Arizona Vaccines for Children (VFC) Program

Operations Guide

ARIZONA DEPARTMENT OF HEALTH SERVICES

Last Revision: April 2019

Contents

About This Guide

The Arizona Vaccines for Children (VFC) Operations Guide:

- reflects current Arizona VFC program policies and processes
- defines Arizona VFC requirements and outlines the steps or components necessary to meet the requirements

Design

Sections are color-coded for easy reference.

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VFC programmatic requirements for provider offices are indicated by a grey box with a green check icon.

VFC Program Requirement

Important and supplemental information can be found in boxes throughout the Guide.

Best practices are noted throughout the document.

Terms Used in this Guide

For purposes of this guide:

- **Awardee** refers to the Arizona State Immunization Program staff responsible for implementation of the VFC program
- **Facility** refers to a specific VFC provider location
- **AHCCCS-enrolled** and **AHCCCS-eligible** are used interchangeably and refer to children who have health insurance covered by the State of Arizona Medicaid program
- **Parent** refers to anyone who has legal authority to make decisions on behalf of a VFC-eligible child. This can refer to parents, legal parents, or individuals of record
- **Provider** refers to a health care provider licensed to administer vaccines, as well as the staff within a provider facility who store and handle vaccines, order and bill for vaccines, or screen for VFC eligibility. A "provider" is enrolled in the VFC program and has ordered vaccine within the past 12 months. (Providers who have not ordered vaccine in 12 months are considered inactive and will be unenrolled from the program.)

Future Changes to the Guide

Modules will be revised and replaced if information changes after the Arizona VFC Operations Guide is published.

Unless otherwise noted, effective dates of any new requirements will be 30 days after notice of the change.

The AIPO will notify providers by e-mail anytime changes are made.

Summary of Arizona VFC Program Requirements

	Requirement	Steps/Components
	Module 1 – Vaccine Accountability and Management Plan	
	Providers must display, on a VFC cold storage unit, the Vaccine Accountability and Management Plan that includes procedures for routine and emergency vaccine management	• Contact information for the current primary and back-up VFC coordinators must always be listed on the Vaccine Accountability and Management Plan • Provider staff roles and responsibilities are defined • Documented training related to vaccine management is kept on site and on file for six (6) years • Proper storage and handling practices, including how to handle a temperature excursion are included • Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste • Procedures for emergency situations, including transport, equipment malfunction, power failure and natural disaster • Plans must be signed and dated annually, when there are changes to the staff roles and/or responsibilities or as needed. • The Vaccine Accountability and Management Plan can be found here.

	Requirement	Steps/Components
	Module 2 – VFC Program Participation Requirements	
	Providers must meet the eligibility criteria required for VFC program enrollment.	VFC providers must: • be licensed in the State of Arizona to administer vaccines to children aged 18 and younger *(IHS Exception) • be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities • have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines • be open at least 4 days a week and 4 consecutive hours in a day to receive VFC vaccines • all VFC providers are required to have a primary and back-up coordinator on site. Primary and back-up coordinators are not permitted to float between facilities
	Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (yearly).	• Submitting a Provider Agreement signed by a M.D., D.O., N.P., or F.N.P and ensuring it is complete and accurate • The signing provider in a group practice must be authorized to prescribe pediatric vaccines under state law • The provider signing the Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity • All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed on the Provider Agreement • If pharmacists are administering vaccines under the direct supervision of a physician, both the pharmacist and the physician must sign the Provider Agreement • Valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger must be submitted to the AIPO prior to the new provider visit

	Requirement	Steps/Components
	Providers are responsible for re-enrolling in the VFC Program every year.	Re-enrollment includes: • submitting a Provider Agreement signed by a M.D., D.O., N.P., or F.N.P and ensuring it is complete and accurate • submitting Provider Profile data • submitting the annual training requirement required for the primary and back-up VFC coordinators • submitting valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger • submitting an updated Vaccine Accountability and Management Plan
	Providers must abide by the proper billing procedures for VFC vaccine	• Vaccines are provided at no cost to providers • An administration fee, not to exceed $21.33 per injection may be charged to AHCCCS or the parent/patient. If a patient is enrolled in AHCCCS, providers may NOT bill the patient. • If a parent/patient cannot afford the administration fee, it must be waived. Sending parents/patients bills or sending parents/patients to collections is prohibited
	Provider Request for a Change in VFC Status (Inactivation, Office Closure, Office Relocation or Other Changes)	• Providers must notify the AIPO in writing at least 30 days prior to their intended date of inactivation • Providers are required to notify the AIPO in writing at least 30 days prior to a move or office closure • Providers must submit a profile change form to the AIPO for any staff changes, facility name changes and any other pertinent changes
	Providers are required to use and submit the most up-to-date AIPO forms	• All required VFC forms are kept up-to-date on our website, www.azdhs.gov/vfc • If requests and information are submitted to the AIPO on outdated forms, the request/action will be denied until the most up-to-date form is received by the AIPO
	If the Provider Agreement is terminated, the provider is responsible for transferring or returning any unused VFC vaccine prior to termination.	• Please refer to Module 6 for transferring and returning instructions

	Requirement	Steps/Components
	Module 3 – VFC Eligibility and Requirements	
	Providers must screen for VFC eligibility at every visit.	• VFC eligibility screening must occur at every visit • Patients are eligible for VFC vaccine if they meet one or more of the following requirements: -American Indian/ Alaska Native (AI/AN) -Medicaid-eligible -Uninsured -Underinsured • VFC vaccines can only be given to children ages 0 through 18 years of age (up to the day before their 19th birthday) that meet the eligibility requirements • Providers may utilize the Patient Eligibility Screening Record or the electronic medical record (EMR) to document the screening information • Keep the eligibility screen records for six (6) years from the date of the last visit • If a child has AHCCCS as a secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent/patient to pay out of pocket for vaccines, the patient should be considered VFC-eligible if the family has not yet reached its deductible. VFC vaccines should be administered and the administration fee should be billed to AHCCCS until the deductible is reached • Underinsured means that the patient has private insurance but the insurance policy does not cover any or all ACIP recommended vaccines or does not cover ACIP recommended vaccines, but has a fixed dollar limit or cap for vaccines. The patient is considered underinsured once the fixed dollar amount is reached • Underinsured patients can receive VFC vaccines only at federally qualified health centers (FQHCs), rural health centers (RHCs), or a deputized provider

	Requirement	Steps/Components
	Module 4 – Arizona State Immunization Information System (ASIIS)	
	Each individual is required to have their own log in to ASIIS and must not use other users log ins.	• Email a provider profile change form to asiishelpdesk@azdhs.gov to obtain a username and password
	Providers are required to report VFC and private doses to ASIIS for children 18 years old and younger.	• Per Arizona Revised Statute A.R.S. §36-135, all health care professional administering immunizations to children "birth to 18" years of age must report those immunizations to ASIIS
	Providers must report administered doses to ASIIS using either HL7 reporting or manual entry reporting.	• Providers may report administered doses to ASIIS using their EHR system to send administered information to ASIIS • Providers may report administered doses to ASIIS by manually entering all administered doses directly into ASIIS

	Requirement	Steps/Components
	Module 5 – Vaccine Storage and Handling	
	Provider practices must comply with vaccine storage and handling requirements as outlined in this Operations Guide.	• Stand-alone units are highly recommended but not required unless a provider is purchasing new units, then stand-alone units are required to be purchased. Dual control household units can be used if it has a temperature control for the refrigerator and a temperature control for the freezer • Do not store any VFC vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances • Data loggers with continuous monitoring and reporting capabilities and a current certificate of calibration are required for all units storing VFC vaccine • A back-up data logger with a current calibration certificate is required to be on site • The back-up data logger must be portable to be used in the event of vaccine transport • Provider offices are responsible for calibrating all data loggers that monitor the temperatures of any VFC vaccine before the calibration expires per the calibration certificate • Data logger data must be downloaded and reviewed two times per month • Temperatures must be reviewed and documented on a temperature log two times per day • The min/max temperatures must be reviewed and documented on a temperature log in the morning of the previous 24 hours • If a provider office will be closed for more than four (4) days, someone must come in on the fifth and subsequent days to take the temperatures twice a day or transfer the vaccine to another VFC provider before the closure occurs. Consult Module 6 – Vaccine Management Activities and Reporting for transfer instructions • Data logger reports must be emailed to arizonavfc@azdhs.gov with each order and on a monthly basis • All publicly supplied vaccines (VFC and KidsCare vaccines) can be stored and labeled as VFC • All privately purchased vaccines must be separated from publically supplied (VFC and Kids Care) vaccines

	Requirement	Steps/Components
	Module 6 – Vaccine Management Activities and Reporting	
	Providers are required to report all vaccine incidents (including temperature excursions, power outages, theft etc.) to the AIPO immediately	• Providers must complete and email the VFC Incident Report, all applicable electronic data logger reports and written temperature logs for each incident. The reports may be emailed directly from the data logger application or in data format (.xls, .txt, or .csv) • Providers must email all required documents to arizonavfc@azdhs.gov • Once the AIPO receives all required incident documents, providers will receive a response regarding viability of the VFC vaccines from the AIPO in 4-5 business days • The AIPO will not be able to determine VFC vaccine viability if all documents are not received via email from the provider • If vaccines are required to be wasted due to a vaccine incident, providers will be required to email five (5) consecutive days of in-range temperatures before an order can be placed • If a provider's cold storage unit experiences more than 2 unexplained temperature excursions in a 3 month period, the provider will be required to have the cold storage unit serviced and the provider will be required to provide the AIPO with the service receipt • Providers will be required to purchase stand-alone units if a temperature excursion occurs in a household unit within 3 months of the unit being serviced that results in wastage of any VFC vaccine. The provider will be required to provide the AIPO with a receipt of sale for a new stand-alone unit • Providers will be required to replace stand-alone units if VFC vaccines are wasted more than twice in a 6 month period after the unit has been serviced due to unexplained temperature excursions. The provider will be required to provide the AIPO with a receipt of sale for a new stand-alone unit

	Requirement	Steps/Components
	Providers must abide by the proper procedures when transferring vaccines.	Vaccine transfers can only occur: • after a **transfer has been requested in ASIIS** • after up-to-date temperatures have been received by the AIPO from the sending and receiving facilities • after the ASIIS transfer request has been approved by the AIPO in ASIIS • **Data loggers** must be used to monitor the temperature during transport • If a provider has open VFC vaccine incidents, providers are not allowed to accept a transfer from another facility until the VFC vaccine incidents have been closed by the AIPO
	Provider offices must have their vaccines delivered to the same location that they will be administered at.	• The use of mobile units is limited to those providers that are currently approved by the AIPO to operate mobile units to administer vaccines • Provider offices are prohibited from using mobile units to administer vaccine if the vaccine is not shipped to the location the mobile unit will be administering vaccine at
	Providers are required to replace VFC doses that are borrowed from private stock and administered to non-VFC eligible patients.	• Vaccine borrowing **must be a rare occurrence** • VFC vaccines should never be used as a replacement system for a providers privately purchased vaccine inventory • A borrowing report must be submitted to the AIPO for every instance of borrowing
	Providers must return expired or spoiled vaccines and must dispose of wasted vaccines.	When managing expired, spoiled and wasted vaccine, providers must: • remove the vaccines from any storage unit that stores viable vaccines • label vaccines “do not use” • email a completed wasted/expired form to arizonavfc@azdhs.gov • return expired and spoiled vaccines to the depot (McKesson) within 6 months of the expiration date or spoilage • wasted vaccines should be disposed of following state and local disposal requirements • all expired, spoiled and wasted vaccines must be removed from the ASIIS inventory with the appropriate category and reason

	Requirement	Steps/Components
	Reporting administered doses to ASIIS	• All VFC and private administered doses must be linked to a patient in ASIIS • All VFC administered doses must be accounted for in ASIIS • Always use the lot number and NDC from the vaccine box (not the vial) • Providers should only add historical doses into ASIIS if the doses were administered at another facility (i.e. out of state)
	Restitution (Dose for Dose Replacement)	• The VFC/KidsCare doses required to be replaced will be doses exceeding 5% of doses distributed if: -this is the first incident and the total loss is 5% or over; or -this is the 2nd incident (or greater) regardless of total value; or -it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in non-viable vaccine, regardless of total value; or -it is due to failure to contact the AIPO at the first instance of a recorded temperature excursion resulting in spoiled vaccines • In addition, effective July 1, 2018, all doses that are removed from the ASIIS inventory using "matches physical inventory", "administered but not linked to a patient", "administered but chose not to be in the registry" (without supporting documentation) for reconciling VFC vaccines doses, or any unauthorized transfer of vaccine, or wasting vaccine without providing the appropriate documentation, must be replaced on a dose for dose basis by purchasing vaccines from the private market

	Requirement	Steps/Components
	Module 7 – Vaccine Ordering	
	Providers must reconcile their inventory before placing an order.	• Providers will be prompted to reconcile the inventory during the ordering process on the "Reconcile Inventory" page • Input the number in the "Quantity on Hand" column into the "Physical Inventory" box for each vaccine every time • Provider offices may remove doses in this screen by placing the quantity on hand number minus the number of doses that need to be removed in the physical inventory box. The "Adjustment" column will show how many doses will be removed • Provider offices may only remove doses if the doses are expired, have been spoiled (i.e. a temperature excursion), wasted (e.g. drawn-up but not used) or a recall has occurred from the manufacturer • Removing doses as a means of matching up your inventory is not allowed
	Providers must email up-to-date data logger reports every time an order is placed.	• Every time an order is placed, providers must email data logger reports from the last recorded data and time of the previously emailed data logger reports up until the date and time the order is submitted. The reports must be sent directly from the data logger application or in data format (.xls, .txt, or .csv) to arizonavfc@azdhs.gov • If the AIPO does not receive provider temperatures when the order is placed, the order may be cancelled and another order will have to be placed
	Providers must receive the shipment of vaccines into the ASIIS inventory immediately after vaccines arrive in the provider office.	• Log in to ASIIS • Under the "Orders/Transfers" tab on the left hand side menu, select "Create/View Orders" • Under the "Inbound Orders" heading, click on the arrow under select • Input the quantity received in the "Receipt Quantity" box for all vaccines received *If all vaccines are not received, please leave the receipt quantity blank and return to this page and enter the quantity received when the vaccines are physically received in the office • Click the button that states "Receive"

	Requirement	Steps/Components
	Module 8 – Vaccine Administration and VAERS	
	VFC makes all ACIP recommended vaccines available for program participants	• All CDC contracted vaccines are available for provider choice • During vaccine shortages presentations may be substituted
	Providers are required by federal law to provide all parents/patients all applicable Vaccine Information Statements (VIS) at every visit before the administration of any vaccine	• VFC providers are required to distribute the most current Vaccine Information Statements (VIS) at every immunization visit prior the vaccines being administered • Provider offices may provide laminated VISs to the parent/patient prior to vaccination • Provider offices may provide VISs on a computer monitor or video display • VISs may be downloaded by the parent/patient to a smartphone or other electronic device to read
	All VFC providers must report any clinically significant adverse events that occur after the administration of any vaccine licensed in the United States to the Vaccine Adverse Event Reporting System (VAERS).	• 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 -medication errors do not need to be submitted to VAERS, however if you feel that it is directly related to the patients reaction, please report the medication error to VAERS

	Requirement	Steps/Components
	Module 9 – Arizona Immunization Program Office Provider Visits	
	All VFC providers must participate in VFC program compliance visits, including unannounced storage and handling visits and other education opportunities associated with the VFC program requirements.	• All new/previously enrolled VFC provider locations are required to participate in a new provider training • The AIPO can provide training to new provider office staff and anyone who needs a refresher in VFC policies and procedures • At a minimum, once every 24 months, and perhaps more frequently AIPO program staff will conduct a VFC compliance visit at VFC enrolled provider offices • Unannounced storage and handling visits can occur at any time with no notice
	All VFC providers must also participate in Assessment, Feedback, Incentive and Exchange (AFIX) visits.	• At a minimum, once every 24 months, and perhaps more frequently AIPO program staff will conduct an AFIX visit at VFC enrolled provider offices • Follow-up assessments will be sent to VFC providers via email 4-6 months after the initial visit • Fully implemented strategies to increase vaccine uptake should be completed 6 months after the initial visit • If strategies to increase vaccine uptake are not fully implemented 6 months after the initial visit, providers are encouraged to work towards full implementation

	Requirement	Steps/Components
	Module 10 – Fraud and Abuse/Discipline Process	
	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.	• If the AIPO 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 • If VFC provider offices have not met Arizona VFC requirements or not followed Arizona VFC procedures as outlined in this guide, but the AIPO finds no intentional deception, misrepresentation, or negligence on the part of the VFC provider, the staff at the provider office may be required to participate in training and/or to take other actions to rectify the situation

Vaccines for Children (VFC) Program Overview

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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 (AIPO) to provide information to enrolled providers to ensure compliance with federal and state VFC guidelines regarding safe handing, administration and reporting of VFC vaccines.

Recommendations from the Centers for Disease Control and Prevention and American Academy of Pediatrics are included. We wish to thank CDC staff who have advised and assisted us in preparation of this guide.

If you have any questions regarding this guide, please call the AIPO at 602-364-3642.

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

http://www.azdhs.gov/vfc

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

AIPO Directory

AIPO Mailing Address:	Arizona Immunization Program Office 150 N 18th Avenue, Suite 120 Phoenix, AZ 85007-3233
AIPO Telephone Numbers:	602-364-3642 602-364-3630
ASIIS Helpdesk Numbers:	602-364-3899 1-877-491-5741
AIPO Fax Numbers:	602-364-3276 602-364-3285 602-364-3232
AIPO Emails:	arizonavfc@azdhs.gov asiishelpdesk@azdhs.gov

VFC Overview

The Vaccines for Children (VFC) program was established by Congress in 1994 to increase access to vaccination for children who might not get vaccinated because of financial barriers.

The VFC program serves children through 18 years of age who meet at least one of the following criteria:

- American Indian or Alaska Native (AI/AN)
- Medicaid-eligible
- Uninsured
- Underinsured

For full information on patient eligibility, see Module 3 – VFC Eligibility and Requirements.

To reach VFC-eligible children, the Centers for Disease Control and Prevention (CDC) uses federal funds to purchase vaccines and distribute them at no cost to public health clinics and private providers enrolled in the program.

VFC Fast Facts

- VFC benefits an estimated 40 million children
- Approximately 39,000 enrolled health care providers
- 61 VFC state, local, and territorial immunization program awardees
- Approximately 79 million VFC vaccine doses distributed in 2017

VFC Program Benefits

- Reduces referrals of children from private providers to state health departments for vaccination
- Saves VFC-enrolled providers out-of-pocket expenses for vaccines
- Eliminates or reduces vaccine cost as a barrier to vaccinating eligible children

VFC Program At-a-Glance

CDC's immunization program awardees enroll public and private health care providers into the VFC program to meet the immunization needs of VFC-eligible children in their respective jurisdictions.

Awardees educate enrolled providers on VFC program requirements, vaccine management, and fraud and abuse violations.

CDC contracts with vaccine manufacturers to buy vaccines at a federal discount.

VFC providers order vaccines (including seasonal influenza vaccine) recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost through their state, local, or territorial VFC program.

VFC providers agree to follow all VFC requirements, which include screening patients for VFC eligibility at each immunization encounter and documenting their eligibility status. VFC vaccines must be administered only to children who are eligible.

Awardees monitor providers to ensure VFC compliance and provide guidance, with the goal of vaccinating more infants, children, and teens on schedule.

VFC Vaccines

Vaccines covered by the VFC program are recommended by ACIP to protect infants, children, and teenagers from 16 vaccine-preventable diseases.

ACIP is a federal advisory group of medical and public health experts that develops recommendations on the use of vaccines to prevent and control diseases in the United States. The group provides guidance on:

- age for vaccine administration
- number of doses and dosing intervals
- precautions and contraindications to vaccination

Table: Diseases and ACIP-Recommended Vaccines Covered by the VFC Program

Disease	Vaccine	Disease	Vaccine
Chickenpox	Varicella, MMRV§	Measles	MMR,** MMRV§
Diphtheria	DTaP,* DT,** Td,** Tdap,* Kinrix,¶ Quadracel,¶ Pentacel,§§, Pediarix¶¶	Mumps	MMR,** MMRV§
Hib (*Haemophilus influenzae* type b)	Hib, Pentacel§§	Pertussis (whooping cough)	DTaP,* Tdap, Kinrix,¶ Quadracel,¶ Pentacel,§§ Pediarix¶¶
Hepatitis A	Hep A	Polio	IPV, Pentacel,§§ Pediarix¶¶
Hepatitis B	Hep B, Pediarix¶¶	Pneumococcal	PCV13, PPSV23
Human Papillomavirus (HPV)	HPV	Rotavirus	RV
Influenza (Flu)	Flu	Rubella	MMR,** MMRV§
Meningococcal	MenACWY, MenB	Tetanus	DTaP,* DT,** Td,** Tdap,* Kinrix,¶ Quadracel,¶ Pentacel,§§ Pediarix¶¶

*DTaP and Tdap combine protection against diphtheria, tetanus, and pertussis.
**DT and Td combine protection against diphtheria and tetanus.
**MMR combines protection against measles, mumps, and rubella.
§MMRV is a combination vaccine containing MMR and varicella.
¶Kinrix and Quadracel are combination vaccines containing DTaP and IPV.
§§Pentacel is a combination vaccine containing DTaP, IPV, and Hib.
¶¶Pediarix is a combination vaccine containing DTaP, IPV, and Hep B.
Source: Centers for Disease Control and Prevention (CDC)

VFC Program History

Congress created the VFC program in response to the 1989–1991 measles outbreak in the United States, at a time when vaccination coverage was low. The measles epidemic resulted in tens of thousands of cases and hundreds of deaths.

The VFC program was created as part of the Omnibus Budget Reconciliation Act of 1993. It was established as a new entitlement program required to be a part of each state's Medicaid plan. The VFC program is a Title XIX Medicaid program.

Section 1928 of the Social Security Act (42 U.S.C. §1396S) provides the legal authority for the VFC program by requiring each state to establish a program for pediatric vaccine distribution to registered providers. It provides authority for purchase of vaccines for administration to eligible children using federal Medicaid and state funds (including 317).

VFC was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative.

The VFC program is available in all 50 states, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

VFC Program Funding

Funding for the VFC program is approved annually by the Office of Management and Budget (OMB).

The funds are allocated through the Centers for Medicare and Medicaid Services (CMS) to CDC.

CDC awards VFC funding through a cooperative agreement to 61 state, local, and territorial immunization programs.

Medicaid

Title XIX of the Social Security Act is a federal/state entitlement program that pays for medical assistance for certain individuals and families with low incomes and limited resources. This program, known as Medicaid, became law in 1965 as a cooperative venture, jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible persons.

Medicaid is the largest source of funding for medical and health-related services for America's low-income citizens.

Within broad national guidelines established by the federal government, each state Medicaid program can:

- Establish its own eligibility standards
- Determine the type, amount, duration, and scope of services
- Set the rate of payment for services
- Administer its own program

As a result, Medicaid programs vary considerably from state to state.

VFC Program Oversight

- The VFC program is administered at the national level by CDC through its National Center for Immunization and Respiratory Diseases (NCIRD).
- CDC is the lead agency responsible for VFC policy development and national program oversight.
- CDC's immunization program awardees manage and implement a VFC program in their state, city, or territory.

ACIP and VFC Resolutions

ACIP has unique legal authority from Congress to provide recommendations for the VFC program. When recommending a new vaccine or a change in vaccine use, ACIP votes on a resolution to include the vaccine change in the VFC program. VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

Vaccines procured through the VFC program must be administered according to the guidelines outlined by ACIP in VFC resolutions. (VFC vaccines may also be administered in accordance with state school attendance laws.)

CDC establishes contracts for VFC vaccines only after a VFC resolution is in place.

Vaccine Administration Fees and Fee Caps

VFC providers cannot charge an eligible child's parent a fee for the vaccine itself. However, they can charge a fee to administer each vaccine.

The legislation that created the VFC program sets a limit on the dollar amount a provider can charge and be reimbursed for administering vaccines to VFC-eligible children. This means a provider may charge a patient any amount up to, but not exceeding, the vaccine administration fee. The amount of the administration fee differs from state to state, based on a regional scale determined by CMS.

There is no lower limit, so providers have the option to charge what they feel is fair, including not charging a fee at all.

Arizona VFC providers may charge up to $21.33 per injection as set forth in the Federal Register.

An initial Federal Register notice setting forth the interim maximum amounts a participating provider may charge for administering a vaccine to a VFC child was published on October 3, 1994. An updated fee schedule was published in November 2012.

According to the initial VFC program legislation, enrolled providers agree to the following vaccine administration fee requirements:

- Providers cannot deny access to federally purchased vaccines to an established patient whose parent is unable to pay the vaccine administration fee. Providers also cannot bill a patient if they are unable to pay the vaccine administration fee at the time of the visit.
- Providers cannot charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceed the federal administration fee cap. For Medicaid VFC-eligible children, the provider must accept the reimbursement for vaccination set by the state Medicaid agency or the contracted Medicaid health plans.

Note: Providers may charge an office visit fee in addition to the vaccine administration fee. This is not prohibited by the VFC statute.

Children's Health Insurance Program (CHIP)

The Children's Health Insurance Program (CHIP) was created through the Balanced Budget Act of 1997 to address the fact that one in seven children (more than 10 million nationwide) is uninsured, and therefore, at significantly increased risk for preventable health problems. Many of these children are part of working families who earn too little to afford private insurance on their own but earn too much to be eligible for Medicaid.

CHIP and VFC Eligibility

Children enrolled in a Medicaid expansion program are eligible for VFC vaccines. Arizona's CHIP program is also known as KidsCare and is considered a Medicaid expansion program.

Module 1 – Vaccine Accountability and Management Plan

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Overview

All VFC providers must maintain the Vaccine Accountability and Management Plan that includes procedures for routine and emergency vaccine management. The Vaccine Accountability and Management Plan must be displayed on the VFC refrigerator or freezer at all times and utilized as appropriate.

Vaccine Accountability and Management Plan Components

The vaccine accountability and management plan contains:

- provider staff roles and responsibilities
- proper storage and handling practices, including how to handle a temperature excursion
- procedures for vaccine ordering, receiving, inventory control, stock rotation and handling vaccine loss and waste
- procedures for emergency situations, including transport, equipment malfunctions, power failure and natural disaster

The provider staff is responsible for the following items:

- signatures are required from the signing physician, primary and back-up coordinators and the office manager (if the site has one)
- the signing physician or primary or back-up coordinator or office manager must initial the individual modules on the Vaccine Accountability and Management Plan
- filling in the demographics of the facility, contact information for the current primary and back-up VFC coordinators and the demographics of another VFC provider that is willing and able to store VFC vaccines in the case of an emergency
- emergency VFC locations must be less than 10 miles from the provider's location, unless the provider office has permission from the AIPO to have an emergency VFC location that is more than 10 miles away
- documentation of training related to vaccine management
- updating the vaccine accountability and management plan annually, when there are changes to the staff roles and/or responsibilities or as needed

VFC Vaccine Accountability and Management Plan

Office Name:	**Phone:**
Address:	
Facility Pin#:	

By signing this form, I certify on behalf of myself and all immunization staff in this facility as listed on the VFC Provider Agreement and below, that I have read and agree to the Vaccine Accountability & Management Plan items listed and understand I am accountable (and each listed person is individually accountable) for compliance with these requirements.
All signatures from the signing physician, primary and back-up coordinators and the office manager (if the site has one) are required.

Signing Provider signature:	Date:
Print Name:	
Signing Provider email:	Signing Provider phone:
Office Manager signature:	Date:
Print Name:	
Office Manager email:	Office Manager phone:
VFC Coordinator signature:	Date:
Print Name:	
VFC Coordinator email:	VFC Coordinator phone:
VFC Back up Coordinator signature:	Date:
Print Name:	
VFC Back up Coordinator email:	VFC Back up Coordinator phone:

Submit a revised Vaccine Accountability and Management Plan to the AIPO (Arizona Immunization Program Office) EVERY TIME facility changes occur (including changes in staff).

Vaccines must be maintained within the manufacturers temperature requirements in order to remain viable to administer to patients. Below list the emergency vaccine storage location that staff will transport vaccine to in the event of a storage unit malfunction, extended power failure, natural disaster or other emergency that might compromise the appropriate vaccine storage. (Module 6).

Emergency storage facility

Name:	Pin# :
Address:	
Phone number:	
Contact at facility:	
Major cross streets:	

Useful Contacts	**Name**	**Phone Number**
Electricity company		
Building maintenance		
Building security company		
Storage unit maintenance & repair		

Data Logger company		
County Health Department		
ADHS Immunization Program Office (AIPO)		602-364-3630 (main office number)
Vaccine Manufacturer	GSK	1-888-825-5249
	Merck	1-800-672-6372
	Pfizer	1-800-438-1985
	Sanofi	1-800-822-2463
	Seqirus	1-855-358-8966
	Dynavax	1-877-848-5100
	AstraZeneca	1-800-236-9933
	Mass Biologics	1-617-474-3000

Vaccine Storage Unit/ Data Logger Inventory

Vaccine storage and data logger	**Unit #1**	**Unit #2**	**Unit #3**	**Unit #4**	**Unit #5**
Refrigerator or freezer?					
Unit grade: -Pharmaceutical -Stand-alone -Household Dual Control					
Model number					
Last routine maintenance?					
Water bottles in all VFC refrigerators and freezers as required?					
Data logger in unit (Y/N)					
Data logger Model Number					
Data logger Serial Number					
Last calibration date					
Calibration expiration date					
Location of back up data logger	Data logger Model Number	Data logger Serial Number	Last calibration date	Calibration expiration date	

Vaccines for Children Program (VFC) Requirements (overview)

More detailed information is available in the Arizona VFC Operations Guide.
The signing physician or primary or back-up coordinator or office manager must handwrite their initials on the individual modules of the Vaccine Accountability and Management Plan.

Vaccine Management and Accountability Plan (Module 1) Initials: _____

- Providers must display, in an easily accessible location, the Vaccine Accountability and Management Plan that includes procedures for routine and emergency vaccine management.
- Submit a revised Vaccine Accountability and Management Plan to the AIPO (The Arizona Immunization Program Office) EVERY TIME facility changes occur (including changes in staff).

VFC Program Participation Requirements (Module 2) Initials: _____

- Providers must meet eligibility criteria required for VFC program enrollment.
- Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (annually).
- Annual program re-enrollment is required. Program inactivation may occur due to failure to re-enroll.
- VFC program participation is required for participating in AHCCCS; if you are inactivated your AHCCCS panel may be removed/reassigned.
- If a Provider Agreement is terminated, the provider is responsible for transferring or returning any unused vaccine prior to termination.
- Annual training for all VFC staff is required.

VFC Eligibility and Requirements (Module 3) Initials: _____

- Facility staff must understand, screen and document VFC/CHIP eligibility at EVERY immunization encounter PRIOR to selecting the vaccine stock for administration.
  **Only VFC/CHIP eligible children may receive VFC/CHIP vaccines.
- Do not charge patients or bill AHCCCS for the cost of VFC or CHIP vaccine. An administration fee, not to exceed $21.33 per injection may be charged to AHCCCS or the parent/patient. If a patient is enrolled in AHCCCS, providers may NOT bill the patient. VFC eligible patients that cannot pay the administration fee may not be denied VFC vaccines. Sending the bill to collections is not allowed.

Arizona State Immunization Information System (ASIIS) (Module 4) Initials: _____

- Each ASIIS user must have a unique (not shared) ASIIS log in.
- Each dose of VFC/CHIP/Private vaccine administered to a patient must be documented in the facilities records and in the Arizona Immunization Information System (ASIIS). All required fields must be included.
- Each dose of VFC/CHIP vaccine administered to a patient must be decremented appropriately from the ASIIS vaccine inventory.
- Annual signature in ASIIS of HIPAA agreement is required for all ASIIS users.

Vaccine Storage and Handling (Module 5) Initials: _____

- Refrigerated vaccine storage units must maintain a temperature range between 36.0° F and 46.0° F (2.0° C and 8.0° C). Freezer vaccine storage units must maintain a temperature range between -58.0° F and +5.0° F (-50.0° C and -15.0° C). Vaccine storage units must have sufficient storage space to accommodate vaccine stock at the busiest times of year without overcrowding. CDC recommends the following vaccine storage unit types (in order of preference): pharmaceutical grade stand-alone or combination units (preferred); household/commercial stand-alone units; household/commercial combination units that have separate controls for each compartment.

  CDC strictly prohibits use of all dorm-style and bar-style units for vaccine storage.
- Each vaccine storage unit is required to have a continuous temperature monitoring device (data logger).
- Portable back up data logger is also required.
- Data logger data must be downloaded and reviewed two times per month.
- Vaccine must be stored under appropriate temperatures as described in the package inserts at all times.
- Vaccine storage unit temperatures must be monitored and documented on a temperature log to include the following:
  - At least two temperature readings per day recorded to the tenths place (i.e. 34.2°F).
  - Exact time and date of each reading.
  - Name (or initials) of the person who assessed and recorded the readings.
  - **Minimum and maximum temperatures of each unit once in the morning for the previous 24 hours.**

Vaccine Management Activities and Reporting (Module 6) Initials: _____

- Temperature Excursions - If a temperature excursion is suspected, providers should follow their Vaccine Accountability and Management Plan, including keeping the vaccines in the cold storage unit, isolating affected vaccines in a bag or box and labeling them “do not use”.
- Providers must complete and email the VFC Incident Report, all applicable electronic data logger reports and written temperature logs for each incident.
- Vaccine should only be transported from the physical location of a VFC provider during an emergency, unexpected extended power outage, or with the permission of the Immunization Program to prevent vaccine wastage. If the power has been out at a provider office for two (2) hours, providers must appropriately pack their vaccines and transport them to the address listed on their VFC Vaccine Accountability and Management Plan. Contact the AIPO for directions and permissions.
- **Expired or spoiled vaccines** should NEVER be kept in a vaccine storage unit. Expired or spoiled vaccines should be placed outside the storage unit in a container labeled “DO NOT USE”. A ‘wasted/expired form’ must be completed and sent to the Immunization Program **within one month** of spoilage or expiration. You will receive an e-mail with a shipping label to use for returning the vaccine to McKesson per CDC requirements.
- **Wasted vaccines** should be disposed of appropriately and documented on the ‘Wasted/Expired form’.

  The following items should NOT be returned to McKesson:
  - Vaccine vials and syringes that have been opened (with OR without needles)
  - Broken or damaged vaccine vials or syringes (with OR without needles), syringes that have been activated and vaccines that have been pre-drawn.
  - Vaccine vials that do not have the original sealed cap intact.
- Vaccine Restitution is required for vaccine wastage exceeding 5% of total doses and/or if proper inventory practices are not maintained this includes writing off doses in ASIIS.

Vaccine Ordering (Module 7) Initials: _____

- Adequate inventory of vaccine for all patients served (VFC, CHIP, private) must be maintained and clearly marked to indicate which funding source provided the vaccine.
  Borrowing VFC or CHIP vaccine must be a very rare occurrence, and cannot be part of the business practice. A borrowing report must be completed and the vaccine repaid to the appropriate funding source. **Excessive borrowing may result in program probation.**
- Regular reconciliation is required. Vaccines should be rotated to keep shorter-dated vaccines in front of longer-dated vaccines. Vaccine orders should reflect the most recent Provider Profile submitted and placed as follows:
  - Vaccines should be ordered at least monthly, smaller more frequent orders are encouraged, to maintain a 3-4 week stock of VFC/CHIP/private vaccines at all times. All efforts should be made to prevent borrowing from other vaccine funding sources.
  - In ASIIS, on the order screen, ensure that vaccines are scheduled to be delivered during your current office hours.
  - The VFC Program entitles children to all ACIP recommended vaccines.
- Receiving and inspecting vaccine shipments: The primary vaccine coordinator or back-up vaccine coordinator should take proper steps to receive and inspect vaccine deliveries.
  NOTE that if **problems** are encountered during any of the steps or there are any **doubts** that the vaccines may not have been shipped properly, immediately **contact the AIPO at 602-364-3642.** ***Vaccine deliveries should NOT be refused.***
- IMMEDIATELY store vaccines in the appropriate refrigerator or freezer vaccine storage unit. Be certain to label the vaccines according to fund type.

Vaccine Administration and VAERS (Module 8) Initials: _____

- The Arizona VFC Program makes all ACIP recommended vaccines available for program participants.
- VFC providers are required to distribute the most current Vaccine Information Sheet (VIS) for every vaccine at every visit prior to a vaccine being administered.
- VFC providers must also maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA); this includes reporting clinically significant adverse events to the Vaccine Adverse Events Reporting System (VAERS).

Arizona Immunization Program Office Provider Visits (Module 9) Initials: _____

- VFC providers must actively participate in all program visits; compliance visits, storage and handling, new provider/staff in services, AFIX, others as needed and defined by the program.

Fraud and Abuse/Discipline Process (Module 10) Initials: _____

- **Fraud** is the 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.
- **Abuse** includes practices that are inconsistent with sound fiscal, business or medical practices that result in unnecessary cost to the Medicaid program, CHIP Program, Immunization Program, Health Insurance Company or patient.
- Any provider that is involved in the fraud or abuse of VFC vaccine will be subject to a progressive disciplinary process that may include; issuance of a Notice of Action- information shared with AHCCCS, program probation, involuntary program separation.
- An appeal process is available in the VFC Operations Guide for providers that request it.

Module 2 – VFC Program Participation Requirements

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Overview

Being a VFC provider is a sound investment in your practice and in your patients. It reduces your up-front costs because you will not have to pay to purchase vaccines for VFC eligible children. Also, you can charge an administrative fee to offset your costs of doing business. Your patients benefit because they won't have to go somewhere else to get the vaccines they need, and there is no charge to you, the provider. Any healthcare provider authorized to prescribe vaccines in Arizona can be a VFC provider.

Provider Enrollment Criteria Requirements

- VFC providers must be licensed in the State of Arizona to prescribe vaccines to children aged 18 and younger. Please note that there are exceptions for providers that are employed by Indian Health Services
- Be willing and able to follow all VFC program requirements, policies and procedures, including participation in site visits and educational opportunities
- Have the capacity to order, receive, manage, store and monitor the temperature of all publicly supplied vaccines
- Be open at least 4 days a week and 4 consecutive hours in a day to receive VFC vaccines

Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (yearly). Providers that are authorized to sign the Provider Agreement are Medical Doctors (M.D.), Doctors of Osteopathic Medicine (D.O), Family Nurse Practitioners (F.N.P.) and Nurse Practitioners (N.P.). The signing provider in a group practice must be authorized to prescribe pediatric vaccines under state law.

The provider signing the Provider Agreement on behalf of a multi-provider practice must have the authority to sign on behalf of the entity. All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed on the provider agreement. If pharmacists are administering vaccines under the direct supervision of a physician, both the pharmacist and the physician must sign the provider agreement.

The following information will be required for initial enrollment into the VFC program:

1) Provider Agreement – defines CDC compliance parameters of the VFC program
2) VFC Provider License Information – lists the names, NPI numbers, and medical license numbers of all providers in the facility that have the authority to prescribe vaccines. The signing provider is responsible for ensuring that all staff within the organization are in compliance with the VFC provider enrollment requirement
3) Provider Profile Form – provides demographic information of the provider site and identifies the number of children in the practice by eligibility and age group. Providers are required to make an educated guess if they are a new practice that has not been seeing patients or they have not been seeing AHCCCS eligible patients. If a facility is already seeing patients, they may obtain private patient demographic information from ASIIS, doses administered, provider encounter data, billing systems or benchmarking. This information is important to accurately order vaccines

4) Refrigerator/Freezer Verification Form – describes refrigeration/freezer requirement for vaccines. Refrigerator and freezer (if applicable) temperatures must be recorded on a temperature log twice daily and data logger reports must be emailed prior to the new provider training. This is to ensure that storage units will maintain proper temperatures to maintain vaccine viability. Providers cannot order frozen vaccines without having an AIPO approved freezer and having a Refrigerator/Freezer Verification Form on file
5) Add/Remove ASIIS Users Form – identifies staff that will need access to ASIIS and the varying levels they may need. Access levels range from being able to only view immunization data, enter and/or edit immunization data to ordering VFC vaccine to removing users. All users are required to have their own unique username and password for ASIIS
6) Training certificates for the primary and back-up VFC coordinators – primary and back-up VFC coordinators are required to complete either the CDC You Call the Shots (Vaccines for Children or Storage and Handling modules) or the AIPO Training (Arizona Vaccines for Children Training module)
7) Valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger prior to receiving a new provider visit
8) Data logger report with five (5) consecutive days of current in-range temperatures

Upon receipt of the completed application by the AIPO, the AIPO will process the application and the assigned Immunization Program Specialist will reach out to the new location to schedule a required new provider training to examine the refrigerator/freezer, data loggers and to train the provider office staff in VFC policies and procedures. Providers that are in compliance with all aspects of the VFC program will be issued VFC provider identification number (pin). Please remember your pin. You will be asked for the pin on all correspondence, orders, and inquiries to the AIPO.

Vaccine Coordinators

During the enrollment process, VFC providers are required to designate a primary vaccine coordinator and at least one back-up vaccine coordinator for each facility. Each facility must have one designated primary and back-up VFC coordinator on site. VFC primary and back-up coordinators are not permitted to float between facilities.

The vaccine coordinators are responsible for overseeing all vaccine management within the facility, including:

- maintaining the Vaccine Accountability and Management Plan
- monitoring storage and handling and vaccine administration practices in the facility
- overseeing vaccine ordering and notifying the AIPO if vaccines will expire before they are administered
- ensuring and documenting annual vaccine management training for designated staff at re-enrollment and as needed, as well as training new staff upon hire
- storing all required documentation for six (6) years as required by Arizona State law

To effectively perform their duties, the vaccine coordinator and back-up coordinator must be fully trained on routine and emergency standard operating procedures for vaccine ordering,

storage, handling, transport, and inventory management. VFC providers are required to notify the AIPO anytime there is a change in vaccine coordinator staff.

Provider Re-Enrollment

Providers are responsible for re-enrolling in the VFC Program every year. The AIPO will communicate to the providers when the re-enrollment period will be open and when it will close. Vaccine ordering privileges may be stopped during the period of time the provider is re-enrolling and restored once the re-enrollment is completed and approved. The AIPO will supply providers with instructions on how to input the re-enrollment into ASIIS. All re-enrollments must be completed in ASIIS. The AIPO no longer accepts re-enrollments via paper.

The following information will be required annually for 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, NPI numbers, and medical license numbers of all providers in the facility that have the authority to prescribe vaccines. The signing provider is responsible for ensuring that all staff within the organization are in compliance with the VFC provider enrollment requirement
3) Provider Profile Form – 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. Providers may obtain patient demographic information from ASIIS, AHCCCS claims data, doses administered, provider encounter data, billing systems or benchmarking. This information is important to accurately order vaccines
4) Refrigerator/Freezer Verification Form – describes refrigeration/freezer requirement for vaccines. Providers cannot order frozen vaccines without having an AIPO approved freezer and having a Refrigerator/Freezer Verification Form on file
5) Completed and signed Vaccine Accountability and Management Plan, see Module 1
6) Training certificates for the primary and back-up VFC coordinators – primary and back-up VFC coordinators are required to complete either the CDC You Call the Shots, VFC or Storage and Handling modules or the AIPO Train Mandatory Primary and Back-Up module.
7) Valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger

Providers are required to submit to the AIPO, the signed provider agreement, the signed refrigerator/freezer verification form, completed and signed Vaccine Accountability and Management Plan, the training certificates for the primary and the back-up VFC coordinators and valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger via email or fax. Upon receipt of the re-enrollment packet and the re-enrollment in ASIIS by the AIPO, the AIPO will review the submitted information and return the re-enrollment to the provider with a message detailing what is needed in ASIIS if the documentation or ASIIS re-enrollment is missing and/or incomplete. If the documents and ASIIS re-enrollment are complete the AIPO will approve the application in ASIIS and the provider will receive a message that their re-enrollment is now approved.

Providers who fail to re-enroll will automatically be inactivated and vaccine ordering, 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 provided by the AIPO to the

AIPO. Providers that were inactivated for failure to re-enroll who also fail to transfer (with prior approval from the AIPO) VFC vaccines to other VFC providers (and, as a result waste the VFC vaccine) will be unable to re-enroll in the VFC program at a future date until they have replaced any wasted vaccine from their previous enrollment that resulted in wastage via dose for dose replacement. In addition, VFC providers that fail to re-enroll may have their AHCCCS panel reassigned.

Provider Billing Procedures

VFC providers are provided VFC vaccines at no cost to the provider. An administration fee, not to exceed $21.33 per injection, may be charged to AHCCCS or the parent/patient. If a patient is enrolled in AHCCCS, providers may NOT bill the patient. $21.33 is the maximum fee set forth by the regional Centers for Medicare and Medicaid Services (CMS). For those children who are Medicaid eligible please contact the individual AHCCCS health plans for specific requirements and rates for billing.

If a parent/patient is unable to pay the administration fee, the administration fee must be waived. It is unacceptable to send those who cannot afford the administration fee bills or send them to collections. Failure to waive the administration fees according the VFC program policy could be considered fraud and abuse (see Module 10).

Provider Request for a Change in VFC Status (Inactivation, Office Closure, Office Relocation or Other Changes)

Providers may inactivate their enrollment from the Arizona VFC program at any time. To prevent wastage of VFC vaccines, providers must notify the AIPO in writing on office letterhead signed by the VFC signing provider at least thirty (30) days prior to their intended date of inactivation. This will allow time for the provider to transfer (with prior approval from the AIPO) VFC vaccines to another VFC provider. Data loggers and any other equipment supplied by the AIPO will need to be returned to the AIPO.

All inactivations will be reported to AHCCCS. Providers that request an inactivation from the VFC program may have their VFC AHCCCS member panel reassigned.

If a VFC provider office is planning to relocate, the office must notify the AIPO in writing at least 30 days prior to the move. This notice will prevent shipments going to the incorrect location. Five (5) consecutive 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 AIPO staff before the transport of vaccines can take place.

Providers that inactivate who fail to transfer VFC vaccines to another VFC provider will not be able to re-enroll in the VFC program at a future date until they have replaced any wasted vaccine from their previous enrollment that resulted in wastage

Providers must notify the AIPO 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 must be reported via the Provider Profile Change Form Google Doc that can be

accessed on the ASIIS home page or the PDF found on our website.

AIPO VFC Forms

All required VFC forms are kept up-to-date on our website, www.azdhs.gov/vfc. Please always submit requests and information on the most up-to-date forms. If requests and information are submitted on outdated forms, the request/action will be denied until the most up-to-date form is received.

Module 3 – VFC Eligibility and Requirements

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Overview

VFC providers agree to screen patients for program eligibility at each immunization encounter prior to administering VFC vaccine and document their eligibility status using the Patient Eligibility Screening Record or the electronic medical record (EMR). Eligibility screening records are required to be kept for six (6) years. VFC vaccines can be administered only to children who meet the congressionally mandated eligibility requirements for the program.

(For more information about VFC provider requirements, see Module 2 – VFC Program Participation Requirements.)

When screening patients, providers should select and document the VFC eligibility category requiring the least out-of-pocket expense to the parent.

The VFC signing provider must ensure that all staff fully understand the VFC eligibility categories and are meeting this basic program requirement of documenting VFC eligibility at each immunization visit.

Program Eligibility Criteria

The VFC program provides vaccines at no cost to children 18 years of age or younger (the day before their 19th birthday) who meet at least one of the following criteria:

- American Indian/ Alaska Native (AI/AN)
- AHCCCS (Medicaid)-eligible
- Uninsured
- Underinsured

VFC Eligibility Criteria for Patients

VFC-eligible children must be 18 years old or younger and meet the definition of at least one of the following criteria:

Table: VFC Eligibility Criteria for Patients

VFC Eligibility Criteria	Definition
Not VFC Eligible Financial class code – V01	Patient's private insurance covers all ACIP recommended vaccines
AHCCCS (Medicaid) – eligible Financial class code – V02	Children who are eligible for the state AHCCCS (Medicaid) program
Uninsured Financial class code – V03	Children not covered by any health insurance plan
American Indian or Alaska Native (AI/AN) Financial class code – V04	This population is defined by the Indian Health Care Improvement Act (25 U.S.C. 1603). (AI/AN children are VFC-eligible under any circumstance)
Underinsured Financial class code – V05	Children who have health insurance, but coverage does not include any vaccines Children who have health insurance, but coverage does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) Children who have health insurance, but there is a fixed dollar limit or cap for vaccines Underinsured children are only eligible to receive VFC vaccines at a federally qualified health center (FQHC), a rural health clinic (RHC), or a deputized provider

American Indian or Alaska Native (AI/AN)

The American Indian or Alaska Native (AI/AN) population, for the purposes of the VFC program, is defined by the Indian Health Care Improvement Act [25 U.S.C. 1603].

AI/AN children are VFC-eligible under any circumstance. However, because VFC is an entitlement program, participation is voluntary.

When an AI/AN child also fits into a second VFC eligibility category, the provider should always choose the category that will cost less for the family. Depending on the facility where an AI/AN parent chooses to have their child vaccinated, the parent may be responsible for the vaccine administration fee if the vaccines are delivered through the VFC program. Therefore, if the child has private insurance (non- grandfathered plan under the Affordable Care Act (ACA) of 2010) or is enrolled in the KidsCare program, it may result in fewer out-of-pocket costs for the child to receive vaccinations through these programs than through VFC, as there would be no cost-sharing. Likewise, if the AI/AN child is also AHCCCS-eligible, AHCCCS should be used for the administration fee because it will provide the least out-of-pocket expense.

AHCCCS-Eligible

Under the legislation that created the VFC program, the term "AHCCCS-eligible" is defined as a child entitled to medical assistance under a Medicaid state plan.

Children enrolled in Medicaid make up the largest category of VFC eligibility.

Medicaid as Secondary Insurance

Some children may have a private primary health insurance plan with AHCCCS as their secondary insurance. These children are considered VFC-eligible because of their AHCCCS enrollment. However, their parents are not required to participate in the VFC program.

There are billing options for the parent and provider in this situation. The provider should choose the option that is most cost-effective for the family. The parent of a child with AHCCCS as secondary insurance should never be billed for a vaccine or an administration fee.

Options include:

Option 1: The provider can administer VFC vaccines and bill AHCCCS for the administration fee.

In most health care situations, AHCCCS is considered the "payer of last resort." This means that claims must be filed with and rejected by all other insurers before AHCCCS will consider payment for the service.

This is not true of the vaccine administration fee for AHCCCS-eligible VFC children. AHCCCS must pay the VFC provider the administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once a claim is submitted to AHCCCS, AHCCCS has the option to seek reimbursement for the administration fee from the primary insurer.

Note: If AHCCCS rejects a claim for a vaccine administration fee and states the claim must first be submitted to the primary insurer for payment, the provider should notify the AIPO.

Considerations regarding this option:

- easiest way for a provider to use VFC vaccines and bill AHCCCS for the administration fee
- no out-of-pocket costs to the parent for the vaccine or the administration fee

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

If the primary insurer reimburses less than AHCCCS for the vaccine administration fee, the provider can bill AHCCCS for the balance, up to the amount AHCCCS pays for the administration fee.

If the primary insurer denies payment of a vaccine and the administration fee, such as in cases where a deductible must be met, the provider may replace the privately purchased vaccine with VFC vaccine and bill AHCCCS for the administration fee. The provider must document this replacement on the VFC borrowing form (see Module 6).

Considerations regarding this option:

- the provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer

AHCCCS as Secondary Insurance and High-Deductible Plans

If a child has AHCCCS as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out of pocket for vaccines, the child should be considered VFC-eligible if the family has not yet reached its deductible.

VFC vaccines should be administered, and the administration fee should be billed to AHCCCS until the deductible is reached.

If a child does **not** have AHCCCS as secondary insurance, the child is **not** VFC-eligible even if a child's family has a high-deductible plan.

Underinsured

Underinsured means the child has health insurance, but the insurance policy:

- doesn't cover any ACIP-recommended vaccines
- doesn't cover all ACIP-recommended vaccines (underinsured for vaccines not covered)
- does cover ACIP-recommended vaccines, but has a fixed dollar limit or cap for vaccines. The child is considered underinsured once the fixed dollar amount is reached

Before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccines. If the provider cannot verify vaccination coverage, for the purposes of the VFC program, the child is considered insured and not eligible to receive VFC vaccines at that immunization encounter.

Note: As required by the Affordable Care Act, insurance plans purchased through the Health Insurance Marketplace are required to cover ACIP-recommended vaccines (including seasonal flu vaccine) for children of all ages, without charging a deductible, copayment, or billing coinsurance.

Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)

Underinsured children can receive VFC vaccines only at federally qualified health centers (FQHCs), rural health clinics (RHCs), or under an approved deputization agreement. FQHCs and RHCs provide health care to medically underserved areas and meet certain criteria under Medicare and Medicaid programs.

What is an FQHC?

An FQHC is a health center designated by the Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) to provide health care to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, and "look-alikes," which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian health centers.

What is an RHC?

An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

Table: Quick View of VFC Eligibility and Insurance Situations

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in AHCCCS	Yes	AHCCCS
Has private health insurance plan with AHCCCS as secondary insurance	Yes	AHCCCS
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit **and** has AHCCCS as secondary insurance	Yes	AHCCCS

Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	No Yes	• Insured until the fixed dollar limit is met • Underinsured after the fixed dollar limit is reached
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured. Child can only receive vaccines not covered by the plan ***FQHCs, RHCs and deputized providers can only vaccinate these patients**
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare ***FQHCs, RHCs and deputized providers can only vaccinate these patients**
Enrolled in a Health Care Sharing Ministry	Yes	Uninsured as Health Care Sharing Ministry plans are not recognized insurance by the State of Arizona Insurance Department
Enrolled in KidsCare	Yes	AHCCCS
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN. However, provider should choose the eligibility category most cost-effective for the child and family
Has AHCCCS and is AI/AN	Yes	Medicaid or AI/AN. Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family

VFC eligibility is not generally retroactive. Contact the AIPO if you discover that a child was actually VFC eligible on the date of service but was treated as an ineligible child. In rare circumstances and when this is not part of the regular business practice VFC may be able to replace the private stock vaccine with VFC vaccine.

Module 4 – Arizona State Immunization Information System (ASIIS)

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Overview

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 the public, health professionals, private and public health providers, parents or guardians.

ASIIS Access

Each individual is required to have their own log in to ASIIS and must not use other user's log-ins. To gain access to ASIIS and obtain a username and password, email a provider change form to asiishelpdesk@azdhs.gov. **Individuals that are not designated as the primary or back-up VFC coordinators that would like access to ordering and inventory reconciliation are required to submit their CDC You Call the Shots (the Vaccines for Children or Storage and Handling module) or the AIPO Training (Arizona Vaccines for Children Training) certificate to gain access to these modules**.

State Law Concerning ASIIS

Requirement: All providers are required to report all (VFC and private) vaccines they administer to children birth through 18 years of age to ASIIS.

Arizona Revised Statute (A.R.S. §36-135)
https://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/00135.htm
requires all providers to report VFC and private doses they administer to children birth through 18 years of age to ASIIS. Reporting administered VFC doses to ASIIS is also a VFC program requirement. Failure to report administered doses to ASIIS can lead to inactivation as a VFC provider.

ASIIS Electronic Reporting

All electronic reporting providers are encouraged to utilize a HL7 upload process allowing electronic health records to communicate with ASIIS thus reducing the need to manually report doses into ASIIS. Please send an email to ASIIS_Group1@azdhs.gov for more information on how to transition to a HL7 upload process.

ASIIS Manual Entry

The following information must be included for all reporting methods:

Provider Demographics	Patient Demographics	Parent Demographics	Vaccine Information
IRMS	Medical Record Number	Parent Last Name	Administration Date
Facility ID	Patient Last Name	Parent First Name	CVX and CPT Codes
	Patient First Name	Parent Relationship	Manufacturing (MVX) Code
	Patient Date of Birth		VFC Eligibility
	Patient Gender		Funding Source
	Patient Address, City, State and Zip		Vaccine Expiration Date
	Patient Phone Number		Lot Number (from the box)

Module 5 – Vaccine Storage and Handling

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Overview

Vaccine loss is both costly and preventable. Providers are responsible for maintaining vaccine quality from the time a shipment arrives at a facility until a dose is administered. Therefore, sound vaccine management practices related to storage and handling are critical to minimizing vaccine loss and waste and potentially putting VFC children at risk from compromised vaccine.

Providers are responsible for:

- ensuring vaccine coordinators are properly trained and that a vaccine accountability and management plan is posted on a VFC cold storage unit to be accessed by all when/if needed
- implementing best practices for vaccine storage and handling to avoid vaccine wastage
- enforcing vaccine inventory accountability policies

Vaccine Storage and Handling

All VFC vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Too much exposure to heat, cold, or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced even further. With loss of potency, vaccines become non-viable and are unable to provide immunity for the vaccinated individual.

CDC's Vaccine Storage and Handling Toolkit provides guidance on safe and effective vaccine management practices for all health care providers. The AIPO strongly encourages all providers to adopt all recommendations and best practices in the Toolkit. Following the Toolkit's guidance can minimize financial burden for providers due to vaccine loss and prevent the need for revaccination. The result is maximum vaccine effectiveness and patient protection.

Please note that all VFC providers must abide by the rules and regulations outlined by the AIPO in this operations guide.

VFC Storage and Handling Equipment Requirements

To ensure the viability of VFC vaccines, providers must have:

- storage units that maintain correct temperatures at all times
- **refrigerator temperatures between 36.0°F and 46.0°F (2.0°C and 8.0°C)**
- **freezer temperature between -58.0°F and +5.0°F (-50.0°C and-15.0°C)**
- data loggers with continuous monitoring capabilities and a current and valid certificate of calibration testing for each unit, as well as at least one data logger as a back-up

Refrigerator and Freezer Units

Storage units must have enough room to store the largest inventory a provider might have at the busiest point in the year without crowding.

The AIPO recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including door less and dispensing units
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the- counter style to a large, stand-alone, pharmaceutical- grade storage unit
- Combination household refrigerator/freezer unit, only if the refrigerator has a separate control and the freezer has a separate control. If the combination household unit has only one control, providers will be required to purchase stand-alone units

The use of dormitory or bar-style refrigerators/freezers is prohibited at all times for VFC program providers.
These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.

Providers should follow the manufacturer's storage specifications for each vaccine, found in the manufacturer package insert.

If a provider office needs to purchase new refrigerator and/or freezer units, providers are required to purchase stand-alone units.

Storage Unit Practices

To protect the viability of vaccines:

- never store food or beverages in a unit with vaccines
- store biologics or other medications on the bottom shelf to avoid inadvertent administration and medication errors
- do not store vaccines on the top shelf, in the deli, fruit, or vegetable bins (remove bins if possible), in the doors or on the floor of the unit, or under or near cooling vents
- place water bottles, marked as "do not drink" throughout the refrigerator and the freezer—against walls, in the back, on the floor, and in the doors—to help maintain proper temperatures
- place vaccines and diluents in the center of the unit, two to three inches away from walls, ceiling, floor, and door
- store vaccines in their original packaging with lids closed until ready for administration

The AIPO will only ship varicella containing vaccines to sites where the refrigerator/freezer used to store VFC 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 the required specifications above. Please contact the AIPO at 602-364-3642 if you have questions about the unit's ability to properly store vaccines.

Storage Unit Set Up

Providers should only plug one storage unit into an electrical outlet to avoid creating a fire hazard. Providers should avoid using power outlets that can be tripped or switched off, including built in-circuit switches (as they may have reset buttons), outlets that can be activated by a wall switch and multi-outlet power strips.

Providers are required to protect the power source for all cold storage units, by means of posting "do not unplug" signs on the wall next to the outlet to ensure cold storage units don't inadvertently become unplugged, resulting in wasted vaccine.
Providers are also required to have a "do not turn off circuit breaker" sign on their circuit breaker box, the number of the circuit breaker that corresponds to the outlet the unit is plugged into and a contact person's name and number.

Red "caution perishable vaccine" magnets are no longer required but the AIPO still recommends having one on the refrigerator and/or freezer with the emergency contact's names and numbers filled out.

Data Loggers

VFC providers must use a data logger with continuous temperature monitoring capability and a current and valid certificate of calibration testing (also known as a report of calibration) in each unit storing public vaccines. **Data loggers must be used during routine, on-site vaccine storage, vaccine transport (with prior approval from the AIPO), and as a back-up. Providers are required to have one data logger for each refrigerator and each freezer that stores VFC vaccine and one on site as the back-up.** In some instances, data loggers may be supplied by the AIPO.

To meet VFC program requirements, the data logger must be equipped with:

- a temperature probe or sensor in a buffered material (usually glycol). The probe must be kept in the middle of the unit with the VFC vaccines to ensure that the temperature of the air around the VFC vaccines is being recorded
- an active temperature display on the outside of the unit that can be easily read without opening the storage unit's door
- continuous temperature monitoring and recording capabilities and the capacity to routinely download data

*There may be providers who have purpose-built or pharmaceutical-grade cold storage units (e.g., door less or dispensing units) with temperature monitoring capabilities that may be as reliable as a data logger in monitoring vaccine temperature. Not all of these units may be capable of digitally logging temperatures. When in doubt, consult the AIPO at arizonavfc@azdhs.gov on whether the unit is capable of meeting VFC temperature monitoring device requirements.

Additional recommended data logger features include:

- alarm for out-of-range temperatures

- temperature display showing current, minimum, and maximum temperatures
- low battery indicator
- accuracy of +/-1°F (0.5°C)

Calibration Certificates must include:

- model/device number
- serial number
- date of calibration (report or issue date)
- confirmation the instrument passed testing (or instrument in tolerance)

Calibration certificates must include at least one of the following items in regards to the calibration testing:

- conforms to ISO 17025
- was performed by an ILAC/MRA Signatory body accredited Laboratory
- is traceable to the standards maintained by NIST
- meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5°C) or better

Providers must ensure that data loggers are properly set up and recording temperatures in all cold storage units that contain VFC vaccines every 15 minutes.

A back-up data logger must be readily available in case a data logger fails or calibration testing is required. The back- up data logger should have a different calibration retesting date than other data loggers to avoid requiring all data loggers to be sent out for recalibration at the same time. Back-up data loggers must be maintained on site. The back-up data logger must be portable to be used in the event of vaccine transport.

Provider offices are responsible for calibrating all data loggers that monitor the temperatures of any VFC vaccine before the calibration expires per the calibration certificate. Both the data logger display and the data logger probe must be recalibrated.

The AIPO recommends that providers keep just the probe (not the digital display) in the refrigerator so it is at temperature so it can be used in the event of an emergency. If providers opt to keep the probe in the refrigerator, the digital display of the back-up data logger must not be operational or on the cold storage unit to avoid conflicting temperature readings between the back-up and main data loggers which can lead to potential confusion.

Daily Temperature Monitoring and Recording

Providers are required to have protocols for reviewing and recording the temperature twice daily, once in the morning and once in the afternoon and the minimum and maximum (min/max) temperature readings of vaccine cold storage units, once in the morning for the previous 24 hours. They should also have procedures for training appropriate staff to document, assess, and interpret temperature monitoring data.

The CDC requires reviewing and recording min/max temperature readings at the beginning of the workday for the previous 24 hours. This helps to identify temperature excursions quickly so corrections can be made to prevent vaccine loss.

Information that is required when documenting a temperature reading:

- temperatures must be handwritten on the appropriate temperature log with the providers pin. The logs must be posted on the VFC refrigerator and freezer
- two temperature readings per day (one in the morning and one in the afternoon) and one min/max temperature reading per day at the beginning of the workday for the previous 24 hours to the tenths place (i.e. 40.2°F)
- exact time (i.e. 8:07am) and date of each reading
- name or initials of the person who assessed and recorded the reading

Data logger data must be downloaded and reviewed two times per month. This will assist you in finding any missed temperature excursions and ensures that the data logger has adequate memory. Providers must maintain all paper temperature logs and data logger reports for a minimum of six (6) years.

If a temperature excursion is suspected, providers should follow their Vaccine Accountability and Management Plan, including keeping the vaccines in the cold storage unit, isolating affected vaccines in a bag or box, labeling them "do not use", complete and email the VFC Incident Report, all applicable electronic data logger reports and written temperature logs for each incident to determine whether the vaccine can still be used. The reports may be emailed directly from the data logger application or in data format (.xls, .txt, or .csv). Providers must email all required documents to arizonavfc@azdhs.gov. Once the AIPO receives all required incident documents, providers will receive a response regarding viability of the VFC vaccines from the AIPO in 4-5 business days. The AIPO will not be able to determine VFC vaccine viability if all documents are not received via email from the provider.

If a provider office will be closed for more than four (4) days, someone must come in on the fifth and subsequent days to take the temperatures twice a day or transport the vaccines to another VFC provider before the closure occurs. Consult Module 6 for transport instructions. If a provider office is closed for more than four (4) days and their data loggers are not operational, vaccines may be wasted as the AIPO will not be able to determine if the cold storage units were maintaining appropriate temperatures for the duration of the office closure.

Cold Storage Unit Temperatures

Refrigerated vaccines must be stored between 36.0°F and 46.0°F (2.0°C and 8.0°C). Refrigerated vaccine freezes when it reaches 32.0°F (0°C). If refrigerated vaccines reach 32.0°F (0°C), the provider will be required to waste them as they are frozen and no longer viable. Store water bottles in all refrigerators, including pharmacy grade units, unless the manufacturer indicates that water bottles negatively impact the functionality of the unit. Water bottles placed in refrigerators help maintain proper temperatures during busy days and power outages.

Frozen vaccines (MMRII, Varivax and Proquad) must be stored at 5.0°F or lower (-15.0°C). MMRII may be stored in the freezer or the refrigerator. MMRII is heat sensitive and much less likely to be spoiled if kept in the freezer. Store water bottles in all freezers, including pharmacy grade units, unless the manufacturer indicates that water bottles negatively impact the functionality of the unit. Water bottles placed in freezers help maintain proper temperatures during busy days and power outages.

Separating Pediatric Vaccine Stock

Providers are required to have two separate vaccine inventories: one for publicly purchased (VFC)

vaccines and one for privately purchased vaccines. VFC vaccines must be labeled as VFC to ensure the correct stock is selected.

Publicly purchased vaccine inventory includes VFC vaccines supplied to the provider for administration to VFC and KidsCare children.

Privately purchased vaccine inventory includes vaccines purchased for the provider's privately insured children. All privately purchased vaccines must be separated from publically purchased vaccines in vaccine storage units.

Maintaining VFC Vaccine Viability

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

- install the refrigerator/freezer away from the any heat sources such as direct sunlight, furnaces or radiators
- keep the refrigerator and freezer sections full, but don't overcrowd the shelves (allow full air circulation)
- when accessing the unit open and close the door quickly to minimize the time the refrigerator door is kept open
- check units frequently for tight door seals
- clean condenser coils at the rear or underside of the refrigerator at least two (2) to six (6) times a year to prevent loss of cooling efficiency when coils become insulated with dust
- defrost the freezer compartment whenever the frost layer is ¼-inch think. Excess frost can prevent a tight door seal
- do not freeze diluent. Providers can call the AIPO to request additional diluent for VFC vaccines
- 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 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

Module 6 – Vaccine Management Activities and Reporting

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Overview

Vaccine management and reporting are broad terms intended to describe vaccine management related to transferring vaccines, returns and reporting practices that should be followed by VFC providers and their staff. The AIPO follows the CDC Storage and Handling Toolkit, a comprehensive resource for providers on vaccine management recommendations and best practices. Please note, the Arizona VFC Operations Guide may have requirements not found in the CDC Storage and Handling Toolkit, providers must comply with the Arizona VFC Operations Guide.

Managing Vaccine Incidents

To ensure vaccines continue to be viable, providers are required to report all vaccine incidents to the AIPO immediately. Vaccine incidents include but are not limited to, temperature excursions, power outages, theft of vaccine etc.

If a temperature excursion is suspected, providers should follow their Vaccine Accountability and Management Plan, including keeping the vaccines in the cold storage unit, isolating affected vaccines in a bag or box and labeling them “do not use”.

Providers must complete and email the VFC Incident Report, all applicable electronic data logger reports and written temperature logs for each incident. The reports may be emailed directly from the data logger application or in data format (.xls, .txt, or .csv). Providers must email all required documents to arizonavfc@azdhs.gov. Once the AIPO receives all required incident documents, providers will receive a response regarding viability of the VFC vaccines from the AIPO in 4-5 business days. The AIPO will not be able to determine VFC vaccine viability if all documents are not received via email from the provider.

When a freezer experiences a defrost cycle and the temperature increases above 5.0°F (-15.0°C) for more than an hour, providers are required to keep the vaccines in the cold storage unit, isolate affected vaccines in a bag or box, label them “do not use” and email electronic data logger reports to arizonavfc@azdhs.gov. Depending on the outcome of the time and temperature analysis, providers may be required to email a VFC Incident Report, additional electronic data logger reports and written temperature logs. The AIPO will email providers if additional information is required.

If vaccines are required to be wasted due to a vaccine incident, providers will be required to email five (5) consecutive days of in-range temperatures before an order can be placed.

If a provider’s cold storage unit experiences more than two (2) unexplained temperature excursions in a three (3) month period, the provider will be required to have the cold storage unit serviced and the provider will be required to provide the AIPO with the service receipt.

Providers will be required to purchase stand-alone units if a temperature excursion occurs in a household unit with three (3) months of the unit being serviced that results in wastage of any VFC vaccine. The provider will be required to provide the AIPO with a receipt of sale for a new stand-alone unit.

Providers will be required to replace stand-alone units if VFC vaccines are wasted more than twice in a six (6) month period after the unit has been serviced due to unexplained temperature

excursions. The provider will be required to provide the AIPO with a receipt of sale for a new stand-alone unit.

Vaccine Transfer/Transport

Proper vaccine inventory management at the provider level plays a major role in preventing the need to transfer vaccines. However, even with proper inventory management, providers may experience a situation where they have to transfer vaccines.

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 VFC facilities.

Requirement: VFC providers are required to gain the approval of the AIPO prior to transporting vaccines except in emergency situations.

Vaccine viability is essential for preventing vaccine preventable diseases and transport of vaccines is strongly discouraged by the CDC therefore transport of vaccines is allowed ONLY under the following circumstances:

- **soon to expire vaccines (at least 90 days prior to the expiration date)**
- **facilities that close temporarily (for more than 4 days) or permanently**
- **emergency situations (providers will need to activate their emergency handing plan within the Vaccine Accountability and Management Plan)**

Varicella and MMRV (Proquad) are not allowed to be transferred between providers except in an emergency due to their fragile nature.

Provider transfer requests will be denied if the request contains the following:

- **open vaccine boxes containing less than a full box (the number of doses in a box that constitutes a full box varies by vaccine presentation and is set forth by the CDC)**
- **split doses/boxes going to multiple facilities**

Due to the fragile nature of vaccines, and the tendency to freeze during transport, vaccine transfer requests may be denied depending on the distance from the sending to the receiving facility.

The AIPO retains the discretion to require providers to replace doses on a dose for dose replacement if vaccines are transferred and the following procedures are not followed:

- a transfer request must be submitted to the AIPO in ASIIS by the sending facility
- both the sending and receiving facilities must email up-to-date in-range data logger reports to the AIPO the same day the transfer request was submitted
- **the transfer request must be approved by the AIPO in ASIIS before transport can take place**
- all transfers must include the use of a data loggers with a current and valid certificate of calibration testing for temperature monitoring during transport, as well as other appropriate equipment. *Please note, if a data logger is not used for transporting to and from facilities, vaccines may be wasted at the discretion of AIPO management

- all data logger reports used during transport must be kept on site for six (6) years
- the receiving facility must inspect the vaccines. If the provider chooses to accept the transferred vaccines they will immediately place the vaccines in the refrigerator and/or freezer and then the receiving provider will receive the vaccines in ASIIS by marking the transfer as received

Off-site Clinics/Mobile Units

Provider offices must have their vaccines delivered to the same location that they will be administered at. The use of mobile units is limited to those providers that are currently approved by the AIPO to operate mobile units to administer vaccines. Provider offices are prohibited from using mobile units to administer vaccine if the vaccine is not shipped to the location the mobile unit will be administering vaccine at. VFC vaccines may not be shipped to, or stored at a private residence.

Vaccine Borrowing

The AIPO's expectation is that vaccine borrowing will be rare as providers should maintain adequate inventories of vaccine for both privately and publicly insured children. VFC vaccines should never be used as a continuous replacement system for a provider's privately purchased vaccine inventory. Borrowing of vaccines must be due to unforeseen delays or circumstances. Borrowing activities will be monitored as part of the compliance with the VFC program and follow-up actions will be taken when excessive or inappropriate borrowing activities are noted.
If a VFC vaccine is intentionally or unintentionally administered to a non-VFC eligible patient, the provider must replace the misused VFC dose with a privately purchased dose and submit a borrowing report to the AIPO immediately upon discovery. Providers should not use privately purchased vaccines to vaccinate VFC eligible patients as the VFC program will not compensate providers for those doses used except in the following approved circumstances:

- a lack of private-stock vaccine due to unexpected circumstances such as a distributor and/or manufacturer shipment delay
- vaccine spoiled in transit to the provider office from the distributor and/or manufacturer
- new staff that calculated ordering time incorrectly

Providers are not permitted to borrow influenza doses. Borrowing reports containing influenza will not be processed.

Vaccine Borrowing Documentation

If any of the above instances occur, providers are required to contact the AIPO for further instructions. In addition, providers are required to submit a complete and accurate borrowing report.

A Vaccine Borrowing Report must be completed when either:

- privately purchased vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a privately insured child

The borrowing report must include the following:

- vaccine type borrowed (name, NDC, lot number, expiration date)
- stock type used (VFC or private)
- patient name and patient D.O.B

- date dose administered
- reason appropriate vaccine was not used
- vaccine type replaced (name, NDC, lot number, expiration date)
- stock used (VFC or private)

AIPO staff will adjust the inventory after receiving borrowing reports from the provider. Provider staff should NOT adjust the inventory in ASIIS themselves. Once the provider's inventory has been adjusted by AIPO staff, the provider office will receive an email indicating the adjustments have been made.
If the number of borrowed doses exceeds 0.2% of reported doses linked to patients in ASIIS over the last year:

- private doses will no longer be replaced with VFC doses
- VFC doses will need to be replaced on a dose for dose basis, by purchasing private doses to be converted into VFC doses. Providers will be required to submit the invoice for the privately purchased vaccine to the AIPO.

Invoices

The AIPO requires a copy of the invoice validating that the privately purchased vaccine was used to replenish the borrowed VFC vaccines. The AIPO may also ask for copies of the packing slips for the privately purchased vaccines.

Management of Expired, Spoiled, and Wasted Vaccines

When managing expired, spoiled, and wasted vaccine, providers must:

- remove the vaccines from any storage unit that stores viable vaccines
- label vaccines "do not use"
- email a completed wasted/expired form to the AIPO via arizonavfc@azdhs.gov. Once the AIPO receives the wasted/expired form, providers will receive an email from the AIPO with the next steps
- return expired and spoiled vaccines to the depot (McKesson) within six (6) months of the expiration date or spoilage
- wasted vaccines should be disposed of following state and local disposal requirements
- all expired, spoiled and wasted vaccines must be removed from the ASIIS inventory using the appropriate category and reason

Types of Vaccine Loss

- Expired or spoiled vaccine: nonviable vaccine in its original container (vial or syringe) that is able to be returned. This includes expired vaccine or vaccine spoiled due to temperature excursions, transport conditions, or emergency situations such as a power failure.
- Wasted vaccine: nonviable vaccine that is unable to be returned. This includes vaccines in an open vial, drawn into a syringe, or compromised because its container was dropped or broken.

Providers must remove wasted/expired doses from the ASIIS inventory monthly, at a minimum. It is recommended to remove wasted/expired doses from the ASIIS inventory at the time of the event to ensure that the ASIIS inventory is up-to-date. The AIPO will work proactively to ensure VFC vaccine is tracked and accounted for at all VFC provider offices. If providers need technical assistance with ASIIS inventory management, please contact the ASIIS helpdesk at 602-363-3899 or 1-877-491-5741.

Every attempt should be made to use VFC vaccine appropriately. If you need assistance with

spoiled, wasted or expired VFC vaccines, please contact the AIPO, do not call the manufacturer.

Reporting Administered Dosed to ASIIS

VFC providers are required to report VFC and privately administered doses to ASIIS. All doses must be linked to a patient. All administered doses must decrement from the ASIIS inventory. When reporting administered doses in ASIIS, it is not acceptable to reconcile administered doses out of the ASIIS inventory using "administered but not linked" or "matches physical inventory" reconciliation reasons.

All administered doses must be accounted for and the vaccine inventory must be reconciled to reflect the doses that were wasted, expired, or spoiled to continue to order VFC vaccine. Doses that are considered accounted for are those doses that were administered and linked to a patient in ASIIS and those doses that were removed from ASIIS as expired, wasted/spoiled and the AIPO has received a wasted/expired form from the provider.

Providers are required to report the lot number from the box (not the vial or syringe). The lot number from the box will be used in the ASIIS inventory. Using the lot number or NDC from the vial or syringe will cause inventory issues. In addition, if there is a vaccine recall, the lot number from the box will be used to determine which patients should be contacted.

The following components are required to be documented in the patient's medical record for every vaccine administered:

- vaccine name
- lot number (from the box)
- manufacturer
- date vaccine given
- site and route given (IM/Sq)
- documentation from the child's parent confirming that the child's parent requests that the designated vaccine be administered to the child
- the name of person giving the vaccine – and their title
- date VIS was given
- VIS publication date
- VFC eligibility code
- name and address of the provider office

Providers may add administered vaccines that were not administered at their facility to ASIIS using the "add historical" button in a patient's vaccination record in ASIIS. For example, a new patient comes into a provider office and presents immunization records administered in the State of Texas, the provider staff could add the doses administered in Texas into ASIIS as historical. Please note, doses that were given at your facility on a previous date are not considered historical.

Restitution (Dose for Dose Replacement)

Vaccine restitution is the replacement of vaccine doses that were lost due to provider negligence. The AIPO acknowledges that providers make good faith efforts to store and handle vaccines appropriately as outlined in this operations guide. However, the 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 their inventory.

The doses required to be replaced will be doses exceeding 5% of doses distributed, if:

- this is the 1st incident and the total loss is 5% or over; or
- this is the 2nd incident (or greater) regardless of total value; or
- it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in non-viable vaccine, regardless of total value; or
- it is due to failure to contact the Arizona VFC Program (the AIPO) at the first instance of a recorded temperature excursion resulting in spoiled vaccines

In addition, effective July 1, 2018, all doses that are removed from the inventory using "matches physical inventory", "correction of invalid entry", "administered but not linked to a vaccine", "administered but chose not to be in the registry" (without supporting documentation), as selected in the Arizona State Immunization Information System (ASIIS) for reconciling VFC vaccine doses, or any unauthorized transfer of vaccine, or wasting vaccine without providing the appropriate documentation, must be replaced on a dose for dose basis.

As a VFC provider you have agreed to account for every VFC dose that you have received. Failure to do so will result in dose for dose replacement, at your expense via private vaccine purchase for all VFC doses that are not appropriately accounted for.

Vaccine wastage will be monitored by the AIPO. Providers will be advised in writing when there is need for restitution. Providers with wastage meeting one or more of the above criteria will receive a letter, a detailed invoice of vaccines that must be replaced, and the VFC Dose for Dose Replacement Form to be completed and returned providing evidence to the program that the doses have been replaced. Providers will be required to replace vaccines within 60 days of notice and return the VFC Dose for Dose Replacement Form along with the shipping invoice of the privately purchased vaccines. Providers will also be required to reconcile their inventory in ASIIS to reflect this replacement.

Providers are allowed to dispute the wastage invoice and adjustments. Waivers may be made on a case-by-case basis for wastage due to refrigerator failure or other events outside of the provider's control.

Providers who do not adhere to this policy and maintain an outstanding wastage invoice beyond the allowed 60 days will have a hold placed on their vaccine ordering privileges until they replace the wasted vaccines and submit the required documentation.

Good storage and handling techniques and proper reporting are essential for preventing vaccine wastage and avoiding the need for dose for dose vaccine replacement.

Module 7 – Vaccine Ordering

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Overview

Vaccine loss due to expiration is frequently a consequence of over-ordering and/or poor inventory management. To prevent this, providers need to determine the appropriate amounts to order for their private and public vaccine inventories.

Requirement: Providers must monitor vaccine orders to ensure they are ordering vaccine in the appropriate amounts and properly maintaining their vaccine inventories.

Vaccine Ordering

All VFC providers must submit their vaccine orders through ASIIS. The following steps are required when placing an order:

- providers will be prompted to reconcile their doses during the ordering process on the "reconcile inventory" page in ASIIS
- to reconcile doses, please move the number in the "quantity on hand" column to the "physical inventory" column for all vaccines regardless if the numbers match or not. Any administered doses removed from the ASIIS inventory using the reconciliation reasons "matches physical inventory," "administered but not linked to a patient," and "administered but chose not to be in the registry" (without proper documentation) are subject to the restitution policy, please see Module 6 for the restitution policy
- if providers need to remove doses that are expired, wasted/spoiled, they can be removed from this "reconciliation inventory" page. Providers will place the quantity on hand number minus the number of doses that need to be removed into the "physical inventory" box. The "adjustment" column will show how many doses will be removed
- providers may only remove doses from the ASIIS inventory if the doses are expired, have been spoiled (i.e. a temperature excursion), wasted (i.e. drawn-up but not used) or a recall has occurred from the manufacturer
- removing doses as a means of matching up the inventory is not allowed
- when the reconciliation inventory page is completed, please press "submit monthly inventory" to ensure the AIPO receives the updated inventory
- once providers press "submit monthly inventory" they will automatically be taken to the order screen
    - confirm the days and times the provider office is available to receive shipments, make any adjustments that are needed
    - select the correct order set from the "Order Set" drop down menu. Providers will have a separate flu order set during flu season
    - enter the quantity, by doses, that are needed in the "Order Quantity" box for all vaccines that need to be ordered
    - take a physical inventory of all doses in each storage unit and enter the current physical inventory count in the "Comments" box next to each vaccine
        - if the "Order Quantity" and "Comments" boxes are gray for a vaccine, enter the physical inventory count in a similar vaccine type (i.e. if Engerix-B is grayed out, you would put the physical inventory of the Engerix-B plus the Recombivax HB into the Recombivax HB "Comments" box)
        - if the current inventory is not listed in the "Comments" box, the order may be denied

- every time an order is placed, providers must email data logger reports from the last recorded data and time of the previously emailed data logger reports up until the date and time the order is submitted. The reports must be sent directly from the data logger application or in data format (.xls, .txt, or .csv) to arizonavfc@azdhs.gov
- if the AIPO does not receive provider data logger reports when the order is placed, the order may be cancelled and another order will have to be placed
- As of **June 1st, 2019** orders submitted without a data logger report will be **denied** until the AIPO receives the data logger reports or data loggers are acquired by the provider and data logger calibration certificates are emailed to arizonavfc@azdhs.gov.

Although provider offices are required to utilize data loggers, provider offices must utilize and retain a paper copy of the temperature logs on the VFC refrigerator and freezer.

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.

The provider office VFC primary or back-up coordinator 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
- determine the length of time the vaccine was in transit by looking at the packing list (shipments of frozen vaccine only). This insert will indicate the acceptable transit time based on the shipment date shown. The packing slip will state “vaccines are viable if received on or before (this date). If vaccines are received after the documented date on the packing slip, please call the AIPO immediately
- checking the cold chain monitor (CCM) for any indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container and may not be included when vaccines are shipped directly from the manufacturer. CCMs are for one-time use only and should be thrown away after being checked
- inspect the packages and vaccines for damage
- compare the vaccine received with the vaccine products that appear on the packing list
- 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
- making sure lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluents. (Diluents for varicella-containing vaccines are stored in a separate compartment in the lid of the shipping container and are stored separately in the refrigerator.)

- checking both vaccine and diluent expiration dates to ensure none are expired or soon-to-expire products
- check the diluents (any diluents arriving frozen must not be used). Call the AIPO immediately if the diluents are frozen
- remove vaccines from the shipping container and immediately store refrigerated vaccine in the refrigerator and frozen vaccine in the freezer
- MMR can be stored in the freezer or the refrigerator; varicella and varicella containing vaccines must be stored in the freezer

All VFC providers must receive the shipment of vaccine into the ASIIS inventory immediately after vaccines arrive in the provider office. To receive the order into ASIIS, follow the following steps:

- log into ASIIS
- under the "orders/transfers" tab on the left hand side menu, select "create/view orders"
- under the "inbound orders" heading, click on the arrow under select
- compare the order in ASIIS to the vaccine shipment
- input the quantity received in the "receipt quantity" box for all vaccines received. If all the vaccines are not received, please leave the "receipt quantity" blank and return to this page and enter the quantity received when the vaccines are physically received in the provider office
- click on the button that states "receive." The received vaccine quantities will be transferred to the ASIIS inventory for use
- write any shipment discrepancies and/or problems with the vaccine order on the packing slip and email or fax the slip to the AIPO within 2 hours of receipt. Do not call the manufacturer with any VFC vaccine problems. Notify the AIPO immediately of all vaccine shipping problems – AIPO staff will determine what should be done
- do not fax the packing slip to the AIPO unless there are discrepancies with the shipment or the shipment is rejected in ASIIS
- it is critical that each VFC provider label and store VFC vaccine separately from private stock vaccines to be used for adults 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
- 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 AIPO 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 AIPO using the forms request order form which can be found at http://azdhs.gov/documents/preparedness/epidemiology-disease-control/immunization/forms-request.pdf and keep these labels on hand at all times

The AIPO 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 an order.

Providers are encouraged to keep a 3-4 week supply of vaccine on hand based on the providers' 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 AIPO to approve or deny the

order.

Order Delays or Cancellations

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

- up-to-date data logger reports have not been received via email
- the data logger temperatures are out of range
- previous order(s) have not been "received" in ASIIS

If orders are delayed or cancelled, the reason will be posted in the ASIIS comments.

Maintaining Vaccine Inventory

When establishing vaccine needs, please consider:

- vaccine deliveries usually take 7-10 days to arrive in the provider office
- vaccine usage patterns (i.e., increased orders during July and August for "back- to-school" children)
- length of time before the next order is approved, shipped and received
- 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)

Vaccine Shipments

The AIPO acts as the coordinating center in Arizona for federally purchased vaccines. The AIPO will notify the provider via the comments section in ASIIS if there are any changes to the standard vaccine shipping routine. The AIPO will utilize the ASIIS Newsflash to communicate McKesson's holiday shipping schedule.

When an order for VFC vaccine is placed by the provider the order is reviewed and approved by the AIPO. The order is then transmitted to McKesson, the vaccine distributor. McKesson will facilitate the delivery of the vaccines to the provider's office. 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.

Module 8 – Vaccine Administration and VAERS

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Overview

Appropriate vaccine administration is critical to vaccine effectiveness. Only properly trained individuals should administer, report and record vaccines. All persons who administer vaccine should have continuing vaccine administration education and regular skills assessments. All VFC providers are required to report any clinically significant adverse events to the VAERS system.

Advisory Committee Immunization Practices (ACIP) Recommended Vaccines

Providers are required to comply with the appropriate immunization schedule, dosage and contraindications established by the ACIP in VFC resolutions and included in the VFC program unless (a) in the provider's medical judgement 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.

All childhood vaccines recommended by the ACIP are available through the 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.

During vaccine shortages, presentations may be substituted. The AIPO 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 AIPO due to procurement processes or due to technical changes or updates to ASIIS that require planning, clinical review and implementation by technology staff
- the AIPO 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), AIPO staff may take the following action under the authority and approval of the AIPO 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., Trumenba vs. Bexsero)
- 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 AIPO will honor provider preference for packaging (e.g., syringes vs. vials) whenever possible. If syringes become unavailable for an extended period of time, the AIPO will ship vials without notification to the provider. If vials become unavailable for an extended period of time the AIPO 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 to ensure sufficient storage space availability.

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 AIPO 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 dose for dose vaccine replacement from the AIPO.

Vaccine Information Statements (VISs)

According to federal law VFC providers must provide a current Vaccine Information Statement (VIS) at every immunization visit before a patient receives a vaccine and document the publication date of the VIS and the date it was given to the parent/patient in the patient's medical record. VISs are CDC fact sheets that inform parents/patients of the benefits and risks of a vaccine.

Providers can have paper VISs, laminated VISs or electronic VISs available to parents/patients. If a parent/patient asks for a paper copy, provider offices must provide the parent/patient with a paper copy. It is not necessary to have the parent/patient sign anything to show they have received the VIS, unless provider offices require this.

VISs can be downloaded from the CDC's current VIS webpage at:
www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm.
Ensure that parents/patients have a chance to have their questions answered. Give parents/patients 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 from the CDC's current VIS webpage at www.cdc.gov/vaccines/oubs/vis.

All VFC providers are required to 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 parent/patient. It is acceptable to provide a VIS before the immunization visit (i.e. by giving the parent/patient a copy to take home during the prior visit or telling them how download or view a copy from the internet).

Vaccine Adverse Event Reporting System (VAERS)

All VFC providers must report any clinically significant adverse events that occur after the administration of any vaccine licensed in the United States to the Vaccine Adverse Event Reporting System (VAERS).

The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report the following:

- any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine
- any event listed in the VAERS reportable event table that occurs within the specific time period after the vaccination
- any time a parent/patient asks providers and/or provider office staff to report any event (even if it may not be outside of the expected side effects)

Medication errors do not need to be submitted to VAERS, however if you feel that it is directly related to the patients reaction, please report the medication error to VAERS.

All documentation related to VAERS reports must be kept on site for a minimum of six (6) years.

Provider Administration Requirements

Providers are required to provide the following resources and trainings to provider office staff:

- current CDC/ACIP recommended immunization schedule
- vaccine contraindications/precautions
- administration techniques

Vaccine Administration Best Practices

Proper vaccine handling and preparation are equally as important as storing vaccines properly. Providers should follow best practices, including:

- always check the expiration date on vaccines and diluents before administering vaccines. Never use expired vaccine or diluents
  - only use the diluents provided by the manufacturer for that vaccines as indicated in the product insert
  - vaccines should be drawn up immediately before administration only
  - prepare vaccines in a designated, clean medication area, away from any space where potentially contaminated items are placed.
  - vaccines should remain in their original boxes until all syringes and vials have been used
  - vaccines may lose their viability if stored in syringes for any period of time. Do not pre-draw doses
  - a single-dose vial contains **one** dose and should only be used for **one** patient.
  - only the number of doses indicated in the manufacturers package insert should be withdrawn from a multidose vial. After the maximum number of doses has been withdrawn the vial should be discarded even if there is residual or the expiration has not been reached
  - a separate, sterile needle and syringe should be used for each injection.
  - 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 doses in ASIIS and provide the AIPO with the supporting documentation.

Module 9 – Arizona Immunization Program Office Provider Visits

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Overview

VFC providers are required to participate in AIPO provider visits. AIPO provider visits must be conducted by the AIPO staff to ensure the ongoing integrity of the VFC program. Multiple types of VFC site visits are designed to evaluate different aspects of provider compliance with and understanding of the VFC requirements.

New Provider Visits

AIPO staff will conduct provider staff training/education on VFC program requirements for all newly enrolled. Providers must email valid data logger calibration certificates for all units storing VFC vaccines and the back-up data logger and data logger reports showing five (5) consecutive days of current in-range temperatures prior to receiving a new provider visit. AIPO staff will ensure that all providers have the required cold storage units in place before ordering can occur. These visits are scheduled at a time that is mutually agreed upon and will take approximately 1-2 hours or longer.

New Staff\Education Visits

AIPO staff members are available to conduct trainings for new provider office staff. AIPO staff will provide training/education on the VFC program requirements. AIPO staff can also conduct this training for those who are in need of a refresher course.

VFC Compliance Visits

Once at a minimum every 24 months and perhaps more frequently AIPO program staff will conduct a VFC compliance visit at VFC enrolled provider offices. The purpose of the VFC compliance 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 VFC 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 are purchased with VFC funds are administered only to VFC eligible children
- ensure VFC vaccine stewardship and accountability

AIPO staff members and provider staff 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 VFC compliance visit will be scheduled in advance. Each visit takes approximately two (2) to three (3) hours or longer based on information obtained prior to and during the compliance visit and training needs at the provider site.

During the VFC compliance visit the Immunization Program Specialist (IPS) 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" signage next to storage unit outlets, or vaccines that have been placed in the back of the unit that will soon expire. While these can be corrected during the visit, staff will still make note of the issues.

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

Unannounced Storage and Handling Visits

These are visits that will occur at any time with no notice. They may last 1-2 hours or longer and will include a short questionnaire. The AIPO staff will look at the cold storage unit(s) to check for proper storage techniques and any expired vaccines. Additionally, staff will review any areas previously found to be out of compliance.

Assessment, Feedback, Incentive and Exchange (AFIX) Visits

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.

e(X)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:

- http://www.cdc.gov/vaccines/programs/afix/index.html

Brief Overview of AFIX Process:

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

a) Quantitative: Generating assessment reports for children (24-35 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 (QI) Goals: During the feedback session, the Immunization Program Specialist will review and discuss the assessment reports and completed AFIX Site Visit Questionnaire and assist in choosing two or more 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
- 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 site visit usually takes approximately an hour to complete depending on the amount of training desired. During the in-person visit, your Immunization Program Specialist will also train you and your staff on how to schedule and run your own assessment reports. This is beneficial to provider offices because now provider staff can utilize ASIIS to assist in improving coverage levels and reducing missed opportunities and providers don't have to wait for the 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 AIPO at 602-364- 3642 and ask to speak to an Immunization Program Specialist or the Assessment Manager.

Provider Survey

The AIPO management team conducts a survey related to the provider's experience with their VFC compliance visit reviewer. Providers will receive this survey via email. In order to better serve our providers we appreciate your feedback.

Module 10 – Fraud and Abuse/Discipline Process

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Overview

The AIPO 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 progressive disciplinary actions. Follow-up visits will occur throughout the process.

The terms "fraud" and "abuse" related to VFC are consistent with the definitions in Medicaid regulations (42 CFR §445.2).

Fraud

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 laws.

Abuse

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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Well-organized and correctly administered VFC accountability programs are the cornerstones for preventing potential fraud and abuse incidents. Accountability measures should be emphasized to all provider staff.

Fraud and Abuse Examples*

- Failing to comply with any part of the Provider Agreement
- Providing VFC vaccine to non-VFC eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional fee for administration of VFC vaccine
- Over-ordering VFC vaccine (e.g., quantities or patterns do not match the provider's profile)
- Waste of VFC vaccine
- Denying VFC-eligible children VFC funded vaccine because of parents' inability to pay the administration fee
- Failing to screen for and document eligibility status at each visit
- Failing to maintain VFC records for a minimum of six (6) years
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine

If VFC provider offices have not met Arizona VFC requirements or followed Arizona VFC procedures as outlined in this operations guide, but the AIPO finds no intentional deception, misrepresentation or negligence on the part of the VFC provider, the staff at the provider office may be required to participate in training and/or take other actions to rectify the situation.

Addressing Provider Non-Compliance with VFC Requirements

Providers agree to comply with the VFC program requirements outlined in the Provider Agreement and discussed during the enrollment and subsequent site visits. Lack of adherence could lead to fraud and abuse charges for providers.

Failure to comply with VFC requirements is defined as:

- any VFC provider who does not maintain the federal and/or state requirements associated with implementation of the Provider Agreement. The details of the federal and state requirements are discussed throughout this operations guide

If a provider's office has been identified by their IPS and/or AIPO staff as being non-compliant in any area of the VFC program and these VFC requirements have not been met by a provider after multiple follow-ups, the provider will be placed on probation. The provider will be asked to submit a corrective action plan to their assigned IPS that addresses how the non-compliant issue(s) have been resolved; the IPS will make any needed edits and approve the corrective action plan. If a provider is placed on probation a site visit is required before the probation ends.

Probation will end when the IPS 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 be inactivated from the VFC program due to non-compliance with VFC program requirements.

The AIPO will report all instances of probation and suspected fraud and abuse to AHCCCS.

Appeals Process

If a provider feels that removal from the AIPO VFC Program has occurred in error, the provider may request a meeting with the Immunization Program Office Chief to address the issue. The request must be submitted in writing to the Immunization Office within ten (10) business days of receipt of the removal notice. All appeals should be addressed to:

ADHS, Immunization Program Office
Office Chief
150 N 18th Avenue, Suite 120
Phoenix, AZ 85007

The Immunization Program Office Chief will schedule a meeting within five (5) business days after receiving the request. A written final decision from the Immunization Office Chief will be issued within five (5) business days of the meeting.

Definitions and Acronyms Used in this Guide

ACIP	**Advisory Committee on Immunization Practices**
AFIX	**Assessment, Feedback, Incentive and eXchange**
AHCCCS	**Arizona Health Care Cost Containment System**
AIPO	**Arizona Immunization Program Office**
ASIIS	**Arizona State Immunization Information System**
Back-Up Coordinator	**Fulfills all the roles of the primary coordinator as a secondary**
CDC	**Centers for Disease Control and Prevention**
Cold Chain	**A temperature-controlled supply chain. An unbroken cold chain is an interrupted 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**
CPT Code	**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.**
CVX Code	**A code used by computer programs to indicate the product used in a vaccination**
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 Health/Medical Record	**A specialized medical information software application which electronically documents patient medical information**
Facility ID	**A patient who meets the criteria for VFC Program participation**
IRMS	**The organization account number. An IRMS (organization) can have multiple facilities**
Lot Number	**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**
NDC	**National Drug Code – universal product identifier for drugs**
Primary Coordinator	**The staff person in the provider's office who is the primary administrator and contact person for the management of vaccines**
Potency	**Vaccine effectiveness**
Reconstituted	**Restoration to original form of a substance previously altered for preservation and storage**
Restitution (Dose for Dose Replacement)	**Repayment for lost, wasted, expired, or spoiled VFC vaccines due to provider negligence**
Syringe	**Single dose pre-filled syringe**
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. VFC vaccines that are spoiled, expired, or lost may be billed to the provider** - **Spoiled or expired vaccine: Non-viable vaccine in its original container (vial or syringe) that is eligible for return. This includes expired vaccine or vaccine that has been spoiled as a result of temperature excursions** - **Wasted vaccine: Non-viable vaccine that cannot be returned. This includes broken vials or syringes, unused vaccine drawn into a syringe, lost and unaccounted vaccines, or remaining doses in a multi-dose vial**

Vaccine Abbreviations

DTaP	Diphtheria, Tetanus, Acellular Pertussis
DTaP/Hep B/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
Hib	*Haemophilus influenzae* type B
HPV	Human Papillomavirus 9-valent
IPOL	Inactivated Polio Vaccine (also known as IPV)
LAIV	Live Attenuated Influenza Vaccine
MCV4	Meningococcal Conjugate Vaccine4-valent
MenB	Meningococcal Serogroup B
MMR	Measles, Mumps, Rubella
MMRV	Measles, Mumps, Rubella/Varicella
PCV 13	Pneumococcal Conjugate Vaccine 13-valent
PPV 23	Polysaccharide Pneumococcal Vaccine 23-valent
Rota	Rotavirus vaccine 5-valent or 1-valent
QIV	Quadrivalent Influenza Vaccine
Tdap	Tetanus, Diphtheria, Acellular Pertussis
Td	Tetanus Diphtheria Vaccine
VAR/VZV	Varicella (chickenpox)

VFC Resources
Where to Find Them

State Websites

Arizona Vaccines for Children (VFC) Program:
http://azdhs.gov/phs/immunization/vaccines-for-children/

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

Federal Websites

Vaccines and Immunizations:
www.cdc.gov/vaccines/

Federal Vaccines for Children (VFC) Program:
http://www.cdc.gov/vaccines/programs/vfc/index.html

CDC Storage and Handling Toolkit:
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

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.whyimmunize.org/

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

Vaccine Manufacturers

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

Grifols:
www.grifolsusa.com

GSK:
http://www.gsk.com/

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

Sanofi Pasteur:
http://www.sanofipasteur.com/en/

Seqirus:
http://www.seqirus-us.com/

Arizona Immunization Program Office

Main Line: 602-364-3630

Vaccine Center: 602-364-3642
Email: ArizonaVFC@azdhs.gov

ASIIS Help Desk: 602-364-3899
Email: ASIISHelpDesk@azdhs.gov

Hours of operation: M-F 8:00am – 5:00pm
Closed on all federal holidays

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