC Program use code “53.”
- If seasonal influenza vaccine is purchased because the vaccine is not available through VFC use code “54” for children 36 months through 20 years, 11 months and code 80 (preservative free) for children 6 months through 35 months.
- If Live Attenuated Influenza Vaccine (LAIV), intranasally administered is provided by the VFC Program use code “71.”
- Code 71 is payable for ages two years through 18 years, 11 months, administration fee only.

RETURN OF UNUSED VIALS OF INFLUENZA VACCINE

Seasonal Flu Vaccine Return

All VFC Providers must return all expired or spoiled seasonal influenza vaccine (including vials, syringes, and nasal sprayer packages) to VFC’s national vaccine distributor: McKesson Specialty.

To return vaccine, complete a VFC Return and Transfer Form, and make a copy for your records. Fax a copy to the VFC Program at 877-FAXX-VFC (877-329-9832). Enclose the original form in the package with the non-viable or expired vaccines you are returning.

When returning your vaccines, please keep doses in their original packaging and use a container in which you receive your normal vaccine shipments. Clearly label the outside of the shipping container "Non-viable vaccine enclosed". You may contact VFC to request a return label for your box.

Monovalent 2009 H1N1 Influenza Vaccine Disposal

Doses of Monovalent 2009 H1N1 influenza vaccine already expired or expiring after September 15, 2010 MUST be disposed of via the [Federal H1N1 Influenza Vaccine Central Recovery Program](#) or disposed locally. Please DO NOT return these doses to VFC's national vaccine distributor under ANY circumstance. For more information, please call the Health and Human Services Supply Center at 1-800-642-0263 (4:00 am – 4:00 pm PST).

FluMist Replacement Program

Similar to last year, LAIV will have expiration dates as early as December 2010. MedImmune has developed a replacement program for expiring doses. Providers may request replacement of eligible LAIV up to 15 days prior to the expiration date printed on the sprayer label. All replacement requests must be made by faxing a request to a toll-free fax number (1-877-633-7375) and must be submitted by January 30, 2011. Information about the program will be included in shipments of vaccine. All questions regarding the Replacement Program can be directed to 1-877-633-7375.

VACCINE INFORMATION STATEMENTS (VISs)

The appropriate influenza [Vaccine Information Statement \(VIS\) for Inactivated or Live, Attenuated Influenza Vaccine \(LAIV\) for 2010-2011](#), must be provided to a parent or guardian before the child receives influenza vaccine.

QUESTIONS?

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

cc: CDPH Immunization Branch Field Representatives

Local Health Officers

Local Health Department Immunization Coordinators

Local Health Department CHDP Program Directors

Tanya Homman, Acting Chief, Medi-Cal Managed Care Division, DHCS

Luis Rico, Acting Chief, Children Medical Services Branch, DHCS

Susan McClair, M.D., Medi-Cal Managed Care, DHCS

Shabbir Ahmad, D.V.M., M.S., Ph.D., Acting Chief, Maternal, Child and Adolescent Health Program, CDPH

Laurie Weaver, Chief, Office of Family Planning, CDPH

Shelley Rouillard, Deputy Director, Benefits and Quality Monitoring Division, MRMIB

Lilia Coleman, Benefits and Quality Monitoring, MRMIB

Jamie Yang, Benefits and Quality Monitoring, MRMIB

Neal Kohatsu, M.D., M.P.H., Medical Policy Section, Medi-Cal Benefits, Waiver Analysis and Rates Division, DHCS

Laura Ann Halliday, M.D. Medical Policy Section, Medi-Cal Benefits, Waiver Analysis and Rates Division, DHCS

Alan Morita, Pharm.D., Medi-Cal Pharmacy Policy Branch, DHCS

Jill Abramson, M.D., M.P.H., Children Medical Services Branch, DHCS