Immunization Updates & Vaccines for Children (VFC) Program

California Department of Public Health Immunization Branch

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Jr. Field Services Representative (Bay Area Region)
What is the Vaccines for Children (VFC) Program?
The creation of the VFC Program is a direct result of the 1989 – 1991 US measles epidemic which resulted in tens of thousands of cases of measles and hundreds of deaths.

- Over 50% of these children with measles had recently seen a healthcare provider but were not immunized.

Two years after this epidemic congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the Vaccines for Children (VFC) Program, as an “entitlement” (a right granted by law) for eligible children 0-18 yrs of age.

- VFC Program became operational in 1994.
The Vaccines For Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

CDC buys vaccines at a discount and distributes them to grantees—i.e., state health departments and certain local and territorial public health agencies—which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers.

Offers all childhood recommended vaccines by the Advisory Committee on Immunization Practices (ACIP).
Children through 18 years of age meeting at least one of the following criteria are eligible to receive VFC vaccine:

- **Medi-Cal/CHDP eligible:** A child who is eligible for the state’s Medicaid program. For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent.

- **Uninsured:** A child who has no health insurance coverage.

- **American Indian or Alaska Native:** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).

- **Underinsured:** Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).
  - Definition: A child who has commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.
VFC Eligibility: Special Populations

- **American Indian/Alaska Natives** are eligible to participate in the VFC program regardless of insurance coverage.
  - Insured children with Medi-Cal as a secondary insurance are covered by VFC
    - VFC vaccines may be administered and Medi-Cal will pay the claim for the administration fee and seek reimbursement from the primary insurance.
- **Incarcerated juveniles under 19 years of age**
  - An individual who loses access to health benefits under his/her insurance while incarcerated is uninsured for purposes of the VFC program.
- **Minors seeking vaccination under confidential services** (as allowed by state law) but only at an STD/Family Planning Clinic.
Not VFC Eligible

- **Children whose health insurance covers the cost of vaccinations**
  - Even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible had not been met.

- **Patients with Health Savings Accounts**
  - Individuals covered by medical savings accounts or health savings accounts are insured

- **Current Healthy Families** subscribers are NOT eligible to receive VFC vaccines

- Minors seeking vaccination under confidential services (as allowed by state law) at a facility whose main purpose is **other than prescribe contraceptives and/or treat sexually transmitted diseases**, i.e., school-based clinics or any VFC-enrolled provider whose main services are primary or acute care services.
State Immunization Updates
Starting in 2014, parents seeking personal belief exemptions (PBEs) need to document for schools:

- Receipt of info about immunizations and communicable diseases from health care practitioners, who are also required to document providing of such information.
  - Documentation may not be signed >6 months prior to when immunization is required (typically, start of school year).
  - Authorized health care practitioners will include licensed physicians, nurse practitioners, physician assistants, naturopathic doctors and credentialed school nurses.
- Which required immunizations the student has received and not received.

AB2109 forms are currently in Sacramento going through the approvals process.
Reimbursement for Administration

Medi-Cal beneficiaries, 2013-2014

- Reimbursement - $9 $26 per injection in California
  - 100% federal funding to cover increased payments
- Applies to
  - Patients of any age, not just VFC
  - Managed care as well as fee-for-service
- Does not apply to
  - Non-Medi-Cal VFC: Un– or Under-insured, Am. Indian
- Applies to public health clinics?
  - Still awaiting clarification from federal government
Primary Care Physician Rate Increase

December 21, 2012

Effective for dates of service from January 1, 2013, through December 31, 2014, Medi-Cal reimbursement to qualifying providers for specified primary care services will be at the same level as Medicare reimbursement for the same services. However, because of questions that remain regarding the final rule released in November 2012, the timing of State Plan approval and changes to the claims processing system, the increased reimbursements will not be immediately available.

The Department of Health Care Services (DHCS) expects implementation to occur during the summer of 2013. The increases will be retroactive and will apply to all services provided from January 1, 2013 through December 31, 2014. It is not necessary for providers to identify eligibility on their claims for the Medicare rate.

DHCS expects that additional guidance will be provided next month regarding implementation in managed care. Managed care plans will not receive additional funding for this increase until the managed care methodology is approved and contracts are amended. Managed care plans are not required to make higher payments to their primary care providers until they receive additional funding from the state.

The rate increase applies to eligible physicians for specified primary care services. For the final rule released by the Centers for Medicare & Medicaid Services, the applicable primary care services include Evaluation and Management codes 99201 through 99205 and vaccine administration codes 90460, 90461, 90464, 90472 and 90473, or their successor codes. In order to be eligible, physicians must self-attest they are board certified in family medicine, general internal medicine, pediatric medicine, or a related subspecialty. Physicians are also eligible if 50 percent of the services they bill Medi-Cal fall within the designated Evaluation and Management and vaccine administration codes. The increased reimbursement will also be provided to non-physician practitioners who work under the supervision of an eligible physician.

DHCS is developing an online tool for physicians to self-attest their eligibility for the payment increase. DHCS will provide additional bulletins and conduct additional outreach as more information becomes available regarding the increase and the self-attestation process.
Increased Admin Fee for VFC Program

- Administration fee that providers may be charged to California VFC patients increased from $17.55 to $26.03
  - Applicable to non-Medicaid VFC eligible children

- However, providers cannot deny administration of VFC vaccines to a vaccine-eligible child due to the inability to pay the administration fee.
Pursuant to Assembly Bill (AB) 1494, (Committee on Budget, Chapter 28, Statutes of 2012), all Healthy Families Program (HFP) enrollees will transition to Medi-Cal as targeted low-income Medicaid children, as allowed under federal law, beginning January 1, 2013. The transition of approximately 875,000 HFP enrollees will be implemented in four separate phases over the course of one year.
Healthy Families Transition to Medi-Cal

4 Phases

- **Phase 1 (No sooner than January 1, 2013)**
  - Individuals enrolled in a Healthy Families Program health plan that is a Medi-Cal managed care health plan shall be enrolled in the same plan. Approximately 411,654 children will transition.

- **Phase 2 (No sooner than April 1, 2013)**
  - Individuals enrolled in a Healthy Families Program managed care health plan that is a subcontractor of a Medi-Cal managed health care plan, to the extent possible, shall be enrolled into a Medi-Cal managed health care plan that includes the individuals’ current plan. Approximately 261,060 children will transition.

- **Phase 3 (No sooner than August 1, 2013)**
  - Individuals enrolled in a Healthy Families Program plan that is not a Medi-Cal managed care plan and does not contract or subcontract with a Medi-Cal managed care plan shall be enrolled in a Medi-Cal managed care plan in that county. Enrollment shall include consideration of the individuals’ primary care providers. Approximately 152,602 children will transition.

- **Phase 4 (No sooner than September 1, 2013)**
  - Individuals residing in a county that is not a Medi-Cal managed care county shall be provided services under the Medi-Cal fee-for-service delivery system. Approximately 42,753 children will transition.
Healthy Families Transition to Medi-Cal

Phase I


- **Part B** – no sooner than March 1, 2013, for children in the counties of Contra Costa, Fresno, Kern, Kings, Los Angeles, Madera, Monterey, Napa, Sacramento, San Diego (Health Net only), San Luis Obispo, Santa Barbara, Santa Cruz, Solano, Sonoma, Tulare, and Yolo.
Vaccine Administration Error Reporting

- Immunizers or LHDs are encouraged to report vaccine administration errors at http://verp.ismp.org/
- Secure online system sponsored by the Institute for Safe Medication Practices (ISMP), a federally certified patient safety organization providing legal protection and confidentiality for submitted patient safety data and error reports.
- Information forwarded in confidence to VAERS and, when applicable, to vaccine manufacturers.
- ISMP plans to work with CDC on information received to address vaccine-related safety.
Vaccine Supply Updates and Flu
2012-2013 Flu Vaccine

- All expired and spoiled seasonal VFC flu doses **must** be returned to McKesson Specialty to recoup the federal excise tax credit.

**IMPORTANT MESSAGE**

Return of Expired 2012-2013 Seasonal Flu Vaccines

Dear VFC Provider,

Supplemental ordering for 2012-2013 flu vaccines has closed. As a reminder, all expired and spoiled seasonal VFC flu doses must be returned to McKesson Specialty to recoup the federal excise tax credit.

Upon expiration, please remove expired flu vaccines from your storage units immediately and then complete and submit a VFC Return form. Expired flu vaccines must be shipped back to McKesson as soon as possible.

To return expired seasonal flu vaccine:

- Log into your MyVFC/vaccines account on www.cdph.ca.gov. Complete and submit a VFC Return and Transfer Form.
- You may request to receive postage-paid labels to send the vaccines back to McKesson.
- Print a copy of the completed form to include with your vaccine shipment.
- When packaging vaccines, clearly label the outsides of the container “EXPIRED VACCINES ENCLOSED”.
- ONLY return any unopened vials, syringes, and needle-syringe packages of seasonal flu vaccine. NEVER return used syringes, with or without needles, open vials, diluent, other pharmaceuticals, or usable vaccines.

Including this cover sheet, the transmission consists of 3 pages.
## U.S. Influenza Vaccine, 2013-2014 Season

### Licensed for children

<table>
<thead>
<tr>
<th>Ages</th>
<th>Trade Name</th>
<th>Mfr.</th>
<th>Presentation</th>
<th>VFC?</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-35 mo</td>
<td>Fluzone*</td>
<td>sanofi pasteur</td>
<td>0.25 mL single-dose syringe 0.25 mL single-dose syringe</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Fluzone* Quadrivalent</td>
<td></td>
<td></td>
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<tr>
<td>2-49 yrs</td>
<td>FluMist* Quadrivalent</td>
<td>MedImmune</td>
<td>0.2 mL intranasal sprayer</td>
<td>Yes</td>
</tr>
<tr>
<td>≥3 yrs*</td>
<td>Fluzone*</td>
<td>sanofi pasteur</td>
<td>0.5 mL single-dose vial 0.5 mL single-dose syringe 5.0 mL multidose vial</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Fluzone* Quadrivalent</td>
<td></td>
<td>0.5 mL single-dose vial</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.5 mL single-dose syringe</td>
<td></td>
</tr>
<tr>
<td>≥3 yrs</td>
<td>Fluarix*</td>
<td>GSK</td>
<td>0.5 mL single-dose syringe 0.5 mL single-dose syringe</td>
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</tr>
<tr>
<td></td>
<td>Fluarix* Quadrivalent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥4 yrs</td>
<td>Fluvirin*</td>
<td>Novartis</td>
<td>0.5 mL single-dose syringe 5.0 mL multidose vial</td>
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<tr>
<td>≥9 yrs**</td>
<td>Afluria*</td>
<td>CSL / Merck</td>
<td>0.5 mL single-dose syringe 5.0 mL multidose vial</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Fluzone is licensed down to 6 months, but typically can only be given to patients 3 yrs and older in CA*

**Afluria is licensed for 5 yrs and older, but ACIP recommends for 9 and older**
# U.S. Influenza Vaccine, 2013-2014 Season

Licensed only for adults

<table>
<thead>
<tr>
<th>Ages</th>
<th>Trade Name</th>
<th>Mfr</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥18 yrs</td>
<td>Flucelvax®</td>
<td>Novartis</td>
<td>0.5 mL single-dose syringe</td>
</tr>
<tr>
<td>≥18 yrs</td>
<td>FluLaval®</td>
<td>ID Biomedical</td>
<td>5.0 mL multidose vial</td>
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<tr>
<td>18-49 yrs</td>
<td>FluBlok® (Recombinant)</td>
<td>Protein Sciences</td>
<td>0.5 mL single-dose syringe</td>
</tr>
<tr>
<td>18-64 yrs</td>
<td>Fluzone® Intradermal</td>
<td>sanofi pasteur</td>
<td>0.1 mL prefilled microinjection system</td>
</tr>
<tr>
<td>≥65 yrs</td>
<td>Fluzone® High-Dose</td>
<td>sanofi pasteur</td>
<td>0.5 mL single-dose syringe</td>
</tr>
</tbody>
</table>
• The department shall provide appropriate flu vaccine to local governmental or private, nonprofit agencies at no charge in order that the agencies may provide the vaccine, at a minimal cost, at accessible locations.

• ...the department may provide guidance to local agencies as to whether one or more population groups shall have priority for the flu vaccine offered through this program.

• In developing this guidance, the department shall consider the influenza recommendations of ... ACIP or other criteria in order to ensure that the vaccination program is efficient and effective in meeting public health goals.
Preparing for VFC’s 2013-2014 Flu Season

- Total doses pre-booked: 2.3M doses
- Products:
  - Sanofi Fluzone 0.25mL SDS (TIV)
  - Sanofi Fluzone 5mL multi-dose vials (TIV)
  - GSK Fluarix 0.5mL SDS (QIV)
  - MedImmune FluMist (QIV)
VFC’s 2013-2014 Flu Season

- Providers have until **July 26th** to confirm their allocations.
  - Allocations are based on the total number of doses that were shipped to them during the 2012-2013 flu season (including any supplemental orders).

- Similar to previous years, providers may confirm the doses that are allocated to them or make the following changes:
  - Decrease the number of doses for the 6-35 month age group (Pediatric 0.25mL formulation)
  - Shift doses between the different brands (increase or decrease individual brands) within the 3-18 year old category, as long as the total number of doses between these three brands do not exceed the total number allocated for the 3-18 year category

- For providers that have Healthy Families patients that have or will transition to Medi-cal, there will be a checkbox and additional table that they can enter additional requests for their increased patients. Remember that these patients are NOT eligible to receive VFC vaccines until they have officially transitioned to Medi-Cal.

- Providers will receive a notification when we have flu vaccine inventory at McKesson and are ready to start shipping their orders (hopefully early August).
Confirm VFC Flu Doses on EZIZ.org

- VFC providers need to log into their MYVFC Vaccines with their PIN and Zip.
2013-2014 VFC Influenza Vaccine Order Form for PIN 071096, STATE OF CA IMMUNIZATION BRANCH-RIC

Primary Phase Request (Step 1 of 3)

Clinic Information
Name: STATE OF CA IMMUNIZATION BRANCH-RIC
Address: 820 MARINA BAY PKWY BUILDING P, RICHMOND, CA 94804
Contact: STEVEN VAN TIJNE Phone: (510) 412-1601
Official practice E-mail: STEVEN.VANTIJE@CDPH.CA.GOV

Allocated doses are based on total doses received by your practice last flu season and expected VFC vaccine supply this season. If you did not receive flu doses last year, allocations are based on selected pediatric vaccine distribution.

The table below displays the TOTAL number of VFC flu doses allocated to your practice.

1. Review the TOTAL doses allocated for each age group. You may reduce doses by entering the desired number in the Edit/Modify Column.
2. Review the product BRAND and doses you will receive for each age group. For the "3-18 Yrs." group, you may request a different BRAND allocation breakdown, as long as doses do not exceed the TOTAL Age Group Allocation. Enter "0" if you do not want doses of a particular brand.

VFC will review your request and approve it based on available vaccine supply.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total Doses Allocated for Age Group</th>
<th>Brand</th>
<th>Allocation</th>
<th>Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months to 35 months*</td>
<td>10</td>
<td>Pediatric Fluzone, Sanofi Inactivated, Trivalent, No Preservative, 0.25mL Prefilled Syringe</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>3-18 years of age (including Pregnant Teens)*</td>
<td>20</td>
<td>Fluzone, Sanofi Inactivated, Trivalent, preservative-containing, multi-dose vials, 5mL</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>FluMist, MedImmune* Live Attenuated, Quadrivalent, 0.20mL nasal sprayer</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flurix, GSK* Inactivated, Quadrivalent, No Preservative, 0.5 mL dose, single dose syringe</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

*FluMist may be used in children 2 years of age and older.
*Preservative-free vaccines should be prioritized for administration to pregnant teens under 18 years of age, but may also be used in children 3-18 years of age. According to the California Mercury Free Act of 2004, 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, Pabst)].

I need additional allocations for our Healthy Families patients that have or will transition to Medi-Cal. I understand that my Healthy Families patients are NOT eligible to receive VFC-supplied vaccines until they have officially transitioned to Medi-Cal.
Preparing for VFC’s 2013-2014 Flu Season

- Provider and parent communication will be key prior to order confirmation
  - What are quadrivalent flu vaccines and their benefit?
  - What types of vaccine are quadrivalent?
  - What should I do if I cannot order quadrivalent vaccines?

Quadrivalent Flu Vaccines
What State and Local Immunization Programs Need to Know

The 2013-2014 pre-book period for flu vaccine has begun. Limited supplies of quadrivalent flu vaccine will be available this flu season. This document contains information about the quadrivalent flu vaccines that may be helpful to consider as you pre-book.

- What are quadrivalent flu vaccines?
  - Recently, the Food and Drug Administration (FDA) approved the use of quadrivalent (four-virus) flu vaccines, which offer protection against four different influenza viruses: two A viruses and two B viruses.

- Influenza A and B viruses cause the majority of influenza illness almost every autumn and winter in the United States. Flu vaccines have been used in the U.S. for more than 50 years, and since the early 1980s have been trivalent (three-virus) vaccines. Trivalent means the vaccine protects against three different influenza viruses: two A viruses and one B virus.

- What is the benefit of quadrivalent vaccines?
  - The seasonal influenza vaccine already included one influenza B virus. Having another B virus in the quadrivalent vaccine may provide people with broader protection against the influenza B viruses that circulate and cause illness each flu season. Influenza B viruses are divided into two distinct lineages: the B/Yamagata lineage, and the B/Victoria lineage. Influenza B viruses from both lineages tend to circulate at the same time globally. These two B virus lineages are different from one another, and a vaccine that protects against one of the lineages is unlikely to provide protection against the other.

- It is challenging to predict each February (when the vaccine formulation for the United States is decided on for the next flu season) which B virus lineage is likely to predominate and cause the most illness that autumn and winter. Adding a second B virus to the vaccine means there is a greater chance that the vaccine will protect against circulating B viruses.

- What types of quadrivalent flu vaccines may be available?
  - Limited amounts of quadrivalent vaccines are expected to be available as a nasal spray and a flu shot. In February 2012, the FDA approved FluMist® Quadrivalent, a quadrivalent live, attenuated nasal spray (LNIV). The nasal spray contains live, but attenuated (weakened) influenza viruses and is given as a spray into the nose. In December 2012, FDA approved Fluarix™ Quadrivalent, a quadrivalent inactivated influenza vaccine (IIV4). Fluarix® Quadrivalent contains killed influenza viruses and is given by injection with a needle, usually in the arm.

- When will quadrivalent flu vaccines be available?
  - Both FluMist® Quadrivalent and Fluarix™ Quadrivalent vaccines will be available for the 2013-2014 flu season. For the 2013-2014 flu season, the nasal spray vaccine will only be available as a quadrivalent vaccine, while the flu shot will be available as both a quadrivalent vaccine and a trivalent vaccine.

- What should I do if I can’t order quadrivalent vaccines?
  - Don’t delay ordering flu vaccine if you want quadrivalent and it isn’t available. Most of the flu vaccine offered this year will be trivalent, quadrivalent vaccine is expected to be in short supply. (While all nasal spray vaccine is expected to be quadrivalent, this makes up only a small portion of total vaccine availability.) As the 2012-2013 flu season has shown, it is important to pre-book vaccine as soon as it is available. Trivalent vaccine offers important protection from flu, so don’t delay ordering if only trivalent is available.

*National Center for Immunization and Respiratory Diseases*
February 16, 2013
VFC Vaccine Supply Update

- **Pentacel**
  - According to Sanofi, limited doses will be available in June; however, doses are still limited
    - Limited allocations expected June-August for states
    - Product will be re-opened for ordering in CA when allocations doses are adequate to fulfill provider orders
  - Adequate supply of single antigen (DTaP, Hib, Polio) as alternative to Pentacel
VFC Vaccine Supply Update Cont’d

- **Pediarix**
  - Continue to have 50% monthly allocations.
  - Pediarix users – can order up to 50% of historic usage.
  - Providers with NO recent history of ordering Pediarix should order increased doses of single antigen to compensate.
  - Refer to program letter that was sent to providers on 4/23/13.
  - Full supply of Pediarix is anticipated to return in September.

- **Comvax**
  - Is available again in full supply

- **Pedvax Hib**
  - Currently on back-order
New VFC Program Requirements
The program’s federal budget is almost $4 billion dollars. This makes the VFC Program a highly visible program and part of the Federal Program Integrity Initiative, which seeks to ensure the integrity of operations in all HHS programs, to reduce the risk of fraud, waste, and abuse.

California’s VFC Vaccine Budget: $479 M
Office of Inspector General (OIG) Report

Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

VACCINES FOR CHILDREN PROGRAM: VULNERABILITIES IN VACCINE MANAGEMENT

Daniel R. Levinson
Inspector General
June 2012
OEI-04-10-00420

California Department of Public Health, Immunization Branch
Are Doctors Improperly Storing Vaccines?

Vaccines Stored Improperly: Warning for Parents

By KIM CAROLLO
June 6, 2012
An investigation by the Department of Health and Human Services' Office of the Inspector General (HHS OIG) found that many providers of immunizations meant for low-income children don't store the vaccines at proper temperatures, potentially rendering them ineffective and placing children at risk for contracting serious diseases.

"I'd be very furious if that happened to me," said one parent. "I would be furious if my doctors were not storing them properly and so her vaccines were not effective."

The investigation found that 76 percent of the providers stored the vaccines at temperatures that were either too hot or too cold. They also found that 13 providers stored expired vaccines along with nonexpired vaccines. In addition, they said they found that none of the providers properly managed the vaccines according to VFC program requirements.

The storage problem could potentially lead to less effective vaccines, but doesn't pose a safety risk, the HHS OIG said.

While the report is concerned with vaccines offered under the VFC program, doctors say the government's investigation is an important reminder to all clinicians about the need to properly and carefully store all vaccines. In its report, the Inspector General's Office recommends that CDC take steps to ensure that providers who participate in the VFC program do their jobs.

OIG Study Background

• **WHY:**
  • The Office of the Inspector General (OIG) of the Federal Health and Human Services Agency conducted a routine planned assessment of the Vaccines for Children (VFC) Program aimed at state and provider adherence to federal requirements for:
    • vaccine management
    • vaccine storage equipment
    • VFC program eligibility screening.

• **HOW:**
  • The study was conducted with 45 VFC providers from the five largest VFC Grantees nationwide.

• **WHEN:**
  • In April and May of 2011, 9 provider offices from California were included in the study (all in the Bay Area Region).
“To ensure diversity of providers, we selected providers according to three characteristics:

1. provider type (i.e., private provider, public health department, FQHC/RHC, other type of public health clinic, or private hospital),
2. vaccine order volume (i.e., high or low), and
3. location type

“Because we also met with grantee staff, we limited our sample of providers to those within 100 miles of each grantee’s office location.”
9 Sites Visited in CA (All in Bay Area)

- 2 clinics in Berkeley (both Private)
- 2 clinics in San Francisco (1 Private, 1 CHC)
- 1 clinic in Richmond (Private)
- 4 clinics in Oakland (All Private)
Overall Report Findings

- Providers had to perform ALL required activities within each category for OIG to conclude that they met the requirements for that category (one deficient activity would mean entire category had not been met).

- Storage and handling of vaccine issues:
  - improper temperature
  - unapproved storage units
  - expired vaccine stored alongside non-expired vaccine.

- Program management issues:
  - lack of required documentation,
  - Lack of program oversight
  - Lack of vaccine management at provider sites.
Specific findings related to CA Providers

- Expired vaccines were not separated from non-expired vaccines:
  - Vaccines expired for 315, 325, 76, and 384 days on the day of site visits
- Other products besides vaccines were stored in the same storage units:
  - Insulin
  - Ice cream bars
  - Pedialyte popsicles and drinks
  - Viral transport medium
  - Children’s fever reducing suppositories
  - Hemoglobin calibrator
  - Penicillin and hydrochloride injections
- Thermometers not placed centrally within the storage unit
- Thermometers not calibrated or certified according to NIST Standards
- Vaccines placed next to wall, in door, vegetable bins, boxes, and bags
OIG independently measured temperatures of the freezers and refrigerators for the 2-week period following their site visits.

- Used a commercially available calibrated temperature-recording device—TempTale®.
- OIG placed one TempTale® in a VFC vaccine freezer and one in a VFC vaccine refrigerator at each selected provider site.
- Each TempTale® recorded temperatures every 15 minutes for 2 weeks.
Temperature Results

- VFC vaccines stored by 76 percent—34 of 45—of the selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period.

- All 45 providers recorded temperatures that differed from OIG’s independently measured temperatures (average difference was between 2°F and 4°F).
CDC’s Response

CDC is not recommending that parents revaccinate their children. The main concern with improper storage temperatures is that they can make vaccines less effective rather than less safe. The OIG report did not assess vaccine potency or effectiveness. While it is possible that some children have received less potent vaccines due to exposure to improper temperatures, our data do not suggest that this is a common or widespread problem. Our national monitoring indicates vaccines are doing their job at providing protection against disease. Most of the diseases we vaccinate against are at record low levels in the United States. Investigations of recent outbreaks of measles and pertussis have been associated with factors such as vaccine refusal and waning of immunity over time. In fact, patterns in these outbreaks suggest that children are receiving potent and effective vaccines. Our vaccine safety monitoring also indicates that we continue to have the safest vaccine supply in our history.

While the safety and health of our nation’s children has not been compromised by the issues identified by the OIG, the findings are important and underscore that we must do better at ensuring that all vaccines are stored properly at all times, including removing expired vaccine from units where viable vaccines are stored. The vaccines that protect children against serious and even deadly diseases should always be stored properly. CDC and our partners are working with a sense of urgency to address the problems identified in the OIG study.
Findings from the OIG Report Have Led to New VFC Program Requirements

## California Vaccines for Children (VFC) Program

### New 2013 Program Participation Requirements at a-glance

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Summary</th>
<th>Agreement Item (Certification of Capacity to Store and Manage Vaccines)</th>
<th>Materials/Job Aids</th>
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<tbody>
<tr>
<td>Designation of Key Clinic Staff</td>
<td>VFC providers must designate a Vaccine Coordinator and Backup Vaccine Coordinator fully trained to oversee and manage the clinic’s vaccine supply. Contact name and information for the primary vaccine coordinator must be current in the clinic’s profile. Any personnel changes in this role must be immediately reported to the VFC Program through MYVFCVaccines.</td>
<td>12 (2)</td>
<td>Primary and backup Vaccine Coordinator’s role and responsibilities are described in the Vaccine Coordinator job aid.</td>
</tr>
<tr>
<td>Completion of VFC on-line educational requirements.</td>
<td>Each clinic’s VFC Provider of Record and Vaccine Coordinator must complete annual EIZIZ lessons to meet new federal education requirements on key program areas. Providers cannot receive full training if training has been completed. Lessons must be completed between January 2013 and December 2013. The designated Provider of Record is required to complete the “VFC Program Requirement Overview” lesson (available fall 2013), however, completion of all lessons is highly encouraged. The designated Vaccine Coordinator must complete the following lessons: 1. Storing Vaccines (20 min) 2. Monitoring Refrigerator Temperatures (17 Min) 3. Monitoring Freezer Temperatures (15 min) 4. Conducting a Vaccine Inventory (19 min) 5. VFC Program Requirements (available this fall-estimated time: 15 min)</td>
<td>10</td>
<td>For instructions on how to access, register, and complete these lessons, visit the EIZIZ Training Required for Annual VFC Recertification page</td>
</tr>
<tr>
<td>VFC Eligibility Screening &amp; Documentation</td>
<td>Screening for VFC eligibility must occur with all clinic patients 0-18 years of age, prior to vaccine administration, and be documented in the patient’s permanent medical record (paper-based or electronic medical record) at each immunization encounter. Eligibility documentation must be kept in the patient’s medical record for three years. Documentation of eligibility screening must include the following elements:  • Date of screening  • Whether the patient is VFC eligible or not VFC eligible  • If patient is VFC eligible, eligibility criteria met</td>
<td>1 &amp; 3</td>
<td>VFC’s Patient Eligibility Screening Record form (MM-1111).</td>
</tr>
<tr>
<td>VFC Vaccine Administration Fees</td>
<td>Providers may charge VFC-eligible children not covered by Medi-Cal (e., uninsured, American Indian/Alaskan Natives, and underinsured children as per a FQHC or RHC) up to the new federal maximum regional administration charge of $26.03 per dose (not antigen) of vaccine.</td>
<td>5 &amp; 6</td>
<td>VFC’s Who’s Eligible flyer, MM-1088</td>
</tr>
</tbody>
</table>
Designate Key Clinic Staff

- Each participating VFC provider must designate a Vaccine Coordinator and Backup Vaccine Coordinator who are fully trained in providing oversight for the clinic’s vaccine supply. Both must be familiar with their role and responsibilities as described in the Vaccine Coordinator job aid.
- Put this information in writing
Annual Training Requirements

- Each clinic’s VFC Provider of Record and Vaccine Coordinator must complete annual EZIZ lessons to meet new federal education requirements on key program areas.
- Providers cannot recertify until training has been completed. Lessons must be completed between January 2013 and December 2013.
- Provider of Record is required to complete the “VFC Program Requirement Overview” lesson (available fall 2013);
- Vaccine Coordinator must complete the following lessons:
  1. Storing Vaccines (20 min)
  2. Monitoring Refrigerator Temperatures (17 Min)
  3. Monitoring Freezer Temperatures (15 min)
  4. Conducting a Vaccine Inventory (19 min)
  5. VFC Program Requirements (available this fall-estimated time: 15 min)
Have you completed these lessons?
VFC Eligibility Screening & Documentation

- Screening for VFC eligibility must occur with ALL clinic patients 0-18 years of age, prior to vaccine administration, and be documented in the patient’s permanent medical record (paper-based or electronic medical record) at each immunization encounter.

- Documentation of eligibility screening must include the following elements:
  - Date of screening
  - Whether the patient is VFC eligible or not VFC eligible
  - If patient is VFC eligible, eligibility criteria met.

- Providers may use VFC’s Patient Eligibility Screening Record form (IMM-1111) to document eligibility or a similar form containing the above listed elements, or they may document eligibility elements on a practice electronic medical record (EMR) or immunization information system.

- Eligibility documentation must be kept in the patient’s medical record for three years.
# VFC Eligibility Screening Record Form

## Patient Eligibility Screening Record for Vaccines for Children Program

### Patient Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Last</th>
<th>First</th>
<th>MI</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent/Guardian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(if applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Provider Name

- [ ] The patient named above qualifies for immunization through the VFC Program because he/she or his/her parent/guardian states the child is 18 years of age or younger and:
  - Choose only one of the following:
    - Is Medi-Cal or Child Health and Disability Prevention (CHDP) eligible; or
    - Is uninsured (does not have private health insurance); or
    - Is an American Indian or Alaskan Native.

- [ ] The patient named above does not qualify for immunization through the VFC Program because he/she has health insurance that pays for vaccines.

### Eligibility Status Verification

<table>
<thead>
<tr>
<th>Screening Date</th>
<th>Medi-Cal or CHDP Eligible</th>
<th>Uninsured</th>
<th>America Indian or Alaskan Native</th>
<th>Under-Insured (health insurance does not cover vaccine(s))</th>
<th>Not VFC Eligible</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Notes

1. This form documents the eligibility status of the patient named above.
2. The health care provider must keep this record for the VFC-eligible child for no less than three (3) years and make it available to state or federal officials for inspection upon request.
3. This record may be completed by the patient (if he or she is an emancipated minor or 18 years of age), his or her parent or guardian or by the health care provider.
4. VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure eligibility status has not changed.
5. Verification of responses is not required.

This publication was supported by Grant Number H23/CU1922357F from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.
Thermometers

- Providers should have 2 thermometers in each unit, a primary and a back-up thermometer.
- According to the CDC, thermometers:
  - Should be accurate within +/- 1°F (+/-0.5°C).
  - Should be digital, with the digital display placed outside the unit to allow for temperature monitoring without opening the unit door.
  - Should have a biosafe glycol-encased probe, placed in proximity with vaccines.
  - Should display current temperature, as well as the minimum and maximum temperatures, and have an audible alarm.
Thermometer Specs

- Display current, minimum and maximum temperatures.
- Temperature reset button
- External digital display to monitoring temperature without opening unit
- Audible alarm
- Digital and have a bio-safe glycol-encased probe.
- Be within +/-.5°C accuracy (+/-1°F).
Thermometer Calibration & Certification

- Primary and back-up thermometers must be calibrated annually (or every other year at the most if recommended by the manufacturer)

- Calibration should be conducted by an ILAC/MRA accredited laboratory. If calibration is conducted by a non-accredited laboratory, calibration certificates must include:
  - Name and address of laboratory conducting testing
  - Date of calibration
  - Thermometer Identification (serial #)
  - Measurement results
  - Statement of conformance with ISO/IE17020 calibration procedure standards
  - Certificate report number.

- Thermometers no longer accurate within, +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced.

- A valid Certification of Calibration must be kept on file and be readily available for review during VFC visits.
Traceable® Certificate of Calibration for Refrigerator Thermometer

**Instrument Identification:**
- Model: 06-664-11
- S/N: 72706927
- Manufacturer: Control Company

**Standards/Equipment:**

<table>
<thead>
<tr>
<th>Description</th>
<th>Serial Number</th>
<th>Due Date</th>
<th>NIST Traceable Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Calibration Bath TC101</td>
<td>A73044</td>
<td>7/11/08</td>
<td>1000222656</td>
</tr>
<tr>
<td>Thermistor Module</td>
<td>A27115</td>
<td>7/13/08</td>
<td>A77100639-4</td>
</tr>
<tr>
<td>Temperature Probe</td>
<td>3639</td>
<td>7/26/08</td>
<td>A78700032</td>
</tr>
<tr>
<td>Temperature Calibration Bath TC150</td>
<td>59139</td>
<td>3/30/08</td>
<td>A7831032</td>
</tr>
<tr>
<td>Thermistor Module</td>
<td>A17118</td>
<td>3/14/08</td>
<td>A68806053</td>
</tr>
<tr>
<td>Temperature Probe</td>
<td>157</td>
<td>3/14/08</td>
<td></td>
</tr>
</tbody>
</table>

**Certificate Information:**

- Technician: SS
- Procedure: CAL 03
- Test Conditions: 23.0°C, 40.0 %RH, 1021 mBar
- Cal Date 12/18/07
- Cal Due 12/17/08

**Calibration Data: (New Instrument)**

<table>
<thead>
<tr>
<th>Unit(s)</th>
<th>Nominal</th>
<th>As Found</th>
<th>As Left</th>
<th>In Tol</th>
<th>Min</th>
<th>Max</th>
<th>End</th>
<th>TUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>°C</td>
<td>N.A.</td>
<td>0.000</td>
<td>-1</td>
<td>Y</td>
<td>-1</td>
<td>1</td>
<td>0.580</td>
<td>1.7:1</td>
</tr>
<tr>
<td>°C</td>
<td>N.A.</td>
<td>50.001</td>
<td>50</td>
<td>Y</td>
<td>49</td>
<td>51</td>
<td>0.580</td>
<td>1.7:1</td>
</tr>
</tbody>
</table>

This Instrument was calibrated using instruments Traceable to National Institute of Standards and Technology.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test as traceable to the NIST. The uncertainty represents an expansion factor calculated using a coverage factor. The uncertainty is the expanded uncertainty calculated in accordance with the ISO 9001:2008 and the Measurement Uncertainty (MUI) of the measurement. The uncertainty represents an expansion factor calculated using a coverage factor. The uncertainty is the expanded uncertainty calculated in accordance with the ISO 9001:2008 and the Measurement Uncertainty (MUI) of the measurement.

**Accredited Laboratory Name:**

CONTROL COMPANY 4455 Rex Road Friendswood, TX 77546 USA
Phone 281-482-1714  Fax 281-482-9448  service@control3.com  www.control3.com

Control Company is an ISO 9001 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1750.01
Control Company is ISO 9001 Quality Certified by (DNV) Det Norske Veritas, Certificate No. CERT-19900-AQ-ROU.
Unacceptable Proof of Calibration
Temperature Monitoring

- Temperatures for each unit must be read and documented **twice each workday**, at the beginning of the day and before closing.
- Additionally, **minimum and maximum temperatures must also be read and documented** at the beginning of each workday.
- Thermometer temperatures must be cleared after each daily MIN/MAX readings.
- Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger.
- Temperature logs must be posted in a visible location.
- Temperature logs must be maintained for three years.

Current VFC Temperature Logs are being modified and tested to allow space for documentation of Minimum and Maximum readings. The VFC Program will notify providers via e-mail once new logs are readily available on www.eziz.org.
# Refrigerator Temperature Log

Record minimum, maximum and current temperatures twice a day.

1. Write your initials and the a.m. or p.m. time.
2. Write an "X" next to the current, minimum, and maximum temperatures. See figure a.
3. If the temperature is unacceptable (above 46°F or below 35°F), write the temperature in the space provided and take action. See figure b.
4. At the end of the month, file this log and keep it for 3 years.

### Staff Initials

<table>
<thead>
<tr>
<th>Day of Month</th>
<th>16</th>
<th>17</th>
<th>18</th>
<th>19</th>
<th>20</th>
<th>21</th>
<th>22</th>
<th>23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>am</td>
<td>pm</td>
<td>am</td>
<td>pm</td>
<td>am</td>
<td>pm</td>
<td>am</td>
<td>pm</td>
</tr>
</tbody>
</table>

### Acceptable Temperatures

<table>
<thead>
<tr>
<th>Temperature</th>
<th>35°F</th>
<th>36°F</th>
<th>37°F</th>
<th>38°F</th>
<th>39°F</th>
<th>40°F</th>
<th>41°F</th>
<th>42°F</th>
</tr>
</thead>
</table>

### Danger! Temperatures above 46°F are too warm!
Write any unacceptable temperature in the spaces provided and take action.

### Take Action!

1. Place an "X" next to the current temperature. Figure a.
2. Then write the minimum and maximum temperatures in the spaces provided. Figure b.
3. If the temperature is too warm or too cool (above 46°F or below 35°F) it is unacceptable - write the temperature in the space provided and take action. Figure c.
4. At the end of the month, file this log and keep it for 3 years.

| Staff Initials | Day of Month | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|----------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Time           | am          | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm |

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</tr>
</thead>
</table>

### Danger! Temperatures below 35°F are too cold!
Write any unacceptable temperature on the lines below and call your VFC Rep. immediately.

### Take Action!

1. Place an "X" next to the current temperature. Figure a.
2. Then write the minimum and maximum temperatures in the spaces provided. Figure b.
3. If the temperature is too warm or too cool (above 46°F or below 35°F) it is unacceptable - write the temperature in the space provided and take action. Figure c.
4. At the end of the month, file this log and keep it for 3 years.

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Write any unacceptable temperature on the lines below and call your VFC Rep. immediately.

### Take Action!

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1. Place an "X" next to the current temperature. Figure a.
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3. If the temperature is too warm or too cool (above 46°F or below 35°F) it is unacceptable - write the temperature in the space provided and take action. Figure c.
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| Time           | am          | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm |

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<th>40°F</th>
<th>41°F</th>
<th>42°F</th>
</tr>
</thead>
</table>
Site Visits

- Providers agree to participate in VFC Program site visits, including:
  - Scheduled compliance visits, also known as Quality Assurance Reviews (QARs)
  - Unannounced Storage & Handling visits
  - Other visits for educational and programmatic support.

- The goal of unannounced storage and handling visits is to ensure VFC supplied vaccines administered to VFC eligible children are managed and stored according to program requirements.
Requirements for participation in the VFC Program are set by CDC and clearly outlined in the Program’s “Participation Agreement.”

Initially and on an annual basis, providers must agree with set requirements in order to renew participation in the program.
Christina Sadorra Sapad, MPA
Jr. Field Services Representative
Phone: (510) 412-1609
Fax: (510) 412-1604
christina.sadorra@cdph.ca.gov