Arizona Vaccines for Children (VFC) Program

Operations Guide 2016

Arizona Department of Health Services
# Table of Contents

Vaccines for Children Program.........................................................................................1
  - Welcome
  - Background
  - Highlights

Definitions, Acronyms, and Abbreviations Used in this Guide.................................3

**Chapter 1: VFC Program Guidelines.........................................................................7**
  - VFC Eligibility Screening
  - Eligibility Criteria
  - VFC Provider Requirements
  - Vaccine Information Statements (VIS)
  - Primary/Secondary Insurance

**Chapter 2: Arizona VFC Supplied Vaccine.................................................................13**
  - Arizona VFC Vaccine Choice Policy
  - Vaccines Supplied by the VFC Program

**Chapter 3: Provider Enrollment in the VFC Program................................................17**
  - Annual Provider Enrollment
  - VFC Re-Enrollment

**Chapter 4: Arizona State Immunization Information System (ASIIS)................19**
  - What is ASIIS?
  - State Law Concerning ASIIS
  - Reporting in ASIIS
  - ASIIS Paper Reporting
  - ASIIS Electronic Reporting
  - ASIIS Contact Information

**Chapter 5: Vaccine Ordering and Documentation.....................................................21**
  - Vaccine Ordering Process
  - Placing an Online Vaccine Order
  - Emergency Vaccine Orders
  - Order Delays and Cancellations
  - Temperature Logs
  - Maintaining Vaccine Inventory
  - Borrowing VFC Vaccines
  - Transferring VFC Vaccines Between Provider Offices
  - Vaccine Shipments
    - Receiving Vaccine Shipments
    - Transferring VFC Vaccines Between Provider Offices

**Chapter 6: Ordering During Influenza Season.......................................................30**
  - VFC Influenza Process
• Influenza Ordering
• Inventory Reconciliation

Chapter 7: Vaccine Management and Accountability
• Vaccine Cold Chain
• Refrigerator/Freezer Equipment
• Temperature Monitoring Equipment
  o Backup Thermometer
  o Thermometer Equipment
• Maintaining VFC Vaccine Viability
• Refrigerator/Freezer Temperatures
• Vaccine Storage and Handling Plan
• Inventory Management
• Vaccine Administration
  o Additional VFC Vaccine Administration Guidance
  o How to Use Vaccines with Diluents
• Vaccine Loss
  o Vaccine Wastage Restitution Policy
  o How to Handle Wasted or Expired Vaccine
  o Vaccine Returns
  o Items to Keep in Mind
• Vaccine Emergency Handling Plan

Chapter 8: VFC Provider Compliance Visits
• Provider Site Visit
• VFC Compliance Requirement
• Satisfaction Surveys

Chapter 9: Continuous Quality Improvement (CQI) through the AFIX (Assessment, Feedback, Incentive, and eXchange) Program
• AFIX Program Overview

Chapter 10: Provider Request for Inactivation or Office Closure
• Voluntary Inactivation
• Office Relocation, Move or Other Changes
• Short-term Office Closure

Chapter 11: Disciplinary Process
• Notice of Action Procedures
  o VFC Corrective Action Process
  o Administrative Observation
  o Involuntary Inactivation
Chapter 12: VFC Vaccine Fraud and Abuse ........................................60
- Definitions/Relevant Terms
- Enforcement Actions for Fraud/Abuse
- Examples of Fraud and Abuse

Chapter 13: Vaccine Adverse Event Reporting System (VAERS) ..........62
- Reporting to VAERS
- Filing a VAERS Report
- VAERS contact Information

Chapter 14: The Health Insurance Portability and Accountability Act ....63
(HIPAA)

Chapter 15: Contacts ......................................................................64
- Directory of VFC and AFIX Staff

Chapter 16: Resources .................................................................66
- VFC Forms
- Job Aids
- Websites
  - State
  - Federal
  - Organizations
  - Vaccine Manufacturers
- References
Welcome to the Arizona Vaccines for Children (VFC) program. The Arizona VFC Operations Guide has been prepared by the Arizona Department of Health Services, Arizona Immunization Program Office to provide information to enrolled providers to ensure compliance with federal and state VFC guidelines regarding safe handling, administration, and reporting of VFC vaccines. Recommendations from CDC and the American Academy of Pediatrics are included. We wish to thank CDC staff who have advised and assisted us in the preparation of the Guide.

If you have questions regarding this guide, please call the Arizona Vaccine Center at (602) 364-3642.

The link below provides access the VFC Program webpage. Please save the VFC webpage link to your internet favorites:


To all VFC providers, we extend our thanks for immunizing Arizona’s children.

Background

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. The program was officially implemented in October 1994 as part of the President’s Childhood Immunization Initiative. Funding for the VFC Program allows the Centers for Disease Control and Prevention (CDC) to buy vaccines at a discount from the manufacturers and distribute them to state health departments and certain local and territorial public health agencies, which in turn distribute them at no charge to private physician offices and public health clinics registered as VFC providers.

The VFC Program represents an unprecedented approach to improving vaccine availability nationwide by making federally-purchased vaccine available to both public and private immunization providers. Over the past 20 years, the VFC program has become increasingly recognized for its success in raising immunization coverage rates among high-risk children and reducing disparities in access to health care. The VFC Program has also helped reduce physician referrals for immunizations to public clinics.

Highlights

The VFC Program:

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers in all states, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the commonwealth of the Northern Mariana Islands
- Provides vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) through passage of VFC resolutions
- Saves parents and enrolled providers out-of-pocket expenses for vaccine
- Provides cost savings to states through bulk purchase of vaccines at lower prices using CDC’s contracts and eliminates state-to-state variations in price
- Eliminates or reduces vaccine cost as a barrier to vaccination of eligible children
- Reduces the practice of referring children from the private sector to the public sector for vaccination

Excerpted from the Federal VFC Operations Guide
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIP</td>
<td>Advisory Committee on Immunization Practices</td>
</tr>
<tr>
<td>AFIX</td>
<td>Assessment, Feedback, Incentive, and eXchange</td>
</tr>
<tr>
<td>AHCCCS</td>
<td>Arizona Health Care Cost Containment System</td>
</tr>
<tr>
<td>AIPO</td>
<td>Arizona Immunization Program Office</td>
</tr>
<tr>
<td>Aseptic</td>
<td>The absence of microorganisms. Free from infection or septic material; also <em>sterile</em>.</td>
</tr>
<tr>
<td>ASIIS</td>
<td>Arizona State Immunization Information System</td>
</tr>
<tr>
<td>Attenuated</td>
<td>Weakened or reduced virulence</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CHD</td>
<td>County Health Department</td>
</tr>
<tr>
<td>Cold Chain</td>
<td>A temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range. It is used to help extend the shelf life and viability of vaccines.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>A five digit numeric code that is used to describe medical, surgical, radiology, laboratory, and evaluation services of physicians, hospitals, and other health care providers. All vaccines have their own CPT code.</td>
</tr>
<tr>
<td>CVX Code</td>
<td>A code used by computer programs to indicate the product used in a vaccination.</td>
</tr>
<tr>
<td>Diluent</td>
<td>A substance used to dilute. In vaccine use, diluent is used to reconstitute lyophilized (powder) vaccine. Diluents may be sterile water, sodium chloride, or other components. Only the diluent provided with the vaccine should be used with that vaccine. Diluents are not interchangeable.</td>
</tr>
<tr>
<td>Electronic Medical Record (EMR)</td>
<td>A specialized medical information software application which electronically documents patient medical information.</td>
</tr>
<tr>
<td>Eligible</td>
<td>A patient who meets the criteria for VFC Program participation.</td>
</tr>
<tr>
<td>Facility ID</td>
<td>The facility account number.</td>
</tr>
<tr>
<td>Inactivated</td>
<td>Considered to be a killed vaccine; cannot replicate, is not infectious and cannot cause disease.</td>
</tr>
<tr>
<td><strong>IRM</strong></td>
<td>The organization account number. An IRMS (organization) can have multiple facilities.</td>
</tr>
<tr>
<td><strong>Lot Number</strong></td>
<td>An identification number assigned to a particular quantity of vaccines from the manufacturer. The lot number helps to identify the vaccine in case it needs to be recalled.</td>
</tr>
<tr>
<td><strong>Potency</strong></td>
<td>Vaccine effectiveness.</td>
</tr>
<tr>
<td><strong>Reconstitution</strong></td>
<td>Restoration to original form of a substance previously altered for preservation and storage.</td>
</tr>
<tr>
<td><strong>Restitution</strong></td>
<td>Repayment for lost, wasted, expired, or spoiled VFC vaccines due to provider negligence.</td>
</tr>
<tr>
<td><strong>Vaccine Coordinator</strong></td>
<td>The staff person in the provider’s office who is the primary administrator and contact person for the management of vaccines.</td>
</tr>
<tr>
<td><strong>Viable</strong></td>
<td>Capable of living; in vaccines, the state in which vaccines are effective.</td>
</tr>
<tr>
<td><strong>Vial</strong></td>
<td>A small bottle, usually of glass.</td>
</tr>
<tr>
<td><strong>Wastage</strong></td>
<td>Wasteful or avoidable loss. VFC vaccines that are spoiled, expired, or lost may be billed to the provider.</td>
</tr>
</tbody>
</table>
**Vaccine Abbreviations**

- **DT**  
  Diphtheria, Tetanus vaccine (Pediatric) <7 years of age

- **DTaP**  
  Diphtheria, Tetanus, acellular Pertussis

- **DTaP/HepB/IPV**  
  Diphtheria, Tetanus, acellular Pertussis/  
  Hepatitis B/Polio

- **DTaP/Hib/IPV**  
  Diphtheria, Tetanus, acellular Pertussis/ 
  *Haemophilus influenzae* type b/Polio

- **DTaP/Polio**  
  Diphtheria, Tetanus, acellular Pertussis/Polio

- **HBIG**  
  Hepatitis B Immune Globulin (hospitals only)

- **Hep A**  
  Hepatitis A

- **Hep B**  
  Hepatitis B

- **HepB/Hib**  
  Hepatitis B and *Haemophilus influenzae* type B

- **Hib**  
  *Haemophilus influenzae* type B

- **HPV**  
  Human Papillomavirus 4-valent or 9-valent

- **IG**  
  Immune Globulin

- **IPOL**  
  Inactivated Polio Vaccine (also known as IPV)

- **LAIV**  
  Live Attenuated Influenza Vaccine

- **MCV4**  
  Meningococcal Conjugate Vaccine 4-valent

- **MCV4/Hib**  
  Meningococcal Conjugate Vaccine 4-valent/*Haemophilus influenzae* type B

- **MenB**  
  Meningococcal Serogroup B

- **MMR**  
  Measles, Mumps, Rubella

- **MMRV**  
  Measles, Mumps, Rubella/Varicella

- **PCV 13**  
  Pneumococcal Conjugate Vaccine 13-valent  
  (6 weeks-5 years and 6-18 years if high risk)

- **PPV 23**  
  Polysaccharide Pneumococcal Vaccine 23-valent  
  (2-18 years - **high risk only**)

- **Rota**  
  RotaVirus vaccine 5-valent or 1-valent (ages 6 weeks through 32 weeks)

- **QIV**  
  Quadrivalent Influenza Vaccine

- **Tdap**  
  Tetanus, diphtheria, acellular pertussis (7-18 years)

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Td</strong></td>
<td>Tetanus Diphtheria Vaccine (Adult) &gt;7 years of age only</td>
</tr>
<tr>
<td><strong>TIV</strong></td>
<td>Trivalent Inactivated Influenza vaccine</td>
</tr>
<tr>
<td><strong>VAR/VZV</strong></td>
<td>Varicella (chickenpox)</td>
</tr>
</tbody>
</table>
## Chapter 1: VFC PROGRAM GUIDELINES

### Eligibility Requirements

- ✓ VFC vaccines can only be given to children ages 0 through 18 years of age that meet the eligibility requirements
- ✓ VFC Eligibility Screening must occur at every visit
- ✓ VFC providers must provide a copy of the Vaccine Information Statement to patients for each vaccine given

### Eligibility Screening

- Prior to administering VFC vaccines each patient must be screened at every visit for VFC eligibility to determine if they are eligible to receive VFC vaccines (see Resources/VFC Forms: Patient Eligibility Screening Record-VFC). If the eligibility status has changed since the previous visit the new status should be documented by copying the child’s new AHCCCS or other insurance card and placing the copy in the patient file.

- Document the screening information on the Immunization Administration Record, the Patient Eligibility Screening Form, or electronic medical record (EMR) so you can retrieve this information from ASIIS for VFC Program reports.

- You are not required to verify the patient’s responses to the screening questions.

- Keep the eligibility screening record for six (6) years from the date of the last visit. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.

- If using electronic records keep the eligibility screening information in the patient’s electronic medical record or in a separate database for six (6) years from the date of the last visit. This information must include the date(s) the patient was screened.
Eligibility Criteria

Children birth through 18 years of age who meet at least one of the following criteria on the day the vaccine is to be administered are eligible to receive VFC vaccine.

<table>
<thead>
<tr>
<th>Arizona VFC/KidsCare Eligibility Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicaid</strong></td>
</tr>
<tr>
<td><strong>Un-insured</strong></td>
</tr>
<tr>
<td><strong>American Indian / Alaska Native</strong></td>
</tr>
<tr>
<td><strong>Under-insured</strong>*</td>
</tr>
<tr>
<td><strong>KidsCare</strong></td>
</tr>
</tbody>
</table>

*Only Deputized Providers have authority to vaccinate “underinsured” children. If you are not deputized please refer all “underinsured” children to an approved deputized VFC provider office. Deputized providers are listed by county at [http://www.azdhs.gov/phs/immunization/documents/vaccine-policy-changes/underinsured-referral-locations.pdf](http://www.azdhs.gov/phs/immunization/documents/vaccine-policy-changes/underinsured-referral-locations.pdf). (Also Exhibit 21) Additionally, underinsured children are eligible to receive VFC vaccines through a Federally Qualified Health Center (FQHC a.k.a. CHC), a Rural Health Center (RHC) or a County Health Department (CHD).

VFC Provider Requirements

- Providers are required to comply with the appropriate immunization schedule, dosage, and contraindications established by the Advisory Committee for Immunization Practices (ACIP) in VFC resolutions and included in the VFC program unless (a) in the provider’s medical judgment and in accordance with accepted medical practice, it is deemed such compliance is medically inappropriate, or (b) the particular requirements contradict the laws in Arizona pertaining to acceptable exemptions. ACIP VFC Resolutions are available at [http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html](http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html).
• Eligibility is not generally retroactive. Contact the VFC Program if you discover that a child was actually VFC eligible on the date of service but was treated as an ineligible child. In certain circumstances VFC may be able to replace private stock vaccine with VFC vaccine.

• An administration fee, not to exceed $21.33 per immunization, may be charged to non-Medicaid patients. $21.33 is the maximum fee set by the regional Centers for Medicare and Medicaid Services (CMS), called AHCCCS in Arizona. For those children who are Medicaid eligible please contact your Medicaid Health Plan for specific requirements and rates for billing or go to: http://www.azahcccs.gov/commercial/ProviderBilling/rates/PCSrates.aspx for more information.

• You may charge patients an administration fee, but if they are unable to pay this fee it must be removed from their bill. Sending these bills to collections is not acceptable.

• No VFC eligible patient may be denied vaccine for failure to pay an administration fee.

• Failure to waive administration fees according to VFC Program policy could be considered fraud and abuse (see chapter 12 of this manual for more information on fraud and abuse).

• The Arizona VFC program requires that all administered doses of VFC vaccine are reported to ASIIS within 30 days of administration. This program requirement is supported by Arizona law (ARS 36-135).

• VFC records must be accurate and complete.

• The following medical protocols must be up-to-date and accessible to all staff who administer vaccines:
  o Current CDC Recommended Immunization Schedule
  o Vaccine Contraindications/Precautions
  o Administration Techniques
  o Emergency Handling Plan

• Only properly trained individuals should administer vaccines.

• Providers must provide ongoing education and training in the following areas:
  o Current immunization recommendations should be provided to staff who prepare and administer vaccines
  o Train any provider staff involved in receipt of vaccine deliveries to immediately open, inspect, and store vaccines upon delivery
  o Ensure all staff with vaccine management responsibilities are trained on proper vaccine storage and handling procedures
  o Train other staff who are responsible for administering vaccines or who may be required
to transport vaccine in an emergency situation on proper vaccine storage and handling procedures
  o Train staff to use ASIIS for vaccine ordering and inventory management

• Providers must maintain training records for staff. Documentation must include the staff member’s name and date of training. Annual training is required for the VFC Coordinator and the backup VFC Coordinator.

• Vaccines supplied by VFC must be identified, labeled, and stored separately from privately purchased vaccines. Contact the Arizona Vaccine Center for “VFC” labels for VFC vaccines.

• Vaccine Adverse Event Reporting System (VAERS) forms must be available and adverse events must be reported promptly and accurately. VAERS forms may be obtained by calling 1-800-822-7967 or visit: https://vaers.hhs.gov/index. Paper copies of VAERS reports should be kept for a minimum of 6 years (for more information on VAERS, see chapter 13).

• Providers are required to participate in the VFC program compliance site visits including unannounced visits and other educational opportunities associated with VFC program requirements. (For more information on site visits see Chapter 8: VFC Provider Compliance Visits.)

Vaccine Information Statement (VIS)

According to federal law you must provide a current Vaccine Information Statement (VIS) every time a patient receives a vaccine and document the publication date of the VIS and the date it was given to the patient in the patient’s medical record. VISs are CDC fact sheets that inform vaccine recipients, or their parents or legal representatives, of the benefits and risks of a vaccine.

Give a VIS (either paper or electronic) to the patient before administering each dose of vaccine. Let the patient keep a paper copy of the VIS, or if they prefer to download the VIS onto a mobile device direct them to CDC’s current VIS webpage at: www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm. Make sure they have a chance to have their questions answered. Give them a phone number to call in case of any questions or unexpected symptoms after receiving a vaccine.

When possible, provide the VIS in the person’s native or preferred language. Translated VISs are available on the web at no charge at www.cdc.gov/vaccines/pubs/vis.

It is not necessary to have the patient sign anything to show they have received the VIS, unless your practice requires this.

Document the publication date of the VIS, located on the bottom corner of each VIS, in the patient’s medical record and the date the VIS was given to the patient.
It is acceptable to provide a VIS before the immunization visit (e.g., by giving the patient a copy to take home during a prior visit, or telling them how to download or view a copy from the internet). We encourage this when possible.

**Private Primary/Medicaid (AHCCCS) as Secondary Insurance**

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

**Option 1:**
A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.

In most health care situations, Medicaid is considered the “payer of last resort.” This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

**Considerations regarding this option:**
- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

**Option 2:**
A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

If the primary insurance pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.

If the primary insurer denies payment of vaccine and the administration fee the provider may replace the private-purchased vaccine with VFC vaccine and bill Medicaid for the
administration fee. The provider must document this replacement on the vaccine borrowing report (see Resources/VFC forms: Vaccine Borrowing Report).

Considerations regarding this option:
• The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
• The deciding factor on which vaccine inventory to use should be based on what will be most cost effective for the family.
• The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or for an administration fee.
Chapter 2: ARIZONA VFC SUPPLIED VACCINES

Arizona VFC Vaccine Choice Policy

All childhood vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are available through the Arizona Immunization Program Office (AIPO), Vaccines for Children (VFC) program. Therefore, VFC providers with a product preference may choose a particular brand as long as it is available through the VFC program. VFC vaccines may be ordered through the Arizona State Immunization Information System (ASIIS).

The Arizona Vaccine Center will make every attempt to honor provider choice whenever possible, but the following situations might result in limited brand choice:

- Manufacturing and distribution product availability or shortage
- Influenza vaccine may not be available due to shortages or delays from the vaccine manufacturers
- New or changing vaccines may not be available immediately upon approval by the VFC program due to procurement processes or due to technical changes or updates to ASIIS that require planning, clinical review and implementation by technology staff
- The Vaccine Center Manager has the authority to remove vaccines from availability as necessary

If a brand chosen by a provider is not available (such as a supply shortage), Vaccine Center staff may take the following action under the authority and approval of the Vaccine Center Manager:

- If an identical vaccine is available, the alternate brand may be shipped without notification (e.g., Pedvaxhib® and Acthib®). Providers are expected to make use of the equivalent vaccine to the best of their abilities until vaccine supplies normalize.
- If a similar, but not equivalent vaccine is available, the provider will be asked to approve a replacement before any vaccine is shipped (e.g., HPV4 vs. HPV9).
- If a combination vaccine becomes unavailable, the provider will be asked to approve a shipment of individual antigen equivalents before the order is placed with CDC.

The Arizona Vaccine Center will honor provider preference for packaging (e.g., syringes vs. vials) whenever possible. If syringes become unavailable for an extended period of time, the Arizona Vaccine Center will ship vials without notification to the provider. If vials become unavailable for an extended period of time the Arizona Vaccine Center will ship syringes to providers ordering less than 50 doses of vaccine in vials. Providers with vial orders greater
than 50 must approve a shipment of syringes as a replacement before the order is placed with CDC.

If a provider chooses to use a different brand of vaccine, the physician bears the responsibility for using all remaining doses of the previously supplied vaccine before the expiration date, or safely transferring that vaccine to another active VFC provider. This must receive prior approval from the Arizona Vaccine Center Staff. Allowing a vaccine to expire because the provider has chosen to change brands will be considered a failure to properly monitor vaccine, and that provider will be subject to a wastage invoice from the Arizona Vaccine Center.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Type</th>
<th># Doses &amp; Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP</td>
<td>Infanrix®</td>
<td>GlaxoSmithKline (GSK)</td>
<td>Inactivated</td>
<td>5 doses 2, 4, 6, 15-18 mos. &amp; 4-6 yrs &amp; 2, 4, 6, 15-18 mos. &amp; 4-6 yrs</td>
</tr>
<tr>
<td></td>
<td>Daptacel®</td>
<td>sanofi-pasteur</td>
<td>Inactivated</td>
<td>3 doses 2, 4 &amp; 6 months</td>
</tr>
<tr>
<td>DTaP/HepB/IPV</td>
<td>Pediarix®</td>
<td>GSK</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6 &amp; 15-18 mos</td>
</tr>
<tr>
<td></td>
<td>Pentacel®</td>
<td>Sanofi-Pasteur</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6 &amp; 15-18 mos</td>
</tr>
<tr>
<td></td>
<td>Kinrix®</td>
<td>GSK</td>
<td>Inactivated</td>
<td>1 dose 4-6 yrs - for 4th dose of polio &amp; 5th dose of DTaP ONLY</td>
</tr>
<tr>
<td>Hib</td>
<td>ActHib®</td>
<td>Sanofi Pasteur</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6, 15-18 mos.</td>
</tr>
<tr>
<td></td>
<td>PedvaxHIB®</td>
<td>Merck</td>
<td>Inactivated</td>
<td>3 doses 2, 4, 15-18 mos</td>
</tr>
<tr>
<td></td>
<td>MENHIBRIX</td>
<td>GSK</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6, 12-15 mos.</td>
</tr>
<tr>
<td>PCV13</td>
<td>Prevnar®</td>
<td>Pfizer</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6, 15-18 mos.</td>
</tr>
<tr>
<td>PPV23</td>
<td>Pneumovax 23®</td>
<td>Merck</td>
<td>Inactivated</td>
<td>1-2 doses 2-18 yrs for high risk only</td>
</tr>
<tr>
<td>Rota</td>
<td>RotaTeq® (RV5)</td>
<td>Merck</td>
<td>Live, oral</td>
<td>3/2 doses 2, 4 &amp; 6 mos</td>
</tr>
<tr>
<td>Rota</td>
<td>Rotarix® (RV1)</td>
<td>GSK</td>
<td>Live, oral</td>
<td>2 &amp; 4 mos</td>
</tr>
<tr>
<td>Polio</td>
<td>IPOL®</td>
<td>Sanofi-Pasteur</td>
<td>Inactivated</td>
<td>4 doses 2, 4, 6, mos. &amp; 4-6 yrs</td>
</tr>
<tr>
<td>Hep B</td>
<td>Recombivax B®</td>
<td>Merck</td>
<td>Inactivated</td>
<td>3 doses 0 (birth), 2, 6 mos</td>
</tr>
<tr>
<td>Hep B</td>
<td>Engerix B®</td>
<td>GSK</td>
<td>Inactivated</td>
<td>0 (birth), 2, 6 mos</td>
</tr>
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<tr>
<td>Hep A</td>
<td>Havrix®</td>
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<td>Manufacturer</td>
<td>Type</td>
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<td>MMRII®</td>
<td>Merck</td>
<td>Live, attenuated</td>
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<tr>
<td>VAR</td>
<td>Varicella</td>
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<td>Merck</td>
<td>Live, attenuated</td>
</tr>
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<td>ProQuad®</td>
<td>Merck</td>
<td>Live, attenuated</td>
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<td>Tenivac™</td>
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<td>Diphtheria, Tetanus</td>
<td>DT</td>
<td>Sanofi-Pasteur</td>
<td>Inactivated</td>
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</table>

**Biologicals provided under special circumstances**

- **HBIG**: Hepatitis B Immune Globulin (birthing hospitals only)
- **DT**: Diphtheria, Tetanus

If 1st dose given at younger than 12 mos, 4 doses are recommended. If 1st dose given at 12 mos or older, 3 doses complete the primary series.

**Revised 10/31/15**
Chapter 3: PROVIDER ENROLLMENT IN THE VFC PROGRAM

New Provider Enrollment

Enrollment in the Arizona VFC Program is simple. Interested health care providers should call the VFC office at (602) 364-3642 to obtain new provider enrollment information. Enrollment forms can be found on the AIPO website: http://www.azdhs.gov/phs/immunization/vaccines-for-children/index.php?pg=enrollment
Completed forms may be emailed to: ArizonaVFC@azdhs.gov.

The following criteria will be considered when determining provider VFC eligibility and enrollment:
• Provider and provider staff are not included on the Office of Inspector General (OIG) List of Excluded Providers
• Provider(s) signing the Provider Agreement has a valid license to administer vaccines within the awardee jurisdiction
• Provider has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring capacity

Annual Re-enrollment

The Arizona VFC Program requires all providers to re-enroll annually by December 31st of each year, however updates and revisions to the 2016 Provider Profile (see Resources/VFC Forms: 2016 Provider Profile) should be made anytime there are changes in the practice during a current enrollment year.

The current process for VFC re-enrollment is for providers to complete electronically fillable re-enrollment forms and email the completed forms to: ArizonaVFC@azdhs.gov (future re-enrollments will occur in ASIIS). Providers will be notified of the date when their re-enrollment process is scheduled to begin. Vaccine ordering privileges will be stopped during the period of time the provider is re-enrolling and restored once re-enrollment is completed and approved.

Providers who fail to re-enroll will automatically be inactivated on January 1st of the new enrollment year and vaccine ordering and delivery will be discontinued. It will then become the provider’s responsibility to transfer all remaining VFC vaccines to other VFC providers and return any equipment to the Arizona VFC program. Providers inactivated for failure to re-enroll who also fail to transfer VFC vaccine to other VFC providers (and, as a result waste the VFC vaccine) will be unable to enroll in the VFC program at a future date until they have replaced any wasted vaccine from their initial enrollment.
The following information will be required for initial and re-enrollment into the VFC program:

1. **Provider Agreement** -- defines CDC compliance parameters of the VFC program.

2. **VFC Provider License Information** -- lists the names, AHCCCS number, and medical license number of the provider signing the agreement. The signing provider is responsible to assure all staff within the organization are in compliance with this VFC provider enrollment requirement.

3. **Provider Profile** -- provides demographic information of the provider site and identifies the number of children in the practice by eligibility and age group. The profile numbers must be based on real data, not provider estimates. This information is important to accurately order vaccines. Providers may obtain patient demographic information from their Medicaid Claims Data, ASIIS, doses administered, provider encounter data, billing systems, or benchmarking. Providers will not be able to obtain this information from the VFC program.

4. **VFC Vaccine Ordering and Arizona State Immunization Information System (ASIIS) User Information and Pledge** -- identifies provider staff who can order VFC vaccine through ASIIS and access the ASIIS database to query, enter and/or edit immunization data. Each person designated to enter orders into ASIIS should have their own unique username and password.

5. **Refrigerator/Freezer Verification Form** -- describes refrigeration requirements for vaccines. For new or returning VFC providers, refrigerator and freezer temperatures must be recorded on a temperature log twice daily for five consecutive days and the temperature log must be submitted prior to receipt of the first VFC vaccine order. This is to ensure that the storage unit will maintain proper temperatures to maintain vaccine viability.

Upon receipt of the completed forms by the Arizona Vaccine Center the provider will be assigned a VFC Provider Identification Number (PIN). The provider PIN is assigned to you upon initial enrollment in the Arizona VFC Program and will remain your unique identification number until you request to be inactivated, request a change due to sale of the provider practice, or other change. Please remember your PIN. You will be asked for the PIN on all correspondence, orders, and inquiries to the Arizona Vaccine Center.

Arizona Vaccine Center staff will contact the new provider to schedule an on-site visit to examine the refrigerator/freezer and authorize the receipt of the initial vaccine order, and to train provider office staff in VFC policies and procedures.
Chapter 4: ARIZONA STATE IMMUNIZATION INFORMATION SYSTEM (ASIIS)

ASIIS REQUIREMENTS

✓ All doses administered must be manually entered into ASIIS or reported electronically. Paper reporting is not accepted.
✓ Doses administered must be reported to ASIIS within 30 days of administration.
✓ By state statute all vaccine doses administered to children 0 through 18 years of age must be reported to ASIIS.
✓ User Information (address, phone number, email) must be updated quarterly.
✓ Providers must adhere to the requirements in the ASIIS Confidentiality Policy.

What is ASIIS?

The Arizona State Immunization Information System (ASIIS) is an immunization registry designed to capture immunization data on individuals throughout the state. The registry serves as a repository for the reported data. In this capacity, the registry provides a valuable tool for the management and reporting of immunization information to public health professionals, private and public healthcare providers, parents or guardians.

State Law Concerning ASIIS

Arizona Revised Statutes (A.R.S. §36-135) http://www.azleg.state.az.us/ars/36/00135.htm requires all providers to report all vaccines they administer to children birth through 18 years of age to ASIIS. Failure to report is a Class 3 misdemeanor. Reporting administered VFC doses to ASIIS is also a VFC program requirement. Failing to report administered doses in ASIIS will lead to inactivation as a VFC provider.

Reporting to ASIIS

When reporting administered doses in ASIIS it is not acceptable to reconcile administered doses out of the ASIIS inventory using “Administered, but not linked to a vaccine” or “Matches Physical Inventory” reconciliation reasons. All administered doses must decrement from the ASIIS inventory. All administered doses must be accounted for and vaccine inventory must be reconciled to reflect the doses that were wasted, expired, or spoiled to continue to order VFC vaccine.

Patients whose parents or guardians do not consent to have the child be added to ASIIS must cross out and initial their intent on Statement 2 of the Childhood/Adolescent
Immunization Administration Record (AIR 111-1) (see Resources/VFC Forms: Childhood/Adolescent Immunization Administration Record).

Note: VFC vaccines administered at the provider’s office should not be marked as “historical” in ASIIS. “Historical” classification in ASIIS should only be used to record vaccinations administered at another provider’s office.

ASIIS Paper Reporting

Paper reporting of immunizations is no longer allowed. All immunization doses must be reported into ASIIS via manual entry or electronic reporting. Please contact the ASIIS Hotline at (602) 364-3899 or 1-877-491-5741 for further information.

ASIIS Electronic Reporting

ASIIS was recently upgraded and all DTT upload processes and flat file transfers must be transitioned to a different reporting method. All electronic reporting providers will transition to an HL7 upload process. We realize not all providers are able to easily migrate to the current HL7 format and/or many providers are in the process of upgrading to the current HL7 version. An alternate method for uploading your data into ASIIS is available until your EHR system is able to send HL7 data. Please send an email to ASIIS.Group1@azdhs.gov for more information.

The following information must be included for all reporting methods:

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<tr>
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<th>Patient Medical Record #</th>
<th>Guardian Last Name</th>
<th>Administration Date</th>
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<td>Patient Last Name</td>
<td>Guardian First Name</td>
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</tr>
<tr>
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<td></td>
<td>Funding Source (PBF/PVF)</td>
<td></td>
</tr>
<tr>
<td>Patient Address, City, State, and ZIP</td>
<td>Expiration Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Phone</td>
<td></td>
<td>Lot Number</td>
<td></td>
</tr>
</tbody>
</table>

ASIIS Contact Information

Call the ASIIS Hotline Toll Free 1-877-491-5741 or, in the Phoenix area, (602) 364-3899. You can also email the ASIIS Help Desk at ASIIS.HelpDesk@azdhs.gov, or visit the ASIIS website at https://asiis.azdhs.gov/.
Chapter 5: VACCINE ORDERING AND DOCUMENTATION

VACCINE ORDERING REQUIREMENTS

- Vaccine storage unit temperatures must be recorded twice daily.
- Temperature logs must be submitted to the Arizona VFC program monthly, whether you are ordering vaccine or not.
- Providers must order vaccine at least annually and maintain appropriate inventories.

Vaccine Ordering Process

Providers are required to submit their inventory in ASIIS before placing an order. All administered doses must be reported to ASIIS as an administered dose. Any administered doses removed from the ASIIS inventory using the reconciliation reasons “Administered but not linked to a vaccine”, “Administered but patient chose not to be in the Registry” or “Matches physical inventory” may be counted as wastage. Only wasted, spoiled, or expired doses should be reconciled out of the ASIIS inventory.

Placing an Online Vaccine Order

Use ASIIS to place an order for VFC vaccine. You will need an ASIIS username and password to access ASIIS. To obtain an ASIIS username and password for the VFC program complete the 2015 VFC Provider ASIIS User Information form (see Resources/VFC Forms: 2015 VFC Provider ASIIS User Information). Once the form is complete please email it to: ASIISHelpDesk@azdhs.gov.

For step-by-step instructions on how to place a vaccine order, see the VFC Order Placement Training Module.

To ensure you have the necessary data to complete an ASIIS order, follow these steps prior to placing the order:

Collect your Arizona VFC Patient Immunization Log(s) (see Resources/VFC Forms: Arizona VFC Patient Immunization Log) and place the total number of doses of each vaccine administered in the row marked, “Page Totals.”

- VFC providers are required to keep the Arizona VFC Patient Immunization Logs on site for six (6) years. Please do not submit the Arizona VFC Patient Immunization Logs to the Arizona Vaccine Center; these logs are meant to be in-house documents to assist with tracking administered doses.
Complete the VFC Vaccine Order Worksheet (see Resources/VFC Forms: Vaccine Order Worksheet-VFC)

- Enter the totals from the immunization log(s) for each vaccine administered into the column marked “doses administered” on the Vaccine Order Worksheet. If there is more than one log total all pages before entering the total “doses administered.” These numbers should be for the time period stated at the top of the order form.
- Count the inventory (number of doses of each vaccine) in the refrigerator(s) and freezer(s) and enter the total numbers on the Vaccine Order Worksheet in the column marked “Doses on Hand.”
- Log on to ASIIS and verify the data you recorded on the VFC ASIIS Ordering Worksheet (see Resources/Job Aids: VFC ASIIS Ordering Worksheet) against the information that is in ASIIS.

Compare this information to what is in ASIIS in the reconciliation screen. Please be sure to choose the correct reason from the drop down menu in your reconciliation screen for vaccines that are no longer in your inventory. Reasons that will not be accepted include: administered but not linked, unaccounted for in provider inventory, correction of invalid entry, and/or matches physical inventory. Knowing the correct reasons will help us to monitor vaccines on a dose by dose basis as required by CDC. If any of the above reasons are used for reconciliation ordering privileges will be stopped.

- Enter temperatures into the cold storage module in ASIIS using information from your Refrigerator/Freezer Temperature Log. Beginning January 1, 2016 entering temperatures into the Cold Storage Module in ASIIS will be an AZ VFC program requirement.
- If temperatures are not received by the Arizona Vaccine Center within four (4) days of placing the order vaccine orders will be denied. A new order will have to be placed by the provider office once we receive your temperature logs.
- Although you are entering your temperatures into ASIIS you must retain a paper copy of the temperature logs on your cold storage unit.
- The ASIIS Cold Storage Module allows you to manage cold storage units and track temperatures in ASIIS. The temperatures recorded in ASIIS replace faxing or emailing temperature logs, allowing the Arizona Vaccine Center Team to review your temperature logs within ASIIS. This enhances the Arizona Vaccine Center team’s ability to efficiently receive, review, and process your vaccine orders.
- Log into ASIIS to place your vaccine order.
- For help with placing vaccine orders please refer to the ASIIS Vaccine Orders training module which can be found on the ASIIS home page.
- Doses administered and doses on hand must be recorded for each VFC vaccine in your inventory, not just for the vaccine you are ordering.
The Arizona Vaccine Center uses comments in ASIIS to provide direct communication to individual provider offices regarding their orders. It is important to frequently check ASIIS “comments” to determine the status of your order.

Providers are encouraged to keep a 3-4 week supply of vaccine on hand based on the provider’s anticipated VFC eligible population and previous order history. If a provider must order more than a 3-4 week supply a comment must be placed by the provider on the order screen in ASIIS stating the reason for ordering additional vaccine. It will be at the discretion of the Arizona Vaccine Center to approve or deny the order.

**Emergency Vaccine Orders**

Emergency vaccine orders should occur infrequently. VFC providers are encouraged to keep a 3-4 week supply of vaccine on hand based on the provider’s anticipated VFC eligible population and previous order history. Emergency vaccine orders will be approved at the discretion of the Vaccine Center Manager.

VFC providers are to use the comments section in ASIIS to add the reason they are requesting an additional order outside of their normal ordering schedule.

**Order Delays or Cancellations**

Orders will be denied or placed on hold for the following reasons:

- Temperatures not submitted to the Cold Storage Module in ASIIS
- The temperatures are out of range
- Number of “doses administered” is missing
- Number of doses on hand (inventory) is missing
- Inventory reconciliation has not been completed in ASIIS
- Previous orders are not “received” in ASIIS

If orders are delayed or cancelled, the reason will be posted in ASIIS comments. It is important to frequently check the “comments” section within your order screen.

**Temperature Logs**

VFC providers are required to enter temperatures into the Cold Storage Module in ASIIS monthly whether or not an order will be placed (see Resources/Job Aids: Cold Storage Training Module). Please note that you must continue to record temperatures on a temperature log and keep those logs in your records for six years. AIPO recommends keeping the paper temperature logs posted on your refrigerator and/or freezer.
Temperature logs must include the date and time the temperature was checked, initials of the person who checked the temperature, and indicate whether the temperature is Fahrenheit or Celsius. Temperature logs must be received by the Arizona Vaccine Center before an order can be approved. Temperature logs should be completed up to the date the vaccine order is placed. For example, if you order vaccine on the 15th of the month, the temperature log should be filled out through the 14th of that month. The Arizona Vaccine Center team will ensure that current temperatures in the provider’s refrigerator and freezer are within normal limits before an order can be approved.

Note: All correspondence regarding missing information will be added as a message in the comments section on your ASIIS order screen. Please regularly check the “comments” section within your order for these messages to avoid order delays or cancellations. If temperatures are not reported in the Cold Storage Module in ASIIS within four (4) business days of placing the order the VFC Vaccine Order Specialist will enter a comment informing the provider that their vaccine order was canceled and a subsequent order will have to be placed by the provider office.

Maintaining Vaccine Inventory

When establishing vaccine needs, consider:

- Vaccine usage patterns (e.g., increase orders during July and August for “back-to-school” children)
- Length of time before the next ordering date
- Storage capabilities (do not order more vaccine than you can store and do not order pre-filled syringes if you do not have a large refrigerator – pre-filled syringes take more room than vials)
- Order enough vaccine to last for approximately 3-4 weeks

VFC providers must conduct a monthly physical inventory of VFC vaccines. When conducting the monthly inventory, check the expiration dates for all vaccines. Move soon-to-expire vaccines to the front of the refrigerator/freezer so they are used first.

Vaccine Shipments

The Arizona Vaccine Center acts as the coordinating center in Arizona for federally purchased vaccines. The Arizona Vaccine Center will notify the provider via the comments section in ASIIS if there are any changes to the standard vaccine shipping routine.

When an order for VFC vaccine is placed by the provider the order is reviewed and approved by the Arizona Vaccine Center. The order is then transmitted to McKesson, the vaccine distributor. McKesson will facilitate the delivery of the vaccines to the provider’s office.
Providers should expect their vaccine order within 5-10 business days from the time they place the order. Providers must plan ahead when ordering to allow time for delivery. Orders from McKesson should arrive in provider offices on Tuesdays, Wednesdays, or Thursdays.

- Varicella and Varicella containing vaccines are shipped directly from Merck Manufacturing. Please allow 2-4 weeks to receive these vaccines.

Receiving VFC Vaccine Shipments

Proper handling and temperature maintenance of any vaccine shipment is imperative to maintain the cold chain and vaccine viability. Each provider site is required to have a standard office procedure in place for receiving vaccine shipments. Because a VFC vaccine shipment can be worth hundreds or thousands of dollars, proper handling of each dose is critical in preventing unnecessary loss or wastage. If vaccines are improperly handled they will lose viability and will have to be replaced. (See Chapter 7 for more information about Vaccine Management and Accountability).

The provider office VFC Coordinator or backup should:
- Notify other office staff that vaccine shipments will be arriving
- Instruct front office staff on how to receive and store refrigerated and frozen vaccine shipments

As soon as a VFC vaccine shipment arrives, office staff should do the following:
- Receive and sign for vaccine orders placed by your office only
- Open vaccine packages immediately
- Inspect the packages and vaccines for damage
- Determine length of time the vaccine was in transit by looking at the packing list
- Compare the vaccine received with the vaccine products that appear on the packing list
- Check temperature indicators enclosed in each container. Notify the Arizona Vaccine Center immediately if the temperature indicator shows that the temperature has gone out of range, the ice packs are soft, the vaccines are warm, or frozen vaccines shipped by Merck are not received within 4 days of the shipping date on the container
- Review the information provided on the packing slip to ensure:
  - the number of doses shipped and the number received are the same
  - the vaccine expiration dates are the same on the vaccine boxes and the packing slip
  - the lot number(s) on the vaccine boxes match the packing slip
• Remove vaccines from the shipping container and immediately store in refrigerator and/or freezer.
• MMR can be stored in the freezer or the refrigerator; varicella and varicella containing vaccines must be stored in the freezer.
• Check the diluents (any diluents arriving frozen must not be used), and call the Arizona Vaccine Center immediately if the diluents are frozen.
• Log in to ASIIS to receive the VFC order in ASIIS
  o Compare your order in ASIIS to the vaccine shipment
  o If there are no discrepancies, “receive” the order in ASIIS (this will add the VFC vaccine to your ASIIS inventory)
  o If you have vaccines with issues “reject” them in ASIIS, appropriately store these vaccines in a separate area, and label them “DO NOT USE”
  o Contact the Arizona Vaccine Center immediately for further assistance.
• Write any shipment discrepancies and/or problems with the vaccine order on the packing slip and fax or scan and email the slip to the Arizona Vaccine Center within 2 hours of receipt. Do not call the manufacturer with any VFC vaccine problems. Notify the Arizona Vaccine Center immediately of all vaccine shipping problems – Arizona Vaccine Center staff will determine what should be done.
It is critical that each VFC provider label and store VFC vaccine separately from private stock vaccines or other non VFC public stock vaccines. VFC vaccine must not be administered to adults, even if the packaging indicates that the vaccine can be used for adults. VFC vaccine is ordered on CDC pediatric vaccine contracts and is not allowed to be used for adults.
• Do not fax the packing slip to the Arizona Vaccine Center unless there are discrepancies in the shipment.
• Carefully examine each Varicella shipment packing slip to determine whether it is VFC or private stock. The box that contains the Varicella vaccine shipment will not be marked “VFC” so be sure to check the shipment before putting it into the freezer. Do not call the Arizona Vaccine Center about a missing Varicella shipment until all shipments received in the past month have been checked.
• Place a “VFC” label on all VFC vaccine boxes or mark the boxes “VFC”. Order “VFC” labels from the Arizona Vaccine Center and keep these labels on hand at all times.
• See Resources/VFC Forms: Frozen Vaccine Storage Requirements (Varicella & MMRV) for Varicella (chicken pox) and MMRV (Measles, Mumps, Rubella and Varicella) vaccine storing procedures.
Borrowing VFC Vaccines

AIPO’s expectation is that VFC enrolled providers will maintain adequate inventories of vaccine to administer to both privately insured and VFC patients. Borrowing vaccine must be due to unforeseen delays or circumstances surrounding the vaccine that was ordered.

The Vaccine Borrowing Report (see Resources/VFC Forms: Vaccine Borrowing Report) must be completed in all settings for all vaccine borrowed in either direction. The Borrowing Report must be completed when either:

- Privately purchased vaccine is administered to a VFC patient, or
- VFC vaccine is administered to a privately insured patient

The provider must document the following on the Vaccine Borrowing Report:

- Vaccine type borrowed
- Stock type used (VFC or Private)
- Lot number(s)
- Number of doses administered
- Patient name
- Patient date of birth
- Date the borrowed dose was administered
- Reason appropriate stock type was not used
- The date the vaccine was replaced and the inventory was made whole, or
- The date the public vaccine was replaced and the vaccine replacement information was submitted to the Arizona Vaccine Center

Note: AIPO may ask for a copy of the invoice validating that the privately purchased vaccine was used to replenish the borrowed VFC vaccine. The invoice date should correspond with the replacement date on the borrowing report. AIPO may also ask for copies of the private and/or VFC packing slips.

Borrowing activities will be monitored as part of the VFC compliance site visit, and follow-up actions will be taken when excessive or inappropriate borrowing activities are noted.

VFC vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory. The provider’s VFC vaccine supply must adequately meet the needs of the provider’s VFC patients. Borrowing VFC vaccine must not prevent a VFC patient from receiving a needed vaccination because VFC vaccine was administered to a non-VFC patient.

Borrowing of vaccine between two vaccine inventories must be a rare, unplanned occurrence. Borrowing can occur only when there is:
• A lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment
• Vaccine spoiled in-transit to provider
• New staff that calculated ordering time incorrectly

For seasonal influenza vaccine, providers may use private-stock seasonal influenza vaccine to vaccinate VFC patients if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC patients can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine.

Borrowing of vaccine may occur to prevent vaccine loss due to expiring vaccine.

• This two-way exchange can be used by a VFC provider with a patient population that is mostly VFC-eligible. This means the provider has a small number of privately insured patients.
• Privately purchased vaccine that is short-dated may be administered to VFC patients, and the dose replaced with a longer-dated VFC dose.
• Providers must document any vaccine borrowing on the Vaccine Borrowing Report regardless of inventory origin (VFC versus private stock).

If a provider borrows privately purchased vaccine to administer to a VFC patient because no VFC vaccine is available or if VFC stock is borrowed, the provider must document that borrowing and replacement on the VFC Borrowing Report. This action is to ensure that the private-stock or VFC-stock vaccine is replaced and the inventory is made whole.

• Once the borrowed vaccine is replaced, the replacement date must be entered on the form.
• The completed form must be saved and submitted with a copy of the invoice to the Arizona Vaccine Center for review.

Transferring VFC Vaccine Between Provider Offices

Vaccines are increasingly expensive and are now a large part of any office or clinic’s costs. They must be managed closely to avoid unnecessary loss. Every attempt should be made to avoid vaccine wastage and minimize the amount of vaccine allowed to expire. AIPO’s restitution policy is currently being reviewed, but AIPO retains the discretion to bill providers for excessive vaccine wastage (see Chapter 7 for additional information related to the wastage and restitution policy).

**Please note, the CDC does not allow for the use of vaccine depots and therefore provider offices cannot order large quantities of VFC vaccine for re-distribution to their
other clinic sites. Shipping of vaccines is not allowed without prior approval from the Arizona Vaccine Center.

Transferring VFC vaccines between provider sites is discouraged due to potential risks to the cold chain, but permitted on occasion. Please adhere to the following when completing a transfer:

- The transferring provider office must contact the Arizona Vaccine Center to obtain a current list of available VFC providers in their area. The transferring provider must contact a provider on the list to determine if a transfer will be accepted by a provider.
- Once this occurs, the “sending” provider must complete the transfer in ASIIS to the “receiving” provider.
- The Arizona Vaccine Center must have the sending and receiving providers’ current temperature logs (within 4 business days of the transfer request).
- The Arizona Vaccine Center must approve the transfer in ASIIS before the physical inventory can be transported by the “sending” provider to the “receiving” provider’s office.
- Once the transfer has been approved in ASIIS by the Arizona Vaccine Center, the “sending” provider will pack the vaccine according to CDC guidance (see resources/ VFC Forms: Transporting Refrigerated Vaccines and Packing Refrigerated/Frozen Vaccine Checklist), and transport the vaccines to the “receiving” provider’s office.
- The “receiving” provider will inspect the vaccines. If the provider chooses to accept the transferred vaccine they will immediately place the vaccines in the refrigerator and/or freezer. The provider will then “receive” the vaccines in ASIIS by marking the transfer as received. This action will add the vaccines into their ASIIS inventory. At this point the transfer process is complete.

Providers wishing to transfer vaccine should contact other VFC providers at least 90 days prior to the vaccine expiration dates. Vaccine with less than 90 days before the expiration date cannot be transferred to other providers unless the receiving provider is aware of the short date and confident they will be able to utilize the doses. If your practice has vaccine that will expire soon and you do not think it will be used during that time. Begin contacting other VFC providers who might be able to use the vaccine before it expires.

Note: VFC vaccine may not be shipped to, or stored at, a private residence or a location that is not the provider’s office address. Varicella and MMRV are not allowed to be transferred between providers due to their fragile nature.
Chapter 6: ORDERING DURING INFLUENZA SEASON

VFC Influenza Process

The Arizona VFC Program places an annual influenza order for publicly funded vaccines with the CDC around February or March each year for the upcoming influenza season. Doses may begin to arrive in late July but often arrive much later. The delivery of doses is outside of the Arizona Vaccine Center’s control. This can cause delays in the influenza order approval process. The doses that we receive during that time will be released to providers as quickly as possible.

Providers should expect this type of delay to occur annually with VFC influenza vaccines. When this happens, it does not mean there is a shortage of VFC influenza vaccines. It means the CDC distributor does not have any additional doses available at that time. As soon as more doses become available to the distributor more doses will be made available to the Arizona VFC Program and we will release them to the provider offices. If you place an order for flu vaccines and the vaccines are unavailable, your order will be denied. You will then have to place another order when the vaccines are available.

In some instances during the end of influenza season, we may run out of a particular influenza presentation. In most cases we will contact you to inform you of this situation and in some situations we will replace the vaccines (please see the Arizona VFC Choice Policy in chapter 2 of this manual).

Influenza Ordering

Influenza orders are placed in ASIIS. Providers should place orders at least once a month to replenish your influenza supply. Please review the Influenza Order Training Module (see Resources/Job Aids: VFC Influenza Order Training Module) to learn how to place a VFC flu order in ASIIS. If you still require assistance for placing an influenza vaccine order after reviewing the training module please contact the Arizona Vaccine Center at (602) 364-3642.

Inventory Reconciliation

You will need to reconcile your vaccine inventory prior to placing an order for VFC influenza vaccine. ASIIS will not allow the provider to advance to the order screen without inventory first being reconciled. All administered VFC vaccine doses must be reported to ASIIS and decremented from the ASIIS inventory. Any wasted/expired/spoiled VFC influenza vaccine doses must be accounted for by reconciling your ASIIS inventory.

Please contact the Arizona VFC Program at (602) 364-3642 or ArizonaVFC@azdhs.gov for additional questions related to VFC Influenza ordering. For technical questions related to ASIIS please contact by phone at (602) 364-3899 or 1-877-491-5741, or by email at ASIISHelpDesk@azdhs.gov.
Chapter 7: VACCINE MANAGEMENT AND ACCOUNTABILITY

Handle with Care!

If you don’t protect your vaccine, it won’t protect your patients!

* MMR can be stored in the freezer or the refrigerator
**Vaccine Management**

Vaccine management is a broad term intended to describe the vaccine storage and handling practices that should be followed by VFC providers and their staff. We strongly encourage VFC Provider and staff members to review the CDC Vaccine Storage and Handling Toolkit, a comprehensive resource for providers on vaccine storage and handling recommendations and best practice strategies. Link to this resource at: [http://www.cdc.gov/vaccines/recs/storage/toolkit/](http://www.cdc.gov/vaccines/recs/storage/toolkit/).

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**Vaccine Management Requirement**

- ✓ Providers must be able to distinguish between private and public purchased vaccine stocks; stocks must be separate. VFC Vaccine must be labeled “VFC.”
- ✓ The use of a dormitory or bar-style refrigerator/freezer is **not allowed** at any time for the storage of VFC vaccines.
- ✓ Providers must use a digital thermometer with a biosafe glycol encased probe that will measure liquid temperature. The refrigerators and freezers that store VFC vaccines must have NIST Certified and calibrated thermometers.
- ✓ Providers must have at least one backup thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer).
- ✓ Thermometers must be placed in a central area of the storage unit with the vaccines.
- ✓ Providers must have a primary VFC Coordinator and a backup person at each site.

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**The Vaccine Cold Chain**

The cold chain is a system or process used to maintain vaccines at optimal conditions. Vaccines must be stored properly from the time they are manufactured until the time they are administered to ensure those who receive the vaccines are protected from disease. Excess heat or cold will reduce vaccine viability and increase the risk that recipients will not be protected against disease. All VFC vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.

**Refrigerator/Freezer Equipment**

A standard-size, two-door, household-type refrigerator with a separate temperature control for each compartment can be used for storing vaccines but stand-alone...
Commercial units are the preferred standard. The Arizona VFC program does not allow the use of combination refrigerator/freezers with one exterior door and a freezer inside of the refrigeration unit to store Arizona VFC vaccines. This includes “dormitory” or “bar” style units.

The Arizona Vaccine Center will only ship varicella vaccine to sites where the refrigerator/freezer used to store vaccine is CDC/VFC approved. The VFC program does not endorse any specific refrigerator/freezer brand or manufacturer, however, units used to store VFC vaccine must meet required specifications (see Resources/Forms: VFC Required Specifications for Refrigerators & Freezers). Please contact the Arizona Vaccine Center at (602) 364-3642 if you have questions about your refrigerator’s ability to properly store vaccines.

Refrigerator/Freezer Temperatures

- Keep your refrigerator and freezer at appropriate temperatures:
  - Your refrigerator should be kept between 35°F and 46°F (2°C - 8°C).
  - Your freezer should be kept between -58°F to +5°F (-50°C and -15°C).

- Record refrigerator and freezer temperatures twice daily (beginning and end of work day) in F or C. The time must be recorded. Providers should not go more than 4 days without monitoring and recording refrigerator and freezer temperatures. If you will be away from the office for longer than this amount of time, please contact the Arizona Vaccine Center for guidance on storing the VFC vaccines.

- Maintain a working NIST certified or traceable thermometer in both the refrigerator and freezer and check/monitor calibration due date. The thermometer probes must be placed in a central location of the storage unit near the vaccines.

The following vaccines must be stored at temperatures between 35°F and 46°F (2°C - 8°C) (see Resources/VFC Forms: Fahrenheit to Celsius Conversion Chart)

- The temperature should never go below 35°F for the following vaccines and they should never be exposed to temperatures at or below 32°F. Vaccine will be removed from provider offices if refrigerator temperatures reach 32°F.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temperatures</th>
</tr>
</thead>
<tbody>
<tr>
<td>hepatitis A</td>
<td>PPSV23</td>
</tr>
<tr>
<td>hepatitis B</td>
<td>TD</td>
</tr>
<tr>
<td>HPV</td>
<td>Tdap</td>
</tr>
<tr>
<td>MMR</td>
<td>Influenza</td>
</tr>
<tr>
<td>MCV4</td>
<td>MenB</td>
</tr>
<tr>
<td>PPSV23</td>
<td>DT/DTAP</td>
</tr>
<tr>
<td>MCV4</td>
<td>MenB</td>
</tr>
<tr>
<td>TD</td>
<td>Hib</td>
</tr>
<tr>
<td>Tdap</td>
<td>PCV13</td>
</tr>
<tr>
<td>Influenza</td>
<td>IPV</td>
</tr>
<tr>
<td>MenB</td>
<td>HBIG</td>
</tr>
</tbody>
</table>
If the temperature is outside of the appropriate range notify the Arizona Vaccine Center immediately. Do not wait until it is time to place an order to report out of range temperatures to the Arizona Vaccine Center. Your VFC vaccines will be wasted and you may be required to replace wasted doses of VFC vaccines.

- MMR may be stored in either the freezer or the refrigerator. Store MMR in the freezer if you need more refrigerator space. MMR is heat sensitive and much less likely to be spoiled if kept in the freezer. MMR must be stored in its original box to protect from light.

- Varicella and MMRV must be stored in the freezer. To prevent light exposure, store these vaccines in their original boxes, keeping the ends and tops closed at all times.

- Store ice packs in the freezer to help maintain acceptable temperatures in the event of a power outage.

- Call the Arizona Vaccine Center immediately at (602) 364-3642 for any problems with refrigerator and/or freezer temperature controls. You must speak with a person, do not leave a message. Notify the Arizona Vaccine Center if the refrigerator or freezer temperatures register out of range, at any time.

**Temperature Monitoring Equipment**

In each refrigerator/freezer used to store vaccine VFC providers are required to use a thermometer that is calibrated, NIST Certified, and has a current certificate of traceability. A certificate of traceability confirms that measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standard agency.

Each thermometer must be digital with a probe that is placed in a bio-safe, glycol filled bottle to monitor vaccine temperature and not the ambient air inside of the unit. It is the responsibility of the provider’s office to ensure that the thermometer is calibrated and certified annually. For more information on current calibration standards, please contact the Arizona Vaccine Center at (602) 364-3242.

The CDC and AIPO strongly recommend the use of continuous temperature monitoring systems (e.g., digital data loggers). These units provide a more accurate reading of actual temperatures than other temperature monitors. Digital Data Loggers provide comprehensive monitoring of temperature excursions to which vaccines may be exposed. They also diminish the need for opening the unit door while conducting routine temperature monitoring.
The data stored in the temperature monitor should be easily downloadable for review. This means that the digital temperature monitoring device should have a detachable probe (kept in the glycol-filled bottle). A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator-caused temperature variability. The digital data logger (continuous temperature monitoring system) should also include the following capabilities:

- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)

CDC recommends assessing and documenting minimum/maximum temperatures for each storage unit at the beginning and end of the workday.

**Back Up Thermometer**

VFC providers must have at least one backup thermometer with a current certificate of calibration on hand (not stored in vaccine storage unit). It should be available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.

**Thermometer Placement**

Because a major risk factor affecting viability of refrigerated vaccines is exposure to freezing temperatures, it is important and required that glycol-encased probes be placed with the vaccine. Additionally, for refrigerated vaccines, vaccine and temperature monitors should be located in the center of the refrigerator unit, where appropriate temperatures are best maintained.

**Maintaining VFC Vaccine Viability**

The following tips are intended to assist in maintaining a safe refrigerator environment and constant temperature for your vaccine supply:

- Install the refrigerator/freezer away from any heat sources such as direct sunlight, furnaces, or radiators.
• Keep refrigerator and freezer sections full, but don’t overcrowd shelves (allow full air circulation).

• Add water bottles to the sides and back of the refrigerator to assist in maintaining an even temperature and to serve as physical blocks preventing the placement of vaccines in the areas of the unit that are at higher risk for temperature excursions (water bottles will also stabilize or extend temperatures during a power outage).

• Open and close door quickly to minimize the time the refrigerator door is kept open.

• Check units frequently for a tight door seal.

• Clean condenser coils at the rear of the refrigerator at least two to six times a year to prevent loss of cooling efficiency when coils become insulated with dust.

• Always store vaccines in their original boxes with the lids closed.

• Store vaccines on the middle shelves of the refrigerator. Do not store vaccines in vegetable bins, in the doors, on the floor of the unit, or under or near cooling vents in the refrigerator or freezer doors. The temperatures in these sections do not remain constant. We recommend removing the vegetable bin drawers and replacing them with water bottles.

• In the freezer, place ice packs around and on top of the vaccine in the freezer as if covering it with a blanket.

• MMR, Varicella, MMRV, Rotavirus, HPV, and meningococcal vaccines are extremely sensitive to light. To prevent exposure to light, keep the ends and top of the box closed at all times during storage.

• If you are using a two door refrigerator, the freezer compartment must be separate, sealed, and insulated.

Note: Freezer compartments that are inside the refrigerator do not meet Arizona VFC and CDC storage requirements and cannot be used at any time for any reason. These units are called “dorm” style or “bar style” units.
• Defrost the freezer compartment whenever the frost layer is 1/4-inch thick. Excess frost can prevent a tight door seal.

• Do not freeze diluent. Please see the table: Vaccines with Diluents: How to Use Them later in this chapter for correct storage of diluents. The Arizona Vaccine Center is unable to ship additional diluents if wasted.

• Rotate vaccine according to expiration dates every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit while those soonest-to-expire are stored in the front.

• Open only one vial or box of a particular vaccine at a time to control vaccine use and allow for easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.

• Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.

• In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC strongly recommends AGAINST pre-drawing doses before they are needed.

• In mass vaccination clinics providers may pre-draw up to 10 doses or use pre-filled syringes.

**Vaccine Storage and Handling Plan**

The routine vaccine storage and handling plan must include guidance on routine vaccine management processes/practices.
The minimum required components of VFC Provider Vaccine Storage and Handling Plan (see Resources/VFC Forms: Vaccine Storage and Handling Plan) include the following:

- Name of the current primary vaccine coordinator and at least one back-up coordinator at each location
- General operations for the following vaccine storage and handling practices including:
  - Proper vaccine storage and handling practices
    - Temperature monitoring
    - Vaccine storage (e.g., storage equipment and vaccine placement)
  - Vaccine shipping and receiving procedures
  - Vaccine ordering procedures
  - Inventory control (e.g., stock rotation)
  - Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
  - Staff training (and documentation of training) on VFC requirements, including proper vaccine storage and handling

**Inventory Management**

Inappropriate monitoring, handling or administration of vaccine may result in vaccine that does not provide protection against disease. In addition to the best practices listed below, follow the storage and handling instructions contained in the package inserts of each vaccine.

VFC providers must assign responsibility for vaccine management to the VFC Vaccine Coordinator, and one backup Vaccine Coordinator. **If a provider has multiple clinics, there must be backups at each of those clinics that can answer questions regarding VFC related issues.** If the VFC Vaccine Coordinator leaves the practice, it is the responsibility of the office manager or medical professional who signed the provider profile to ensure that refrigerator and freezer temperatures are checked and recorded twice each day by trained staff. Please do not leave this responsibility in the hands of untrained staff. Notify the Arizona Vaccine Center immediately of any changes (see Resources/VFC Forms: Provider Contact/Address Change Form).

In addition to monitoring storage conditions the VFC Vaccine Coordinator or their backup should regularly review each vaccine vial for expiration dates placing “short-dated” vaccine (vaccine soon to expire) in the front of the refrigerator or freezer for immediate use. Observe the expiration date on each box of new vaccine; it is possible to receive vaccine that will expire sooner than vaccines in your current inventory.

Develop and conduct training for all office staff based on facility needs. Document this process according to your facility procedure. Complete a vaccine inventory by using the
Reconciliation Worksheet in ASIIS (see Resources/Job Aids: How to Print Reconciliation Worksheet in ASIIS) at least monthly. Monitoring vaccine inventory will prevent wastage and ensure vaccine is being used appropriately.

Ensure that temperatures are entered into ASIIS monthly. Providers will still need to keep written temperature logs on file for six years.

Create a safe environment for vaccines:

- Instruct custodial staff not to unplug a refrigerator or freezer unit while cleaning; Post “Do Not Unplug” signs above the plug, and/or on the refrigeration unit if the unit or other objects obscure the plug (see Resources/VFC Forms: Vaccine Signs).
- Post a “Do not turn off” or “Do not unplug” sign above the surge protector if one is used for the refrigerator or freezer plug.
- Protect and mark circuit breaker switches to prevent accidental shut down of power by maintenance and/or repair crews.
- If possible, utilize a remote alarm system in case of power failure.
- Install receptacle covers or plug guards to prevent power loss from accidental unplugging.
- Post a red/white “Caution Perishable Vaccine” sign (call the Arizona Vaccine Center at (602) 364-3642 to order) on the refrigerator and freezer unit where VFC vaccine is stored. Lock storage facilities and equipment to prevent unauthorized removal of vaccine and use of storage for other purposes.
- In the event of power failure, do not open the refrigerator or freezer. Call the Arizona Vaccine Center immediately.
- Maintain an average temperature of 40° F (4.4° C) in the refrigerator.
- Store bottles of water in the refrigerator door and alongside the refrigerator wall (if space permits) to prevent the coils in the walls of the refrigerator from freezing vaccine. This will also assist in maintaining appropriate temperatures in the event of a power/refrigerator failure. Mark these bottles “Do Not Drink.”
- Do not store food or drinks in the vaccine refrigerator. Frequent opening of the door to retrieve food results in temperature fluctuations.
- For more information on Vaccine Storage and Handling review the CDC Storage and Handling Toolkit located at. [http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf)
**Vaccine Administration**

Appropriate vaccine administration is critical to vaccine effectiveness. All persons who administer vaccines should have continuing vaccine administration education and regular skills assessments.

Further information on safe vaccine administration may be found on the CDC vaccine web site at [www.cdc.gov/vaccines/recs/vac-admin/default.htm](http://www.cdc.gov/vaccines/recs/vac-admin/default.htm). An additional handout on the Rights of Vaccine Administration can be found in the Resource Section (see Resources/Job Aids: *The Rights of Vaccine Administration*).

The Immunization Action Coalition (IAC) also has many resources and handouts specific to clinic practice which can be found at [http://www.immunize.org/handouts/administering-vaccines.asp](http://www.immunize.org/handouts/administering-vaccines.asp).

Certain vaccines must be reconstituted correctly before they are administered. Lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluents (liquid) in another vial. **Only use the diluents provided by the manufacturer for that vaccine as indicated on the chart.** Always check the expiration date on the diluents and the vaccine. **Never** use expired diluents or vaccine.

Please use the IAC handout on Vaccine Diluents found on page 43 and in the Job Aids Section (see Resources/Job Aids: *Vaccines with Diluents: How to Use Them*).
The 6 Rights of Vaccine Administration

Right Patient
- Verify the patient’s name, date of birth and vaccine history

Right Medication
- Check and re-check the labels for both the vaccine and diluent before drawing them up and again before administering vaccine.
- Watch out for vaccines with similar names and packaging!

Right Time
- VFC healthcare providers are expected to comply with the immunization schedule, ages, and intervals established by the ACIP.
- The current vaccination schedules can be found online at: http://www.cdc.gov/vaccines/schedules/hcp/index.html

Right Dosage
- Always give vaccine in the dosage recommended by the ACIP. Split or partial doses of vaccine are not valid doses!

Right Route
- Make sure that you are using the route, injection site and needle size indicated for the vaccine being administered.

Right Documentation
- The following information must be recorded on the vaccine recipient’s permanent record or office file each time a vaccine is administered:
  - The type of vaccine.
  - The vaccine manufacturer and vaccine lot number.
  - The date the vaccine was administered.
  - The name, title, office address and signature of the person administering the vaccine.
  - The VFC/KidsCare eligibility category.
  - VIS publication date and date the VIS was given to the responsible person.
  - This information must be maintained in the patient’s chart and in ASIIS, and must be available for review during a VFC Site Visit.

Further information on safe vaccine administration can be found at the CDC vaccine web site at www.cdc.gov/vaccines/recs/vac-admin/default.htm.
Additional VFC Vaccine Administration Guidance

- Vaccines should be drawn up immediately before administration only.

- Vaccines should remain in their original boxes until all vials have been used. Open only one box of each vaccine at a time.

- Vaccines may lose their viability if stored in syringes for any period of time.

- Vaccines that are not used within the acceptable reconstituted time frames are considered non-viable and must be discarded and accounted for in ASIIS. Please reconcile wasted VFC vaccine in ASIIS.
**Vaccines with Diluents: How to Use Them**

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluents (liquid) in another. Only use the diluents provided by the manufacturer for that vaccine as indicated on the chart. ALWAYS check the expiration date on the diluents and the vaccine. NEVER use expired diluent or vaccine.

<table>
<thead>
<tr>
<th>Vaccine Name</th>
<th>Manufacturer</th>
<th>Lyophilized vaccine (powder)</th>
<th>Liquid diluent (may contain vaccine)</th>
<th>Time allowed between reconstitution and use*</th>
<th>Diluent storage environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActHIB (Hib)</td>
<td>Sanofi Pasteur</td>
<td>HIB</td>
<td>0.4% sodium chloride</td>
<td>24 hours</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Hiberix (Hib)</td>
<td>GlaxoSmithKline</td>
<td>Hib</td>
<td>0.9% sodium chloride</td>
<td>24 hours</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>MMR II (MMR)</td>
<td>Merck</td>
<td>MMR†</td>
<td>Sterile water</td>
<td>8 hours</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Menomune (MPSV4)</td>
<td>Sanofi Pasteur</td>
<td>MPSV4</td>
<td>Distilled water</td>
<td>30 min (single-dose vial)</td>
<td>Refrigerator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35 days (multidose vial)</td>
<td></td>
</tr>
<tr>
<td>MenHibrix (Hib-MenCY)</td>
<td>GlaxoSmithKline</td>
<td>Hib-MenCY</td>
<td>0.9% sodium chloride</td>
<td>Immediately</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Menomune (MPSV4)</td>
<td>Sanofi Pasteur</td>
<td>MPSV4</td>
<td>Distilled water</td>
<td>30 min (single dose vial)</td>
<td>Refrigerator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35 days (multidose vial)</td>
<td></td>
</tr>
<tr>
<td>Menveo (MCV4)</td>
<td>GlaxoSmithKline</td>
<td>MenA</td>
<td>MenCWY</td>
<td>8 hours</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>Sanofi Pasteur</td>
<td>HIB</td>
<td>DTaP-IPV</td>
<td>Immediately (i.e, within 30 minutes or less)</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>ProQuad (MMRV)</td>
<td>Merck</td>
<td>MMRV†</td>
<td>Sterile water</td>
<td>30 minutes</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Manufacturer</td>
<td>Product Code</td>
<td>Reconstitution Solution</td>
<td>Time Required</td>
<td>Storage Temperature</td>
</tr>
<tr>
<td>---------</td>
<td>--------------</td>
<td>--------------</td>
<td>-------------------------</td>
<td>---------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Rotarix (RV1)</td>
<td>GlaxoSmithKline</td>
<td>RV1</td>
<td>Sterile water, calcium carbonate and xanthan</td>
<td>24 hours</td>
<td>Room temp</td>
</tr>
<tr>
<td>Varivax (VAR)</td>
<td>Merck</td>
<td>VAR</td>
<td>Sterile water</td>
<td>30 minutes</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Zostavax (HZV)</td>
<td>Merck</td>
<td>HZV</td>
<td>Sterile water</td>
<td>30 min</td>
<td>Refrigerator or room temp</td>
</tr>
</tbody>
</table>

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow these steps:

1. For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix\(^1\)), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.\(^1\)

2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
   - that they are the correct two products to mix together
   - that the diluent is the correct volume (especially for Menomune in the multi-dose vial)
   - that neither vaccine nor diluent has expired

3. Reconstitute (i.e., mix) vaccine just prior to use\(^4\) by
   - removing the protective caps and wiping each stopper with an alcohol swab
   - inserting needle of syringe into diluent vial and withdrawing entire contents
   - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder

4. Check the appearance of the reconstituted vaccine.
   - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
   - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.

5. If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose Menomune),
   - clearly mark the vial with the date and time the vaccine was reconstituted
   - maintain the product at 35°–46°F (2°–8°C); do not freeze
   - protect reconstituted vaccines from light
   - use only within the time indicated on chart above

Revised 10/31/15
If the reconstituted vaccine is not used within this time period, it must be discarded.

MMRV contains seven times as much varicella component as does the single antigen VAR.

Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

HZV contains fourteen times as much varicella component as does the single antigen VAR.

Note: MMR, MMR-V, HPV, Rota, MCV4, and Varicella are extremely sensitive to light and heat and must be kept in their original boxes with lids closed until ready to use.
**Vaccine Loss**

By participating in the VFC program, you have agreed to be accountable for publicly purchased vaccine. Accountability includes documentation procedures and compliance with Arizona VFC Program policies on vaccine loss.

This section will serve as the Arizona VFC Program’s policy for management of incidents that result in loss of publicly purchased vaccine. The action taken by the Arizona VFC Program will depend on the cause of vaccine loss: preventable or non-preventable. Preventable vaccine loss stems from negligence, fraud, or abuse. Non-preventable vaccine loss is caused by circumstances outside of the provider’s control.

**Vaccine Wastage Restitution Policy**

Vaccine is purchased through the Centers for Disease Control (CDC) contracts and is distributed to participating VFC providers. As a condition of provider enrollment into the VFC program, providers are required to adhere to Federal Fraud and Abuse laws. These laws apply to the entire VFC program. For more information about Fraud and Abuse requirements please see chapter 12.

AIPO’s vaccine restitution policy is currently under review. AIPO reserves the right to require providers to repay wasted and expired vaccines on a dose-for-dose replacement basis. We will notify providers when the restitution policy is finalized. Although subject to change, the remainder of this section is the foundation of AIPO’s restitution policy. Please use it for your reference.

The Arizona Vaccine Center acknowledges that providers make good faith efforts to store and handle vaccines appropriately as outlined in the manual. However, AIPO will require providers to provide restitution for any doses of federally purchased vaccines that have been lost due to the provider’s failure to properly receive, store, or account for in inventory. Listed below are examples of provider negligence that will require dose-for-dose restitution of the federally funded vaccine:

- Failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value
- Failure to contact the Arizona VFC program at the first instance of a recorded temperature excursion
- Inability to account for the vaccine in inventory
  - Excessively reporting vaccine in ASIIS as lost and unaccounted for
  - Selecting “Matches Physical Inventory” when reconciling inventory
  - Reporting administered doses in ASIIS using “Administered but not linked to a vaccine” or “Administered to a client who chose not to be in the registry” (this reason is acceptable only if the client’s wishes are documented)
• Wasted vaccine due to being spilled, dropped, or otherwise mishandled by provider staff
• Vaccine lost or damaged in transit between providers
• Allowing vaccine to expire. Providers must contact the Arizona Vaccine Center at least 3 months prior to vaccine expiration to arrange a vaccine transfer to another VFC provider able to use the vaccine. If the provider is unable to transfer the doses, they are still responsible for the doses that have expired
• Refrigerator or freezer left unplugged, or electrical breaker switched off by provider staff, contractors, or any other individual
• Refrigerator or freezer door left open or ajar by provider staff, contractors, or any other individual
• Vaccine is left out of the refrigeration unit and becomes non-viable (always call the Arizona Vaccine Center at (602) 364-3642 and speak to a staff member to determine if vaccine is viable)
• Not moving vaccine to a backup unit or facility when a refrigerator or freezer is without power or not functioning properly
• Freezing vaccines meant to be refrigerated, or refrigerating vaccine meant to be frozen
• Any power outages in which the provider fails to act according to their vaccine storage backup plan
• Administering VFC vaccines to ineligible children

The restitution policy will require that the providers purchase private stock vaccine to replace VFC vaccine doses that were lost.

When restitution is required the Arizona Vaccine Center will notify the provider of the number of doses of each vaccine that must be replaced. Vaccine orders from the provider will not be processed by the Arizona Vaccine Center until a copy of the invoice or packing list for the replacement vaccine has been received. All replacement vaccines will be added to ASIIS by the Arizona Vaccine Center showing provider replacement of the VFC vaccine. A copy of the invoice or packing slip should be submitted to the Arizona Vaccine Center along with the completed VFC Dose for Dose Vaccine Replacement Form (see Resources/VFC Forms: VFC Dose for Dose Vaccine Replacement Form). These documents must be submitted to the Arizona Vaccine Center within 60 days of notification that doses need to be replaced.

These documents can be emailed to arizonaVFC@azdhs.gov. Once reviewed, the documents will either be approved by the Arizona Vaccine Center or the provider will be notified of any additionally required action(s).

The Arizona Vaccine Center recommends that all health care provider offices contact their insurance companies to verify that they have adequate coverage to cover any type of vaccine loss. This coverage should be at a level adequate to cover the private market cost of fully replacing the largest amount of vaccine inventory potentially
maintained in their offices. This coverage should also be evaluated and updated annually as the provider’s vaccine formulary changes and the vaccine prices increase.

If the provider receives a wastage replacement statement for the VFC vaccines and wishes to dispute the replacement of public vaccine, the provider must submit a letter explaining the reason for the dispute to the Arizona Vaccine Center Manager. This letter must include the provider’s name, address, and VFC PIN number. Please submit all supporting documentation with the dispute letter so a determination can be made regarding the wastage. Please send this correspondence to the following address:

Arizona Department of Health Services
Immunization Program Office
Attn: Vaccine Center Manager
150 N. 18th Ave
Ste. 120
Phoenix, AZ  85007

If a provider receives a replacement statement for wasted vaccines and the provider fails to contact the Vaccine Center Manager to resolve the issue, or a waiver is not granted, the doses must be replaced by the specified due date on the replacement statement. If the provider does not replace VFC vaccine doses by the due date, vaccine orders will be held until all doses are replaced.

**How to Handle Wasted or Expired Vaccine**

- Do not discard expired vaccine. Do not send expired or wasted vaccines to the manufacturer.

- Remove expired vaccines from the refrigerator or freezer to prevent inadvertent use.

- Mark the vaccines as expired or wasted so they are not put back into the refrigerator or freezer.

- These doses must be accounted for in your ASIIS inventory reconciliation screen.

You can enter wasted/expired doses into ASIIS at any time during the month. It is recommended to enter this information in ASIIS at the time of the event to ensure the ASIIS inventory is up-to-date. The Arizona Vaccine Center will work proactively to ensure VFC vaccine is tracked and accounted for at all VFC provider offices. If you need technical assistance with ASIIS inventory management, please review the Inventory Management training guide: https://asiis.azdhs.gov/ASIIS%20Inventory%20Management.pdf.
If you have additional questions after reviewing the guide, please contact the ASIIS hotline at (602) 364-3899 or 1-877-491-5741.

- Once you have entered the expired and wasted vaccines into ASIIS please contact the Arizona Vaccine Center for instructions on how and where to send the vaccine.

- Email the Wasted/Expired Vaccine Return Form (see Resources/ VFC Forms: Wasted/Expired VFC Vaccine Return Form) to the Arizona Vaccine Center at ArizonaVFC@azdhs.gov.

Vaccine Returns

VFC vaccines should never be discarded unless providers are told to do so by the Arizona VFC Program. VFC vaccines that have expired, spoiled or wasted should be returned to the CDC central distribution center. Providers must contact the Arizona Vaccine Center to receive a VFC vaccine return label and to obtain additional information on how to send these vaccines to the distribution center. Vaccines must be returned to the CDC Central Distribution Center within 6 months of spoilage/expiration.

Items to Keep In Mind

- Every attempt should be made to use VFC vaccine appropriately. If you need assistance with spoiled, wasted, or expired VFC-supplied vaccines contact the Arizona Vaccine Center. Do not call the manufacturer.
- Never administer expired vaccine. Individuals will remain susceptible to the disease if given an expired, non-viable vaccine and will have to be recalled for revaccination.
- Vaccines in open multi-dose vials are valid and usable until the manufacturer’s expiration date regardless of the length of time since the first dose was withdrawn.
- If the expiration date is a month and year, the vaccine is valid until the last day of the month (e.g., July 17 is valid until July 31, 2017).
- All VFC vaccines should be used until the expiration date. In order to ensure vaccines are viable until their expiration date, aseptic technique must be used when withdrawing vaccine from a multi-dose vial. No visible contamination should be present.
- Monitor vaccine use closely.
- Inventory your vaccine monthly to check expiration dates.
- Use vaccines that have the soonest expiration date first.
- Maintain the “cold chain” and implement vaccine quality controls to ensure vaccine viability and unnecessary loss of vaccine.
• To protect patients with viable vaccine: maintain accurate, appropriate, and consistent temperatures in your refrigeration units. An average temperature of 40°F in the refrigerator and 0°F in the freezer is ideal.

When in doubt, call the Arizona Vaccine Center at 602-364-3642.

<table>
<thead>
<tr>
<th>Vaccine Emergency Management Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ A “review date” is required to verify all plans are current.</td>
</tr>
<tr>
<td>✓ All plans must include the signature, name, and title of the preparer of the documents.</td>
</tr>
<tr>
<td>✓ All provider vaccine storage and handling plans must be reviewed and updated annually, or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan.</td>
</tr>
</tbody>
</table>

**Vaccine Emergency Handling Plan**

Unforeseen circumstances and human error result in vaccines exceeding or falling below recommended temperature ranges. All VFC providers must have an established plan in writing for safe vaccine storage during emergencies, (e.g., keep vaccines safe and at recommended temperatures during an equipment malfunction, power outage or natural disaster). A Vaccine Emergency Handling Plan should be developed for use in every office enrolled in the VFC Program (see Resources/ VFC Forms: Vaccine Emergency Handling Plan –VFC). The VFC site visit reviewer will ask for a copy of the office vaccine emergency handling plan during compliance visits.

All staff should review the vaccine emergency handling plan and receive a copy of the plan. Post the plan in a highly visible location, such as the door to your vaccine area or on the refrigerator. All office staff, including after-hours personnel (e.g., facilities, security guard, etc.) must know what to do in the event of a vaccine emergency. It is recommended to have all staff initial the vaccine emergency handling plan to document that they have read it.

**In the event of equipment breakdown or power outage:**

• Do not open the refrigerator or freezer door until you are ready to move the vaccine(s).
• Immediately notify the Arizona Vaccine Center and speak to a staff member. Do not leave a voice message.
• If the event occurs after hours or during the weekend you must follow your Vaccine Emergency Handling Plan.
• Never discard VFC vaccine unless instructed to do so by Arizona Vaccine Center staff.
• Record temperatures of the new unit making sure it is within the required temperature range.
• Move the VFC vaccine supply to another refrigerator and freezer unit as soon as possible.
• Separate the VFC vaccine that may have been stored at improper temperatures from any other vaccine supply and label “Do Not Use”.
• VFC vaccine should not be used until a VFC representative or the Arizona VFC Program has been contacted for instructions on what to do. Depending on manufacturer specifications, there is a possibility that the vaccine is viable (able to be used).
• All spoiled or wasted vaccine supplied by VFC must be returned to the CDC centralized vaccine distributor within 6 months of spoilage/expiration.

For assistance with spoiled or wasted VFC supplied vaccines, contact the Vaccine Center first at (602) 364-3642.

**Note on Mobile Units**

Mobile units or temporary vaccine clinics using VFC vaccine that is transported off site are not allowed without prior approval from the Arizona Vaccine Center.
Chapter 8: VFC PROVIDER COMPLIANCE VISITS

VFC Compliance Visit Requirements

✓ All VFC providers must participate in VFC program compliance site visits, including unannounced storage and handling visits and other educational opportunities associated with the VFC program requirements.

The following activities are requirements of the VFC Program and must be conducted by the Arizona Vaccine Center staff to ensure the ongoing integrity of the program. These activities include:

Provider Site Visits

Compliance Visit
Once every other year AIPO Program staff will conduct a VFC compliance site visit at VFC enrolled provider offices. The purpose of the visit is to evaluate for proper screening of VFC eligibility, vaccine administration documentation, vaccine ordering protocols, and vaccine management which includes storage and handling requirements. The compliance visit is designed to protect against fraud and abuse and observe office practices that:

- Ensure compliance with VFC program requirements (reporting/documentation/vaccine storage and handling)

- Minimize vaccine loss and wastage

- Ensure that vaccines purchased with VFC funds are administered only to VFC eligible children

- Ensure VFC Vaccine stewardship and accountability

VFC program staff members are also required to follow up on corrective action plans or improvements received during the VFC compliance site visit.

Note: AIPO staff will make every attempt to schedule and conduct these visits at a time that will not interrupt office practice. A visit may or may not be pre-scheduled. Each visit takes approximately two to three hours or longer based on information obtained prior to and during the compliance visit.
Education Visits/New Provider Visit
Arizona Vaccine Center staff will conduct provider staff training/education on VFC program requirements for all newly enrolled providers, new office staff and other staff in need of updates. These visits are scheduled at a time that is mutually agreed upon and will take approximately two to three hours.

Unannounced Storage and Handling Visits
These are visits that can occur at any time with no notice. They may last an hour and will include a short questionnaire. The VFC representative will look at your storage units to check for proper storage techniques and any expired vaccines.

VFC Annual Education Requirement

Each VFC Coordinator and their VFC backup are required to complete an annual educational training as designated by AIPO and the CDC. Providers will be notified by AIPO of the specified training. It is strongly recommended that all staff members who handle VFC vaccine also complete the training. All new VFC Coordinators are required to complete this educational training before they begin handling VFC vaccines.

VFC Provider Surveys

The Arizona VFC Program conducts a provider satisfaction survey every two years to evaluate the impact of the VFC program on the delivery of immunization services in the public and private sectors. The survey allows the VFC program team to determine if the VFC program is meeting the needs of enrolled providers.

The VFC Program management team also conducts a separate survey related to the provider’s experience with their VFC compliance visit reviewer. Please visit http://www.surveymonkey.com/s/VFCSurvey to complete this short survey.
Chapter 9: CONTINUOUS QUALITY IMPROVEMENT (CQI) THROUGH THE AFIX (ASSESSMENT, FEEDBACK, INCENTIVE, AND EXCHANGE) PROGRAM

AFIX Program Overview

The Centers for Disease Control and Prevention’s AFIX (Assessment, Feedback, Incentives, and eXchange) is a research-supported continuous quality improvement process. AFIX works collaboratively with providers to increase and sustain high immunization coverage and incorporate evidence-based immunization practices at the immunization provider level.

(A)ssessment: A standardized method for collecting and analyzing quantitative and qualitative vaccination coverage data and information. The assessment provides the opportunity to understand practice patterns that may affect the delivery of immunizations to the provider’s patient population.

(F)eedback: Informs immunization provider and staff about assessment observations and results while encouraging discussion on ways to improve immunization rates, reduce missed opportunities, and improve the immunization delivery system. Feedback results in the development of clear and achievable quality improvement activities.

(I)ncentives: Recognition of improved performance quality for providers and staff making practice-based changes, developing more effective immunization delivery systems, and ultimately improving immunization coverage. Incentives are used in combination with immunization educational aspects covered during feedback. An example of an incentive is the Daniel T. Cloud Award.

(eX)change: Follow-up with providers used to monitor and support progress towards implementing quality improvement strategies discussed during feedback. The exchange ensures providers have the necessary resources and information to improve the quality of their immunization services.

There is strong evidence that assessment and feedback, along with other elements such as incentives and exchange, are effective in increasing vaccination rates. In 2008, the Task Force on Community Preventive Services updated its original 1999 literature review on the topic and reaffirmed its earlier recommendation for using assessment and feedback “based on strong evidence of its effectiveness across a range of settings and populations.” In addition, the task force recommends assessment and feedback for their effectiveness in improving immunization rates in adults and children when used alone or with additional components (such as incentives). This same review is cited in CDC’s Advisory Committee on Immunization Practices (ACIP) 2011 General Recommendations in its endorsement of assessment and feedback.

More detailed information about the AFIX process can be found at:
- Arizona AFIX Operational Guide and Policies and Procedures
Brief Overview of AFIX Process:

1) **Assessment**: Providers are notified in advance of the AFIX visit. After a visit is scheduled, the Assessment specialist will perform a quantitative and qualitative assessment on the provider office.

   a) **Quantitative**: Generating assessment reports for children (24-25 months of age) and adolescents (13-18 years of age) for the provider practice. This is conducted through the use of ASIIS (Arizona State Immunization Information Systems).

   b) **Qualitative**: The AFIX Site Visit Questionnaire is the primary tool used for the qualitative portion of an AFIX assessment. This is a requirement for every AFIX visit. The AFIX Site Visit Questionnaire is designed to assess and evaluate a provider’s implementation of evidence based strategies proven to improve immunization coverage. The provider will fill this out prior to the AFIX visit.

2) **Feedback**: Feedback is the process of informing immunization providers and staff about observations and results from the assessment. It is an important component of the AFIX process. Feedback provides a forum to discuss the provider’s immunization delivery system, missed opportunities, and steps to improve quality and coverage.

   a) **Quality Improvement Goals**: During the feedback session, the AFIX coordinator will review and discuss the assessment reports and completed AFIX Site Visit Questionnaire and assist in choosing two to three QI strategies that would be most beneficial in improving the quality of immunization services and increasing immunization rates at the practice.

3) **eXchange (Follow-Up)**: The eXchange of information (follow-up) is a component of the AFIX program aimed at following up with providers to monitor and support progress toward implementing the QI strategies discussed during the feedback process. The eXchange (follow-up) process ensures not only continuous QI, but also that providers have the necessary resources and information to improve the quality of their immunization services. The follow-up occurs about 4-6 months after the initial assessment. Additionally, if QI strategies selected were not 100% implemented, there will be a subsequent follow up to help identify any additional barriers that were not initially addressed.

**What will an AFIX assessment do for your practice?** An assessment will:

- Provide you and your staff with ASIIS generated reports showing the coverage levels of your patients in the assessed age groups.
- Identify patients who are missing immunizations and specify the doses needed.
- Identify missed opportunities to immunize and other barriers to immunization delivery.
• Collaboratively develop strategies to improve immunization coverage levels and reduce missed opportunities to vaccinate.
• Identify any invalid vaccine doses.
• Present up-to-date provider resource materials.
• Provide you with reminder/recall strategies to strengthen coverage levels.
• Track your progress through follow up assessments.

The AFIX portion of a site visit usually takes at least an hour to complete depending on the amount of training desired. During the in-person visit, your AFIX assessment specialist will also train you and your staff on how to schedule and run your own assessment reports. This is great because now you and your staff can utilize ASIIS in your office to assist in improving coverage levels and reducing missed opportunities and you don’t have to wait for your next AFIX visit to get some of these useful reports.

If you have questions about the AFIX process, would like access to AFIX-ASIIS training materials, or would like to request an AFIX visit, please contact the Arizona Immunization Program Office at 602-364-3642 and ask to speak to an Assessment Specialist or the Assessment Manager.
Chapter 10: PROVIDER REQUEST FOR INACTIVATION OR OFFICE CLOSURE

Voluntary inactivation

Providers may inactivate their enrollment in the Arizona VFC program at any time. To prevent wastage of VFC vaccines, providers must notify the Arizona Vaccine Center in writing on office letterhead at least 30 days prior to their intended date of inactivation. This letter must be signed by the medical director or equivalent. This will allow time for the provider to transfer VFC vaccines to another VFC provider. Data loggers and any other equipment supplied by the Arizona Vaccine Center will need to be returned to the VFC program. For detailed inactivation requirements and instructions use the VFC Inactivation Checklist (see Resources/VFC Forms: VFC Inactivation Checklist).

Upon inactivation the provider will be responsible for replacing any vaccine not accounted for or returned in a non-viable state (e.g., vaccine no longer effective due to mishandling or within 90 days of expiring).

Office Relocation, Move, or Other Changes

If a VFC office is planning to relocate, the office must notify the Arizona Vaccine Center in writing at least 30 days prior to the move. This notice will prevent shipments going to the incorrect location. Five days of refrigerator/freezer temperatures within normal limits must be recorded at the new location prior to transferring the vaccines from the previous location. All vaccine transfer requests must be entered into ASIIS and approved by Arizona Vaccine Center staff.

Providers must notify the Arizona Vaccine Center of any changes, such as name change, mailing address, shipping address, contact information, new VFC coordinator, new backup VFC coordinator, email, phone, fax, or VFC population changes within one week of the change(s). These changes can be reported on the Provider Contact Change Form (see Resources/VFC Forms: VFC Contact Information Update Form).

Short-Term Office Closure

If a VFC provider office will be closed for more than five consecutive days the provider must notify the Arizona Vaccine Center. Refrigerator and freezer temperatures must continue to be taken twice daily. Failure to do so may result in the site being required to replace any vaccine determined by the Arizona Vaccine Center to be non-viable. Upon re-opening the office temperatures must be recorded for five consecutive days before VFC vaccine is shipped to the office.
Notice of Action Procedures

The Arizona VFC Program is responsible for ensuring that providers meet all VFC program requirements. Failure to comply with Arizona VFC program requirements as described in this operations guide will result in one of the following progressive disciplinary actions. Follow up visits will occur throughout the process.

VFC Corrective Action Process

During the VFC compliance visit the site reviewer may identify areas that need attention/correction. The findings are documented and shared with the provider staff during the visit. Provider staff members are given verbal and written feedback on items identified for correction and are educated on the importance of the VFC Program requirements.

The following are examples of issues that can be resolved during the compliance visit: outdated Vaccine Information Statements (VIS), lack of “Do Not Disconnect” sign next to storage outlets, missing refrigerator plug guards, or vaccines that have been placed in the back of the unit that will soon expire.

If non-compliance issues identified during a VFC site visit cannot be resolved during the visit the VFC representative will try to determine the root cause behind the non-compliance issue. The VFC representative will discuss the purpose of the requirement with the VFC Coordinator and/or their backup and educate them on how to become compliant. The VFC representative will provide a timeframe for corrective actions during the site visit. Additional follow up will occur in the form of a letter, phone call, or follow up visit to ensure that corrections were made.

Administrative Observation (Probation)

If VFC requirements have not been met by a provider after multiple follow ups, or an incident has occurred that cannot be corrected on the day of the site visit the provider will be placed on Administrative Observation (also referred to as Probation), and will receive a Corrective Action Plan from the site’s VFC Representative specifying the needed areas of compliance and notification of a follow up visit at the end of the probation period.

All instances of probation will be reported to AHCCCS.

Probation will end when the VFC site reviewer has observed sustained improvement by the provider. If the items in the needed areas of compliance are not corrected while on probation the provider will receive a secondary and final Corrective Action Plan notification from the VFC Representative.
**Involuntary Inactivation by the Arizona Vaccine Center or the VFC Program**

Involuntary inactivation occurs when the provider has failed to adhere to VFC requirements after multiple attempts by the VFC program staff to correct non-compliance issues and failure of the provider to complete the components of the Corrective Action Plan(s).

**All inactivations will be reported to AHCCCS.**

Note: All administrative actions implemented by the Arizona VFC Program are reported to AHCCCS. Since AHCCCS enrolled providers must be enrolled in the VFC program, inactivation from the VFC Program will result in the provider losing the privilege of being an AHCCCS provider for children birth through 18 years of age.
Federal fraud and abuse laws apply to the entire VFC program, consistent with “fraud and abuse,” as defined in the Medicaid regulations at 42 CFR §455.2. For the purposes of this Arizona VFC Operations Guide, the following definitions will be used:

**Definitions:**

**Fraud** is defined as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

**Abuse** is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

**Oversight** by the Arizona VFC program will ensure (through compliance visit reviews, monitoring of vaccine ordering practices and inventory reconciliation, and unannounced storage and handling visits) that federally funded VFC vaccines are administered, recorded, stored and handled appropriately according to VFC requirements. These areas will be monitored and checked regularly for all providers enrolled in the VFC program.

**Enforcement** is the Arizona VFC program’s responsibility to ensure all providers adhere to current VFC requirements. If it is found that VFC providers are intentionally misusing federally funded VFC vaccines, disciplinary steps will be taken to ensure immediate correction.

**Enforcement Actions for Fraud and Abuse**

The Arizona VFC program will formally investigate all instances of possible fraud and abuse on a case-by-case basis.

If you have not met Arizona VFC requirements or followed Arizona VFC procedures as outlined in this guide, but the Arizona VFC program finds no intentional deception, misrepresentation, or negligence on your part, you may be required to participate in training and/or to take other actions to rectify the situation.
If the Arizona VFC program finds evidence of intentional deception, misrepresentation, or negligence on the part of the VFC provider, further investigation and potential enforcement of relevant laws, including fraud and abuse, consumer protection, and professional licensure will occur.

**Examples of Fraud and Abuse**

- Providing VFC vaccine to non-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional rate (in Arizona the rate is $21.33) for administration of a VFC vaccine to a federally vaccine eligible child
- Not providing VFC eligible children VFC vaccine because of parents’ or guardians’ inability to pay the administration fee
- Not implementing provider enrollment requirements of the VFC program
- Failing to screen patients for VFC eligibility
- Failing to maintain VFC records and comply with other requirements of the VFC program
- Failing to fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match the provider profile or otherwise involve over-ordering VFC vaccines
- Wastage of VFC vaccine
Chapter 13: VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. The information from the VAERS report is added to a VAERS data bank which is further analyzed to look for trends or suggestions of potential vaccine safety concerns.

Who can file a VAERS report?
Anyone can submit a VAERS report. This includes healthcare providers, vaccine providers, public health officials, vaccine manufacturers and persons vaccinated or their caregivers. Healthcare providers may visit https://vaers.hhs.gov/index for additional information.

What adverse events should be reported?
VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. Report such events even if you are unsure whether a vaccine caused them. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the VAERS Reportable Events Table that occurs within the specified time period after vaccination.

A copy of the Reportable Events Table can be obtained by calling VAERS at 1-800-822-7967 or by downloading it from:
http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Additional VAERS Information:
- Send e-mail inquiries to info@vaers.org
- Fax inquiries to the toll-free information fax line at 1-877-721-0366
- Call the Arizona Vaccine Center at (602) 364-3642

This information has been adapted from the VAERS website http://www.vaers.hhs.gov
Chapter 14: THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) was enacted on August 21, 1996. Provisions of the act that apply to health care providers took effect April 14, 2003. A simplified description of some of the provisions follows:

The U.S. Department of Health and Human Services (DHHS) recognized the importance of sharing Protected Health Information (PHI) to accomplish essential public health objectives and to meet certain other social needs (e.g., administration of justice and law enforcement). Therefore, the Privacy Rule expressly permits PHI to be shared for specified public health purposes. For example, covered entities may disclose PHI, without individual authorization, to a public health authority legally authorized to collect or receive the information for the purposes of preventing or controlling disease, injury or disability [45 CFR §164.512(b)]. Further, the Privacy Rule permits covered entities to make disclosures that are required by other laws, including laws that require disclosures for public health purposes.

The full document is available at: http://www.hhs.gov/ocr/privacy/
## Directory of Arizona VFC and AFIX Staff

### VFC Mailing Address:
Arizona Immunization Program Office  
Vaccine Center  
150 N. 18th Avenue, Suite 120  
Phoenix, Arizona 85007-3233

**Telephone:** (602)-364-3642  
**Fax:** (602)-364-3276  
**Web Site:** [http://www.azdhs.gov/phs/immun/act_aipo.htm](http://www.azdhs.gov/phs/immun/act_aipo.htm)

### VFC Manager:
Lisa Underhill  
**Vaccine Center Manager**  
**Office:** (602) 364-3644  
**Fax:** (602) 364-3276  
**lisa.underhill@azdhs.gov**

Phoenix office  
All counties

### VFC Representatives:
- **Faith Herbert**  
  Office: (602) 364-3641  
  Fax: (602) 364-3276  
  Phoenix office  
  [faith.herbert@azdhs.gov](mailto:faith.herbert@azdhs.gov)

- **Marcellina Lopez**  
  Office: (602) 364-3645  
  Fax: (602) 364-3276  
  Marcellina.lopez@azdhs.gov

- **Scott Elliott, MSW**  
  Office: (602) 364-3652  
  Fax: (602) 364-3276  
  scott.elliott@azdhs.gov

- **Teresa Saenz**  
  Office: (602) 364-3650  
  Fax: (602) 364-3276  
  teresa.saenz@azdhs.gov

### Vaccine Ordering Team:
- **Rosita Davis**  
  **VFC Program Specialist**  
  Phoenix Office  
  Office: (602) 364-3651  
  Fax: (602)364-3276

- **Zachary Guzman**  
  **Vaccine Order Specialist**  
  Phoenix Office  
  Office: (602) 364-3757  
  Fax: (602) 364-3276
<table>
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<tr>
<th>Position</th>
<th>Name</th>
<th>Office</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFIX Specialist</td>
<td>Melissa Murrieta</td>
<td>(520) 770-3105</td>
<td>(520) 770-3307</td>
</tr>
<tr>
<td>Tucson office</td>
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<td><a href="mailto:melissa.murrieta@azdhs.gov">melissa.murrieta@azdhs.gov</a></td>
<td></td>
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<tr>
<td>VFC Administrative Assistant</td>
<td>Debra Dill</td>
<td>602-364-3642</td>
<td>602-364-3276</td>
</tr>
<tr>
<td>Phoenix Office</td>
<td><a href="mailto:Debra.dill@azdhs.gov">Debra.dill@azdhs.gov</a></td>
<td></td>
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Chapter 16: RESOURCES

VFC Forms

Arizona VFC Patient Immunization Log
Childhood/Adolescent Immunization Administration Record
2016 Provider Enrollment Agreement
2016 Provider Profile
2016 Refrigerator-Freezer Verification Form
ASIIS User Agreement Form-VFC
ASIIS HIPAA Pledge to Protect Confidential Information
Fahrenheit to Celsius Conversion Chart
Inactivation Checklist-VFC
Packing Refrigerated Vaccines Checklist
Patient Eligibility Screening Record-VFC English
Patient Eligibility Screening Record-VFC Spanish
Provider Contact/Address Change Form-VFC
Refrigerator/Freezer Temperature Log
Required Specifications for Refrigerators/Freezers-VFC
Vaccine Borrowing Report
Vaccine Emergency Handling Plan-VFC
Vaccine Order Worksheet-VFC
Vaccine Signs (e.g., Do Not Unplug, Caution Perishable)
VFC Dose for Dose Replacement Form
Wasted/Expired VFC Vaccine Return Form

Job Aids

ASIIS Inventory Tips for VFC Vaccine (for Electronic Reporters)
ASIIS Inventory Tips for VFC Vaccine (for Manual Reporters)
Cold Storage Training Module
Deputized Provider List
Frozen Vaccine Storage Requirements
How to Fix Inventory Issues Using ASIIS Reports

Revised 10/31/15
How to Print Reconciliation Worksheet in ASIIS
How to Run the Provider Profile Report in ASIIS
Inventory Management Guide
VAERS form
Vaccines with Diluents: How to Use Them
Vaccine Storage Temperatures
VFC ASIIS Ordering Worksheet
VFC Influenza Order Training Module
VFC Order Placement Training Module
VIS-HPV9-Gardasil

**Websites**

**State:**


ASIIS Help Desk Email Address: [ASIISHelpDesk@azdhs.gov](mailto:ASIISHelpDesk@azdhs.gov)

**Federal:**

Vaccines and Immunizations [www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/)


Advisory Committee on Immunization Practices (ACIP) [http://www.cdc.gov/vaccines/pubs/ACIP-list.htm](http://www.cdc.gov/vaccines/pubs/ACIP-list.htm)

CDC-Morbidity and Mortality Weekly Report (MMWR) [www.cdc.gov/mmwr/](http://www.cdc.gov/mmwr/)
Local/National Immunization Organizations:

The Arizona Partnership for Immunization (TAPI)
http://www.whyimmunize.org/

Immunization Action Coalition (IAC) provides Vaccine Information Statements (VIS) in a number of languages at:
http://www.immunize.org/

National Institute for Standards and Technology
http://www.nist.gov/index.html

Vaccine Manufacturers:

Merck
https://www.merckvaccines.com/is-bin/INTERSHOP.enfinity/WFS/Merck-MerckVaccines-Site

MedImmune

GSK
http://www.gsk.com/

Pfizer
http://www.pfizer.com/home/

Sanofi Pasteur
References


