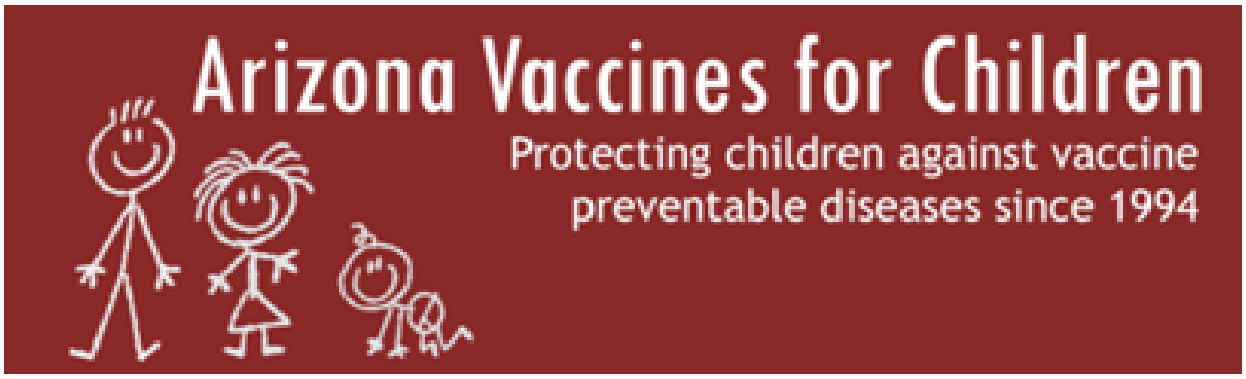
Arizona Vaccines for Children (VFC) Program



Operations Guide

ARIZONA DEPARTMENT OF HEALTH SERVICES

Last Revision: June 2024

Vaccines for Children (VFC) Program Operations Guide

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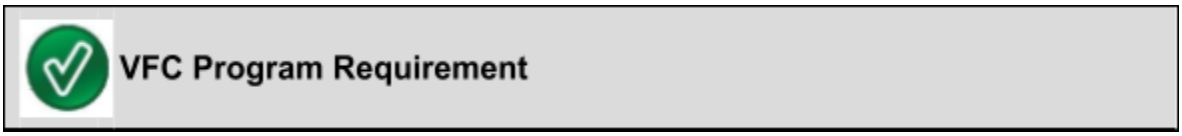
VFC programmatic requirements for provider offices are indicated by a gray box with a green check icon.



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

Best practices are noted throughout the document. While not required, providers are encouraged to implement these practices where possible.

Terms Used in this Guide

For purposes of this guide:

- **Awardee** refers to the Arizona State Immunization Program staff responsible for the 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/Guardian** refers to anyone with the legal authority to make decisions on behalf of a VFC-eligible child. This can refer to parents, legal guardians, or individuals of record
- **Provider** refers to a health care provider licensed to administer vaccines and the staff within a provider facility that stores and handles vaccines, orders, and bills for vaccine administration or screens for VFC eligibility. A “provider” is enrolled in the VFC program and has ordered vaccines within the past 12 months. (Providers who have not ordered vaccines in the past 12 months are considered inactive and may be unenrolled from the program.)
- **Provider location** refers to a specific VFC provider facility, practice, or clinic

Future Changes to the Guide

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

Unless specified otherwise, any new requirements will take effect 30 days after the change notice.

Providers will be notified electronically of any updates by the BIZS.

Summary of Arizona VFC Program Requirements

	Requirement	Steps/Components
	Module 1 – Vaccine Accountability and Management Plan	
	Providers must display the Vaccine Accountability and Management Plan on their VFC cold storage unit.	• Contact information for the signatory physician, current primary and backup VFC coordinators, and the office manager (if applicable) must always be listed on the Vaccine Accountability and Management Plan • Provider staff roles and responsibilities are defined • Records related to vaccine management training must be kept for six (6) years, either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable • 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 four consecutive hours on a day other than a Monday to receive VFC vaccines to accommodate shipment delivery window ● VFC providers are required to designate a primary vaccine coordinator and at least one backup vaccine coordinator who must be on-site for each facility. Primary and backup coordinators are not permitted to float between facilities
	Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (annually)	● Submitting a Provider Agreement signed by an 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 backup data logger must be submitted to the BIZS 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 an 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 backup VFC coordinators ● Submitting valid data logger calibration certificates for all units storing VFC vaccines and the backup data logger ● Submitting an updated Vaccine Accountability and Management Plan (VAMP)
	Providers must abide by the proper billing procedures for VFC vaccines	● 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
	Providers must notify BIZS of any change in VFC Status (Inactivation, Office Closure, Office Relocation, or Other Changes)	● Providers must notify the BIZS in writing at least 30 days prior to their intended date of inactivation in a BIZS-approved format ● Providers are required to notify the BIZS in writing at least 30 days prior to a move or office closure ● Providers must submit a profile change form to the BIZS for any staff changes, facility name changes, and any other pertinent changes
	Providers are required to use and submit the most up-to-date BIZS 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 BIZS on outdated forms, the request/action will be denied until the BIZS receives the most up-to-date form
	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 (the day before their 19th birthday) who meet the eligibility requirements
		• Providers may utilize the Patient Eligibility Screening Record or the electronic medical record (EMR) to document the screening information
		• Records related to eligibility screening must be kept for six (6) years from the date of the last visit, either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable
		• 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 login to ASIIS and must not use another user's login	• Complete the Provider Profile Change Form to obtain a username and password
	Providers are required to report VFC and private doses to ASIIS for children 18 years old and younger within 30 days of administration	• Per Arizona Revised Statute A.R.S. §36-135, all health care professionals 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 via HL7 • 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 separate temperature control for the refrigerator and a separate temperature control for the freezer for the use of the refrigerator compartment only • The freezer compartment of a dual-control household unit is not acceptable and a separate freezer unit will need to be purchased to store frozen vaccines • **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 calibration certificate are required for all units storing VFC vaccine • A backup data logger with a current calibration certificate is required to be on-site • The backup data logger must be portable to be used in the event of vaccine transport • Provider offices are responsible for ensuring all data loggers that monitor the temperatures of any VFC vaccine are sent for calibration testing by an appropriate company before the calibration expires per the calibration certificate • Data logger data must be downloaded and reviewed two times per month • At the start of the workday, one reading of the minimum/maximum temperature should be recorded either on a temperature log or with an electronic continuous temperature monitoring system • If a provider's office is closed for more than four (4) days, someone must come in on the fifth day and subsequent days to take at least one min/max temperature reading at the beginning of the workday or transfer the vaccine to another VFC provider before the closure occurs. Consult Module 6 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 CHIP vaccines) can be stored and labeled as VFC • All privately purchased vaccines must be separated from publicly supplied (VFC and CHIP) vaccines

	Requirement	Steps/Components
	Module 6 – Vaccine Management Activities and Reporting	
	Providers are required to report all vaccine incidents (including temperature excursions, power outages (that result in out-of-range temperatures), theft, etc.) to the BIZS immediately	• Providers must complete a VFC Incident Report in an approved BIZS format, provide all applicable electronic data logger reports for each incident, and upload all applicable electronic data logger reports. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv) • If the provider contacts the manufacturer(s), the provider will use the Temperature Incident Instructions & Checklist to complete the incident report • If BIZS contacts the manufacturer(s), providers will receive a response regarding the viability of the VFC vaccines from the BIZS in 4-5 business days once the incident is received • The BIZS 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 and there is no previous history of an excursion in the unit, the providers will be required to submit a data logger report with three (3) full consecutive days of current-in-range temperatures before an order can be placed. If the provider's unit has a history of a prior excursion, a data logger report with five (5) full consecutive days of current in-range temperatures must be submitted before an order can be placed • If a provider's cold storage unit experiences more than 2 unexplained temperature excursions in 3 months, the provider will be required to have the cold storage unit serviced and the provider will be required to provide the BIZS 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 BIZS with a receipt of sale for new stand-alone units • 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 BIZS with a receipt of sale for new stand-alone units

	Requirement	Steps/Components
	Providers must abide by the proper procedures when transferring vaccines	Vaccine transfers can only occur: ● **After the ASIIS transfer request has been approved by the BIZS in ASIIS** ● After up-to-date temperatures have been received by the BIZS from the sending and receiving facilities ● Conditioned water bottles must be used during vaccine transport of refrigerated vaccines ● Data loggers with a current valid certificate must be used to monitor the temperature during transport ● If a data logger is not used for transporting the vaccine, vaccines may be wasted at the discretion of BIZS management ● If a provider has open VFC vaccine incidents, providers will not be allowed to initiate a transfer to or accept a transfer from another facility until the VFC vaccine incidents have been closed by the BIZS ● Please follow the steps in the How to Create and Receive Transfers in ASIIS (VOMS 2.0) job aid to complete this process
	Provider must abide by the proper procedures when operating a Temporary, Mobile, Off-Site, or Satellite Clinic	● The use of mobile units is limited to those providers that the BIZS approves to operate mobile units to administer vaccines ● Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement ● Vaccines are only transferred to the mobile unit on the day of the clinic ● Providers must submit plans for the temporary, mobile, off-site, or satellite clinic to their Immunization Program Specialist (IPS) or ArizonaVFC@azdhs.gov for approval
	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 provider's privately purchased vaccine inventory ● A borrowing report must be submitted to the BIZS for every instance of borrowing

	Requirement	Steps/Components
	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” ● Follow the instructions in Vaccine Returns for Wasted/Expired Doses (VOMS 2.0) ● 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 as listed in the Vaccine Returns for Wasted/Expired Doses (VOMS 2.0)
	Report all administered doses to ASIIS	● All VFC and privately 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 (e.g., out of state)

	Requirement	Steps/Components
	Module 7 – Vaccine Ordering	
	All VFC providers are required to submit a vaccine order through ASIIS at least once per calendar year. Providers must order all ACIP vaccines, including COVID-19, Nirsevimab, and seasonal flu vaccines.	
	Providers must reconcile their inventory before placing an order	• Providers will be prompted to reconcile the inventory during the ordering process in ASIIS VOMS 2.0 if they have not reconciled their inventory within the previous 14 days • Enter the number of doses under the "Physical Count" for each vaccine. This number should match the number of doses in cold storage units. 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 Count box. The "Adjustment" column will show how many doses will be removed • The appropriate Adjustment Category will need to be selected from the dropdown menu • Provider offices may only remove doses if the doses are expired, have been spoiled (e.g., a temperature excursion), wasted (e.g. drawn-up but not used), or a recall has occurred from the manufacturer • Please follow the steps in the ASIIS Inventory Reconciliation job aid to complete this process
	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 date 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, .ltd, or .csv) to arizonavfc@azdhs.gov • If the BIZS does not receive provider temperatures when the order is placed, the order may be canceled and another order will have to be placed

	Requirement	Steps/Components
	Providers must receive the shipment of vaccines into the ASIIS inventory immediately after vaccines arrive in the provider office	• Log in to ASIIS • Go to Inventory Management, then click VOMS 2.0 • Select Orders & Returns Tab, and select Orders & Transfers from the drop-down menu on the left • Under the Inbound (Orders & Transfers section), find the order you want to receive and click receive • Verify the Lot Number and Expiration Date and make sure it matches your packing slip • Enter the Receipt Quantity for the items that have physically arrived at your facility (Leave blank if the vaccine has not yet arrived at your facility. Once the other shipment arrives, you may receive the other doses) • Once you have verified the Lot Number and the Expiration Date and entered your Receipt Quantity for vaccines that physically arrived at your facility, click Receive ***If there are any issues with your order upon arrival (e.g., the order arrives broken, doses are missing, etc.), please contact the ASIIS helpdesk for the next steps.***

	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 guardians/patients with 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 to the vaccines being administered • Provider offices may provide laminated VISs to the parent/guardian/patient prior to vaccination • Provider offices may provide VISs on a computer monitor or video display • VISs may be downloaded by the parent/guardian/patient to a smartphone or other electronic device to read

	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 healthcare providers to report:
		  ■ Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine
		  ■ Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination 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 patient's reaction, please report the medication error to VAERS

	Requirement	Steps/Components
	Module 9 – Bureau of Immunization Services Provider Visits	
	All VFC providers must participate in VFC program compliance visits, including unannounced storage and handling visits and other educational opportunities associated with the VFC program requirements	• All new/previously enrolled VFC provider locations are required to participate in a new provider training • The BIZS 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, BIZS 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 advance notice
	All VFC providers must also participate in Immunization Quality Improvement for Providers (IQIP) visits	• At a minimum, once every 24 months, and perhaps more frequently, BIZS program staff will conduct an Immunization Quality Improvement for Providers (IQIP) visit at VFC-enrolled provider offices • 2-month and 6-month check-ins will be conducted via phone or email after the initial IQIP visit is conducted • 12-month follow-ups after the initial IQIP visit will also be conducted in a BIZS-approved virtual platform • Fully implemented strategies to increase vaccine uptake should be completed 12 months after the initial visit

	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 BIZS 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 • 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, and involuntary program separation • If VFC provider offices have not met Arizona VFC requirements or followed Arizona VFC procedures as outlined in this guide, but the BIZS 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 corrective actions.

Vaccines for Children (VFC) Program Overview

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Children's Health Insurance Program (CHIP)
CHIP and VFC Eligibility

Welcome to the Arizona Vaccines for Children (VFC) program. The Arizona VFC Operations Guide has been prepared by the Arizona Department of Health Services and Bureau of Immunization Services (BIZS) to provide information to enrolled providers to ensure compliance with federal and state VFC guidelines regarding the safe handling, administration, and reporting of VFC vaccines.

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

To all providers, we extend our gratitude for your interest in participating in the VFC program and for your commitment and dedication to vaccinating Arizona's children against vaccine-preventable diseases.

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

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

http://www.azdhs.gov/vfc

Bureau of Immunization Services (BIZS) Directory

BIZS Mailing Address:	Bureau of Immunization Services 150 N 18th Avenue, Suite 260 Phoenix, AZ 85007-3233
BIZS Telephone Numbers:	602-364-3642 602-364-3630
ASIIS Helpdesk Numbers:	602-364-3899 1-877-491-5741
BIZS Fax Numbers:	602-364-3276 602-364-3285 602-364-3232
BIZS Emails:	ASIISHelpdesk@azdhs.gov - General ASIIS questions, ASIIS user requests ArizonaVFC@azdhs.gov - VFC general questions, VFC issues, VFC forms ASIIS_Electronic_Reporting@azdhs.gov - HL7 and Interoperability ASIIS_Data_Quality@azdhs.gov - Data Quality Issues/Questions AIPOTrain@azdhs.gov - BIZS Training, Provider education, LMS Immunization_Records@azdhs.gov - Immunization Record Requests

VFC Overview

The Vaccines for Children (VFC) program was established by Congress in 1994 to increase access to vaccination for children who might not otherwise 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

VFC Fast Facts

- VFC benefits an estimated 40 million children
- Approximately 38,000 enrolled health care providers
- 61 VFC state, local, and territorial immunization program awardees
- Approximately 72 million VFC vaccine doses distributed in 2022

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 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 healthcare 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 20 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

NOTE: For the purposes of the VFC program, the term 'vaccine' is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program.

Immunization schedules are available on the CDC website: https://www.cdc.gov/vaccines/index.html.

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

Disease	Vaccines and other immunizing agents		Disease	Vaccines and other immunizing agents
Chickenpox	Varicella, MMRV§		Measles	MMR,** MMRV§
COVID-19	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine, SPIKEVAX®/Moderna COVID-19 Vaccine , and Novavax COVID-19 Vaccine		Mpox	Jynneos
Dengue ł	Dengvaxia		Mumps	MMR,** MMRV§
Diphtheria	DTaP,* Td,** Tdap,* Kinrix, ¶ Quadracel,¶ Pentacel,§§ Pediarix,¶¶ Vaxelis §§§		Pertussis	DTaP,* Tdap, Kinrix, ¶ Quadracel, ¶ Pentacel, §§ Vaxelis, §§§, Pediarix
Hib (Haemophilus influenzae type b)	Hib, Pentacel, Vaxelis §§§		Polio	IPV, Pentacel,§§ Pediarix,¶¶ Vaxelis §§§, Kinrix, Quadracel
Hepatitis A	HepA		Pneumococcal	PCV15, PCV20, and PPSV23
Hepatitis B	HepB, Pediarix,¶¶ Vaxelis §§§		Respiratory synctial virus (RSV)	Respiratory synctial virus (RSV) monoclonal antibody: nirsevimab Respiratory synctial virus (RSV) vaccine: Abrysvo maternal RSV vaccine
Human Papillomavirus (HPV)	HPV		Rotavirus	RV
Influenza (Flu)	IIV4 and LAIV4		Rubella	MMR,** MMRV§
Meningococcal	MenACWY, MenABCWY, MenB		Tetanus	DTaP,* Td,** Tdap,* Kinrix,¶ Quadracel,¶ Pentacel,§§ Pediarix,¶¶ Vaxelis §§§

ł Dengue vaccine is available only for endemic regions specified in current ACIP recommendations.
*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 HepB.
§§§Vaxelis is a combination vaccine containing DTaP, IPV, Hib, and HepB.
Source: Centers for Disease Control and Prevention (CDC)

VFC providers are required to comply with the immunization schedules, dosages, and contraindications commended by the ACIP unless:

- In the provider's medical judgment and in accordance with accepted medical practice, such compliance is medically inappropriate for the child.

- State law, including laws pertaining to religious and other exemptions, applies.

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 the 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.

Medicaid

Title XIX of the Social Security Act is 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 nation 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 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.

VFC Program Oversight

The VFC program is administered at the national level by the 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 city, state, or territory. NCIRD's Immunization Services Division (ISD) provides technical assistance to awardees.

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.

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.

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

VFC Administration Fees

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 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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Module 1 – Vaccine Accountability and Management Plan

- Overview
- Vaccine Accountability and Management Plan Components
- VFC Vaccine Accountability and Management Plan

Overview

All VFC providers must maintain the Vaccine Accountability and Management Plan (VAMP) that includes procedures for routine and emergency vaccine management. The VAMP 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 backup coordinators, and the office manager (if applicable)
- the signing physician, primary or backup 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 backup 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 BIZS to have an emergency VFC location that is more than 10 miles away
- documentation of training related to vaccine management
- maintaining valid calibration certificates for all primary and backup data loggers
- 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 (VAMP)

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 backup coordinators, and the office manager (if applicable) are required. Electronic Signatures are acceptable.

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

Submit a revised Vaccine Accountability and Management Plan to the BIZS (Bureau of Immunization Services) **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 vaccines 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 Information *(less than 10 miles from your 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 (BIZS)		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
	Novavax	1-855-239-9174
	Moderna	1-866-663-3762

Vaccine Storage Unit/ Data Logger Inventory

Vaccine storage and data logger	**Unit #1**	**Unit #2**	**Unit #3**	**Unit #4**	**Unit #5**
Indicate cold storage unit type: Refrigerator or Freezer					
Unit grade: -Pharmaceutical -Stand-alone -Household Dual Control					
Brand Name unit					
Unit Model number					
Last routine maintenance?					
Water bottles in unit as required? (Y/N)					
Data logger in cold storage unit (Y/N)					
Data logger Name					
Data logger Model Number					
Data logger Serial Number					
Last calibration date					
Calibration expiration date					
Location of backup data logger	Data logger Name & 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, primary or backup coordinator, or office manager must provide their initials on the individual modules of the Vaccine Accountability and Management Plan.

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

- Providers must display the Vaccine Accountability and Management Plan which includes procedures for routine and emergency vaccine management on the VFC refrigerator or freezer at all times and utilized as appropriate.
- Submit a revised Vaccine Accountability and Management Plan to the BIZS (Bureau of Immunization Services) EVERY TIME facility changes occur (including changes in staff).

VFC Program Participation Requirements (Module 2) Initials: _____

- Providers must meet the eligibility criteria required for VFC program enrollment.
- Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (annually). 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.
    - If a VFC provider fails to transfer VFC vaccines to other VFC providers, resulting in vaccine wastage, they will not be able to re-enroll in the VFC program until they have replaced the wasted vaccine from their previous termination on a dose-for-dose basis.
- 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 who cannot pay the administration fee may not be denied VFC vaccines. Sending the bill to collections is not allowed.
- Annual documented 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.

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

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

Vaccine Storage and Handling (Module 5) Initials: _____

- Providers are responsible for maintaining vaccines appropriately from the time a shipment arrives at a facility until a dose is administered to an eligible patient.
- 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 the year without overcrowding. CDC recommends the following vaccine storage unit types (in order of preference): purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units; Stand-alone refrigerator and freezer units; combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines if it has a separate temperature control for the refrigerator and freezer. A separate stand-alone freezer should be used to store frozen vaccines. CDC strictly prohibits the use of all dorm-style and bar-style units for vaccine storage.

- If a new unit is purchased, the provider office will be required to provide the BIZS with a receipt of sale for a new stand-alone unit(s) and a data logger report with five (5) full consecutive days of current in-range temperatures, after the date of purchase, before the new unit(s) can be used to store VFC vaccines.
- Each vaccine storage unit is required to have a VFC-approved data logger.
- A portable backup data logger, readily accessible in the office, is also required.
- Data logger data must be downloaded and reviewed two times per month.
- Vaccines must be stored under appropriate temperatures as described in the package inserts at all times.
- Vaccine storage unit temperatures must be monitored and documented. Information that is required when documenting a temperature reading:
    - At least one min/max temperature reading per day at the beginning of the workday.
    - Time and date of each reading.
    - Name or initials of the person who assessed and recorded the reading.
- Providers have two options for documenting temperature readings:
    - Option 1: Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location.
    - Option 2: Use a continuous temperature monitoring and recording system that allows providers to document temperature readings electronically.

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 the VFC Incident Report in an approved BIZS format and provide all applicable electronic data logger reports for each incident. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv). See (Module 6)
- Vaccines should only be transported from the physical location of a VFC provider during an emergency or 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's 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 BIZS 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.”
- Return expired/spoiled vaccines to the depot (McKesson) within six (6) months of expiration.
- All Vaccine Returns for Wasted/Expired Doses must be reported and processed through VOMS 2.0 on the reconciliation page while reconciling your inventory.
- Wasted vaccines should be disposed of appropriately, following state and local disposal requirements. 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.
- VFC providers are required to report VFC and privately administered doses to ASIIS for children 18 years and younger within 30 days. All doses must be linked to a patient. All administered doses must decrement from the ASIIS inventory.
- Providers are required to report the lot number from the box (not the vial or syringe).

Vaccine Ordering (Module 7) Initials: _____

- VFC providers are required to submit a vaccine order at LEAST once per calendar year through ASIIS.
    - Providers must order all ACIP-recommended vaccines (e.g., COVID-19, influenza) and immunizations (e.g., Nirsevimab).
- Adequate inventory of vaccines 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 must be repaid to the appropriate funding source immediately. 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. This will 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 backup vaccine coordinator should take proper steps to receive and inspect vaccine deliveries. NOTE: 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 BIZS at 602-364-3642. Vaccine deliveries should NOT be refused.
- IMMEDIATELY store vaccines in the appropriate VFC-approved cold storage unit. 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 Statements (VIS) at every immunization visit prior to the vaccines 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 Event Reporting System (VAERS).

Bureau of Immunization Services Provider Visits (Module 9) Initials: _____

- VFC providers must actively participate in all program visits; compliance visits, storage and handling, new provider/staff in-services, IQIP, and 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 costs 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, and 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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Module 2 – VFC Program Participation Requirements

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- Vaccine Coordinators
- Provider Re-Enrollment
- Provider Billing Procedures
- Provider Request for a Change in VFC Status
- BIZS VFC Forms

Overview

Being a VFC provider is a sound investment in your practice and 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 elsewhere to get the necessary vaccines, 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 four consecutive hours on a day other than a Monday to receive VFC vaccines to accommodate shipment delivery window

Providers must complete the Provider Agreement for initial program enrollment and program re-enrollment (annually). 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 healthcare 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 supervising 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 comply 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 already sees patients, they may obtain private patient demographic information from ASIIS, doses administered, provider encounter data, billing systems, or benchmarking. This information is important to order vaccines accurately.
4. Refrigerator/Freezer Verification Form – describes the cold storage unit requirements for VFC vaccines. Providers cannot order frozen vaccines without having a BIZS-approved freezer and a Refrigerator/Freezer Verification Form on file.
5. After the New Provider In-Service Visit, a data logger report with five (5) full consecutive days of current in-range temperatures must be emailed after the New Provider In-Service Visit. In-range

temperatures ensure that storage units maintain proper temperatures to maintain vaccine viability.

6. Provider Profile Change Form – identifies staff needing access removed in ASIIS or staff that will be added to ASIIS and the varying levels they may need. Access levels range from viewing immunization data, entering and editing immunization data, and reconciling and ordering VFC vaccines. All users are required to have their own unique username and password for ASIIS. Sharing passwords is prohibited.
7. Training certificates for the primary and backup VFC coordinators – primary and backup VFC coordinators are required to complete the CDC You Call the Shots (Vaccines for Children or Storage and Handling modules) or the AIPO Train (Arizona Vaccines for Children Training module)
8. Valid data logger calibration certificates for all units storing VFC vaccines and the backup data logger.
9. Completed and signed Vaccine Accountability and Management Plan; see Module 1.

Upon receipt of the completed application in a BIZS-approved format, the BIZS will process the application, and the assigned Immunization Program Specialist (IPS) will reach out to the new location to schedule a required New Provider In-Service (NPIS) 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 a VFC provider identification number (pin). Please remember the unique VFC pin assigned to your facility. You will be asked for the pin on all correspondence, orders, and inquiries to the BIZS.

Vaccine Coordinators

VFC providers are required to designate a primary vaccine coordinator and at least one backup vaccine coordinator who must be on-site for each facility. VFC primary and backup 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 (VAMP)
- Monitoring storage and handling and vaccine administration practices in the facility
- Overseeing vaccine ordering and notifying the BIZS 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. The BIZS may require a new staff in-service for new staff
- Storing all required documentation (vaccine management training documentation, patient records, etc.) for six (6) years as required by Arizona State law. Required documentation can be kept either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable.

To perform their duties effectively, the vaccine coordinator and backup coordinator must be fully trained and actively engaged in routine and emergency standard operating procedures for vaccine ordering, storage, handling, transport, and inventory management. VFC providers are required to notify the BIZS anytime there is a change in vaccine coordinator staff. If any VFC coordinator does not cooperate or respond after three (3) attempts to contact them or resolve the issue, the BIZS may contact the office manager or signing physician to seek a resolution.

Provider Re-Enrollment

Providers are responsible for re-enrolling in the VFC Program every year. The BIZS will notify providers when the re-enrollment period opens and closes. During the re-enrollment period, providers may not be able to place vaccine orders, but once the re-enrollment is approved, their vaccine-ordering privileges will be restored. The BIZS will provide instructions to providers on how to input the re-enrollment into ASIIS and provide additional instruction on any BIZS-approved data collection platform that will be used. All re-enrollments must be completed in ASIIS and a BIZS-approved data collection platform. The BIZS 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 a BIZS-approved freezer and having a Refrigerator/Freezer Verification Form on file
5) Training certificates for the primary and backup VFC coordinators – primary and backup VFC coordinators are required to complete the CDC You Call the Shots (Vaccines for Children or Storage and Handling modules) or the AIPO Train (Arizona Vaccines for Children Training module)
6) Valid data logger calibration certificates for all units storing VFC vaccines and the backup data logger
7) Completed and signed Vaccine Accountability and Management Plan, see Module 1

Providers are required to provide all required re-enrollment documents in the manner described in the re-enrollment notification. The required documents are: signed VFC Provider Agreement Signature Page, all 6 pages of the completed and signed Vaccine Accountability and Management Plan, certificates for completed annual training for the primary and backup coordinators, signed Refrigerator and Freezer Verification Form, and the valid data logger calibration certificates for all units storing VFC vaccines and the backup data logger. Upon receipt of the re-enrollment in ASIIS and the re-enrollment documents, the BIZS will review the submitted information. If the documents and ASIIS re-enrollment are complete, the BIZS will approve the application in ASIIS, and the provider will receive a message that their re-enrollment has been approved. If the documents or ASIIS re-enrollment contain errors, missing information, and/or incomplete, the BIZS will inform the provider and request corrections.

Providers who fail to re-enroll will automatically be inactivated and vaccine ordering and delivery will be discontinued. It will then be the responsibility of the provider to transfer any remaining VFC vaccines to other active VFC providers and return any equipment provided by the BIZS. Providers that were inactivated for failure to re-enroll who also fail to transfer (with prior approval from the BIZS) VFC vaccines to other VFC providers (and, as a result, wastage of VFC vaccine(s) occur) 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 via dose for dose replacement.

In addition, VFC providers who fail to re-enroll may be inactivated from the VFC program for non-compliance and may have their AHCCCS panel reassigned. The provider may be permitted to return to the VFC program by submitting a new enrollment no earlier than one (1) year after the Notice of Action.

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 guardian/patient. If a patient is enrolled in AHCCCS, providers may NOT bill the guardian/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 billing rates.

If a guardian/parent 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 to the VFC program policy could be considered fraud and abuse (see Module 10).

Provider Request for a Change in VFC Status

VFC Providers are required to update the BIZS on provider changes outlined below and may include:

- Inactivation
- New Signatory Physician
- Office Closure,
- Office Relocation,
- Other Changes)

Provider Inactivation

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

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

Providers that inactivate and 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 via dose for dose replacement.

New Signing Physician

If a VFC provider office has a new signing physician, the Provider Profile Change Form must be completed by selecting “New Signatory Physician.” A copy of the annual training certificate for the primary and backup coordinator, and an updated vaccine accountability management plan (VAMP) will be required to be completed and submitted. The BIZS may also require a new staff in-service for staff training.

Provider Relocation

If a VFC provider office is planning to relocate, the office must notify the BIZS in writing at least 30 days prior to the move. This notice will prevent shipments from going to the incorrect location. Data logger reports with five (5) full consecutive days of current in-range temperatures 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 BIZS staff before vaccine transport can occur.

Provider Closure

If a VFC provider office is closing, the office must notify the BIZS in writing at least 30 days prior to the closure. This notice will prevent any orders from being shipped. This will allow time for the provider to transfer (with prior approval from the BIZS) VFC vaccines to another VFC provider. Data loggers and any other equipment supplied by the BIZS will need to be returned to the BIZS.

Other Changes To Report

Providers must notify the BIZS of 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.

BIZS VFC Forms

All required VFC forms are kept up-to-date on our website, www.azdhs.gov/vfc. Please always submit requests and information using the most up-to-date forms and BIZS-approved platforms. 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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  - *AHCCCS as Secondary Insurance and High-Deductible Plans*
- Underinsured
- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)

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/guardian chooses to have their child vaccinated, the parent/guardian may be responsible for the vaccine administration fee if the vaccines are delivered through the VFC program. Therefore, if the child has private insurance (a 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, "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/guardians are not required to participate in the VFC program.

There are billing options for the guardian/parent and provider in this situation. The provider should choose the option that is most cost-effective for the family. The guardian/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 BIZS.

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 guardian/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 vaccine cost 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 ($21.33 is the maximum administration fee set forth by the regional Centers for Medicare and Medicaid Services (CMS)).

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 a 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/guardian 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)

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 people experiencing homelessness 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 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.

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.

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 a Medicaid-expansion Children's Health Insurance Program (CHIP), also known as 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, the 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 AHCCCSfor the administration fee because this provides the least out-of-pocket expense for the family

VFC eligibility is not generally retroactive. Contact the BIZS 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.

Temporary, Mobile, Off-Site, or Satellite Clinics

Providers should not assume a child is VFC-eligible when vaccinating in temporary, mobile, off-site, or satellite clinics. All children must be screened and their eligibility documented prior to administering VFC vaccines.

Module 4 – Arizona State Immunization Information System (ASIIS)

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- ASIIS Electronic Reporting
- ASIIS Manual Entry

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, and parents or guardians.

ASIIS Access

Each individual is required to have their own login to ASIIS and must not use other users' logins. To gain access to ASIIS and obtain a username and password, complete the Provider Profile Change Form. **Individuals who are not designated as the primary or backup VFC coordinators that would like access to ordering and inventory reconciliation are required to complete the Provider Profile Change Form and upload their CDC You Call the Shots (the Vaccines for Children or Storage and Handling module) or the AIPO Train (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 in ASIIS.

Arizona Revised Statute (A.R.S. §36-135) requires all providers to report VFC and private doses they administer to children birth through 18 years of age in ASIIS within 30 days of administration. 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.

The following information must be included for all reporting methods:

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

ASIIS Electronic Reporting

All electronic reporting providers are encouraged to utilize an HL7 upload process, allowing electronic health records (EHRs) to communicate with ASIIS, thus reducing the need to report doses into ASIIS manually. Please complete the ASIIS HL7 Data Exchange Initial Interest form for more information on how to transition to an HL7 upload process. This form can be used by providers already enrolled in ASIIS who want to connect their EHR to ASIIS to submit and query immunization data electronically. If your organization has never enrolled in ASIIS, please start your enrollment process by completing the Provider Profile Change Form. Once your ASIIS enrollment is completed, you can complete your data exchange request.

Module 5 – Vaccine Storage and Handling

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Module 5 – Vaccine Storage and Handling

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- Storage Unit Set Up
- Data Loggers
- Daily Temperature Monitoring and Recording
- Cold Storage Unit Temperatures
- Separating Pediatric Vaccine Stock
- Maintaining VFC Vaccine Viability

Overview

Vaccine loss is both costly and preventable. Providers are responsible for appropriately maintaining vaccines from when a shipment arrives at their facility until a dose is administered to a VFC-eligible patient. Vaccine appearance is **not** a reliable indicator that vaccines have been stored in the appropriate temperatures and are viable. Providers can ensure patients receive uncompromised, high-quality vaccines by following the VFC vaccine storage and handling requirements and recommendations. A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

Providers are responsible for:

- Ensuring vaccine coordinators and all staff members handling vaccines receive proper training
- Posting a Vaccine Accountability and Management Plan on a VFC cold storage unit to be accessed by all when/if needed
- Having reliable storage and temperature monitoring equipment
- 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 the administration of the vaccine to the VFC-eligible 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 healthcare providers. The BIZS strongly encourages all providers to adopt all recommendations and best practices in the Toolkit. Following the Toolkit's guidance can minimize providers' financial burden due to vaccine loss and prevent the need for revaccination. The result is maximum vaccine effectiveness and patient protection.

VFC Storage and Handling Equipment Requirements

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

- BIZS approved 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))
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current and valid Certificate of Calibration Testing for each unit, as well as at least one back-up.

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

Refrigerator and Freezer Units

Storage units must have enough room to accommodate a provider's largest inventory at the busiest point in the year without crowding.
The BIZS recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless 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, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer should then be used to store frozen vaccines. Use of the freezer compartment of a household combination unit is discouraged. 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 ice maker/freezer compartment.

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

If a provider office is purchasing new refrigerator and/or freezer units, they 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 units—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.

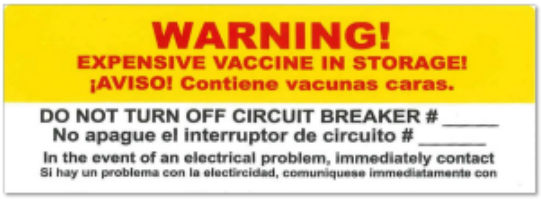
The BIZS will only ship varicella-containing vaccines to sites where the refrigerator/freezer used to store VFC vaccine is CDC/VFC approved. The VFC program does not endorse any specific refrigerator/freezer brand or manufacturer; however, units used to store VFC vaccines must meet the required specifications above. Please contact the BIZS 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 an up-to-date "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 the current contact person's name and number.



Red "caution perishable vaccine" magnets are no longer required, but the BIZS 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 calibration certificate (also known as a report of calibration or certificate of calibration) in each unit storing VFC vaccines. **Data loggers must be used during routine, on-site vaccine storage, vaccine transport (with prior approval from the BIZS), during temporary, mobile, off-site, and satellite clinics, and as a backup. Providers are required to have one data logger for each refrigerator and each freezer that stores VFC vaccine and one on-site as the backup.** In some instances, data loggers may be supplied by the BIZS.

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 or has another way of seeing the data (cloud, download, another screen away from the unit, etc.)
- 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., doorless 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 BIZS at arizonavfc@azdhs.gov on whether or not 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 are required for all data loggers monitoring temperatures in all units storing VFC vaccines as well as the backup and must include:

- Model/device number
- Serial number
- Date of calibration (report or issue date)
- Calibration expiration date (not to exceed three (3) years)
- Confirmation the instrument passed testing (or instrument in tolerance)

Calibration certificates must include at least one of the following items regarding 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. The lower data logger alarm for the refrigerator must be set to 35.9°F (1.9°C) and the upper alarm to 46.1°F (8.1°C). The lower data logger alarm for the freezer must be set to -40.0°F (-40.0°C) and the upper alarm to 5.1°F (-14.9°C).

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

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

Provider offices are responsible for ensuring all data loggers that monitor the temperatures of any VFC vaccine are sent for calibration testing by an appropriate company before the calibration expires per the calibration certificate.

Repeated data logger issues within provider offices may require staff to take training and/or vaccines may be wasted.

Daily Temperature Monitoring and Recording

Providers are required to have protocols for reviewing and documenting temperatures in each cold storage unit with at least one min/max temperature reading per day at the beginning of the workday. Providers 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:

- At least one min/max temperature reading per day at the beginning of the workday.
- Time and date of each reading.
- Name or initials of the person who assessed and recorded the reading.

Providers have two options for documenting temperature readings:

- **Option 1:** Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location.
- **Option 2:** Use a continuous temperature monitoring and recording system that allows providers to document temperature readings electronically.

Note: Not all data loggers will have the capability to record temperatures that meet the criteria for option 2. Please submit the data logger report to BIZS for approval.

Data logger data must also be downloaded and reviewed at a minimum of two times per month. This will assist you in finding any missed temperature excursions and ensure that the data logger has adequate memory.

The provider is required to enable access to all saved data logger reports to its staff (e.g., public computer drive, shared drive, external storage device, etc.). Provider staff must maintain all paper temperature logs and data logger reports for a minimum of six (6) years as required by Arizona State law. Required documentation can be kept either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable.

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 a VFC Incident Report in a BIZS-approved format and provide all applicable electronic data logger reports for each incident. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv). Consult Module 6 for Incident Reporting methods.

If a provider's office is closed for more than four (4) days, someone must come in on the fifth day and subsequent days to take at least one min/max temperature reading at the beginning of the workday or transfer the vaccine to another VFC provider before the closure occurs. Consult Module 6 for transfer 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 BIZS 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. If the HPV9 (Gardasil®9) is exposed to temperatures between 32.1°F and 35.9°F (0.1°C and 2.0°C) for more than 72 hours, it needs to be wasted. If the open IPV (IPOL®) is exposed to temperatures above 46.0°F for more than 30 minutes, it needs to be wasted.

In all instances, the provider must complete a VFC Incident Report in a BIZS-approved format and provide all applicable electronic data logger reports for each incident. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv). Consult Module 6 for the Incident Reporting methods.

Store water bottles in all refrigerators, including pharmaceutical-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 less likely to spoil if kept in the freezer. Store water bottles in all freezers, including pharmaceutical-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, during power outages and will ensure the provider is prepared for an emergency transport of vaccines as conditioned frozen water bottles are used to pack refrigerated vaccines.

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. To order VFC stickers for your provider office, complete the Immunization Forms Order Request.

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 publicly 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 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 thick. Excess frost can prevent a tight door seal
- Do not freeze diluent. Providers can call the BIZS to request additional diluent for VFC vaccines

- Rotate vaccines 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 BIZS follows the CDC Storage and Handling Toolkit, a comprehensive resource for providers on vaccine management recommendations and best practices. Please note that 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.

To ensure vaccines continue to be viable, providers are required to report all vaccine incidents to the BIZS immediately. Vaccine incidents include but are not limited to, temperature excursions, power outages (that result in out-of-range temperatures), theft of vaccines, 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 a VFC Incident Report in an approved BIZS format and provide all applicable electronic data logger reports for each incident. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv).

Vaccine Incident Reporting

Option 1: BIZS CONTACTS MANUFACTURER(S):

The provider submits a Vaccine Incident Report to BIZS and the BIZS will review the form in the order it was received, contact the manufacturers to determine vaccine viability, and notify the provider within 4-5 business days if the vaccines are viable and any next steps the provider must take. The BIZS will not be able to determine VFC vaccine viability if all documents are not received from the provider.

Option 2: PROVIDER CONTACTS MANUFACTURER(S):

The provider takes ownership of the process of contacting the manufacturers. The provider will use the Temperature Incident Instructions & Checklist, contact the manufacturers directly to determine vaccine viability, report the viability statement, submit the supporting data loggers to the BIZS, and continue the use of any viable vaccine. ***Note: The provider is responsible for disclosing any previous incidents involving the vaccine(s) to the manufacturer(s)***.

Vaccine Incidents Guidelines

If vaccines are required to be wasted due to a vaccine incident and there is **no previous history of an excursion in the unit, the provider will be required to email data logger report(s) with three (3) full consecutive days of current-in-range temperatures before an order can be placed.** Providers with a history of an incident in the unit will be required to email a data logger report with five (5) full consecutive days of current 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 BIZS with the service receipt and five (5) full consecutive days of current in-range temperatures before an order can be placed.

Providers will be required to purchase stand-alone units if a temperature excursion occurs in a household unit within three (3) months of the unit being serviced, which results in the wastage of any VFC vaccine.

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.

If a new unit is purchased, the provider office will be required to provide the BIZS with a receipt of sale for a new stand-alone unit(s) and a data logger report with five (5) full consecutive days of current in-range temperatures after the date of purchase, before the new unit(s) can be used to store VFC vaccines. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv).

If a location continues to experience unexplained temperature excursions after replacing a storage unit with a stand-alone unit, an action plan will be required.

Power-Outages

Vaccines should 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's 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 BIZS for directions and permissions.

If provider offices experience multiple vaccine incidents due to power outages, the BIZS will require a summary document from the power company, documenting the dates and times of the power outages in the provider offices' area.

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 soon-to-expire vaccine stock. Where practical, and as long as the cold chain is maintained, transfer of short-dated vaccine can occur between VFC provider locations to avoid wasting vaccine. Providers must notify the BIZS of a short-dated vaccine so that a transfer can be coordinated. This should be a rare practice if provider locations are appropriately managing inventory.

Please note: The CDC does not allow for the use of vaccine depots; therefore, provider offices cannot order large quantities of VFC vaccine for redistribution to their other VFC facilities.

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

Vaccine viability is essential for preventing vaccine-preventable diseases and the 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), including open or partial boxes

- Facilities that close temporarily (for more than 4 days) or permanently
- Emergency situations (providers will need to activate their emergency handling plan within the Vaccine Accountability and Management Plan)
- Approved Plans for a temporary, mobile, off-site, or satellite clinic. (see Off-site Clinics/Mobile Units)

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:

- **If a provider has open VFC vaccine incidents, providers are not allowed to initiate a transfer to or accept a transfer from another facility until the VFC vaccine incidents have been closed by the BIZS**

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 BIZS retains the discretion to require providers to replace vaccine doses if vaccines are transferred and the following procedures **are not** followed:

- A transfer request must be submitted to the BIZS in ASIIS by the sending facility
- Both the sending and receiving facilities must email up-to-date, in-range data logger reports to the BIZS the same day the transfer request was submitted
- The transfer request must be approved by the BIZS in ASIIS before transport can take place
- Conditioned water bottles must be used during vaccine transport of refrigerated vaccines
- All transfers must include the use of data loggers with a current and valid calibration certificate 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 BIZS management
- All data logger reports used during transport must be kept for six (6) years, either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable
- 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 VOMS 2.0 by marking the transfer as received

Off-site Clinics/Mobile Units Overview

VFC providers are allowed to include a mobile/off-site immunization clinic in their practice under certain conditions. Off-site Clinics/Mobile Units allow providers to vaccinate VFC-eligible patients at non-traditional locations such as schools and health fairs. The mobile/off-site immunization clinic is an extension of the provider's practice and will use the same unique VFC provider identification number (PIN) assigned to the provider. The mobile/off-site immunization clinic must also comply with all VFC Program requirements listed in the Provider Agreement and adhere to all general VFC Program and storage and handling requirements.

Temporary, Mobile, Off-Site, or Satellite Clinics Requirements:

1. The provider must be enrolled in the VFC Program and in good standing.
2. Mobile/off-site Immunization Clinics may only be conducted within the State of Arizona; VFC-eligible patients are not required to be Arizona residents to receive vaccinations.
3. Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement.
    - Vaccines are only transferred to the mobile unit on the day of the clinic.
4. The number of vaccines transported to a temporary, mobile, off-site, or satellite clinic should be based on the anticipated number of VFC-eligible patients to be served.
5. The provider must complete the Mobile Immunization Clinic Log that lists the clinic dates, locations, and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each mobile clinic and/or off-site location.
6. Vaccines must be transported to a temporary site using the Emergency Transport of Refrigerated Vaccines, a pharmaceutical-grade cold cube, or a BIZS-approved transport unit.
    - This includes transporting vaccines to and from the site using appropriate equipment, monitoring temperatures with a Digital Data Logger (DDL) probe in buffered material, and documenting temperatures.
    - Transport should not take longer than 30 minutes.
        - Transport longer than 30 minutes requires prior approval from the VFC Special Programs Manager each time.
7. Only staff that have knowledge of how to transport vaccines between the provider's practice and the mobile/off-site clinic should be utilized.
8. Vaccine storage and handling equipment during the mobile/off-site clinic must meet CDC requirements:
    - A portable vaccine refrigerator or qualified container and pack-out.
    - VFC-compliant DDL(s) with a probe in buffered material for temperature monitoring in each storage unit.
        - DDLs that are routinely stored outside a refrigerator or freezer should be placed in a functioning storage unit at least six hours, or the night before the clinic, to allow time for the DDL and probe to acclimate and register any issues.
9. Vaccines must be stored correctly upon arrival at the temporary site to maintain appropriate temperature throughout the clinic day.
10. Temperature data must be reviewed and documented on a temperature log every hour during the clinic using a DDL with a digital display and probe in buffered material.
11. The facility must submit data logger reports to the BIZS upon request (in an acceptable file format: .xls, .txt, .ltd, or .csv).
12. If the vaccines are exposed to out-of-range temperatures, isolate the vaccines in the affected unit, label them **DO NOT USE**, and keep them in the affected unit. Do not administer any doses exposed to out-of-range temperatures. The Bureau of Immunization Services must be notified by submitting a Vaccine Incident Report and corresponding data logger data.
13. At the end of the clinic day, temperature data must be assessed prior to placing vaccines back into storage units to prevent the administration of vaccines that may have been compromised.
14. All documentation related to vaccine management must be kept for six (6) years from the date of the last visit, either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable
15. The mobile/off-site immunization clinic must pass the storage and handling site visit; this is an initial and bi-annual requirement.
16. All immunizations administered must be entered into ASIIS within ***30*** days of administration.
17. **Plans for the temporary, mobile, off-site, or satellite clinic must be submitted to your**

Immunization Program Specialist (IPS) or ArizonaVFC@azdhs.gov for approval.

Temporary, Mobile, Off-Site, or Satellite Clinics Vaccine Handling and Preparation

- Do not draw up vaccines before arriving at the clinic site. Drawing up doses days or even hours before a clinic is not acceptable.
- Use manufacturer-filled syringes, if possible, as an alternative to pre drawing vaccines.
- Each person administering vaccines should pre-draw no more than one multidose vial (MDV) at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in pre-drawn syringes at the end of the workday.

Vaccine Borrowing

The BIZS's expectation is that vaccine borrowing will be rare, as providers should maintain adequate inventories of vaccines for both privately and publicly insured children. VFC vaccines should never be a continuous replacement system for a provider's privately purchased vaccine inventory. Borrowing of vaccines must be due to unforeseen delays or circumstances. VFC vaccines not delivered or ordered during a planned holiday do not constitute a sufficient reason to justify borrowing against privately purchased vaccines. The BIZS will not repay private doses administered to VFC-eligible patients. Additionally, hosting a temporary, mobile, off-site, or satellite clinic without appropriate amounts of public and private vaccine does not qualify for borrowing.

Borrowing activities will be monitored to ensure 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 BIZS 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 VFC-stock vaccine due to unexpected circumstances, such as a distributor and/or manufacturer shipment delay (i.e. inclement weather, limited supply from the vendor)
- VFC vaccines spoiled in transit to the provider office from the distributor and/or manufacturer
- New staff that calculated the ordering time of VFC vaccine incorrectly
- VFC seasonal influenza vaccine stock is not yet available. Provider locations may use private stock, seasonal influenza vaccine for VFC-eligible children and replace it when VFC vaccine becomes available. This one-directional borrowing is unique to seasonal influenza vaccine.

(Note: Borrowing should only occur in exceedingly rare circumstances)

Approval of borrowing reports may be subject to BIZS's discretion. Excessive use of borrowing reports may lead to the VFC provider being placed on probation for failure to comply with program policies and procedures.

Vaccine Borrowing Documentation

If any of the above instances occur, providers are required to complete a Vaccine Borrowing Report and email it to arizonavfc@azdhs.gov immediately. For COVID-19 and Nirsevimab borrowing, see Addendum: Special Considerations for COVID-19 Vaccine.

BIZS staff will adjust the inventory after receiving borrowing reports from the provider. Provider staff must **NOT** adjust the inventory in ASIIS themselves. Once the provider's inventory has been adjusted by BIZS staff, the provider's 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 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 BIZS along with the borrowing form.

Invoices

The BIZS requires a copy of the invoice validating that the privately purchased vaccine was used to replenish the borrowed VFC vaccines. The purchase invoice must include:

- Vaccine Name
- Manufacturer
- Lot Number
- Expiration Date
- National Drug Code (NDC)

The BIZS 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 vaccines, providers must:

- Remove the vaccines from any storage unit that stores viable vaccines
- Label vaccines "Do Not Use"
- All wasted/expired doses must be reported and processed through VOMS 2.0. In some circumstances, the doses must also be physically returned. Wasted/expired doses are first reported as such through the reconciliation page while reconciling your inventory.
- Once doses have been reconciled, if any doses were removed with a return category (e.g., spoiled, recalled, or expired), they will need to be processed as Vaccine Returns for Wasted/Expired Doses in VOMS 2.0
- 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

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.
- Lost or unaccountable vaccine: Vaccine for which the physical vaccine vial or syringe is missing.

Providers must remove wasted/expired doses from the ASIIS inventory monthly, at a minimum. It is recommended that wasted/expired doses be removed from the ASIIS inventory at the time of the event to ensure that the ASIIS inventory is up-to-date. The BIZS will work proactively to ensure the 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 602-364-3899 or 1-877-491-5741.

Every attempt should be made to use the VFC vaccine appropriately. If you need assistance with spoiled, wasted, or expired VFC vaccines, please contact the BIZS, do not call the manufacturer.

Reporting Administered Doses to ASIIS

VFC providers are required to report VFC and privately administered doses to ASIIS for children 18 years and younger. 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 "matches physical inventory" as a reconciliation reason.

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 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 with a return category of wasted, spoiled, recalled, or expired will need to be processed as Vaccine Returns for Wasted/Expired Doses in VOMS 2.0.

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/guardian confirming that the child's parent/guardian 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, if a new patient comes into a provider's office and the parent/guardian presents immunization records administered in the State of Texas, the provider staff, with the consent of the parent/guardian, could add the doses

administered in Texas into ASIIS as historical. Please note: doses given at your facility on a previous date **are not** considered historical.

Year-End Report Card

As a VFC provider, you have agreed to account for every VFC dose you have received. The BIZS acknowledges that providers make good faith efforts to store and handle vaccines appropriately, as outlined in this operations guide.

All VFC vaccines will need to be fully accounted for by their expiration date. Once the doses have expired and are removed from the ASIIS inventory, sites will not be allowed to go back and account for the doses. ***Arizona state law requires all pediatric vaccine records to be entered in ASIIS within 30 days of administration.***

The report cards are a quarterly review of the accounting of VFC vaccinations in ASIIS. The report cards show the number of VFC doses administered to patients as recorded in ASIIS and can help providers complete an accurate reconciliation of the VFC inventory in ASIIS. Providers will receive quarterly report cards in April, July, and October and the year-end report card in January of the following year notifying them of their current wastage percentage **per ASIIS records**.

Providers should use the Report Card to determine if staff are correctly utilizing ASIIS for VFC dose documentation. The discrepancies between provider records and ASIIS should be corrected. Also, if the potential year-end wastage is increased, the provider should take immediate action as this indicates a need for change to ensure data is submitted correctly and VFC vaccines are not wasted.

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.

Providers are encouraged to keep a 3-4 week supply of vaccine on hand, based on their anticipated VFC-eligible population and previous order history, to allow for potential shipping delays, stockouts, and manufacturing shortages. If a provider orders 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 BIZS to approve or deny the order.

Maintaining Vaccine Inventory

When establishing vaccine needs consider the following:

- Vaccine deliveries usually take 7-10 days to arrive at the provider office
- Vaccine usage patterns (e.g., increased orders during July and August for "back-to-school")
- 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 BIZS acts as the coordinating center in Arizona for federally purchased vaccines. The BIZS will notify the provider via email if there are any changes to the standard vaccine shipping routine. The BIZS will utilize the ASIIS Homepage 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 BIZS. 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.
Please note: Varicella and varicella-containing vaccines are shipped directly from Merck manufacturing, and it may take 2-4 weeks to receive them.

The CDC strives to maintain an inventory with the longest possible shelf life. In general, doses will continue to ship out until the following:

- Vaccine is <90 days from expiration for non-flu products
- Vaccine is <30 days from expiration for flu and COVID-19 products

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

Vaccine Ordering

All VFC providers are required to submit a vaccine order at least once per calendar year through ASIIS. Providers must order **all ACIP-recommended vaccines (e.g., COVID-19, influenza) and immunizations (e.g., Nirsevimab).**

The following steps are required when placing an order:

- Providers will be prompted to reconcile their doses during the ordering process on the "reconciliation" page in VOMS 2.0 if they have not reconciled their inventory within the previous 14 days
- Enter the Physical Count in the corresponding box for each vaccine. This should match the number of

doses in the cold storage. Please note: If you report vaccination records through HL7 electronically, it can take 24-48 hours for records to post and doses to decrement from your inventory

- If the Physical Count is NOT the same as the Quantity on Hand because doses have expired or were wasted, click Adjust to pull up the Adjust Quantity box. If the Quantity on Hand matches the Physical Counts, you will not need to enter a reason for adjustment
- Any administered doses removed from the ASIIS inventory using the reconciliation reasons "matches physical inventory" or "administered but chose not to be in the registry" (without proper documentation) are subject to vaccine replacement. See Module 6
- If providers need to remove expired, wasted, or spoiled doses, they can do so from the "Reconcile" page in VOMS 2.0. Providers will enter the quantity on hand number minus the number of doses that need to be removed into the "Physical Counts" box. The "Adjustment" column will show how many doses will be removed
- The appropriate Adjustment Category will need to be selected from the dropdown menu. Providers may only remove doses from the ASIIS inventory if the doses are expired, have been spoiled (e.g., 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 the inventory is **NOT** allowed. When the reconciliation inventory page is completed, please press "submit inventory" to ensure the BIZS receives the updated inventory
- Please follow the steps in the How to Reconcile Inventory in ASIIS (VOMS 2.0) job aid to complete this process
- Once providers press "submit inventory" the provider will automatically be taken to the order screen
- Select the appropriate Order Set from the dropdown
    - Select the VFC PROVIDERS order set for all ACIP-recommended VFC vaccine presentations
    - A separate order set may be needed to place orders for ACIP-recommended seasonal orders for COVID-19, influenza, and immunizations (e.g., Nirsevimab)
- Select the vaccine presentations your site needs and enter the number of DOSES your site needs to order in the "Doses Requested" column
    - if a presentation does not have a box to add an order quantity, then it is not available to order, and you will need to select a different presentation
- Verify the Delivery Hours and edit if necessary. If you have a temporary change to delivery hours, you can set temporary hours/days. Please follow the steps in the How to Create an Order in ASIIS (VOMS 2.0) to complete the process
- Every time an order is placed, providers must email data logger reports from the last recorded date 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, .ltd, or .csv) to arizonavfc@azdhs.gov
- If the BIZS does not receive provider data logger reports when the order is placed, the order may be canceled, and another order will have to be placed

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. VFC vaccine shipments 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 VFC primary or backup 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 BIZS immediately
- Check 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 NDC numbers and lot number(s) on the vaccine boxes match the packing slip
- Make 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 need to be stored separately in the refrigerator. **Do not freeze diluent**
    - COVID-19 diluents will ship separately from the vaccine
- Check 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 BIZS 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 vaccine shipment into the ASIIS inventory immediately after the vaccines arrive in the provider's office. To receive the order into ASIIS, follow the steps below:

- Log into ASIIS
- Under the "Inventory Management" Tab on the left-hand side menu, select "VOMS 2.0"
- Select "Orders & Returns" Tab, and select "Orders & Transfers" from the drop-down menu on the left
- Under the "inbound orders" heading, find the order you want to receive (highlighted in green) and click receive
- Compare the order in ASIIS to the vaccine shipment
    - Verify the Lot Number and Expiration Date and make sure it matches your packing slip; only edit the pre-filled information if there is an error
- Enter the Receipt Quantity for the vaccines that have physically arrived at your facility
    - If the vaccine has not yet arrived at your facility, leave the receipt quantity blank
    - Once the other vaccine shipment arrives, you may receive the order in ASIIS
- Click on the button that states "receive." The received vaccine quantities will be transferred to the ASIIS inventory for use
- Please follow the steps in the How to Create and Receive Transfers in ASIIS (VOMS 2.0) to complete the process

Shipment Discrepancies

It is the provider's responsibility to notify the BIZS immediately of any shipment discrepancies and if there are any issues with the order upon arrival (e.g., the order arrives broken, doses are missing, etc.)

- It is important to note any discrepancies or issues with the shipment of vaccines on the packing slip and notify the BIZS within two hours of receipt by contacting the ASIIS helpdesk at 602-364-3899 or email asiishelpdesk@azdhs.gov. The BIZS staff will determine the next course of action
- **Do not** contact the manufacturer directly regarding any VFC vaccine problems
- Carefully examine each varicella shipment packing slip to determine whether it is VFC or private stock. The box containing the varicella vaccine shipment will not be marked "VFC," so check the shipment before putting it into the freezer. Do not call the BIZS 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"
- 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

The BIZS uses comments in ASIIS to directly communicate with provider offices regarding their orders. It is important for the Primary and Backup coordinators to frequently check the ASIIS "comments" and their email boxes for any additional notifications from the BIZS.

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
    - If there is a temperature gap, your site will be notified and will have 48 hours to email the gap before the order is denied.
- The data logger temperatures are out of range
- Having an open vaccine incident
- Previous order(s) have not been received in VOMS 2.0

If orders are delayed or canceled due to missing data logger reports, the reason will be posted in the comments section within the order, and an email will be sent to the Primary and Backup Coordinator.

Module 8 – Vaccine Administration and VAERS

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- Vaccine Adverse Event Reporting System (VAERS)
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- Vaccine Administration Best Practices

Overview

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

Advisory Committee on 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:

- In the provider's medical judgment and in accordance with accepted medical practice, it is deemed such compliance is medically inappropriate; or
- 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 BIZS 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 BIZS 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 BIZS due to procurement processes, technical changes, or updates to ASIIS that require planning, clinical review, and implementation by technology staff
- BIZS leadership 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), BIZS staff may take the following actions under the authority and approval of BIZS leadership:

- 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 BIZS will honor provider preference for packaging (e.g., syringes vs. vials) whenever possible. If syringes become unavailable for an extended period of time, the BIZS will ship vials without notification to the provider. If vials become unavailable for an extended period of time, the BIZS 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 the 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. All vaccine transfer requests must be entered into ASIIS and approved by BIZS staff before vaccine transport can occur. See Module 6.

Allowing a vaccine to expire because the provider has chosen to change brands will be considered a failure to monitor the vaccine properly, and that provider may be subject to vaccine replacement. See Module 10.

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/guardian/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, laminated, or electronic VIS copies available to parents/guardians/patients. If a parent/guardian/patient asks for a paper copy, provider offices must provide the parent/guardian/patient with a paper copy. It is not necessary to have the parent/guardian/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: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

Ensure that parents/guardians/patients have a chance to have their questions answered. Give parents/guardians/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 https://www.cdc.gov/vaccines/hcp/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/guardian/patient. It is acceptable to provide a VIS before the immunization visit (e.g. by giving the parent/guardian/patient a copy to take home during the prior visit or telling them how to 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/guardian/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 patient's reaction, please report the medication error to VAERS.

All documentation related to VAERS reports must be kept for six (6) years, either on-site or off-site. If kept off-site, they must be made available within 2 hours if requested. Electronic records are acceptable.

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 vaccines or diluents
- Only use the diluents provided by the manufacturer for that vaccine as indicated in the product insert
- Vaccines should only be drawn up immediately before administration
- 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 manufacturer's 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 BIZS with the supporting documentation

Module 9 – Bureau of Immunization Services Provider Visits

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- Immunization Quality Improvement for Providers (IQIP) Visits
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  - *IQIP Strategies*
  - *Brief Overview of IQIP Process*
- Provider Survey

Overview

VFC providers are required to participate in BIZS provider visits. BIZS provider visits must be conducted by the BIZS 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 site visits
- VFC Compliance site visit
- Storage and Handling site visit (scheduled and unannounced)

New Provider Visits

The purpose of the new provider visit is to educate providers on implementing VFC program requirements and supply appropriate resources, as well as to confirm the provider can store and monitor vaccine supply according to program requirements. The assigned Immunization Program Specialist (IPS) will reach out to the new provider location to schedule a required New Provider In-Service (NPIS) training to examine the refrigerator/freezer, data loggers, and to train the provider office staff in VFC policies and procedures. These visits are scheduled at a time that is mutually agreed upon and will take approximately 1-2 hours, or longer.

Providers are required to provide valid data logger calibration certificates for all units storing VFC vaccines and the backup data logger. Prior to receiving ordering permissions, data logger report(s) demonstrating five (5) full consecutive days of current in-range temperatures must be submitted. The reports must be directly from the data logger application or in data format (.xls, .txt, .ltd, or .csv).

Providers must place an order within three (3) months of the new provider staff training to be in compliance with the VFC program and to be able to complete the required VFC compliance visit.

VFC Compliance Visits

Once at a minimum of every 24 months, and perhaps more frequently, BIZS 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 purchased with VFC funds are administered only to VFC-eligible children
- Ensure VFC vaccine stewardship and accountability

BIZS staff members and provider staff are required to follow up on corrective action plans or any necessary improvements during the VFC compliance site visit.

Note: BIZS staff will make every attempt to schedule and conduct these visits at a time that will not interrupt office practice. Every attempt will be made to schedule the visits in advance. If BIZS staff does not receive communication from a provider on their availability, the BIZS staff will schedule the visit and notify the provider of the date and time they will be at the facility to conduct the visit. 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 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 (VISs), 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 through a letter, phone call, and/or follow-up visits to ensure corrections are 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 BIZS 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.

New Staff/Education Visits

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

Immunization Quality Improvement for Providers (IQIP) Visits

IQIP Program Overview

IQIP is the Centers for Disease Control and Prevention's national, Vaccines for Children (VFC) provider-level immunization quality improvement (QI) program. IQIP promotes and supports the implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents. These strategies are designed to increase vaccine uptake among children and adolescent patients, in adherence to the Advisory Committee on Immunization Practices (ACIP) recommended routine immunization schedule.

IQIP Strategies

- Schedule the next immunization visit before the patient leaves the provider's office
- Leverage ASIIS functionality to improve immunization practices (e.g., forecasting due dates)
- Give a strong vaccine recommendation (include an emphasis on HPV vaccine)
- Strengthen vaccination communications (e.g., practice vaccination policy, ACIP immunization schedule, educational items, etc.) in new patient information packets

IQIP serves to assist and support health care providers by identifying opportunities to improve vaccine uptake, determining options for improving immunization delivery practices, and ensuring providers are:

- Aware of and knowledgeable about their vaccination coverage and missed opportunities to vaccinate
- Motivated to try new immunization service delivery strategies and incorporate changes into their current practices
- Capable of sustaining changes and improvements to their vaccination delivery services
- Able to use available data from ASIIS and/or EHRs to improve services and coverage

More detailed information about the IQIP process can be found at IQIP At a Glance|CDC.

Brief Overview of the IQIP Process

IQIP is a 12-month collaborative process where an IQIP Health Program Manager and VFC providers work together to identify QI strategies. This partnership is crucial in increasing vaccine uptake by improving and enhancing immunization workflow.

1) **Site Visit**
   - Discuss provider workflow
   - Review initial coverage
   - Select QI strategies
   - Plan for implementation of QI strategies

2) **2-month and 6-month check-ins**
   - Review progress toward strategy implementation
   - Update Strategy Implementation Plan

3) **12-month follow-up**
   - Review progress toward strategy implementation
   - Review year-over-year coverage change

The IQIP site visit usually takes approximately 1-2 hours to complete, depending on the discussion regarding provider processes and strategies.

For more information about the IQIP process or access to IQIP-ASIIS training materials, visit Immunization Quality Improvement for Providers. If you would like to request an IQIP visit, please contact the BIZS at 602-364-3642 and ask to speak to an IQIP Health Program Manager or email ArizonaVFC@azdhs.gov.

Provider Survey

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

Module 10 – Fraud and Abuse/Discipline Process

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Module 10 – Fraud and Abuse/Discipline Process

- Overview
- Addressing Provider Non-Compliance with VFC Requirements
- Appeals Process

Overview

The BIZS 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 handling VFC vaccines.

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., do not match the location's Provider Profile)
- Wasting 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 three years
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine

*This list provides examples only, and should not be considered comprehensive.

If the BIZS staff 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 followed Arizona VFC procedures as outlined in this operations guide, but the BIZS 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.

Instances of suspected noncompliance or fraud and abuse may be identified by:

- BIZS program staff
- Provider location staff
- A third party

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 provider's 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 Arizona requirements associated with the 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 BIZS 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. A site visit may be required before the probation period ends. In rare circumstances, vaccine replacement may be required at the discretion of BIZS leadership.

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 BIZS will report all instances of probation and suspected fraud and abuse to AHCCCS and, where applicable, to the CDC. The BIZS staff will monitor, document, and track actions related to the VFC program and fraud and abuse. Information supporting an allegation should be based on VFC site visits or reports and information from external sources. Information should include (at a minimum):

- Provider's name (Medicaid ID, if known)
- Address
- Source of allegation
- Date allegation reported to the VFC Program
- Description of suspected misconduct
- Specific VFC requirement(s) violated
- Descriptions and dates of the VFC program response to the allegation (i.e. education, site visit, suspension, removal of vaccines, or other action taken)
- Value of vaccines involved, if applicable
- Outcome of educational intervention, if applicable
- Outcome of the case (closed, referred, or entered into the educational process)

- Date of outcome

Appeals Process

If a provider feels that removal from the BIZS VFC Program has occurred in error, the provider may request a meeting with the Bureau of Immunization Services Bureau Chief or designee 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, Bureau of Immunization Services
Bureau Chief
150 N 18th Avenue, Suite 260
Phoenix, AZ 85007

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

Addendum: Special Considerations for COVID-19 Vaccine and Nirsevimab

This addendum to the Vaccines for Children (VFC) Operations Guide provides supplemental information and guidance related to the COVID-19 vaccine and nirsevimab in the VFC formulary.

VFC Inventory

With the exception of certain specialty providers, temporary/mobile/off-site clinics, and pharmacies, all enrolled VFC provider locations are required to procure and maintain COVID-19 vaccine inventory for the VFC populations they serve.

- In locations where providers report that demand for COVID-19 vaccine or nirsevimab is low.
    - Providers will need to order the minimum packaging of the COVID-19 vaccine and nirsevimab that is feasible.
- VFC provider locations are required to maintain an inventory of both VFC- and privately purchased vaccines based on the populations served in their facility and reflected in the Provider Profile.
- Arizona ***WILL NOT require VFC providers to meet the private inventory minimum*** requirement for the COVID-19 vaccine or nirsevimab ***if they do not intend to vaccinate their private pay patients.***
- VFC providers that plan to not maintain private stock during this season will need to:
    - Explore other in-network options for their privately insured patients to access the COVID-19 vaccine and nirsevimab (i.e., from another local in-network practice or system, Federally Qualified Health Center, Rural Health Clinic, or deputized VFC provider authorized to immunize underinsured children who do have a private inventory of COVID-19 vaccine or nirsevimab).
- If a provider serves only Medicaid-eligible and no privately insured children, they are not required to privately purchase COVID-19 vaccine.
- Specialty providers, including pharmacies and birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of vaccines based on the populations served in their facilities.
- VFC-enrolled birthing facilities offering nirsevimab should offer hepatitis B vaccine at birth, as well (and vice versa).

Eligibility Criteria

- A child's eligibility criteria for the VFC COVID-19 vaccine or nirsevimab are the same as for other VFC vaccines.

Borrowing

- VFC providers who maintain private stock of COVID-19 vaccine or nirsevimab and vaccinate privately insured children, bidirectional borrowing of COVID-19 vaccine and nirsevimab will be allowed for the 2024-2025 respiratory virus season.
- VFC providers should ensure they have funds to procure sufficient private stock before borrowing the COVID-19 vaccine or nirsevimab from VFC stock for a non-VFC-eligible child.
- Borrowing is only applicable if the provider is purchasing private stock and is approved only for instances when:
    - There is a lack of vaccine stock because of delayed or spoiled shipments.
    - As part of the initial setup of private purchasing contracts and ordering systems, there

has been a delay in the provider's ability to procure private stock of COVID-19 vaccine or nirsevimab.
    - Vaccines will expire soon and will be lost if not used.
    - Provider locations with a small privately insured patient population can use this option to administer a short-dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated VFC dose.
    - New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.
- Borrowed COVID-19 vaccine or nirsevimab must be repaid (dose for dose) within 1 month or after five doses borrowed and administered to the appropriate population (i.e., if VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a VFC-eligible child).
- The BIZS will receive a borrowing report and proof of privately purchased doses that include the number of doses, lot numbers, and documentation that authenticates doses returned or doses repaid were administered to the appropriate recipients. See Module 6 - Vaccine Borrowing Documentation.

Definitions and Acronyms Used in this Guide

ACIP	**Advisory Committee on Immunization Practices**
AHCCCS	**Arizona Health Care Cost Containment System**
ASIIS	**Arizona State Immunization Information System**
BIZS	**Bureau of Immunization Services**
Backup 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 that 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 that electronically documents patient medical information**
Facility ID	**A unique identifier assigned by the BIZS when a facility is registered in ASIIS**
IRMS	**The organization account number. An IRMS (organization) can have multiple facilities**
IQIP	**Immunization Quality Improvement for Providers program (IQIP)**
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

1vCOV-mRNA	Monovalent mRNA COVID-19 vaccine (Comirnaty®/PfizerBioNTech COVID-19 vaccine, SPIKEVAX®/Moderna COVID-19 Vaccine)
2vCOV-mRNA	Bivalent mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine)
1vCOV-aPS	Adjuvanted, protein subunit COVID-19 vaccine (Novavax)
DTaP	Diphtheria and tetanus toxoids and acellular pertussis vaccine, pediatric formulation (replaced DTP)
DTaP-HepB-IPV	Diphtheria, tetanus, acellular pertussis, hepatitis B, and inactivated poliovirus combination vaccine (Pediarix®)
DTaP-IPV/Hib	Diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and Haemophilus influenzae type b combination vaccine (Pentacel®)
DTaP-IPV	Diphtheria, tetanus, acellular pertussis and inactivated poliovirus combination vaccine (Kinrix®, Quadracel®)
DTaP-IPV-Hib-HepB	Diphtheria, tetanus, acellular pertussis, inactivated poliovirus, Haemophilus Influenzae type b, and hepatitis B combination vaccine (Vaxelis®)
HBIG	Hepatitis B Immune Globulin (hospitals only)
HepA	Hepatitis A
HepB	Hepatitis B
Hib	*Haemophilus influenzae* type B
HPV	9-valent HPV vaccine (Gardasil®)
IPOL	Inactivated Polio Vaccine (also known as IPV)
LAIV	Live Attenuated Influenza Vaccine (Nasal Spray)
LAIV4	Live, Attenuated Influenza Vaccine (Quadrivalent)
MCV4	Meningococcal Conjugate Vaccine4-valent
MenACWY-TT	Meningococcal Conjugate Vaccine, Quadrivalent (MenQuadfiTM)
MenACWY-CRM	Meningococcal Conjugate Vaccine, Quadrivalent (Menveo®)

MenACWY-D	Meningococcal Conjugate Vaccine, Quadrivalent (Menactra®)
MenB	Meningococcal Serogroup B
MMR	Measles, Mumps, Rubella
MMRV	Measles, Mumps, Rubella/Varicella
Nirsevimab	A monoclonal antibody against Respiratory Syncytial Virus (RSV)
PCV15	Pneumococcal Conjugate Vaccine 15-valent
PCV20	Pneumococcal Conjugate Vaccine (20-valent)
PPSV23	Polysaccharide Pneumococcal Vaccine 23-valent
Rota	Rotavirus vaccine 5-valent or 1-valent
QIV	Quadrivalent Influenza Vaccine
Tdap	Tetanus, diphtheria & acellular pertussis vaccine, adult/adolescent formulation
Td	Tetanus & diphtheria Vaccine, adult/adolescent formulation
VAR/VZV	Varicella (chickenpox)

VFC Resources

State Websites

Arizona Vaccines for Children (VFC) Program:
azdhs.gov/vfc

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

CDC Vaccines for Children (VFC) Operations Guide:
https://www.cdc.gov/vaccines/programs/vfc/downloads/operations-guide-508.pdf

Advisory Committee on Immunization Practices (ACIP):
https://www.cdc.gov/vaccines/acip/index.html

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

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:
http://www.immunize.org/

Vaccine Manufacturers

AstraZeneca:
https://www.astrazeneca-us.com/

Dynavax:
https://www.dynavax.com/

Grifols:
https://www.grifols.com/en/home

GSK:
https://us.gsk.com/en-us/

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

Moderna:
https://www.modernatx.com/

Novavax:
https://www.novavax.com/home/usa

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

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

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

Bureau of Immunization Services

Contact Information:

Main Line: 602-364-3630

Vaccine Center: 602-364-3642
Email: ArizonaVFC@azdhs.gov - VFC Issues, Vaccine Incidents, VFC Forms

ASIIS Help Desk: 602-364-3899
Email: ASIISHelpDesk@azdhs.gov - General ASIIS Questions, ASIIS Enrollment, User Requests

ASIIS_Electronic_Reporting@azdhs.gov - HL7 and Interoperability Questions
ASIIS_Data_Quality@azdhs.gov - Data Quality Issues Questions
AZIDR@azdhs.gov - IDR questions, School and Daycare Requirements
AIPOTrain@azdhs.gov - BIZS training, Provider Education
Immunization_Records@azdhs.gov - Immunization Record Request, Patient Account Changes

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

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