

Arizona Vaccines for Adults (VFA) Program

OPERATIONS GUIDE

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Arizona Department of Health Services

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Vaccines for Adults Program

Welcome to the Arizona Vaccines for Adults (VFA) program. The Arizona VFA Operations Guide has been prepared by the Arizona Department of Health Services, Arizona Immunization Program Office. This guide provides information to enrolled VFA providers to ensure compliance with federal and state guidelines regarding safe handling, administration, and reporting of VFA vaccines. Recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) have been included in this guide.

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

The link below provides access the VFA Program webpage. **Please save the VFA webpage link to your internet favorites. Providers cannot access this webpage from the Arizona Immunization Program Office homepage. This website has all policy and procedure information, as well as forms, resources and job aids to assist you with your program.**

<http://azdhs.gov/phs/immunization/vaccines-for-adults-program/>

Background

In the U.S., more than 42,000 adults die each year from vaccine-preventable diseases. The optimal use of vaccines (e.g., influenza, pneumococcal, hepatitis B) has great potential to protect and improve the health of adults. Although many Arizona adults have health care insurance or health care coverage, there is currently no comprehensive program to finance immunization services for those who are uninsured or underinsured. The VFA Program was created to provide vaccines at no cost to these adults in Arizona.

To all VFA providers, we extend our thanks for immunizing Arizona's adults.

Definitions and Acronyms Used in this Guide

ACIP	Advisory Committee on Immunization Practices
AIPO	Arizona Immunization Program Office
ASIS	Arizona State Immunization Information System
Aseptic	The absence of microorganisms. Free from infection or septic material; also <i>sterile</i> .
Attenuated	Weakened or reduced virulence
CDC	Centers for Disease Control and Prevention
CHD	County Health Department
Cold Chain	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.
Diluent	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.
Electronic Medical Record (EMR)	A specialized medical information software application which electronically documents patient medical information.
Eligible	A patient who meets the criteria for VFA Program participation.
Inactivated	Considered to be a killed vaccine; cannot replicate, is not infectious and cannot cause disease.
Potency	Vaccine effectiveness.
Reconstitution	Restoration to original form of a substance previously altered for preservation and storage.
Restitution	Repayment for lost, wasted, expired, or spoiled VFA vaccines due to provider negligence.

Vaccine Coordinator	The staff person in the provider's office who is the primary administrator and contact person for the management of vaccines.
Viable	Capable of living; in vaccines, the state in which vaccines are effective
Vial	A small bottle, usually of glass.
Wastage	Wasteful or avoidable loss. VFA vaccines that are spoiled, expired, or lost may be billed to the provider.

Adult Vaccine Abbreviations

hep A	hepatitis A
hep B	hepatitis B
HPV	Human Papillomavirus <ul style="list-style-type: none"> • 2 valent - females only • 4 valent - females and males • 9 valent - females and males
IIV 4	Influenza Vaccine - Quadrivalent
LAIV	Live Attenuated Influenza Vaccine
MCV4	Meningococcal Conjugate Vaccine - Quadrivalent
MEN B	Meningococcal Serogroup B
MMR	Measles, Mumps, Rubella
PCV13	Pneumococcal Conjugate Vaccine – 13 valent
PPSV 23	Polysaccharide Pneumococcal Vaccine – 23 valent
Tdap	Tetanus, diphtheria, acellular pertussis
Td	Tetanus Diphtheria Vaccine (Adult)
Varicella/VAR/VZV	Varicella (Chickenpox)
Zoster (HZV)	Zoster (Shingles)

Chapter 1: VFA PROGRAM GUIDELINES

Eligibility Screening

- Prior to administering VFA vaccines, each patient must be screened for VFA eligibility to determine if they are eligible to receive VFA vaccines (see Resources/VFA Forms: *Patient Eligibility Screening Record-VFA*).
- Document the screening information in a paper or electronic file so you can retrieve this information for VFA Program reports.
- If using electronic records, keep the eligibility screening information in the patient's electronic medical record or in a separate database. This information must include the date(s) the patient was screened.
- You are not required to verify the patient's response to the screening questions.
- Keep the paper or electronic eligibility screening record for six (6) years from the date of the last visit.

Eligibility Criteria

Adults age 19 years and older who are

- Uninsured, or
- Underinsured (has health insurance that does not cover one or more vaccines)

Allowable Administration Fees

Charging allowable administration fees

- You may charge VFA eligible patients a fee for administration of the VFA vaccine as determined by your organization
- You may also charge for the office visit, but not for the VFA Program vaccine

Waiving the administration fees

- 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 VFA eligible patient may be denied vaccine for failure to pay an administration fee
- Failure to waive administration fees according to VFA Program policy could be considered fraud and abuse (see Chapter 11 for more information on Vaccine Fraud and Abuse).

Vaccine Information Statements

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 legal representatives of the benefits and risks of a vaccine.

Give a VIS to the patient before administering each dose of vaccine. The VIS may be a laminated copy to read in the office during the immunization visit, or a paper copy to review and take home with them.

If they prefer to download the VIS onto a mobile device, direct them to the CDC's patient download webpage (www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm) during the visit and 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.

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 whenever possible.

Documenting Immunizations in Medical Records

Under federal law you must document certain required information in each patient's medical record for each dose of vaccine given.

- Federally required information:
 - ✓ Clinic/facility name and address
 - ✓ Date vaccine was administered
 - ✓ Vaccine type
 - ✓ Vaccine manufacturer

- ✓ Vaccine lot number
 - ✓ Site and route of injection
 - ✓ Signature and title of person(s) administering vaccine
 - ✓ Publication date of VIS (located at the bottom of VIS)
 - ✓ Date VIS was given to the patient (usually the same as the vaccine administration date, but not always)
- AIPO required information:
 - ✓ Dose number
 - ✓ History of vaccine reaction if the patient has experienced a clinically significant or unexpected event after an immunization (even if there is uncertainty that the vaccine caused the event)
 - ✓ Contraindications and precautions that may apply to this patient
 - For combination vaccines, record the generic abbreviation for the type of vaccine given (e.g., hep B-hepA) in each of the sections that correspond to the separate antigens listed on the record (e.g., hepatitis B section and hepatitis A section). Avoid using brand names.
 - Be sure to give patients a record of their immunizations. Complete a Lifetime Immunization Record Card (LIRC/Blue Book)* or, if your clinic is enrolled in ASIIS, print out the ASIIS immunization record.

*LIRCs may be ordered from AIPO:

<http://azdhs.gov/phs/immunization/documents/vaccines-for-children/forms/vfc-provider-contact-update-form-fillable.pdf>.

VFA Program Records

Keep all records related to the VFA Program for at least six (6) years.

- VFA Refrigerator/Freezer Temperature logs
- VFA Patient Eligibility Screening records (reviewed at each visit)
- Wasted/Expired VFA Vaccine Return forms (if applicable)
- Packing lists of vaccine shipments or logs with lot numbers

If requested, make these records available to the Arizona VFA Program.

Check with your own clinic's policies about keeping records beyond six years.

Chapter 2: ARIZONA VFA SUPPLIED VACCINE

Arizona VFA Vaccine Choice Policy

Adult vaccines recommended by the ACIP are made available through the AIPO VFA program. These vaccines may be ordered through ASIIS. VFA providers with a product preference may choose a particular brand.

The 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: the CDC and vaccine manufacturers have established manufacturing and distribution systems for influenza vaccines which require significant planning to avoid delays.
- New or changing vaccines may not be available immediately upon approval 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 available through the VFA program.

If a brand chosen by a provider is not available for any reason (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., Boostrix® and Adacel®). 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., Cervarix® and Gardasil4® and/or Gardasil®9).
- If a combination vaccine becomes unavailable the provider will be asked to approve a shipment of single antigen equivalents before the order is placed with CDC.

The 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 Vaccine Center will ship vials without notification to the provider. If vials

become unavailable for an extended period of time, the Vaccine Center will ship syringes to any provider ordering less than 50 doses of vaccine in vials.

If a provider chooses to use a different brand of vaccine the provider bears the responsibility for using all remaining doses of the previously received vaccine before the expiration date, or safely transferring that vaccine to another active VFA provider. Allowing a vaccine to expire because the provider has chosen to change brands will be considered a failure to properly monitor vaccine, and the provider will be subject to a wastage invoice from the Arizona Vaccine Center.

VACCINES SUPPLIED BY THE VFA PROGRAM

Vaccine	Brand Name	Manufacturer
hep A hepatitis A - Adult	Havarix [®]	GlaxoSmithKline (GSK)
	Vaqta [®]	Merck
hep A- hep B hepatitis A – hepatitis B - Adult	Twinrix [®]	GSK
hep B hepatitis B - Adult	Engerix - B [®]	GSK
	Recombivax HB [®]	Merck
HPV9 9-valent Human Papillomavirus Types 6,11,16, 18, 31, 33, 45, 52, and 58 Recombinant	Gardasil ^{®9}	Merck
HPV4 Quadrivalent Human Papillomavirus Types 6,11,16 and 18 Recombinant	Gardasil [®]	Merck
HPV2 Bivalent Human Papillomavirus Types 16 and 18 Recombinant	Cervarix [®]	GSK
MenB Serogroup B Meningococcal	Trumenba [®]	Pfizer
	Bexsero [®]	GSK
MCV Meningococcal Conjugate	Menveo [®]	GSK
	Menactra [®]	Sanofi [®]
MMR Measles, Mumps, & Rubella - Adult	M-M-R ^{®II}	Merck
PCV13 Pneumococcal Conjugate Vaccine – 13-valent - Adult	PCV13 [®]	Pfizer

PPSV23 Pneumococcal Polysaccharide Vaccine 23- valent	Pneumovax 23 [®]	Merck
Tdap Tetanus Toxoid, reduced Diphtheria Toxoid and acellular Pertussis	Boostrix [®]	GSK
	Adacel [®]	Sanofi
TD Tetanus and Diphtheria Toxoids	TD [®]	Merck
	Tenivac [®]	Sanofi
Varicella - Adult	Varivax [®]	Merck
Zoster Vaccine Live	Zostervax[®]	Merck

Chapter 3: COUNTY HEALTH DEPARTMENT AND PUBLIC PARTNER ENROLLMENT IN THE VFA PROGRAM

Enrollment in the Arizona VFA program is limited to CHDs and, if desired, their public partners. AIPO will provide the CHDs with an estimating tool with an allocated dollar amount based on available federal 317 funds, population information and immunization activity data. CHDs will then determine the number of adult vaccine doses needed to serve the targeted adult population in the county.

If a CHD determines there is little to no capacity to administer all allocated VFA vaccines by its own department the CHD may decide to either opt out of the program or work with other public (not private) providers to assist in the administration of VFA vaccines. Examples of public providers a CHD may decide to work with include Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), fire departments, jails/prisons, non-profit agencies, or special high-risk population providers which may be public or private.

CHDs will be required to work closely with the chosen public providers in monitoring vaccine use and ensuring compliance with VFA requirements. Due to the complexity of monitoring vaccine use it is recommended that each CHD partner with fewer than 20 public providers.

CHDs and public providers that participate in the VFA program must qualify as VFA providers with AIPO and complete a VFA Enrollment Application. CHDs and their public providers will be assigned unique VFA PIN numbers for vaccine ordering and VFA IRMS numbers for ASIIS reporting. CHDs and their public providers will each order vaccine directly through ASIIS and will report all administered and wasted/expired/spoiled doses to ASIIS via the unique VFA PIN and IRMS numbers. This will allow for the separate tracking of VFA vaccine.

Initial enrollment (and subsequent re-enrollment) in the VFA program will be on a three-year contract. An annual survey will be given to CHDs to evaluate the status of their program, the addition or deletion of partners, and a review of program effectiveness. If, during the course of the contract, no federal funding is made available for the VFA program for the next year, the contract will become void at the end of the current year. CHDs and partners may continue to provide already received VFA vaccine until the supply is gone.

The following enrollment documents should be signed and submitted by both the CHD and the Public Partner(s) to Arizona Vaccine Center before VFA vaccine can be ordered.

- VFA Provider Enrollment Agreement
- VFA Provider Profile Form
- VFA Refrigerator/Freezer Verification Form
- VFA ASIIS User Agreement Form
- VFA HIPAA Pledge to Protect Confidential (ASIIS) Information Form

If, during the course of the three-year enrollment period, a CHD chooses to inactivate/end their participation with a public partner, the CHD will notify the partner of that decision and all remaining VFA vaccine will be returned/transferred to the CHD. The CHD will also inform AIPO of the inactivation through an email.

It is critical that each VFA provider label and store VFA vaccine separately from VFC vaccine and private stock. VFA vaccine must not be used for children, even if the packaging indicates that the vaccine can be used for children. VFA vaccine is ordered on the CDC adult vaccine contracts and is not allowed to be administered to children. VFA labels are available from the Vaccine Center.

Chapter 4: ARIZONA STATE IMMUNIZATION INFORMATION SYSTEM (ASIIS)

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 or patients.

VFA ASIIS Reporting Requirements

VFA providers are required to report all VFA doses administered to ASIIS.

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 ASIISHelpDesk@azdhs.gov. Visit the ASIIS website at <http://azdhs.gov/phs/asiis/index.htm>.

Note: VFA vaccine must be ordered through ASIIS. Temperature logs must be entered monthly through the Cold Storage Module in ASIIS (see Resources/Job Aids: *Cold Storage Training Module*).

Chapter 5: VACCINE ORDERING AND DOCUMENTATION

County Health Department Public Partner Ordering

If CHDs are working with public partners each CHD partner must place their order in ASIIS, using their own unique VFA Pin number and IRMS. CHDs will serve as local approvers for all vaccine orders placed within their jurisdiction. Public partners will not be allowed to receive vaccines directly from the CHD. The CDC does not allow vaccine depots. CHDs will be responsible for working with their public partners to ensure that orders remain within allocated budget amounts. The new dose allocation functionality in ASIIS will enhance the CHDs and public partners' ability to track allocated doses. The Arizona Vaccine Center will allocate the doses requested on the VFA Vaccine Estimating Tool to the CHDs in ASIIS and CHDs are able to allocate doses to their partners (see Resources/Job Aids: *VFA Order Placement Training Module*, *VFA Order Approval Training Module*, *Adding Local Vaccine Allocations Training Module*).

Vaccine Ordering Process

Please have vaccine orders submitted by the 20th of the month. Orders received later than this will be held until the start of the subsequent month and updated temperature logs will be required before the held vaccine order will be processed.

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 VFA Vaccine. You will need an ASIIS username and password to access ASIIS. To obtain an ASIIS username and password for the VFA program complete the VFA ASIIS User Agreement Form (see Resources/VFA Forms: *ASIIS User Agreement Form-VFA*). Once the form is complete please email it to: ASIISHelpDesk@azdhs.gov.

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

- Collect your VFA Patient Immunization Log (see Resources/VFA Forms: *Arizona VFA Patient Immunization Log*) and place the total of each vaccine administered in the row marked, “Page Totals.”
 - ✓ VFA Providers are required to keep the Arizona VFA Patient Immunization Logs on site for six (6) years. Do not fax or mail the patient immunization logs to the Vaccine Center; these logs are meant to be in-house documents to assist with tracking administered doses.

- Enter temperatures into the Cold Storage Module in ASIIS using information from your Refrigerator/Freezer Temperature Log (see Resources/VFA Forms: *Refrigerator/ Freezer Temperature Log-VFA*).
 - ✓ **If temperature logs are not received by the Vaccine Center within four (4) business days of placing the order, the vaccine order(s) will be denied. A new order will have to be placed by the provider office.**
 - ✓ You must still 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 Vaccine Center Team to review your temperature logs within ASIIS. This enhances the Vaccine Center Team’s ability to efficiently receive, review, and process your vaccine orders.

- Complete the VFA Vaccine Order Worksheet (See Resources/VFA Forms: *Vaccine Order Worksheet-VFA*).
 - ✓ Count the inventory (number of doses of each vaccine) in the refrigerator(s) and freezer(s) and enter the total numbers on the VFA Vaccine Order Worksheet in the column marked “Doses on Hand.” If the number of doses on the worksheet does not match the doses on hand in ASIIS you will need to account for the missing administered doses. All wasted/spoiled/expired doses should be reconciled from your inventory (see Resources/Job Aids: *ASIIS Inventory Tips for VFC Vaccine for Manual, ASIIS Inventory Tips for VFC Vaccine for Electronic* and *How to Fix Inventory Issues Using ASIIS Reports*).

- Log into ASIIS and 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 VFA vaccine in your inventory, not just for the vaccine you are ordering.

Emergency Vaccine Orders

Emergency vaccine orders should occur infrequently. Providers are encouraged to keep a 6-8 week supply of vaccine on hand based on the provider's anticipated VFA eligible population and previous order history. Emergency vaccine orders will be approved at the discretion of the Vaccine Center Manager.

VFA 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:

- Temperature log is missing or temperatures are out of range
- Provider has exceeded the VFA allotted budget as specified by the Arizona VFA Program Office

Note: The Vaccine Center uses the comment section in ASIIS to provide direct communication to individual provider offices regarding their order. To avoid order delays or cancellations it is important to frequently check ASIIS "comments" to determine the status of your order. If you have questions, please contact the Vaccine Center at 602-364-3642.

Reporting to ASIIS

It is a requirement that each time a dose of VFA vaccine is administered it is reported 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 VFA vaccine.

Adult patients who do not consent to be added to ASIIS must cross out and initial their intent on Statement 2 on the Adult Immunization Administration Record (AIR 111-2).

Note: VFA 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 that were administered at another provider's office.

Temperature Logs

VFA 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.

Maintaining Vaccine Inventory

When establishing vaccine needs, consider:

- Vaccine usage patterns
- 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 require more storage space than vials)
- Keep a 6-8 week supply of vaccine on hand.

VFA providers should conduct a monthly physical inventory of VFA 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 if there are any changes to the standard vaccine shipping routine.

When an order for VFA vaccine is placed by the provider, the order is approved by the CHD local approver then submitted to the Arizona Vaccine Center where it is reviewed and approved. The orders are then transmitted to McKesson, the vaccine distributor. McKesson will facilitate the delivery of the vaccines directly to the provider's office.

Providers should expect their vaccine order within 5 – 10 business days from the time the order was placed. 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 VFA Vaccine Shipments

Proper handling and temperature maintenance of any vaccine shipment is imperative to maintain the cold chain and vaccine potency. Each provider site is required to have a standard office procedure in place for receiving vaccine shipments. Because a VFA 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 potency and will have to be replaced (see Chapter 5 for more information about Vaccine Management and Accountability).

The provider office VFA Vaccine Coordinator should:

- Notify other office staff that VFA vaccine shipments will be arriving
- Instruct front office staff on how to receive and store refrigerated and frozen shipments.

As soon as a VFA vaccine shipment arrives, office staff should do the following:

- Receive and sign for vaccine orders placed by your office only.
- Check temperature indicators enclosed in each container. Notify the Arizona Vaccine Center immediately if the temperature indicator has changed color, 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 as appropriate to vaccine type.
- Check the diluents. Any diluents arriving frozen must not be used. Call the Arizona Vaccine Center immediately if the diluents are frozen.

- Log in to ASIIS to receive the VFA order in ASIIS. Compare your order to the shipment. If there are no discrepancies, “receive” the order in ASIIS. This will add the VFA vaccine to your ASIIS inventory.
- If you have vaccines with issues “reject” them in ASIIS, appropriately store these vaccines in a separate area, and label them “DO NOT USE.” 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 the slip to the Vaccine Center within 2 hours of receipt. Do not call the manufacturer with any VFA 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 VFA provider label and store VFA vaccine separately from VFC vaccine and private stock. VFA vaccine must not be used for children, even if the packaging indicates that the vaccine can be used for children. VFA vaccine is ordered on CDC adult vaccine contracts and is not allowed to be administered to children.

Borrowing VFA Vaccines

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

The Vaccine Borrowing Report (see Resources/VFA 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 VFA patient, or
- VFA 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 (VFA 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 private 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 VFA vaccine. The invoice date should correspond with the replacement date on the borrowing report.

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

VFA vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider's VFA vaccine supply must adequately meet the needs of the provider's VFA patients. Borrowing VFA vaccine must not prevent a VFA patient from receiving a needed vaccination because VFA vaccine was administered to a non-VFA 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 VFA patients if VFA seasonal influenza stock is not yet available. Those private stock doses used on VFA patients can later be replaced when VFA 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 VFA provider with a patient population that is mostly VFA-eligible. This means the provider has a small number of privately insured patients.
- Privately purchased vaccine that is short-dated may be administered to VFA patients, and the dose replaced with a longer-dated VFA dose.

- Providers must document any vaccine borrowing on the Vaccine Borrowing Report regardless of inventory origin (VFA versus private stock).

If a provider borrows privately purchased vaccine to administer to a VFA patient because no VFA vaccine is available or if VFA stock is borrowed, the provider must document that borrowing and replacement on the Vaccine Borrowing Report. This action is to ensure that the private-stock or VFA-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 awardee for review.

Transferring VFA Vaccines 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 6 for additional information related to the wastage and restitution policy).

Transferring VFA vaccines between provider sites is permitted on occasion. Please note, the CDC does not allow for the use of vaccine depots and therefore provider offices cannot order large quantities of VFA vaccine for re-distribution to their public partners or other clinic sites. 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 VFA providers in their area. The transferring provider must contact a provider on the list to determine if a transfer will be accepted by that provider.
- Once this occurs, the "sending" provider must initiate 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/VFA Forms: *Transporting Refrigerated Vaccines* and *Packing Refrigerated/Frozen Vaccines Checklist*), and transport the vaccines to the “receiving” provider’s office.

- The “receiving” provider will inspect the vaccine. 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.

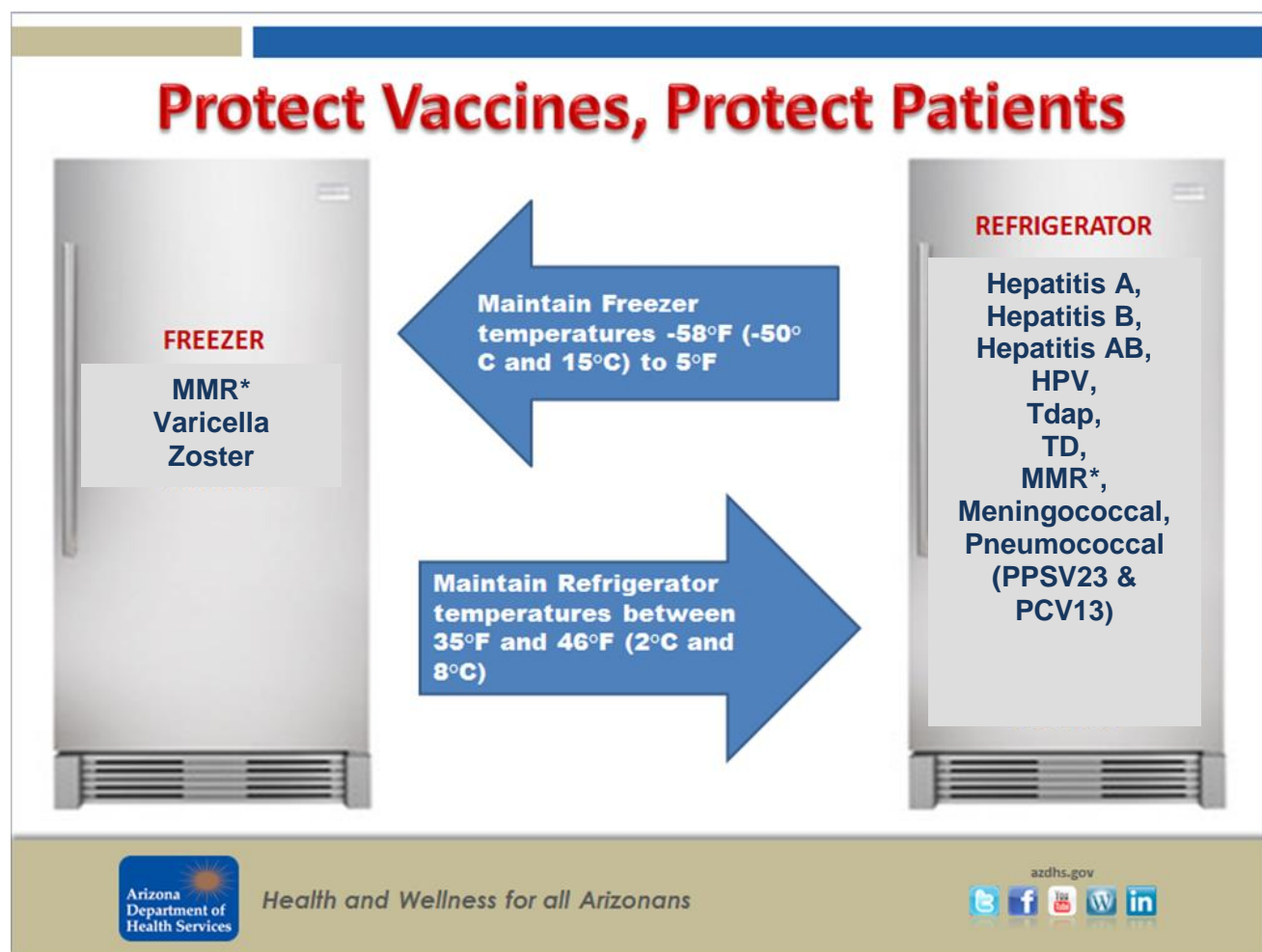
Providers wishing to transfer vaccine should contact other VFA providers at least three (3) months prior to the vaccine expiration dates. If your practice has VFA vaccine that will expire soon and you do not think it will be used during that time contact the Vaccine Center and then begin contacting other VFA providers who might be able to use the vaccine before it expires.

Note: VFA vaccine may never be shipped to or stored at a private residence or a location that is not the provider’s office address.

Chapter 6: 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 is a broad term intended to describe the vaccine storage and handling practices that should be followed by VFA providers and their staff. We strongly encourage VFA 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/>.

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 that 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 VFA vaccine storage and handling requirements and recommendations are in place to ensure that 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 VFA program does not allow the use of combination refrigerator/freezers with one exterior door and a freezer inside of the refrigeration unit to store VFA vaccines. This includes “dormitory” or “bar” style units. The Arizona VFA program does not endorse any specific refrigerator/freezer brand or manufacturer; however, units used to store VFA vaccine must meet required specifications (see Resources/VFA Forms: *Required Specifications for Refrigerators & Freezers-VFA*). Please contact the Arizona Vaccine Center at 602-364-3642 if you have questions about your refrigerator’s ability to properly store vaccines.

Temperature Monitoring Equipment

In each refrigerator/freezer used to store vaccine VFA 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 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.

Backup Thermometer

VFA providers must have at least one backup thermometer with a current certificate of calibration on hand (not stored in unit). The backup thermometer 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 potency 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 VFA Vaccines 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.
- 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. This will 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 near cooling vents in the refrigerator or in freezer doors. The temperatures in these sections do not remain constant. We recommend removing the crisper 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, 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 located inside the refrigerator do not meet Arizona VFA 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 reduce a tight door seal.
- Do not freeze diluent. Please see Resources/Job Aids: Vaccines with Diluents – How to Use Them for correct storage of diluents. The Arizona Vaccine Center is unable to ship additional diluents if wasted.
- Place water bottles throughout storage units in order to:
 - ✓ Stabilize or extend temperatures during a power outage
 - ✓ Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions
- 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 use up to 10 doses of pre-drawn or pre-filled syringes at a time.

Refrigerator/Freezer Temperatures

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

- Record refrigerator and freezer temperatures twice daily (beginning and end of work day) in F or C. 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 VFA vaccines.
- Maintain a working NIST certified or traceable thermometer in both the refrigerator and freezer and check/monitor the calibration due date. It is the provider's responsibility to ensure thermometers are calibrated annually.
- The following vaccines must be stored at temperatures between 35°F and 46°F (2°C and 8°C) (see Resources/VFA 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.

hepatitis A	PPSV23
hepatitis B	TD
HPV	Tdap
MMR	Influenza
MCV4	MenB

- 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 Vaccine Center. Your VFA vaccines will be wasted and you may be required to replace wasted doses of VFA 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 Zoster must be stored in the freezer. To prevent light exposure store these vaccines in the original box keeping the ends and tops closed at all times. Varicella and Zoster are heat sensitive.
- Store ice packs in the freezer to help maintain acceptable temperatures in the event of a power outage.
- Maintain an average freezer temperature between -58°F and +5°F (-50°C and -15°C). The ideal freezer temperature is 0° F or below.

- Call the Arizona Vaccine Center immediately at 602-364-3642 for any problems with refrigerator and/or freezer temperature controls. Notify the Vaccine Center if refrigerator or freezer temperatures register out of range at any time.

Vaccine Storage and Handling Plan

The requirements for VFA vaccine storage and handling are the same as those for VFC. Follow your VFC vaccine and storage and handling plan.

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.

Providers must assign responsibility for vaccine management to the Vaccine Coordinator and one backup Vaccine Coordinator. If the 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/VFA Forms: *Provider Contact/Address Change Form-VFA*).

In addition to monitoring storage conditions the Vaccine Coordinator or their backup should regularly review each vaccine vial for expiration dates and place “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 other vaccines in your inventory.

Develop and conduct internal 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 expired vaccine is not being used.

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 to not 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/VFA 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 on the refrigerator and freezer unit where VFA 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 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.
- 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>.

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. 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>.

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 in the Job Aids Section (see Resources/Job Aids: *Vaccines with Diluents: How to Use Them*).

Vaccine Loss

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

This section will serve as the Arizona VFA Program's policy for management of incidents that result in loss of publicly purchased vaccine. The action taken by the Arizona Vaccine 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 Restitution (Wastage) Policy

Vaccine is purchased through the CDC contracts and is distributed to participating VFA providers. As a condition of provider enrollment into the VFA program providers are required to adhere to Federal Fraud and Abuse laws. These laws apply to the entire

VFA program (see Chapter 11 for more information about Fraud and Abuse requirements).

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 VFA program at the first instance of a recorded temperature excursion
- Inability to account for the vaccine in ASIIS
 - Excessively reporting vaccine in ASIIS as "Lost and Unaccounted"
 - Selecting "Matches Physical Inventory" when reconciling the inventory in ASIIS
 - Reporting administered doses in ASIIS using "Administered but not linked to a vaccine" or "Administered to client who chose not to be in 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 VFA 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 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 VFA vaccines to ineligible adults

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

When restitution is required the 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 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 showing replacement of the VFA vaccine by the Arizona Vaccine Center. A copy of the invoice or packing slip should be submitted to the Arizona Vaccine Center along with the completed VFA Dose for Dose Vaccine Replacement Form (see Resources/VFA Forms: *VFA Dose for Dose Vaccine Replacement Form*). These documents must be submitted to the 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 Vaccine Center or the provider will be notified of any additionally required action(s).

The 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 vaccine prices increase.

If the provider receives a wastage replacement statement for the VFA vaccines and wishes to dispute the replacement of public vaccine, the provider must submit a letter explaining the reason for the dispute to the Vaccine Center Manager. This letter must include the provider's name, address, and VFA 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 VFA 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 Vaccine Center will work proactively to ensure VFA vaccine is tracked and accounted for CHDs. CHDs will be responsible to track and account for VFA vaccine being used by their sites/partners. 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 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/VFA Forms: *Wasted/Expired VFA Vaccine Return Form*) to the Arizona Vaccine Center at ArizonaVFC@azdhs.gov.

Vaccine Returns

VFA vaccines should never be discarded unless providers are told to do so by the Arizona Vaccine Center. VFA 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 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 vaccines appropriately. If you need assistance with spoiled, wasted, or expired VFA-supplied vaccines contact the Arizona Vaccine Center. Do not call the manufacturer.
- Never administer expired or otherwise non-viable vaccine. Individuals will remain susceptible to the disease if given an expired, non-viable vaccine and will have to be recalled for revaccination.
- If the expiration date is a month and year, the vaccine is valid until the last day of the month (e.g., July 13 is valid until July 31, 2013).
- All VFA 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 VFA vaccine use closely.
- Inventory your VFA vaccine monthly to check expiration dates.
- Use VFA vaccines that have the soonest expiration dates first.

- Maintain the cold chain and implement vaccine quality controls to ensure vaccine viability and unnecessary loss of VFA vaccine.
- To protect patients with viable VFA vaccine: maintain accurate, appropriate, and consistent temperatures in your refrigeration units. An average temperature of 40°F in the refrigerator and 0° in the freezer is ideal.
- When in doubt call the Vaccine Center at 602-364-3642.

Vaccine Emergency Handling Plan

Unforeseen circumstances and human error result in vaccines exceeding or falling below recommended temperature ranges. All VFA providers must have an established plan in writing for safe vaccine storage during emergencies, (e.g., keeping 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 VFA Program (see Resources/VFA Forms: *Vaccine Emergency Handling Plan-VFA*). Arizona Vaccine Center staff will ask for a copy of the office vaccine emergency handling plan during compliance visits.

All office 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 (i.e., facilities, security guard, etc.) must know what to do in the event of a vaccine emergency. It is advisable 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 VFA 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 VFA vaccine unless instructed to do so by Arizona Vaccine Center staff.
- Move the VFA vaccine supply to another refrigerator and/or freezer unit that has the ability to maintain appropriate temperatures.
- Check the unit's temperature before storing the VFA vaccines that were moved.
- Record the temperatures inside the new unit.

- Separate the VFA vaccine that may have been stored at improper temperatures from any other vaccine supply.
- VFA vaccine should not be used until a VFA representative or the Arizona Vaccine Center 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 VFA must be returned to the CDC centralized vaccine distributor within 6 months of spoilage/expiration.

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

Chapter 7: ORDERING DURING INFLUENZA SEASON

VFA Influenza Process

The Arizona VFA Program places an annual influenza vaccine order for publicly funded vaccines with the CDC in 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 AIPO'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 VFA influenza vaccines. When this happens it does not mean there is a shortage of VFA influenza vaccines. It means the CDC distributor does not have any additional doses available at that time, and as soon as more doses become available to the distributor more doses will be made available to Arizona. The Arizona VFA Program will then release the additional doses to VFA provider offices.

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 may need to replace the vaccines with available influenza presentations.

Influenza Ordering

Influenza ordering is done through ASIIS. Providers should place orders once a month to replenish the supply of influenza vaccine. Please review the Influenza Order Training Module (see Resources/Job Aids: *VFA Influenza Order Training Module*) to learn how to place a VFA flu order in ASIIS. If you still require assistance for placing an influenza vaccine order after reviewing the training module, contact the Vaccine Center at 602-364-3642.

Inventory Reconciliation

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

For additional questions related to VFA Influenza ordering, please contact the Arizona Vaccine Center at 602-364-3642. For technical questions related to ASIIS please contact 877-491-5741.

Chapter 8: VFA PROVIDER COMPLIANCE VISITS

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

Provider Site Visits

Once a year AIPO Program staff will conduct a VFA compliance site visit at VFA enrolled provider offices. If you are currently a VFC provider the VFC and VFA site visits will occur on the same day. The purpose of the visit is to evaluate VFA eligibility and review record keeping, screening, vaccine ordering protocols, and vaccine management including storage and handling requirements. The compliance visit is designed to protect against fraud and abuse and observe office practices that:

- Ensure compliance with VFA program requirements (reporting/documentation/vaccine storage and handling)
- Minimize vaccine loss and wastage
- Ensure that vaccines purchased with VFA funds are administered only to VFA eligible adults
- The VFA provider program staff is also required to follow up on corrective action plans or improvements received during the VFA compliance site visit.

Note: AIPO Staff will make every attempt to schedule and conduct these visits at a time that will not interrupt the CHD schedule and will provide a minimum of 3 weeks lead time for the visit. Each visit takes approximately two to three hours or longer based on information obtained during the compliance visit.

VFA Compliance Requirement

The VFA Coordinator and VFA Backup Coordinator are required to complete an annual 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 VFA vaccine also complete the training. All new VFA Coordinators are required to complete this educational training before they begin handling VFA vaccines.

Satisfaction Survey

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

Chapter 9: PROVIDER REQUEST FOR INACTIVATION OR OFFICE CLOSURE

Voluntary Inactivation

CHD VFA Providers may inactivate their enrollment in the Arizona VFA program at any time. To prevent wastage of VFA vaccines providers must notify the Arizona Vaccine Center in writing of their intention to inactivate. This will allow time for the provider to transfer any remaining VFA vaccines to another Arizona VFA provider. For detailed inactivation requirements and instructions use the VFA Inactivation Checklist (see Resources/VFA Forms: *Inactivation Checklist-VFA*).

Any equipment supplied by the Arizona Vaccine Center must be returned to the Arizona Vaccine Center. Upon inactivation from the program the provider will be responsible for replacing any vaccine not accounted for or returned in a non-viable state (i.e., vaccine no longer effective due to mishandling or within 90 days of expiring).

Office Relocation or Other Changes

If a VFA provider is planning to relocate, the provider 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, address, contact information, email, phone, fax, or VFA population changes. These changes can be reported on the Provider Contact Change Form (see Resources/VFA Forms: *Provider Contact/Address Change Form-VFA*).

Short-term Office Closure

If a VFA 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 VFA vaccine is shipped to the office.

Chapter 10: DISCIPLINARY PROCESS

Notice of Action Procedures

The Arizona Vaccine Center administers the VFA program, which provides ACIP recommended vaccines to immunize uninsured and underinsured adults ages 19 and older. The Arizona Vaccine Center is responsible for ensuring that providers meet all VFA program requirements. Failure to comply with the VFA Program and Vaccine Center requirements will result in disciplinary action. The following program infractions will result in one of the following progressive disciplinary actions. Compliance follow up visits will occur throughout the process.

VFA Corrective Action Process

During the VFA 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 VFA 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 issues are identified during a VFA site visit that cannot be resolved during the visit the site visit reviewer will try to determine the root cause behind the non-compliance issue. The site visit reviewer will discuss the purpose of the requirement with the VFA Coordinator and/or their backup and educate them on how to be compliant. The VFA site reviewer will provide a timeframe for corrective actions at the time of 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

Providers will be placed on administrative observation when VFA requirements have not been met after multiple attempts to follow ups are not completed.

Reasons a provider could be placed on administrative observation include:

- Administering VFA vaccine to ineligible adults, e.g., adults who have private insurance that covers vaccine
- Administering VFA vaccine to inappropriate age groups, e.g., persons 18 years of age and younger
- Failing to provide patients with current VISs for each vaccine administered
- Failing to maintain vaccine storage and handling requirements
- Failing to record refrigerator and freezer temperatures twice daily during the work week
- Failing to replace a broken thermometer
- Failing to send in temperature logs
- Failing to record and report the following to the Arizona Vaccine Center:
 - ✓ VFA vaccine inventory
 - ✓ Correct VFA eligibility data
- Failing to report administered immunizations to ASIIS within 30 days
- Failing to record the vaccine lot number, manufacturer, administration site, and immunization administrator name on the administration record
- Storing Varicella or MMR-V in an unapproved freezer
- Pre-drawing vaccine and/or storing it in the syringe
- Failing to report out of range temperatures to the Arizona Vaccine Center
- Failing to comply with issues discovered during a site visit and written into a corrective action plan
- Failing to screen patients for VFA eligibility
- Failing to provide vaccines to VFA eligible adults when VFA vaccines are available
- No private vaccine supply is found at the provider site when records indicate privately insured adults are seen at this site
- Administering expired vaccine
- Administering vaccine in incorrect dosages based on ACIP and manufacturer's recommendations
- Vaccine borrowing that indicates an inventory/stock problem
- Denying administration of a publicly purchased vaccine to a patient because the patient is unable to pay the administration fee

Administrative observation will end when the VFA site reviewer has observed substantial improvement by the provider. If the items in the needed areas of compliance are not corrected while on administrative observation, the provider will receive a Corrective Action Plan notification from the site visit reviewer.

Involuntary Inactivation

Involuntary inactivation occurs when the provider has failed to adhere to Arizona VFA requirements after multiple attempts by the Arizona VFA program staff to correct non-compliance issues and failure of the provider to complete a Corrective Action Plan or its components or for the following reasons:

- Any complaint of fraud and abuse that is substantiated
- Failure to comply with the terms of the VFA Program enrollment agreement
- Provider's name appears on the Exclusions Database of the Department of Health and Human Services, Office of Inspector General
- Provider is not currently licensed or in good standing by any Arizona State Board governing their practice
- Failure to submit re-enrollment forms/complete annual survey
- Failure to become program compliant while on administrative observation

Chapter 11: VFA VACCINE FRAUD AND ABUSE

Federal fraud and abuse laws apply to the entire VFA program, consistent with “fraud and abuse,” as defined in the Medicaid regulations at 42 CFR §455.2. For the purposes of this Arizona VFA 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 intentional deception or misrepresentation 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 VFA program to ensure (through compliance visit reviews, monitoring of vaccine ordering practices and inventory reconciliation, and unannounced storage and handling visits) that federally funded VFA vaccines are administered, recorded, stored, and handled appropriately according to VFA requirements. These areas will be monitored and checked regularly for all providers enrolled in the VFA program.

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

Enforcement Actions for Fraud and Abuse

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

If you have not met Arizona VFA requirements or followed Arizona VFA procedures as outlined in this manual, but the Arizona VFA 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 VFA program finds evidence of intentional deception, misrepresentation, or negligence on the part of the VFA 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 VFA vaccine to non-eligible Adults
- Providing VFA vaccine to patients under 19 years of age
- Selling or otherwise misdirecting VFA vaccine
- Billing a patient or third party for VFA vaccine
- Not providing VFA-eligible adults VFA vaccine because of patients' inability to pay an administration fee
- Not implementing provider enrollment requirements of the VFA program
- Failing to screen patients for VFA eligibility
- Failing to maintain VFA records and comply with other requirements of the VFA program
- Failing to fully account for VFA vaccine
- Failing to properly store and handle VFA vaccine
- Wastage of VFA vaccine

Chapter 12: 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

Chapter 13: CONTACTS

VFA Program Address: Vaccine Center
150 N. 18th Avenue, Suite 120
Phoenix, Arizona 85007-3233

Telephone: (602) 364-3642
Fax: (602) 364-3276
eMail: Arizona VFC@azdhs.gov (for VFA & VFC vaccine related issues)
Web Site: <http://azdhs.gov/phs/immunization/vaccines-for-adults-program/>

VFA Managers:	Lisa Underhill, MPA Vaccine Center Manager Office: (602) 364-3644 Fax: (602) 364-3276 lisa.underhill@azdhs.gov	Brenda Jones, RN, BSN, MA, AzCSN Immunization Services Manager Office: (602) 364-3626 Fax: (602) 364-3276 Brenda.Jones@azdhs.gov
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VFA Vaccine Center Representatives:	Faith Herbert faith.herbert@azdhs.gov Marcellina Lopez marcellina.lopez@azdhs.gov Scott Elliott, MSW scott.elliott@azdhs.gov Teresa Saenz teresa.saenz@azdhs.gov	Office: (602) 364-3641 Fax: (602) 364-3276 Cell: (602) 463-4256 Office: (602) 364-3645 Fax: (602) 364-3276 Cell: (602) 881-9993 Office: (602) 364-3652 Fax: (602) 364-3276 Cell: (480) 276-1532 Office: (602) 364-3650 Fax: (602) 364-3276 Cell: (602) 463-4229
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Arizona Vaccine Center Ordering Team:	Rosita Davis Vaccine Return Specialist All Counties Zachary Guzman Vaccine Order Specialist All Counties	Office: (602) 364-3651 Fax: (602) 364-3276 Office: (602) 364-3757 Fax: (602) 364-3276
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Chapter 14: RESOURCES

VFA Forms

Arizona VFA Patient Immunization Log
ASIIS User Agreement Form-VFA
Fahrenheit to Celsius Conversion Chart
Inactivation Checklist-VFA
Packing Refrigerated/Frozen Vaccines Checklist
Patient Eligibility Screening Record –VFA
Provider Contact/Address Change Form-VFA
Refrigerator/Freezer Temperature Log
Required Specification for Refrigerators/Freezers-VFA
Transporting Refrigerated Vaccines
Vaccine Borrowing Report
Vaccine Emergency Handling Plan-VFA
Vaccine Order Worksheet-VFA
Vaccine Signs (e.g., Do Not Unplug, Caution Perishable)
VFA Dose for Dose Replacement Form
Wasted/Expired VFA Vaccine Return Form

Job Aids

Adding Local Vaccine Allocations Training Module (CHD local approvers only)
ASIIS Inventory Tips for VFC Vaccine (for Electronic Reporters)
ASIIS Inventory Tips for VFC Vaccine (for Manual Reporters)
CDC Adult Patient Intake Form/Questionnaire
Cold Storage Training Module
How to Fix Inventory Issues Using ASIIS Reports
How to Print Reconciliation Worksheet in ASIIS
IAC Vaccinations for Adults - You Are Never Too Old

NAIIS Quick Guide to Adult Vaccine Messaging
The Rights of Vaccine Administration
Vaccines with Diluents: How to Use Them
VFA Influenza Order Training Module
VFA Order Approval Training Module (CHD local approvers only)
VFA Order Placement Training Module (all VFA Providers)

Websites

State:

Arizona Immunization Program Office, Vaccine Center
Phone: 602-364-3642
Fax: 602-364-3276

Arizona Immunization Program Website
<http://www.azdhs.gov/phs/immunization/index.htm>

Arizona Immunization Program VFA Website
<http://azdhs.gov/phs/immunization/vaccines-for-adults-program/>

Arizona State Immunization Information System (ASIIS) Website
<https://asiis.azdhs.gov/>

Federal:

Centers for Disease Control (CDC) Vaccines and Immunizations
www.cdc.gov/vaccines/

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

CDC-Morbidity and Mortality Weekly Report (MMWR)
www.cdc.gov/mmwr/

Local/National Immunization Organizations:

The Arizona Partnership for Immunization (TAPI)

<http://www.whymmunize.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.merck.com>

MedImmune

<http://www.medimmune.com/>

GlasxoSmithKline (GSK)

<http://www.gskvaccines.com/>

Pfizer

<http://www.pfizer.com/>

Sanofi Pasteur

<https://www.sanofipasteur.us/>

References:

2015 Vaccines for Children Operations Guide, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (2015)

Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition, Centers for Disease Control and Prevention, 2015

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), January 28, 2011

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm>

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention (CDC) “Vaccine Storage and Handling Toolkit”, May 2014 <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

Committee on Infectious Disease, American Academy of Pediatrics, Red Book, 30th Edition, American Academy of Pediatrics, 2015

<http://aapredbook.aappublications.org/content/current>