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TO: Vaccines for Children (VFC) Providers
FROM: John Talarico, DO, MPH, Interim Chief Immunization Branch *John Talarico, DO, MPH*

SUBJECT: Influenza Vaccine Availability for VFC Children; and
2008-2009 VFC Vaccine Order Form, DHS IMM 376F

This memo is divided into sections to enable you to quickly access the information you need:

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SUMMARY

On July 17, 2008, the federal Advisory Committee on Immunization Practices (**ACIP**) published its annual **Influenza Recommendations (MMWR, July 17, 2008 / 57(Early Release);1-60)**, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm>. The VFC Influenza Resolution for this current flu season can also be found online at: <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0208influenza.pdf>.

The 2008 recommendations for pediatric influenza vaccination include the expansion of recommended ages for annual vaccination. Beginning in the 2008-09 influenza season, all children aged 5-18 years should receive an annual influenza vaccination, if feasible. However, annual vaccination of all children aged 6 months through 4 years (59 months) continue to be a

primary focus of vaccination efforts because these children are at higher risk for influenza complications compared with older children.

When vaccinating healthy individuals over 2 years of age, either trivalent inactivated influenza vaccine, or live attenuated influenza vaccine (LAIV) can be used. The previous recommendation was to administer LAIV to person aged 5-49 years.

The California VFC Program is now accepting influenza vaccine orders for the 2008-09 influenza season. Providers are encouraged to submit their initial vaccine order, and submit subsequent supplemental orders throughout the season. Orders will continue to be filled as supply permits.

The enclosed 2008-2009 "Influenza Season Vaccine Order Form" must be used when placing influenza vaccine orders. This year's form includes available products during this year's influenza season. Orders submitted prior to this notification must be re-submitted utilizing the updated Influenza Season Vaccine Order Form.

An initial supply of flu vaccine is expected from vaccine manufacturers by mid September, with multiple subsequent shipments expected throughout September-November that will complete our State's vaccine order. The VFC Program will notify providers when products are received at VFC's vaccine distributor and delivery of approved orders begins.

2008-2009 INFLUENZA VACCINE COMPOSITION

- The 2008--09 trivalent vaccine virus strains in this year's influenza vaccine are:
 - A/Brisbane/59/2007 (H1N1)-like;
 - A/Brisbane/10/2007 (H3N2)-like; and
 - B/Florida/4/2006-like antigens.

These viruses will be used because they are representative of influenza viruses that are anticipated to circulate in the United States during the 2008-09 influenza season. Both inactivated and live-attenuated influenza vaccines are grown in eggs.

AVAILABLE INFLUENZA VACCINES

The Vaccines for Children (VFC) Program will make available a variety of approved influenza vaccine products for immunization of VFC-eligible children 6 months to 18 years of age during the 2008-09 influenza season. Please refer to the attached "Approved Influenza Vaccine Products" chart for detailed description on available product, how they're supplied, formulation, and recommended ages for use.

Available products:

Children ages 6-35 months

- Fluzone[®](sanofi), No Preservative: Pediatric Dose (children 6 through 35 months of age)

Children ages 3 years – 18 years

- Fluzone[®](sanofi), Preservative-containing (children and adolescents aged 3 - 18 years)

- Fluvirin® (Novartis), Preservative-containing (children and adolescents aged 4 – 18 years)
- FluMist® (MedImmune), Preservative free, live, attenuated intranasal vaccine (healthy children and adolescents aged 2-18 years of age **only**)

Pregnant women under 18 years of age

- Fluzone® (sanofi), No Preservative (Pregnant women, under 18 years of age)

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 under 18 years of age. According to the California Mercury Free Act of 2004, which took effect July 1, 2006, 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)].

ELIGIBILITY FOR VFC-SUPPLIED INFLUENZA VACCINE

VFC-supplied Influenza vaccine may be used for all VFC-eligible children in the following ACIP recommended groups:

Eligible Groups for Inactivated Influenza Vaccine

- All children aged 6 months through 18 years.

Eligible Groups for Live Attenuated Influenza Vaccine (LAIV)

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

DOSAGE AND ADMINISTRATION

Inactivated Influenza Vaccine

Children under 9 years of age, receiving inactivated influenza vaccine for the first time, require two doses, one month apart.

- For children 6-35 months of age, one dose is 0.25mL.
- For children >35 months of age, one dose is 0.5mL

Children under 9 years who received only 1 dose of influenza vaccine during a prior season are recommended to receive 2 doses this season.

Children under 3 years of age should receive preservative-free influenza products.

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

Children aged 2-9 years previously unvaccinated with influenza vaccine or who received only 1 dose of any influenza vaccine in their first year of vaccination are recommended to receive 2 doses the following year, separated by at least 4 weeks.

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 (.10 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.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Prior to placing this year's influenza vaccine request for your practice, please ensure that:

- You have sufficient space in your vaccine storage unit to store your flu vaccine request along with all other vaccines in your refrigerator. Vaccines may not be stored in drawers or deli/ vegetable bins, and must be kept in their original packaging until they are ready to be administered (DO NOT take vaccine vials or syringes out of their packaging).
- Any expired and unused flu vaccine for the 2007-2008 flu season is removed from your refrigerator and sent back to VFC's National Distributor, McKesson Specialty.

Both **Trivalent Inactivated Vaccine (TIV)** and **Live, Attenuated Influenza Vaccine (LAIV), 2008-2009 New formulation**, will be shipped to your practice directly from VFC's third party distributor, 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. Also, carefully verify that the vaccine doses received match the doses reflected in your shipment's packing slip. Refrigerate vaccines at a temperature range of 35° to 46°F (2° to 8°C), with a preferred temperature of 40°F. Do not freeze or expose vaccines to freezing temperatures.

Please 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.

ORDERING INSTRUCTIONS

The enclosed copy of the **2008-2009 VFC Influenza Vaccine Order Form**, DHS 8501F (9/08), **must** be used when placing influenza vaccine orders. The order form includes a variety of different products available for the 2008-09 influenza season. Please retain a copy of submitted orders for your records to assist you in placing future orders. You may fax your completed influenza vaccine order to 1-877-329-9832 (877-FAXX-VFC). In order to avoid

unnecessary delays in the processing of your influenza vaccine order, please make sure to follow these steps:

- a. Submit your influenza order utilizing this year's VFC Influenza Vaccine Order Form, DHS 8501 F (9/08). **Please do not utilize any other VFC order form to place your influenza vaccine order.** Product availability is listed in this year's form may differ from previous years.
- b. If you have placed an influenza vaccine order on an old form, please re-submit your order utilizing the new form.
- c. Please estimate your initial vaccine order based on influenza vaccine doses received during the 2007-2008 season, and submit subsequent supplemental vaccine orders throughout influenza season. VFC will continue to accept orders as long as available supplies last.
- d. Orders received after this notification is issued will be placed in a "Back Order" listing until vaccine inventories are received from manufacturers at the VFC Program distributor. The VFC Program will notify providers as soon as inventories of influenza vaccine are received and approved vaccine orders begin to be shipped.
- b. When placing your vaccine order, indicate the number of doses requested in order to vaccinate children in your practice according to ACIP recommendations. When indicated, select your practice's preferred brand and presentation (vials or syringes). In circumstances where your preferred brand or presentation may not be readily available, delayed, or no longer available, VFC may substitute your product or presentation in order to delay the fulfillment of your order.
- c. Please note that influenza vaccine orders will be approved according to your practice's profile estimates and estimate of the proportion of children you will vaccinate.
- d. **You may reorder influenza vaccine as needed throughout the 2008-09 Flu season.** The VFC Program will continue to ship vaccines as long as our inventory and national supplies last. Unlike all other pediatric vaccines, influenza vaccine supplemental orders may be submitted at any time. You do not have to wait to order on your assigned order frequency.

If necessary, the VFC Program may adjust the number of doses sent due to demand or limitations on supply.

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. 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.

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

- If inactivated influenza vaccine is provided by the VFC Program use code "53" for 6 months through 18 years 11 months.
- If inactivated influenza vaccine is purchased because the vaccine is not available through VFC use code "54" for ≥ 36 months of age and code "80" for preservative free vaccine for 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

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

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) and enclose the original copy of the form in the package with the non-viable or expired vaccines you are returning to the VFC Program. Return vaccines to:

McKesson Specialty Distribution
4853 Crumpler Road
Memphis, TN 38141
Attn: Eric Doss/ Tommy McRae

When returning your vaccines, please use a postage-paid container in which you receive your normal vaccine shipments, and clearly label the outside of the shipping container "Non-viable Vaccine enclosed."

LAIV products received early in the flu season will have a shorter expiration date. Products with a shorter expiration date (December 2008) may be returned directly to McKesson in exchange for the same doses with a longer expiration date. Instructions on how to request replacement vaccine will be included in your vaccine shipment and can also be found at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/med-fm-rrf.doc> or by calling 888-606-3273.

VIS STATEMENTS

Copies of the current interim Vaccine Information Statement (VIS) for the Inactivated Influenza Vaccine and the Live, Attenuated Influenza Vaccine (LAIV), dated 7/24/08, are included in this mailing and are also at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. Federal regulation requires that you provide the VIS to a parent or guardian before the child receives influenza vaccine.

August 22, 2008

HELPFUL RESOURCES

To help you remind parents about new pediatric flu shots recommendations, we are enclosing two copies of the **“Guess Who Needs a Flu Shot” (IMM-782)** self-adhering cling-on flyer. This piece is suitable for posting in a medical office waiting room or patient exam room and requires no tape or thumb tacks. In addition, a sample **“Guess Who Needs a Flu Shot” (IMM-781)** reminder postcard is enclosed. To order additional copies of these materials, VFC providers should contact their local health department. Listings are at <http://www.cdph.ca.gov/programs/immunize/Pages/CaliforniaLocalHealthDepartments.aspx>.

QUESTIONS?

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

Enclosures: Inactivated Influenza Vaccine Information Statement (7/24/08)
 Live Intranasal Influenza Vaccine Information Statement (7/24/08)
 VFC Vaccine Order Form, DHS 8501 F (9/08)
 “Guess Who Needs a Flu Shot” postcard (IMM-781)
 “Guess Who Needs a Flu Shot” cling-on flyers (IMM-782)
 Approved Influenza Products Chart

cc: CDPH Immunization Branch Field Representatives
 Local Health Officers
 Local Health Department Immunization Coordinators
 Local Health Department CHDP Program Directors
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