ARKANSAS DEPARTMENT OF Health

Keeping Your Hometown Healthy

Arkansas

Vaccines for Children Provider Staff Training Manual

Vaccines for Children Program
Arkansas Department of Health
Immunization Section
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Vaccines for Children Provider Guide
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For Immunization questions and WebIZ assistance, call the Immunization Program Help Desk. For VFC questions, contact your regional VFC Representative.

Immunization Program Help Desk	PHONE: 501-574-4040 FAX: 501-661-2300

VFC/IQIP Representatives

NAME-ADDRESS-REGION	EMAIL ADDRESS	PHONE NUMBERS	FAX NUMBER
Southwest Region Susan Carter 702 Hornbeck Ave Polk County LHU Mena, AR 71953	susan.carter@arkansas.gov	479.394.2707 870.807.0601 Cell	479.394.6610
Southeast Region Jamie Martin 940 Scogin Drive Monticello, AR 71655	jamie.l.martin@arkansas.gov	870.367.6234 870.224.1439 Cell	870.460.6210
Central Region Alicia Clark 1425 Malvern Ave Hot Springs, AR 71901 Garland County LHU	alicia.clark@arkansas.gov	501.624.3394 501.249.8485 Cell	501.624.2706
Northeast Region VACANT		870.273.3564 Cell	
Northwest Region-Central Erin Conard 402 Hailey Road Berryville, AR 72616 Carroll County LHU	erin.conard@arkansas.gov	870.423.2923 870.204.4777 Cell	870.423.5315
Northwest Region-West Gina Cox 203 Weir Road Russellville, AR 72802	gina.cox@arkansas.gov	479.968.6004 479.264.9551 Cell	479.964.0928
Arkansas VFC Coordinator **VACANT** 4815 West Markham St., Slot 48 Little Rock, AR 75502		501.537.8969	501.661.2300

Sample VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

FACILITY INFORMATION			
Facility Name:			VFC Pin#:
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address (*if different than facility address):*			
City:	County:	State:	Zip:

MEDICAL DIRECTOR OR EQUIVALENT		
Instructions: *The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.*		
Last Name, First, MI:	Title:	Specialty:
License No.:	Medicaid No:	NPI #
Provide Information for second individual as needed:		
Last Name, First, MI:	Title:	Specialty:
License No.:	Medicaid No.:	NPI #

VFC VACCINE COORDINATOR	
Primary Vaccine Coordinator Name:	
Telephone:	Email:
Completed annual training: ○ Yes ○ No	Type of training received:
Back-Up Vaccine Coordinator Name:	
Telephone:	Email:
Completed annual training: ○ Yes ○ No	Type of training received:

PROVIDERS PRACTICING AT THIS FACILITY *(additional spaces for providers at end of form)*

Instructions: *List below all licensed health care providers (MD,* DO, *NP, PA, pharmacist) at your facility who have prescribing authority.*

Provider Name	Title	License No.	Medicaid No.	NPI Number

PROVIDER AGREEMENT	
To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:	
1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories: A. Federally Vaccine-eligible Children (VFC eligible) 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid; 3. Have no health insurance; 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non- covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement. B. State Vaccine-eligible Children 1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317-funded doses) to such children. 2. Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible) are **not** eligible to receive VFC-purchased vaccine.
3.	For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless: a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions
4.	I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6.	I will not charge a vaccine administration fee to non-Medicaid federal vaccine-eligible children that exceeds the administration fee cap of $19.54 per vaccine dose. I will not charge a vaccine administration fee to non-Medicaid state vaccine-eligible children that exceeds the administration fee cap of $9.56 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

7.	I will not deny administration of publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	I will comply with the requirements for vaccine management including: a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Arkansas Department of Health Immunization Program storage and handling requirements; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration
10.	I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: **Fraud:** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law. **Abuse:** provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Arkansas Department of Health Immunization Program to serve underinsured VFC-eligible children, I agree to: a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit; b) Vaccinate "walk-in" VFC-eligible underinsured children; and c) Report required usage data Note: *"Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.*
13.	For pharmacies, urgent care, or school located vaccine clinics, I agree to: a) Vaccinate all "walk-in" VFC-eligible children and b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee. Note: *"Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.*

14.	All providers shall report to the Department of administration of any childhood immunization to any person under twenty-two years of age. 1. A Department approved format for reporting of data shall be used by all Providers to report immunizations given. 2. Providers shall submit information on immunization provided within two weeks of administration. 3. When reporting immunization, previous unreported doses shall also be reported to provide a complete immunization history to the registry. 4. Failure to report shall result in the Department contacting the Provider to encourage compliance. Continued non-compliance may result in sanctions not to exceed $25.00 and/or removal from the Vaccines for Children (VFC) program.
15.	I understand this facility or the Arkansas Department of Health Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Arkansas Department of Health Immunization Program.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.	
Medical Director or Equivalent Name (print):	
Signature:	Date:
Name (print) *Second individual as needed*:	
Signature:	Date:

Clinic Hours-These are the times your vaccines can be safely delivered:

Mon Tues Wed Thurs Fri

Sat Sun Closed for Lunch between: _____

Sample Vaccines for Children (VFC) Program
Provider Profile Form

All health care providers participating in the Vaccines for Children (VFC) program must complete this form annually or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

Date: _____/__ ___/ _____ _ ___ **Provider Identification Number#**_____

FACILITY INFORMATION		
Provider's Name:		
Facility Name:		
Vaccine Delivery Address:		
City:	**State:**	**Zip:**
Telephone:	**Email:**	

FACILITY TYPE (select facility type)

Private Facilities	Public	
☐ Private Hospital	☐ Public Health Department Clinic	☐ STD/HIV
☐ Private Practice (solo/group/HMO)	☐ Public Health Department Clinic as agent for FQHC/RHC-deputized	☐ Family Planning
☐ Private Practice (solo/groups as agent for FQHC/RHC-deputized)	☐ Public Hospital	☐ Juvenile Detention Center
☐ Community Health Center	☐ FQHC/RHC (Community/Migrant/Rural)	☐ Correctional Facility
☐ Pharmacy	☐ Community Health Center	☐ Drug Treatment Facility
☐ Birthing Hospital	☐ Tribal/Indian Health Services Clinic	☐ Migrant Health Facility
☐ School-Based Clinic	☐ Woman, Infants and Children	☐ Refugee Health Facility
☐ Teen Health Center	☐ Other_____	☐ School-Based Clinic
☐ Adolescent Only Provider		☐ Teen Health Center
☐ Other_____		☐ Adolescent Only

VACCINES OFFERED (select only one)

☐ All ACIP Recommended Vaccines for children 0 through 18 years of age.

☐ Offers Select Vaccines (**This option is only available for facilities designated as Specialty Providers by the VFC Program)**

A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g., OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0-18. Local health departments and pediatricians are not considered specialty providers. The VFC Program has the authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.

Select Vaccines Offered by Specialty Provider:

○ DTaP	○ Meningococcal Conjugate	○ TD
○ Hepatitis A	○ MMR	○ Tdap
○ Hepatitis B	○ Pneumococcal Conjugate	○ Varicella
○ HIB	○ Pneumococcal Polysaccharide	○ Other, specify:
○ HPV	○ Polio	
○ Influenza	○ Rotavirus	

PROVIDER POPULATION

Provider Population based on patients seen during the previous 12 months. *Report the number of children who received vaccinations at your facility, by age group. Only count a child once based on the status at the last immunization visit, regardless of the number of visits made. The following table documents how many children received VFC vaccine, by category, and how many received non-VFC vaccine.*

VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or Deputized Facility[1]				
Total VFC:				
Non-VFC Vaccine Eligibility Categories	**# of children who received non-VFC Vaccine by Age Category**			
	<1 Year	**1-6 Years**	**7-18 Years**	**Total**
Insured (private pay/health insurance covers vaccines)				
Other Underinsured[2]				
Children's Health Insurance Program (CHIP)[3]				
Total Non-VFC:				
Total Patients (must equal sum of Total VFC + Total Non-VFC)				

[1]Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance.
In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate these underinsured children.
[2]Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.
[3]CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION (choose all that apply)

- ○ Benchmarking
- ○ Medicaid Claims
- ○ IIS
- ○ Other (must describe):
- ○ Doses Administered
- ○ Provider Encounter Data
- ○ Billing System

Provider Training on VFC Provider Requirements

A provider's understanding of how the VFC Program works is critical to maintaining the integrity of the program. The initial enrollment visit is conducted by the Arkansas Vaccines for Children (VFC) Regional Representative. Providers are responsible for training all other appropriate office staff. Follow-up training can be provided by the VFC Representative upon request.

As a VFC provider, it is a federal requirement that you have certain written immunization policies (on immunization staff assignments, emergencies, ordering and receiving vaccine, monitoring vaccine inventory, storing and handling vaccine, and vaccine wastage). You can use this training manual to fulfill most of this requirement if:

1) Your vaccine manager and backups read this training manual. In addition, consider having all staff whose work relates to immunizations read this overview.
2) You complete or customize the routine and emergency storage and handling templates to reflect your office practice or develop your own. If you develop your own vaccine management plan, it must be approved by the VFC Program. Both plans should be reviewed and updated by the clinic staff annually and any time there is a change in contacts, staff, or protocols. All staff members who handle VFC vaccines should be aware of this plan, which should be posted on or near the refrigerator. Ensure that all staff (current, new, and temporary) read the plan and understand it. Also ensure that janitorial and security staff are aware of the plan and know the procedures to follow to notify designated personnel about any problems with the vaccine storage equipment or power outages. A log should be kept to document and track training.

Annually, the primary and backup vaccine managers must complete the two CDC "You Call the Shots" trainings online:

1) You Call the Shots: Vaccines for Children
2) You Call the Shots: Storage and Handling

These trainings are located at https://www.cdc.gov/vaccines/ed/youcalltheshots.html.
One Continuing Education (CE) credit is provided for each training.
The primary and backup vaccine managers must print and keep the certificate on file in the clinic and be able to show the certificate upon request.
Many other free CE credit courses are also available on this web page.

VFC PROGRAM STAFF TRAINING

1 Overview

VFC Basics

The federal Vaccines for Children (VFC) Program was created to increase access to immunizations outside of public health departments to allow eligible children to remain in their medical homes for immunization services to the extent possible. The program was designed to help raise childhood immunization levels by providing vaccines at no charge to VFC providers to administer to eligible children. Federal law established the VFC program and set the policies that govern it. This training manual simplifies AR VFC requirements in a way we hope will be clear and workable for you. For that reason, it does not try to cover the full range of immunization best practices and recommendations, though we refer you to many other resources that do.

VFC Program Highlights

- Provides vaccine for eligible children at no charge to VFC-enrolled providers.
- Covers vaccines recommended by the ACIP
- Saves parents and enrolled providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to vaccinate eligible children.
- Reduces the practice of referring children for vaccination.

Vaccines Available Through the VFC Program

Currently, the ACIP includes in the Vaccines for Children program vaccines and/or combination vaccines which are used to prevent the following 16 diseases and to be administered as provided in the VFC resolutions found at:
http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html:

Diphtheria
Haemophilus influenzae type b (Hib)
Hepatitis A
Hepatitis B
Human Papillomavirus (HPV)
Influenza (flu)
Measles
Meningococcal disease
Mumps
Pertussis (whooping cough)
Pneumococcal disease
Polio
Rotavirus
Rubella (German measles)
Tetanus (lockjaw)
Varicella (chickenpox)

VFC Provider Enrollment Form

The Provider Enrollment form is a legally binding agreement that must be completed every 2 years. When you sign it, you are agreeing to comply with all the points listed on the form and with the appropriate immunization schedules, dosage, and contraindications established by state and federal recommending groups such as the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, and the American Academy of Family Physicians. All health care providers providing VFC vaccine should be listed on the form and must agree to comply with program requirements. It is necessary to include the Medicaid National Provider Identifier (NPI) number, medical license number, and an e-mail contact address for the clinic. If health care providers practicing at the clinic change during the year, it is the responsibility of the medical facility to contact the VFC Program to update the Provider Enrollment Form. Hospitals enrolled to provide hepatitis B vaccine at birth do not have to list all physicians but may include the medical director, or equivalent, to represent all physicians.

Annual VFC Provider Profile

The Provider Profile is used to establish the number of VFC eligible children served by the facility for a one-year period. When enrolling in the VFC Program for the first time, an estimated number of children must be provided on the VFC Provider Profile. Annually thereafter, the VFC Provider Profile form must be completed using data from the previous 12 months. Provider Profile data should be obtained from the clinic electronic medical record or from the Arkansas IIS, if all vaccination information is entered into the IIS. This vaccination information must include the vaccine name, patient VFC eligibility status at the time of vaccination and the vaccine funding source administered. The WebIZ Provider Profile report may not be used if all of this information is not entered for each vaccination. The Provider Profile should be updated if the needs of the facility change (e.g., change in number children seen by clinic).

VFC Eligibility

Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the ACIP through the passage of VFC resolutions. All children less than 19 years of age who meet one of the following criteria are considered VFC eligible:

- American Indian or Alaskan Native--as defined by the Indian Health Services Act (eligible to participate in the VFC program regardless of insurance status);
- Enrolled in Medicaid (or qualifies through ARKids First);
- Uninsured (has no health insurance); or
- FQHCs/RHCs and LHUs ONLY: Underinsured—defined as children who have commercial (private) health insurance but the coverage does not include vaccines, or covers only selected vaccines (VFC eligible for non-covered vaccines only), or caps vaccine coverage at a certain amount (once that coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccine only through a FQHC, or RHC, or a local health unit (LHU). Underinsured children are not eligible to receive VFC vaccine at private medical provider offices and should be referred to an FQHC, RHC, or an LHU.

Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs): For the purposes of the VFC Program, FQHCs and RHCs are defined as those health care facilities that are:

community-based, and owned by a nonprofit public benefit organization, exempt from taxation under Section 501(c)(3) of the Internal Revenue Service Code, exempt from state franchise or income tax by the Franchise Tax Board, and licensed by the Arkansas Department Human Services as a CHC/FQHC.

2 Basic VFC Provider Responsibilities

Screen and Document VFC Eligibility

Screening to determine a child's eligibility must take place with each immunization visit prior to obtaining the vaccine from the refrigerator/freezer. Document a child's current eligibility status in the AR immunization registry with each immunization encounter. VFC-public purchased vaccine should be administered only to children who are VFC eligible. SCHIP vaccine should be administered only to children who are SCHIP eligible (if applicable). Private vaccine should be administered to any insured child and any patient 19 years of age or older. The screening and documentation eligibility requirement will be monitored by AR VFC staff during the VFC site visit by conducting a random sample. Consider posting a Vaccine Eligibility Reminder sign (Appendix on page 32) on your vaccine storage units.

Occasionally, children may have more than one eligibility category. Select the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations. Children who have Medicaid as secondary insurance are VFC-eligible. You may choose the option of administering VFC vaccine and billing Medicaid for the administration fee or, if the child's primary insurance includes full immunization benefits and no out-of-pocket expense for the parent, you may opt to use private stock vaccine and bill the private/primary insurance for the cost of the vaccine. You MUST NOT administer VFC vaccine and bill the private/primary insurance for the cost of the VFC vaccine.

If a clinic is not a FQHC, RHC, or a local health department and the patient has insurance, advise the patient/parent there are places to receive no or low-cost vaccines if they are not sure if vaccinations are covered. Note: Children with insurance that covers the cost of vaccinations are not eligible through the VFC program, even when that coverage requires a deductible.

Charge Only Allowable Fees

There are three costs associated with each immunization, the cost of the vaccine, administering the vaccine, and the office visit. Because some children may qualify for VFC and also have private insurance, ensure that billing can determine when VFC vaccine is given. Clinics cannot bill for cost of VFC vaccine. This can be considered fraud and abuse. During the site visit, the provider must be able to explain or demonstrate how much the practice charges.

The administration fee for a VFC vaccine is per vaccine and not per antigen. Clinics must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans for Medicaid VFC-eligible children. Do not charge a vaccine administration fee to a non-Medicaid VFC-eligible child that exceeds the administration fee cap of $19.54 per vaccine dose. If the patient is unable to pay this fee, it must be removed from the bill. Having these fees go to collections is not acceptable. The only fee that must be waived is the vaccine administration fee. Other visit or office fees may be charged as applicable. Do not deny the administration of a federally-purchased vaccine (VFC vaccine) to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee. Note: FQHC, RHC and LHUs must agree to serve underinsured VFC-eligible children and to vaccinate all "walk-in" VFC-eligible children.

For VFC-eligible Medicaid patients, providers must document the correct CPT code(s) when billing Medicaid for the administration fee on the claim form for each immunization administered in order to receive reimbursement for the administration of a vaccination(s) from VFC stock. An office visit or an EPSDT screening visit may be billed in addition to vaccination administration fees. For questions, clinics may contact the Medicaid Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and Out-of-State at (501) 376-2211.

Report Vaccine Borrowing

Providers who care for VFC-eligible and privately-insured children are expected to maintain two separate adequate inventories of publicly-purchased VFC vaccine and privately-purchased vaccine. Enter all vaccine doses received into the immunization registry inventory as either VFC or private. Physically label vaccine accordingly. Borrowing between the vaccine inventories may occur but it must be a rare occurrence. VFC eligible children should receive VFC vaccine (public vaccine) and non-VFC eligible should receive private vaccine unless the dose is a borrowed dose or a replaced dose. All borrowing regardless of direction must be documented on the AR VFC Borrowing Report either electronically in WebIZ or on the paper form (Appendix on pages 56-57). The paper VFC Borrowing Report must be used if vaccination information is incorrect in WebIZ or not updated with each vaccination encounter (includes patient VFC eligibility at the time of vaccination and vaccine funding source administered).

The borrowing of vaccine must be due to unforeseen delay or circumstance surrounding the vaccine that was ordered. VFC vaccine cannot be used as a replacement system for a provider's privately-purchased vaccine inventory. Borrowing VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing can occur only when there is a lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to a provider, or new staff that calculated ordering time incorrectly.

Please note: For seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine. For all other vaccines, limited borrowing may occur bi-directionally.

Two-way borrowing can be used by a VFC-enrolled provider with a patient population that is mostly VFC-eligible and has only a small number of privately-insured children in order to prevent loss of privately-purchased vaccine due to expiring vaccine. Privately-purchased vaccine that is short dated may be "borrowed" and administered to a VFC-eligible child and the borrowed dose replaced with a longer-dated VFC dose. This borrowing may occur to prevent vaccine loss due to the vaccine reaching the expiration date. Please remember that this type of "borrowing" must be documented on the VFC borrowing report.

For each borrowed vaccine a patient receives, all of the following must be documented: vaccine name, patient's name OR unique patient ID, private, SCHIP, or VFC stock borrowed (each vaccine listed on a separate row), patient's date of birth, date vaccine borrowed; reason vaccine borrowed, date vaccine paid back to the VFC, SCHIP or private stock, and provider signature certifying accuracy and compliance with VFC requirements. Doses should be repaid as soon as possible and not to exceed 90 days. As soon as the doses

of vaccine are replaced to the appropriate vaccine stock, enter the replacement date on the VFC Borrowing form.

Borrowing reports must be kept by the provider as part of the VFC program records for 3 years. The reports should be made available to the VFC staff during the VFC Site Visit or upon request by the AR Immunization Program. The State may ask for information validating that borrowed VFC vaccine was replaced by asking for a copy of the invoice for the privately-purchased vaccine used to replenish the borrowed VFC vaccine; the invoice date should correspond with the replacement date on the borrowing report.

Administer Vaccines per ACIP Schedule

Providers who provide medical services for children less than 19 years of age shall administer all vaccines recommended by the ACIP and shall comply with the immunization schedule, dosage, and contraindications that are established by the ACIP and included in the VFC program unless: a.) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate. b.) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

The ACIP issues resolutions by vaccine type following licensure and/or as recommendations for usage change. VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine availability and usage. VFC vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. These consolidated resolutions are placed on the VFC website soon after ACIP approval and are found at:
http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html

Each year, the ACIP publishes immunization schedules which summarize recommendations for routine vaccines. Vaccines and/or combination vaccines and schedules regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines are included in the ACIP recommendations. ACIP schedules can be found at:
http://www.cdc.gov/vaccines/schedules/index.html

TIP: Consider signing up for automatic notification of updates:
http://www.cdc.gov/Other/emailupdates/

All recommended vaccines for a provider's patient population must be kept in supply and made available to eligible patients. Licensed combination vaccines (such as Pediarix, Pentacel, etc.) may be used when at least 2 components of the combination are indicated and the vaccine's other components are not contraindicated. Doses not given at the recommended age should be given at any future visit when indicated and feasible. Consult the manufacturers' package inserts for detailed recommendations and contraindications. Providers who provide specialty medical services for children or adolescents shall administer all vaccines recommended by the ACIP as appropriate for the type of care provided. Vaccines that are recommended by the ACIP but are not routine, such as PPSV23 and Men B, should be made available to patients as needed. These non-routine can be stocked by the clinic or ordered as needed through the AR Vaccine Management Team.

Medical exemptions - A physician statement outlining medical reasons for an exemption of a specific immunization is to be submitted to the Medical Director of the Immunization Section. The Medical Director will decide whether to grant the medical exemption based on the CDC guidelines. PLEASE NOTE: Incomplete forms will be returned for completion. A new exemption form must be completed every school year.

Philosophical exemptions - Philosophical exemptions can be granted for children on the grounds that such immunization conflicts with the religious and or philosophical tenets or beliefs. PLEASE NOTE: The form requires a signature and seal of a Notary Public. Incomplete forms will be returned for completion. A new Exemption Form Must Be Completed Every School Year.

To obtain an exemption form, go to https://www.healthy.arkansas.gov/programs-services/topics/immunizations or email the ADH Immunization Section at immunization.section@arkansas.gov.

Web link for Arkansas Immunization Requirements - for colleges, schools, and daycares:
https://www.healthy.arkansas.gov/images/uploads/rules/ImmunizationRequirements.pdf

Immunization Documentation

The National Childhood Vaccine Injury Compensation Act (NCVIA) of 1986 established a "no-fault" system to compensate children and their families following adverse events associated with childhood immunization. NCVIA also established documentation standards for immunization providers, mandated the use of Vaccine Information Statements, and mandated the reporting of certain adverse events following vaccination. Federal law requires that, for all vaccines covered by the NCVIA, regardless of the funding source (public or private), providers must record the following information for each dose of vaccine administered:

- The type of vaccine
- The vaccine manufacturer and lot number
- The date administered
- The name, office address and title of the person who administers the vaccine
- The edition date of the VIS (found on the bottom corner)
- The date the VIS is provided

Vaccine Information Statements (VIS)

Vaccine Information Statements are CDC fact sheets that inform vaccine recipients, or their parents or legal representatives, of the benefits and risks of a vaccine. The law applies to all doses of vaccine covered by the NCVIA program and administered by a provider, whether VFC vaccine or privately purchased. Some of the legal requirements for providers regarding the use of VISs are as follows:

- Before vaccinating a child with a dose of any routine childhood immunization, provide a copy of the most current VIS available for that vaccine to the child's parent/legal guardian or the patient.
- The parent/guardian must be given time to read the VIS prior to administration of the vaccine and have a chance to have their questions answered.
- You must offer the parent/guardian a copy of the VIS to take home after the immunization is given every time a dose in a vaccine series is given, even if the child has received previous doses of the same vaccine.

- You must record the date the VIS was given in the patient's chart (date of administration) and the publication date of the VIS (at bottom of the VIS).
- CDC's "multi-vaccine" VIS may be used as a substitute for any or all of the VISs for routine vaccines given from birth through six months: DTaP, IPV, Hib, PCV, and Hepatitis B.
- When possible, provide the VIS in the person's native or preferred language. Translated VISs are available on the web at no charge at VISs in different languages can be found on the Immunization Action Coalition website:
  http://www.immunize.org/vis/
- Providers should have a process to frequently check for updated VIS forms on the CDC website. VIS forms can be downloaded as a .pdf file and printed:
  https://www.cdc.gov/vaccines/hcp/vis/index.html

Report Adverse Events

Report any clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. VAERS is a national vaccine safety monitoring program. By reporting possible vaccine side effects to VAERS, you provide valuable information that is needed for the ongoing evaluation of vaccine safety. The CDC and FDA use VAERS information to ensure the safest strategies of vaccine use and to further reduce the rare risks associated with vaccines.

You may submit information by phone, by fax, or through the VAERS website. For more information or for a copy of the form and help completing it, call VAERS at 800-822-7967 or visit: http://vaers.hhs.gov/index. A VAERS form is also available on WebIZ.

Be Prepared to Manage Vaccine Side Effects

Most people experience no side effects, or only mild ones, following immunization. Severe side effects, such as severe allergic reactions, following vaccination are extremely rare. However, any provider who administers vaccines should have procedures in place for the emergency care of a person who experiences an anaphylactic reaction.

Consider posting an emergency plan for managing vaccine reactions. For an example of a protocol, see Medical Management of Vaccine Reactions in Children and Teens and Medical Management of Vaccine Reactions in Adult Patients by the Immunization Action Coalition:
http://www.immunize.org/handouts/vaccine-reactions.asp

AR Immunization Registry/WebIZ

Immunization providers are to abide by Arkansas Code Annotated §§20-15-1201 – 1203 which mandates reporting of immunizations given to individuals less than 22 years of age to the immunization registry. Although real time documentation is always the best practice, providers must submit information on immunizations provided within two weeks of administration.

Maintain Records

All records related to the VFC program must be maintained for a minimum of three years and made available to public health officials, including AR Department of Health upon request.

Practice Changes

VFC-enrolled providers may be notified about changes to the VFC program via email, fax, phone calls, and/or registry notifications. Any changes to the VFC contact, physicians, address, phone number, office hours or patient eligibility numbers should be reported to the Arkansas VFC Program immediately.

Communicable Disease Reporting

Health care providers are required to report cases of certain diseases (suspected or confirmed) immediately to the Arkansas Department of Health. For a list of reportable diseases and contact information, see "Instructions for Reporting Communicable Diseases to the Arkansas Department of Health" https://www.healthy.arkansas.gov/images/uploads/pdf/List_and_Instructions_Reportable_Diseases_2017.pdf

3 Vaccine Management

Elements of Vaccine Management

Vaccines must be maintained properly to protect their viability prior to administration. Adhering to proper storage and handling procedures will minimize vaccine loss, waste and the potential need to revaccinate that may result from administration of compromised vaccine. The required and recommended vaccine management and storage and handling policies of the VFC program are based on guidance from CDC's *Vaccine Storage and Handling Toolkit* and other relevant resource materials developed for proper vaccine management. This guidance is intended as the approved standard of care for all public and private sector providers and can be found at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Minimum elements required for VFC provider participation are outlined below:

- Designate one staff member to be the primary vaccine manager and at least one back-up vaccine manager who is able to perform the same responsibilities in the event that the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office.
- The designated vaccine manager and back-up must be responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended ranges and documenting the temperature on the temperature logs for each storage unit twice a day.
- Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training must be kept and displayed as documentation.
- Unless otherwise noted, the vaccine manager and/or back-up will be the VFC contact for the office. The Provider is required to notify the AR VFC Program when there is a change in vaccine managers or key staff.
- Develop and follow routine and emergency vaccine storage and handling plans.
- Utilize and maintain proper vaccine storage equipment.
- Utilize and maintain proper temperature monitoring devices.
- Record and assess data logger temperatures and respond appropriately to temperature excursions.
- Download and review data logger temperatures at least once a week.
- Perform vaccine management practices through proper ordering, inventory management, temperature monitoring, and use of storage equipment.
- Order vaccine based on actual need of eligible children served by the practice.
- Develop and maintain complete, accurate, and separate stock records for both publicly-and privately-purchased vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock.
- Post "DO NOT DISCONNECT" notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

- The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention, strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** pre-draw doses before they are needed.

Office Management and Staff Training

Providers and staff are responsible for maintaining vaccine quality from the time a shipment arrives until the moment a dose is administered. Vaccine storage practices are the responsibility of the vaccine managers. If delegated, the designated vaccine manager must monitor these activities regularly.

Storage and Handling Plans

Providers must have written routine and emergency storage and handling plans. Providers should customize routine and emergency storage and handling templates to reflect office practice or develop your own (must be approved by the VFC Program). Both plans should be reviewed and updated as necessary and at minimum annually. Refer to the Routine Vaccine Management Plan (Appendix page 61).

The routine vaccine storage and handling plan should include guidance on routine vaccine management practices. The emergency vaccine storage and handling plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. All staff members who handle VFC vaccines and maintenance staff should be aware of this plan and it should be posted on or near the refrigerator. In any type of power outage, freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location. Temperatures and duration of power outage must be monitored. Vaccine should not be discarded or administered until the situation has been discussed with AR Immunization Program and vaccine manufacturers.

Vaccine Storage Equipment

CDC recommends the use of stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. The use of dormitory or bar-style refrigerator/freezers is not allowed at any time. The characteristics of an appropriate storage unit include:

- enough room to store the year's largest inventory without crowding;
- sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature; and
- a working, calibrated digital data logger with Certificate of Traceability and Calibration (also known as Report of Calibration) placed in a central area inside each storage compartment (this is a VFC requirement).

In addition, frost-free or automatic defrost cycle units are preferred. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine. Use of stand-alone units is a best practice. An alternative is to use only the refrigerator compartment of a combination

household refrigerator/freezer unit to store refrigerated vaccines. The combination household refrigerator/freezer should have separate exterior doors and thermostat controls. A separate stand-alone freezer should then be used to store frozen vaccines. Studies conducted by the National Institute of Standards and Technologies (NIST) have demonstrated that the freezer section of combination units is not capable of reliably maintaining appropriate temperatures.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the provider/clinic vaccine coordinator or the vaccine coordinator's back-up. If delegated to the back-up, the designated vaccine coordinator must monitor these activities regularly.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine at least weekly.
- Notify the awardee immunization program of any vaccine doses that will expire (within 90 days) before they can be administered. Only with the approval and direct guidance of the awardee immunization program and only if the cold chain can be ensured, short-dated vaccines can be transferred to high-volume providers who are able to administer it before it expires.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine with enough space to allow for cold air circulation around the vaccine.
- Never store vaccines in the door of the storage unit.
- Never store food or drink in the storage unit.
- Keep public vaccine separate from private vaccine and clearly label both.
- Never use a dormitory-style refrigerator/freezer to store vaccine at any time.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store frozen water bottles in the freezer to be used for vaccine transport. Water bottles should be frozen prior to storage in a vaccine freezer so the freezer temperature isn't affected. Do not overfill freezer.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Store all vaccine diluents in their original boxes.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Keep vaccines organized.
- Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of back-up power (generator) and a security system to alert appropriate personnel in the event of a power outage.

- If applicable, test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Temperature Monitoring

All vaccines have specific storage temperature requirements, and vaccine stored at temperatures outside of the recommended ranges can be damaged and/or rendered ineffective. Do not assume that your refrigerator and freezer will maintain the proper temperatures without monitoring. As with all equipment, refrigerators and freezers are subject to mechanical failure and/or user error. The only way to assure that your vaccine supply is being maintained at the proper temperatures is to regularly monitor your freezer and refrigerator temperatures. Temperature monitoring should be the primary responsibility of the provider/clinic vaccine coordinator and back-up. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible and visible location.
- A digital data logger must be used to monitor vaccine storage unit temperatures.
- Review and record refrigerator and freezer temperatures twice each day (beginning and end) and review and record minimum and maximum temperature readings at the beginning of the work day ensuring that refrigerator temperatures are between 36° and 46° F (2° and 8°C) and that freezer temperatures are between -58° and +5° F (-50° and -15°C). The minimum and maximum temperatures of the digital data logger should be cleared each day after documentation. Monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the temperature log.
- Maintain an ongoing file of temperature logs, and store completed logs for three years.

Thermometer Requirements and Recommendations

CDC requires having a working, calibrated digital data logger (DDL) thermometer with Certificate of Traceability and Calibration placed in a central area inside each storage compartment. Digital Data Logger calibration must be performed annually or according to manufacturer recommendations by a laboratory with accreditation from an ILAC MRA signatory body. If the costs or logistics of calibration testing are not feasible, another option is to purchase of a new digital data logger with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Providers are responsible for maintaining Certificates of Traceability and Calibration Testing (also known as Report of Calibration). If there is not a calibrated digital data logger with valid documentation (i.e., certificate) at the time of the VFC compliance site visit in any of the vaccine storage units, then action must be taken by the clinic to correct the situation.

CDC recommends use of a digital data logger with a bio safe, glycol-encased probe that will measure liquid temperature. In addition, the digital data logger must be able to provide continuous data monitoring information in an active display that can be placed on the outside of the unit door to allow for reading temperatures without opening the unit door. The data stored in the digital data logger should be easily downloadable for review. A detachable probe facilitates downloading temperature data without removing

the probe from the storage unit and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Alarm for out-of-range temperatures,
- Current temperature, as well as minimum and maximum temperatures,
- Reset button,
- Low battery indicator,
- Accuracy of +/-1°F (0.5°C),
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full, and
- User programmable logging interval (or reading rate).

Vaccine Ordering and Inventory Management

Providers enrolled in the VFC program are responsible for the proper maintenance of their vaccine inventories and for ordering vaccine in the appropriate amounts. Vaccine need for a practice is based on the number of VFC-eligible children seen in a practice as reported on the **VFC Provider Profile** and validated by the Arkansas VFC/Immunization Program. Providers order VFC vaccine through the Arkansas Immunization Information System, WebIZ. Providers should maintain no more than a two-month inventory based on your clinic's 2 highest use months and order in a manner enabling support of that inventory. Vaccine inventory should be reconciled no more than 14 days prior to placing each order. Order all vaccines at one time. Orders should be appropriate, timely, and accurate to maintain a minimum inventory and avoid stockpiling. Vaccine loss due to expiration is a frequent consequence of over ordering and lack of stock rotation. Excessive vaccine loss can be considered fraud and abuse.

VFC Providers are required to notify the AR VFC Program within 90 days of any vaccine doses that will expire before they can be administered. Short dated vaccine transfers between providers can occur but must be approved by the VFC Program. When feasible and if the cold chain can be maintained, the AR VFC Program will provide instructions on redistributing short-dated vaccines to high-volume providers who are able to administer them before they expire.

Expired and spoiled vaccines should be removed from the storage unit immediately, marked "Do Not Use", and returned to McKesson following the WebIZ return process. Open vials and syringes should not be returned to McKesson.

Nonviable vaccine must be returned to the centralized distributer (currently McKesson) within six months of expiration of product to facilitate collection of federal excise tax credit. There are instructions for this in the Appendix.

Receiving Vaccine Shipments

Open vaccine packages immediately, check the temperature monitor, inspect the vaccine, verify the packing slip is correct, and then store vaccines at the appropriate temperature. If a vaccine shipment is compromised, temperature monitors are out-of-range, or a warm indicator is activated, they should contact Immunization Program immediately at 800.574-4040.

4 Vaccine Accountability

Provider Quality Assurance

VFC Providers must participate in program compliance site visits, storage and handling unannounced visits, and other educational opportunities associated with VFC program requirements. The provider site visits are conducted by authorized representatives of the VFC Program. The AR VFC Program will follow-up on improvement or corrective plans you receive as a result of an AR VFC site visit. Failure to allow a site visit may result in the temporary suspension of services from the VFC Program and removal of VFC-supplied vaccines.

The intention of the site visit is to offer VFC providers support and guidance and to assure the federal and state requirements are being met. VFC compliance visits include a formal educational component and count as meeting the educational requirement for the calendar year. Unannounced storage and handling visits serve as "spot checks" for proper storage and handling practices. The goal of these visits is to provide guidance and education and to ensure all VFC-eligible children are receiving properly managed vaccines. The VFC representative may also assess clinic immunization rates, review clinic immunization practices, and assist to develop an action plan to improve them.

Clinic VFC primary and back-up managers must complete an educational training prior to re-enrollment each calendar year. The educational training must cover all VFC requirements and the proper vaccine storage and handling of VFC vaccine. AR VFC staff must verify training completion during VFC compliance site visits.

At a minimum, the VFC Provider primary and back-up managers must complete the "CDC VFC Requirements -You Call the Shots" and the "Storage and Handling- You Call the Shots" modules annually to meet the provider educational requirement. The modules certificate of completion must be kept on file in the clinic for a minimum of 3 years. The VFC Reviewer will request a copy of the completion certificates during the VFC Provider Compliance Site Visit.
http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp
http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

In the event a new person is appointed to replace the primary VFC clinic manager, AR VFC staff must be notified no later than 15 days after the new VFC manager is appointed. The new VFC manager must submit to the AR VFC staff, a certificate of completion of the education modules within 30 days after their appointment.

Disenrollment

A VFC facility or the state/local immunization program may terminate this agreement at any time for any reason or for failure to comply with requirements. If for any reason a provider decides to discontinue enrollment in the VFC Program, contact the VFC Program at 501-661-2170. The Provider is responsible for all VFC vaccine received. The VFC Program will furnish the provider with information on returning any remaining VFC-provided vaccine or assist with transferring the vaccine to another VFC Provider. If the agreement is terminated, then the provider will properly return any unused VFC vaccine or have the vaccine transferred within 30 days of the termination date.

VFC Providers can be suspended from the VFC Program for a variety of program violations. The suspension is not a permanent termination of program privileges, so long as the violations are addressed in a timely manner. Upon suspension, no vaccine will be delivered to the provider until the suspension is lifted. Grounds for VFC Program suspension include:

- Negligence in vaccine storage and handling.
- Inability to account for vaccine supplied by VFC.
- Improper vaccine administration (not following ACIP recommendations, etc.).
- Transferring vaccine between sites without prior approval.
- Administering VFC vaccine to patients who are not VFC eligible.

Fraud and Abuse Policy

As the cost of childhood vaccines increases and the complexity of immunization programs grows, the VFC Program becomes more vulnerable to fraud and abuse. Therefore, the VFC Program actively works to prevent, identify, investigate, and resolve all cases and suspected cases of fraud and abuse within the VFC Program. The following definitions, as defined in the Medicaid regulations at 42 CFR § 455.2, apply to VFC Program Operations:

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 law."

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

Examples of fraud and abuse: Fraud or abuse can occur in many ways. The VFC Program differentiates between intentional fraud and abuse and unintentional abuse or error. Examples of fraud and abuse (not an all-inclusive list):

- 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 charge for administration of a VFC vaccine to a federally-vaccine-eligible child.
- Not providing VFC-eligible-children VFC vaccine because of responsible party's inability to pay the administration fee.
- Not implementing provider enrollment requirements of the VFC Program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC Program.
- Failing to fully account for the VFC vaccine.
- Failing to properly store and handle VFC vaccine.
- Ordering VFC vaccine in quantities or patterns that do not match the provider profiles or otherwise involve over-ordering of VFC doses.
- Wastage of VFC vaccine .

- Failure to report required information into the AR immunization registry in a manner prescribed in the provider enrollment process .

Consequences of fraud and abuse: The VFC Program will attempt to work collaboratively with providers to address issues of program noncompliance. The program will consider previous compliance issues and potential extenuating circumstances in determining remedial action(s). The goal is to work with providers in as positive a manner as possible to correct noncompliant behaviors and restore VFC Program privileges. Intervention may include any or a combination of the following actions:

- Education and follow-up.
- Site visits.
- Formal intervention that requires development of a corrective action plan.
- Termination from the VFC Program.
- Referral to external agency (e.g. Medicaid) for further fraud and abuse investigation.

Appendices

CLINIC VACCINE COORDINATORS ~ ROLES AND RESPONSIBILITIES

Vaccines are expensive and sensitive. They can lose their effectiveness if exposed to temperatures (heat and/or cold) outside the required range and when exposed to light. Failure to adhere to storage requirements may reduce vaccine potency and/or increased local reactions after their administration. The loss of vaccine effectiveness is cumulative, permanent, and irreversible. Careful vaccine management is essential.

The Vaccines for Children (VFC) Program requires providers to designate a **Primary Vaccine Coordinator** and a **Back-Up Vaccine Coordinator.**

> The **Primary Vaccine Coordinator** is responsible for providing oversight for all vaccine management within the office including storage and handling.
>
> The **Back-Up Vaccine Coordinator** assumes oversight responsibilities in the absence of the Primary Vaccine Coordinator.

VFC PROVIDER TRAINING REQUIREMENTS:

Primary and Back-Up Vaccine Coordinators must be fully trained on routine and emergency vaccine management policies and procedures related to vaccine shipments, storage, handling, transport and inventory management.

Primary and Back-Up Vaccine Coordinators must undergo annual training on VFC program requirements, including proper storage and handling. All training must be documented.

Training must occur in one of the following situations:

- During the annual VFC compliance visit
- Attending a regional immunization training session
- Viewing CDC's "You Call the Shots" trainings on the Vaccines for Children Program and Vaccine Storage and Handling

Primary Vaccine Coordinators are responsible for ensuring that all staff receives training on VFC guidelines and proper storage/handling and vaccine administration.

Upon hire and repeating annually, the Primary and Back-up Coordinators should take the online CDC training modules:

> **"You Call the Shots: Vaccines for Children (VFC)"**
>
> **"You Call the Shots: Vaccine Storage and Handling"**

The CDC training modules offer continuing education credits at no charge. The certificate of completion should be printed and filed with VFC records.

Vaccine Eligibility Reminder

Always check current VFC eligibility prior to obtaining vaccine from the refrigerator/freezer! Document the eligibility status in the immunization registry. Choose the correct vaccine lot number designated as "Private or "Public" to match eligibility. Note: Some children may have more than one eligibility. Select the eligibility category that will require the least amount of out-of -pocket expenses to the parent/guardian as well as your clinic policy. Ensure that billing can determine when VFC vaccine is given.

18 or YOUNGER &:

Eligibility	Vaccine
MEDICAID Part A →	**VFC ELIGIBLE** Use public/VFC stock.
NO HEALTH INSURANCE →	**VFC ELIGIBLE** Use public/VFC stock.
NATIVE AMERICAN/ALASKAN NATIVE →	**VFC ELIGIBLE** Use public/VFC stock.
UNDERINSURED (RHC/CHC/FQHC Clinic Only) INSURANCE DOES NOT FULLY PAY FOR IMMUNIZATIONS → Note: Children with insurance that covers the cost of vaccinations are not eligible through VFC, even when that coverage requires a deductible.	Eligible to receive VFC vaccine **only** through a FQHC, RHC or Local Health Department. Private providers should **refer** for no or low cost vaccines. Private stock may be used if parent desires.
INSURANCE PAYS FOR IMMUNIZATION SCHIP Or Medicaid Part B →	**NOT VFC ELIGIBLE** Use Private Vaccine or SCHIP (Medicaid Part B) Stock .

19 or OLDER: NOT VFC ELIGIBLE USE PRIVATE STOCK.

Supplies You May Need at an Immunization Clinic

Vaccines you may need*

Select the ones you need for the age of the patient you expect at your clinic.

Refrigerated *(MMR may also be frozen)*

- ☐ Diphtheria, tetanus, and pertussis (DTaP)
- ☐ DTaP-HepB-IPV (Pediarix)
- ☐ DTaP-IPV/Hib (Pentacel)
- ☐ DTaP-IPV (Kinrix, Quadracel)
- ☐ *Haemophilus influenzae* type b (Hib)
- ☐ Hib-MenCY (MenHibrix)
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ HepA-HepB (Twinrix)
- ☐ HepB-Hib (Comvax)
- ☐ Human papillomavirus (HPV)
- ☐ Influenza, injectable (IIV) (in season)
- ☐ Influenza, live attenuated intranasal (LAIV) (in season)
- ☐ Measles, mumps, rubella (MMR)
- ☐ Meningococcal ACWY
- ☐ Meningococcal B
- ☐ Pneumococcal conjugate (PCV13)
- ☐ Pneumococcal polysaccharide (PPSV23)
- ☐ Polio, inactivated (IPV)
- ☐ Rotavirus (RV)
- ☐ Tetanus-diphtheria, adult (Td)
- ☐ Tetanus, diphtheria, and pertussis (Tdap)
- ☐ Diluent† for ActHIB, Hiberix, MMR, Men-Hibrix, Menveo, Pentacel, and Rotarix

Frozen *(Never pack frozen vaccine with dry ice)*

- ☐ Measles, mumps, rubella, varicella (MMRV)
- ☐ Varicella
- ☐ Zoster
- ☐ Diluent† for MMRV, Varivax, and Zostavax

For instructions on how to pack and transport vaccines, go to www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf, pages 69–72.

Immunization Clinic Documentation

- ☐ Vaccine standing orders and protocols‡
- ☐ Vaccination administration record sheets‡ (i.e., medical records, if needed)
- ☐ Billing forms, if needed
- ☐ Screening Checklist for Contraindications to Vaccines for Children and Teens‡
- ☐ Screening Checklist for Contraindications to HPV, MCV4, and Tdap for Teens‡
- ☐ Screening Checklist for Contraindications to Vaccines for Adults‡
- ☐ Summary of Recommendations for Child/Teen Immunization‡
- ☐ Summary of Recommendations for Adult Immunization‡
- ☐ Immunization record cards for patients (pediatric and adult)§
- ☐ Release of information forms
- ☐ Vaccine Adverse Events Reporting (VAERS) forms
- ☐ Schedules, including dates and times, of future immunization clinics

Emergency Supplies*

- ☐ Medical Management of Vaccine Reactions in Children and Teens‡
- ☐ Medical Management of Vaccine Reactions in Adults‡

First-line medication

- ☐ Epinephrine, aqueous 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least 3 should be available (both pediatric and adult formulation, as needed).

Second-line medications: H_1 antihistamines (either or both of these)

- ☐ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution)
- ☐ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 10 mg or 25 mg tablets, or 25 mg capsules)

Other supplies for emergencies:

- ☐ Syringes (1 and 3 cc) and needles (22 and 25g, 1", 1½", and 2") for epinephrine or diphenhydramine
- ☐ Alcohol wipes
- ☐ Tourniquet
- ☐ Pediatric and adult airways (small, medium, and large)
- ☐ Pediatric and adult size pocket masks with one-way valve
- ☐ Oxygen (if available)
- ☐ Stethoscope
- ☐ Sphygmomanometer (child, adult, and extra-large cuffs)
- ☐ Tongue depressors
- ☐ Light source (e.g., flashlight for examination of mouth and throat)
- ☐ Wristwatch with a second hand or other timing device
- ☐ Telephone access to call 911

Vaccine and Miscellaneous Supplies*

- ☐ Appropriate storage units and monitoring equipment (thermometers) to maintain vaccine cold chain (see www.eziz.org/assets/docs/IMM-983.pdf)
- ☐ 1 or 2 needle disposal "sharps" containers
- ☐ 1 box of 3 cc syringes
- ☐ 22 and 25g needles
  ☐ ⅝"; ☐ 1"; ☐ 1½"; ☐ 2"
- ☐ 1 box of medical gloves (appropriate size range for staff)
- ☐ Alcohol wipes
- ☐ Spot bandaids ☐ Rectangular bandaids
- ☐ 1" gauze pads or cotton balls
- ☐ Thermometers along with probe covers
- ☐ Certified calibrated thermometer for vaccine cooler, if needed
- ☐ Paper towels
- ☐ Bleach solution in spray bottle

Vaccine Information Statements (VISs)*

- ☐ Most current version associated with each vaccine used in the clinic *(available in English and over 30 languages at www.immunize.org/vis)*

Office Supplies

- ☐ Calendar
- ☐ Pens
- ☐ File folders
- ☐ Scissors
- ☐ Pad of paper
- ☐ Stapler/staples
- ☐ Tape
- ☐ Paper clips
- ☐ Post-its

* Always check the expiration dates of all vaccines, medications, and medical supplies before using! In addition, be sure to check that you have the most current versions of the VISs. To learn more about VISs, visit www.immunize.org/vis.

† Diluent should never be frozen.

‡ These materials are available at www.immunize.org/handouts.

§ These materials may be purchased at www.immunize.org/shop.

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p3046.pdf • Item #P3046 (9/15)

Screening Checklist for Contraindications to Vaccines for Children and Teens

PATIENT NAME _____

DATE OF BIRTH ____/____/____
month day year

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Is the child sick today?	☐	☐	☐
2. Does the child have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3. Has the child had a serious reaction to a vaccine in the past?	☐	☐	☐
4. Does the child have a long-term health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy?	☐	☐	☐
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6. If your child is a baby, have you ever been told he or she has had intussusception?	☐	☐	☐
7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	☐	☐	☐
8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
9. Does the child have a parent, brother, or sister with an immune system problem?	☐	☐	☐
10. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments?	☐	☐	☐
11. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	☐	☐	☐
12. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
13. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____

Did you bring your immunization record card with you? yes ☐ no ☐

It is important to have a personal record of your child's vaccinations. If you don't have one, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep it in a safe place and bring it with you every time you seek medical care for your child. Your child will need this document to enter day care or school, for employment, or for international travel.

immunization action coalition
IAC
immunize.org

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p4060.pdf • Item #P4060 (10/20)

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines (Children and Teens)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references in **Notes** *below.*

NOTE: For supporting documentation on the answers given below, go to the specific ACIP vaccine recommendation found at the following website: www.cdc.gov/vaccines/hcp/acip-recs/index.html

1. Is the child sick today? *[all vaccines]*

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see www.cdc.gov/vaccines-pubs/pinkbook/downloads/appendices/B/latex-table.pdf; for an extensive list of vaccine components, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. People with egg allergy of any severity can receive any recommended influenza vaccine (i.e., any IIV, RIV, or LAIV) that is otherwise appropriate for the patient's age and health status. With the exception of ccIIV and RIV (which do not contain egg antigen), people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

3. Has the child had a serious reaction to a vaccine in the past? *[all vaccines]*

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Does the child have a long-term health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy? *[MMR, MMRV, LAIV, VAR]*

A history of thrombocytopenia or thrombocytopenic purpura is a precaution to MMR and MMRV vaccines. The safety of LAIV in children and teens with lung, heart, kidney, or metabolic disease (e.g., diabetes), or a blood disorder has not been established. These conditions, including asthma in children ages 5 years and older, should be considered precautions for the use of LAIV. Children with functional or anatomic asplenia, complement deficiency, cochlear implant, or CSF leak should not receive LAIV. Children on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Children with CSF leak, anatomic or functional asplenia, or cochlear implant, or on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Aspirin use is a precaution to VAR.

5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? *[LAIV]*

Children ages 2 through 4 years who have had a wheezing episode within the past 12 months should not be given LAIV. Instead, these children should be given IIV.

6. If your child is a baby, have you ever been told that he or she has had intussusception? *[Rotavirus]*

Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? *[DTaP, Td, Tdap, IIV, LAIV, MMRV]*

DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccinate as usual (exception: children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap;

NOTE: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

2) Influenza vaccine (IIV, LAIV, or RIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IIV if at high risk for severe influenza complications.

8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, MMRV, RV, VAR]*

Live virus vaccines (e.g., MMR, MMRV, VAR, RV, LAIV) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, VAR should be considered for HIV-infected children age 12 months through 8 years with age-specific CD4+ T-lymphocyte percentage at 15% or greater, or for children age 9 years or older with CD4+ T-lymphocyte counts of greater than or equal to 200 cell/μL. VAR should be administered (if indicated) to persons with isolated humoral immunodeficiency. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including RV. Other forms of immunosuppression are a precaution, not a contraindication, to RV. For details, consult ACIP recommendations (see references in **Notes** above).

9. Does the child have a parent, brother, or sister with an immune system problem? *[MMR, MMRV, VAR]*

MMR, VAR, and MMRV vaccines should not be given to a child or teen with a family history of congenital or hereditary immunodeficiency in first-degree relatives (i.e., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

10. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments? *[LAIV, MMR, MMRV, VAR]*

Live virus vaccines (e.g., LAIV, MMR, MMRV, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement. Some immune mediator and immune modulator drugs (especially the antitumor-necrosis factor agents adalimumab, infliximab, and etanercept) may be immunosuppressive. A comprehensive list of immunosuppressive immune modulators is available in CDC Health Information for International Travel (the "Yellow Book") available at wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers. The use of live vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see General Best Practice Guidelines for Immunization (referenced in **Notes** above). LAIV, when recommended, can be given only to healthy nonpregnant people ages 2 through 49 years.

11. In the past year, has the child received a transfusion of blood/blood products, or been given immune (gamma) globulin or an antiviral drug? *[MMR, MMRV, LAIV, VAR]*

Certain live virus vaccines (e.g., MMR, MMRV, LAIV, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations (referenced in **Notes** above) for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.

12. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? *[HPV, IPV, LAIV, MenB, MMR, MMRV, VAR]*

Live virus vaccines (e.g., MMR, MMRV, VAR, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, IPV and MenB should not be given during pregnancy; however, it may be given if there is a risk of exposure. IIV and Tdap are both recommended during pregnancy. HPV vaccine is not recommended during pregnancy.

13. Has the child received vaccinations in the past 4 weeks? *[LAIV, MMR, MMRV, VAR, yellow fever]*

Children who were given either LAIV or an injectable live virus vaccine (e.g., MMR, MMRV, VAR, yellow fever) should wait 28 days before receiving another vaccination of this type (30 days for yellow fever vaccine). Inactivated vaccines may be given at the same time or at any spacing interval.

VACCINE ABBREVIATIONS

LAIV = Live attenuated influenza vaccine
HPV = Human papillomavirus vaccine
IIV = Inactivated influenza vaccine
ccIIV - cell culture inactivated influenza vaccine
IPV = Inactivated poliovirus vaccine
MMR = Measles, mumps, and rubella vaccine
MMRV = MMR+VAR vaccine
RIV = Recombinant influenza vaccine
RV = Rotavirus vaccine
Td/Tdap = Tetanus, diphtheria, (acellular pertussis) vaccine
VAR = Varicella vaccine

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Children and Teens" at www.immunize.org/catg.d/p4060.pdf). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See the emergency medical protocol on the next page for detailed steps to follow in treating anaphylaxis.

CONTINUED ON NEXT PAGE ▶

Suggested Medications for Managing Anaphylaxis in a Community Immunization Clinic Setting

FIRST-LINE medication

- ☐ **Epinephrine** 1.0 mg/mL aqueous solution (1:1000 dilution) in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules. At least three epinephrine doses should be available on site, dosages as appropriate for patient population.

OPTIONAL medications: H_1 antihistamines
These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension, or shock.

- ☐ **Diphenhydramine** (e.g., Benadryl) oral, 12.5 mg/5 mL liquid; 25 or 50 mg tablets
- ☐ **Hydroxyzine** (e.g., Atarax, Vistaril) oral, 10 mg/5 mL liquid, 10 mg or 25 mg tablets

Additional emergency supplies you may need

- ☐ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- ☐ Alcohol wipes
- ☐ Tourniquet
  Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators
- ☐ Stethoscope
- ☐ Blood pressure measuring device with multiple-sized cuffs depending on patient population
- ☐ Tongue depressors
- ☐ Light with extra batteries (for examination of the mouth and throat)
- ☐ A timing device, such as wristwatch, for checking pulse
- ☐ Cell phone or access to onsite phone

For remote areas without EMS support

- ☐ Pediatric- and adult-sized airways (various sizes)
- ☐ Various-sized pocket masks with one-way valve
- ☐ Oxygen (if available)

REFERENCES

*American Academy of Pediatrics. *Red Book: 2018–2021 Report of the Committee on Infectious Diseases. 31st edition*, p. 64–67.

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. November 2018.

Kroger AT, Duchin J, Vazquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Emergency medical protocol for management of anaphylactic reactions in children and teens in a community setting

1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.

3 **DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**

a First-line treatment: **EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Use epinephrine in a 1.0 mg/mL aqueous solution (1:1000 dilution). See page 3 to determine correct dose to be used based on child's weight. If using an autoinjector or pre-filled syringe, administer a dose of 0.1 mg, 0.15 mg, or 0.3 mg IM (as appropriate for the patient's weight) into the anterolateral thigh. If using another epinephrine format, the recommended dose is 0.01 mg/kg per dose, up to a maximum single dose of 0.5 mg. Administer IM, preferably in the anterolateral thigh. Epinephrine dose may be repeated every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.

b Optional treatment: **H_1 ANTIHISTAMINES** relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving **diphenhydramine** (e.g., Benadryl) or **hydroxyzine** (e.g., Atarax, Vistaril) for relief of itching or hives.

- Administer **diphenhydramine** orally, standard dose of 1–2 mg/kg every 4–6 hours. Maximum single dose is 40 mg for children age <12 years; for children age ≥12 years, 100 mg. See dosing chart on page 3.*
- Administer **hydroxyzine** orally; the standard dose is 0.5–1 mg/kg/dose, up to 50–100 mg maximum per day in children and adolescents. See dosing chart on page 3.

4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

5 Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

6 Notify the patient's primary care physician.

7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

CONTINUED ON NEXT PAGE ▶

For your convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes (or sooner) up to 3 times while waiting for EMS to arrive.

	Age group	Range of weight (lb)	Range of weight (kg)*	Epinephrine Dose: 1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine Dose: Epinephrine autoinjector or prefilled syringe (0.1 mg, 0.15 mg, 0.3 mg)
Infants and children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb†	9–14.5 kg†	0.1 mL (or mg)	0.1 mg†
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range
† 0.1 mg autoinjector is licensed for use in 7.5 to 14 kg infants and children

Optional Treatment: Diphenhydramine

▶ commonly known as Benadryl

Recommended dose is 1–2 mg/kg body weight every 4–6 hrs†

	Age group	Range of weight (lb)	Range of weight (kg)*	Diphenhydramine dose calculations based on 1 mg/kg†: Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg
Infants and children	7–36 months	20–32 lb	9–14.5 kg	10–15 mg/dose†
	37–59 months	33–39 lb	15–17.5 kg	15–20 mg/dose†
	5–7 years	40–56 lb	18–25.5 kg	20–25 mg/dose†
	8–12 years	57–99 lb	26–45 kg	25–50 mg/dose†
Teens	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg single dose)†

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range
† AAP, *Red Book: 2018–2021*, 31st ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40 mg, for children age 12 years and older, 100 mg.

Optional Treatment: Hydroxyzine

▶ commonly known as Atarax, Vistaril

Recommended oral dose is 0.5–1 mg/kg body weight every 4–6 hrs†

	Age group	Range of weight (lb)	Range of weight (kg)*	Hydroxyzine dose calculations based on 0.5 mg/kg: Liquid: 10 mg/5 mL Tablets: 10 mg or 25 mg
Infants and children	7–36 months	20–32 lb	9–14.5 kg	5–7.5 mg/dose
	37–59 months	33–39 lb	15–17.5 kg	7.5–10 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	10–12.5 mg/dose
	8–10 years	57–76 lb	26–34.5 kg	12.5–15 mg/dose
Teens	11–12 years	77–99 lb	35–45 kg	15–25 mg/dose
	13 years & older	100+ lb	46+ kg	25 mg/dose (50–100 mg, maximum per day)

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range

[illegible] and procedure shall remain in effect for all patients of the

name of practice _____
NAME OF PRACTICE OR CLINIC

effective _____ until rescinded or until _____.
DATE DATE

Medical Director

_____
PRINT NAME

_____
SIGNATURE DATE

Immunization Action Coalition • Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (7/19)

VAERS

Vaccine Adverse Event Reporting System

A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS), is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and reviews reports of adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.

VAERS provides valuable information

VAERS is an early-warning system that detects problems possibly related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important information to identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate reports of adverse events

VAERS defines a "serious adverse event" as life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability or death. Once adverse events are identified using VAERS, they may be monitored in other immunization safety systems to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. CDC and FDA encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

How to report to VAERS

You can report to VAERS online at https://vaers.hhs.gov/index.

For further assistance reporting to VAERS, visit https://vaers.hhs.gov/index or contact VAERS directly at info@VAERS.org or 1-800-822-7967.

VAERS data are available to the public

VAERS data can be downloaded at https://vaers.hhs.gov/data/index or searched at http://wonder.cdc.gov/vaers.html. Privacy is protected and personal identifying information (such as name, date of birth and address) is removed from the public data.

For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-800-822-7967

Web site: www.vaers.hhs.gov

*Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event. They are also required to report to VAERS adverse events found in the Reportable Events Table (RET) at https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

FACT SHEET

CS267401

Arkansas Vaccines For Children
Calibration Certificate Form
For use with Clinics/Hospitals with Self-Calibration Certificates
This Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-I and 9001

Clinic ID Name and VFC Pin #_____

Clinic Address_____

Clinic Director_____

Calibration Tool Make_____

Calibration Tool Model_____

Calibration Tool Serial #_____

Refrigerator-Identification Number_____

Temperature Range_____

Temperature Measured_____

Actual Temperature_____

Uncertainty_____

Unit in Tolerance Y/N _____

Unit of Measure_____

Date of Calibration_____

Customer Specified Due Date_____

Freezer-Identification Number_____

Temperature Range_____

Temperature Measured Actual Temperature_____

Uncertainty_____

Unit in Tolerance Y/N_____

Unit of Measure_____

Date of Calibration_____

Customer Specified Due Date_____

Service Technician Name_____

Service Technician Signature_____

Customer Name_____

Storage Unit Requirements

All VFC providers storing federal vaccine must use a digital data logger with an active temperature display, with continuous monitoring and recording capabilities where the data can be routinely downloaded. In addition, recommended digital data logger characteristics include:

- A detachable, buffered probe,
- Alarm for out-of-range temperatures,
- Current, minimum and maximum temperatures,
- Low battery indicator, and
- Accuracy of +/- 1◦F or 0.5◦C.

Provider Responsibilities:

1. Stand-alone refrigerators and freezers should be used to store VFC vaccines.
2. If a refrigerator/freezer combination unit is in use, the freezer portion of the unit should not be used to store frozen vaccines. The refrigerator portion of the combo unit can be used to store refrigerated vaccines and a standalone freezer unit should be used to store frozen vaccines.
3. Ensure there is a digital data logger for each vaccine storage unit storing federal vaccine.
4. Assess and record temperatures twice a day. Specifically, assess temperatures before using vaccine at the beginning of the clinic day. This is required even if a data logger is in use.
5. Assess and record minimum and maximum temperatures each clinic morning and clear the minimum and maximum temperature readings each morning (required).
6. As currently required, report all vaccine excursions to the VFC Program.
7. Document information about the excursion and what steps were taken to correct any issues.

Storage and Handling Data Logger Frequently Asked Questions:

Q. What is a data logger vaccine storage monitor?

A. Data loggers monitor refrigerator and freezer temperatures 24 hours a day 7 days a week and record temperatures in an unloadable format at preset intervals, usually 5 to 15 minutes apart, but no more than 30 minutes apart.

Q. How is a data logger technology different and better than traditional thermometers?

A. Data logger technology is comprehensive. Non-data logger monitoring only captures a “point in time” (AM and PM) reading. These readings may show the storage unit temperatures are within the acceptable range when, in fact, temperatures may have been outside acceptable ranges for extended periods of time which can compromise vaccines.

REFRIGERATOR/FREEZER TEMPERATURE RECORDING FORM

Clinic Name/PIN# _____PROPERTY NUMBER_____ MONTH/YEAR _____

Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an X in the box that corresponds with the temperature. Record minimum and maximum temperatures in the freezer and refrigerator once a day, preferably in the morning.

CALL 1-501-661-2170 IMMEDIATELY FOR ANY TEMPERATURE IN THE SHADED AREA.

RECORD ACTUAL TEMPERATURE FOR REFRIGERATOR ≥48°F/8.8°C OR ≤32°F/0°C AND IF THE FREEZER IS ≤ 3°F/-16°C OR >7°F/-14°C

REFRIGERATOR

Staff Initials																													
Time																													
Day of Month																													
F° Temp	C° Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
≥ 48	≥ 8.8	**CALL 501-661-2170 AND TAKE IMMEDIATE ACTION IF TEMPERATURE IS IN SHADED SECTION!**																											
47	8.3																												
46	7.7																												
45	7																												
44	6.6																												
43	6.1																												
42	6																												
41	5																												
40	4.4																												
39	4																												
38	3																												
37	2.7																												
36	2.2																												
35	2																												
34	1.1	**CALL 501-661-2170 AND TAKE IMMEDIATE ACTION IF TEMPERATURE IS IN SHADED SECTION!**																											
33	1																												
≤ 32	≤ 0																												
MINIMUM TEMP																													
MAXIMUM TEMP																													

FREEZER

≥ 7	≥ -14																												
6	-14.4	**CALL 501-661-2170 AND TAKE IMMEDIATE ACTION IF TEMPERATURE IS IN SHADED SECTION!**																											
5	-15																												
4	-15.5																												
≤ 3	≤-16																												
MINIMUM TEMP																													
MAXIMUM TEMP																													

VACCINE BORROWING REPORT

Facility Name: _____Pin #: _____

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code		Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1		VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2		VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3		Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4		Short-dated VFC dose was exchanged with private dose	11
Accidental use of Private dose for VFC eligible child	5		Accidental use of a VFC dose for a child not eligible for the VFC program	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6		Other – Describe:	13Other
Other – Describe:	7Other			

WHAT TO DO WITH THIS FORM:

Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.

Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): ____/____/_____ **to** ____/____/_____

VACCINE BORROWING REPORT TABLE						
A **Vaccine Type Borrowed**	**B** **Stock Used** (VFC or Private)	**C** **Patient Name**	**D** **Patient DOB** (XX/XX/XXXX)	**E** **Date Dose Administered** (XX/XX/XXXX)	**F** **Reason Appropriate Vaccine Stock was not Used** (Use legend code on page 1 to mark one reason for each dose borrowed)	**G** **Date Dose Returned to Appropriate Stock** (XX/XX/XXXX)

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name:	**Provider Signature:**	**Date:**

Vaccine Returns

When submitting a return:

1. Enter a separate return for expired vaccines and spoiled vaccines. These return types should not be entered in the same WebIZ return.
2. Enter expired VFC and SCHIP vaccines in the same return and enter spoiled VFC and SCHIP vaccines in the same return. There is no need to enter 2 separate returns if the vaccines are being returned for the same reason.
3. Always use the reason “Return Only” when submitting a return. Never choose “Replacement Doses.”

Instructions for completing a vaccine return:

1. Vaccines are completed in WebIZ under the Vaccine Return module. Paper vaccine return forms are not accepted.

2. Pack all vaccine to be returned to McKesson in a cardboard box. ***ONLY PACK THE VACCINES ENTERED IN THE VACCINE RETURN MODULE. THE MCKESSON RETURN LABELS WILL BE FOR THIS RETURN ONLY.***

3. Enclose the WebIZ return information in the package with the wasted or expired vaccines being returned and seal the box securely with packing tape.

4. Once the Vaccine Management Team accepts the WebIZ vaccine return and submits the return to VTrckS, McKesson will email a postage-paid label to the WebIZ contact. Return labels may be available as soon as 15-30 minutes after the Return Status reads “Sent to Distributor”. If you do not receive a return label in your regular email within 1.5 hours after it has been sent to the distributor, check your SPAM folder for the label.

   a. A UPS return label will be emailed from McKesson Specialty Care Distribution [mailto:pkginfo@ups.com] to the contact email address in WebIZ. The subject of the email with the return label will be titled "UPS Label Delivery, <Label tracking Number>.”
   b. The emailed return label will be coded with an internal tracking number used by McKesson to manage vaccine returns. It is strongly recommended that providers wait to create additional returns until they have received the emailed return label for earlier entries. This will allow you to match the correct return label with the appropriate return box.
   c. One unique return label will be included per email. Labels cannot be photocopied or reprinted for multiple uses. This means that if three boxes are indicated in the return, the contact will receive three emails, each containing a single return mailing label. It does not matter which label is put on each of the three boxes for that specific return, because when the boxes are received, McKesson will be looking at the boxes altogether.
   d. If you do not use all of your requested labels, please send any unused labels inside the box to be returned to McKesson.
   e. If an invalid email address is submitted with a return, and McKesson Customer Service receives an error message, McKesson will reach out to the provider to obtain corrected address information for the contact and resend the return label. In addition, the provider will be requested to update the contact information on the vaccine return for each time a vaccine return is submitted.

5. Once the label has been received, affix the label to the package, and give the package to the next UPS driver.

6. Clearly label the outside of the shipping container with ***"Non-viable Vaccine Enclosed"***.

A vaccine return will be rejected if:

1. The vaccine is entered as an expired vaccine but it is not passed the expiration date.
2. The number of expired vaccines in the return does not match the number of expired doses on hand.
    a. Prior to submitting the return, adjust the number of doses on hand in WebIZ to match the number of doses being returned.

If you have questions about the provider returns process, please submit a ticket to the WebIZ help desk at https://adhimmiregistry.hesk.com/.

Vaccines for Children Program
Frequently Asked VFC Questions and Answers Document

Section One: General Questions

Question:
What is the process for including a new vaccine in the VFC program and how are immunization programs informed about the changes?
Answer:
The Advisory Committee on Immunization Practices (ACIP) has the advisory role to determine what vaccines should be recommended for administration to children, adolescents, and adults in the U.S. and the operational role to approve which vaccines should be available through the VFC program. The ACIP meets three times a year, and during these meetings newly licensed vaccines may be discussed and recommended for use. Once a vaccine is recommended by ACIP, a vote is taken about whether or not to include the new vaccine in the VFC program through consideration of a VFC resolution. VFC resolutions are specific to each vaccine and include who is eligible to receive the vaccine, the vaccination schedule, and precautions or contraindications to the vaccine. Once the VFC resolution is approved, CDC must negotiate a contract for the vaccine to make it available under the VFC program. VFC resolutions are posted on CDC's website.

Question:
Do CDC and awardees have any federal requirement to implement ACIP-recommended vaccines?
Answer:
CDC and immunization programs that receive VFC funds are required to implement ACIP-recommended vaccines for which there are VFC resolutions and for which federal contracts have been established to purchase these vaccines. When using 317, state and local funds for immunizations, implementation of all ACIP recommendations is not required.

Question:
When should a provider re-vaccinate?
Answer: The decision to revaccinate a child is a medical decision and ultimately the decision should be made by a medical provider. However, the awardee should gather sufficient information about the particular situation and offer guidance to support the provider where possible. The CDC MMWR, General Recommendations and Reports / Vol. 60 / No. 2 January 28, 2011 describes ACIP recommendations on revaccination for each vaccine type.

Question:
Can the immunization program notify the public if the provider refuses to re-vaccinate?
Answer: The state/local public health department should determine based on the available information and public health risk involved as to whether or not the public should be made aware of public health related issues within their jurisdiction.

VFC and Medicaid
**Note: Included are several general questions related to VFC and Medicaid. Additional questions relevant to Medicaid are included in other sections of the document as well.

Question:
What is the 90-day VFC Medicaid rule?
Answer:
Section 13631(g) of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) provided that vaccination services covered under the Early and Periodic Screening Diagnostic and Treatment (EPSDT) benefit for Medicaid-eligible children will follow the ACIP-established VFC schedule beginning 90 days after establishment of the schedule. CMS considers the 90-day clock to begin on the publication date in the MMWR of ACIP general recommendations for use of a VFC vaccine. Check with the state Medicaid program or CMS for more information regarding the effective date of a new VFC vaccine requirement for EPSDT children and payment of administration fees for such Medicaid children.
Please Note: The 90-day rule does not apply to other categories of federally vaccine-eligible VFC children (i.e., uninsured, underinsured and American Indian/Alaska Natives). The VFC requirement for non-Medicaid federally vaccine-eligible children is effective on the effective date noted in the ACIP VFC resolution for a particular VFC vaccine or the date vaccine is first available through a CDC VFC contract, whichever is later.

Question:
Is Medicaid federally mandated to cover ACIP's VFC-recommended vaccines for the Medicaid population?
Answer:
Yes, all of ACIP's VFC-recommended vaccines are part of the EPSDT benefit package for Medicaid children under age 21. Immunizations through age 18 years are covered by the VFC program. Children 19 years through 20 years are covered by Medicaid program funds.

Question:
Can a state require Medicaid providers to become VFC-program registered providers in order to ensure that Medicaid-eligible children receive vaccine under the VFC program?
Answer:
Yes, the state Medicaid agency does have the option to require participation in the VFC Program.

Question:
Is it acceptable for a VFC-enrolled provider to turn away a VFC-eligible child because his/her parent didn't want all the vaccines that a child was eligible to receive administered at one clinical encounter?
Answer:
This question is outside the scope of the VFC program.

Question:
Is it acceptable for a VFC-enrolled provider to ask that parents who do not wish to have their child vaccinated to find a new medical home?
Answer: This question is outside the scope of the VFC program.

Section Two: Vaccine Administration Fees

Question:
What are the statutory requirements for the VFC program regarding the vaccine administration fee?
Answer:
Section 1928(c) (2) (C) (ii) of the Social Security Act (42 U.S.C. 1396s(c) (2) (C) (ii)) states: *"The provider may impose a fee for the administration of a qualified pediatric vaccine so long as the fee in the case of a federally vaccine-eligible child does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration)."*

Section 1928(c) (2) (C) (iii) of the Social Security Act (42 U.S.C. 1396s(c) (2) (C) (iii)) further provides that: *"The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee."*
The Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), published a notice of the federal regional administration fee caps in the Federal Register on October 3, 1994 (59 FR 50235). The notice also indicated that state Medicaid programs could establish lower administration fees for VFC vaccination of Medicaid children. Except in the case of an inability to pay, the notice further stated that VFC providers can charge non-Medicaid federally vaccine-eligible children (i.e., uninsured, American Indian/Alaska Natives, and when administered by an FQHC or RHC, underinsured children) up to but not more than the maximum regional administration charge (if that charge reflects the provider's cost of administration) regardless of whether the state has established a lower administration fee under the Medicaid program.

The administration fee caps do not apply to vaccination of state vaccine-eligible children. The VFC program does not have any authority over administration fees charged to state vaccine-eligible children or privately insured children.

For example:
State A's Medicaid Agency has set the state Medicaid vaccine administration reimbursement at $10.00. The state's regional administration fee cap is $15.00. A VFC-enrolled provider can expect to receive $10.00 for the administration of a vaccine to a VFC-eligible child enrolled in Medicaid. The VFC-enrolled provider can charge a maximum of $15.00 to a VFC-eligible child NOT enrolled in Medicaid. The VFC program does not regulate administration fees charged to private pay or privately insured patients.

Q**uestion:**
Who should pay the vaccine administration fee for Medicaid-eligible children?
Answer:
The state Medicaid agency should be billed for the administration fee for Medicaid-eligible VFC children immunized by a Medicaid-enrolled VFC provider. State Medicaid agencies establish their own policies and administration fees that may be lower than the regional maximum charges established by CMS. For Medicaid VFC-eligible children, the state Medicaid agency determines and CMS approves the reimbursable amount for their fee-for-service and managed care enrolled recipients. If the provider bills Medicaid the regional maximum charge instead of the Medicaid agency's allowable rate the provider will be reimbursed only the allowable rate and not the amount billed. The difference between the allowable rate and the amount billed cannot be collected from the parents of the child.

Question:
What are the administration fee requirements for insured children who have private health insurance benefits that include immunization coverage?
Answer:
The VFC administration fee caps only apply to VFC eligible children and do not apply to privately insured children.

Question:
What is involved in raising the reimbursement rate for VFC vaccine administration by Medicaid at the state level?
Answer:
State Medicaid agencies, through processes that vary from state to state, may raise the VFC administration fees payable to Medicaid providers for vaccinating Medicaid eligible children up to the regional fee cap that was established for each state in 1994. Should a state consider its CMS-imposed cap to be too low, CMS and CDC should be contacted to discuss potential revision of the fee cap. Because so few state Medicaid agencies are reimbursing at the maximum regional charge, the current fee structure will remain in effect until further notice.

Question:
How does the CMS maximum regional charge for vaccine administration relate to universal-purchase states?
Answer:
CMS allows universal purchase states (states in which the vaccines are purchased by the state for all children in the state) the right to develop administration fees that differ from those established by CMS, provided they are reasonable. Therefore, universal purchase states are provided the flexibility to accept the maximum charges established by the Secretary or develop their own maximum charges. The maximum charges must be developed utilizing a reasonable methodology based on VFC section 1928(c)(2)(C)(ii) of the Social Security Act. The amount of the cap (maximum fee) is not required to be set in state law. However, the authority to set an amount must be based in state law. In either case, CMS gives state Medicaid agencies the option to establish and apply vaccine administration fees that are lower than the specified maximum regional charges if they provide assurances that Medicaid children have access to immunizations to the same extent as the general population.

Question:
How does a VFC-enrolled provider who is not already a Medicaid provider file for Medicaid reimbursement for vaccine administration?
Answer:
It is necessary to be a Medicaid provider in order to receive payment from Medicaid for vaccine administration services provided to Medicaid-eligible children. Providers should consult the state Medicaid agency about the procedures necessary to become a Medicaid provider.

Question:
Does the VFC program require that a sign be posted in all vaccine providers' offices that states "No VFC eligible child may be denied federally-supplied vaccine due to the inability to pay the administration fee"? May we use some other communication tools, such as a flyer that allows for a few paragraphs of explanation?

Answer:
There is nothing in the VFC legislation that mandates a posted sign in provider offices. Other means of communication may be used.

Question:
Can a private provider refuse to administer VFC vaccine to a VFC-eligible child?

Answer:
Section 1928 (c)(2)(C)(iii) of the Social Security Act states, "The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents to pay an administration fee." The statute further notes at Section 1928(c)(2)(C)(i) that "A program-registered provider is not required under this section to administer such a vaccine to each child for whom an immunization with the vaccine is sought from the provider." CDC interprets this to mean that private VFC providers, unless otherwise required by another statute, do not have to honor vaccine requests by VFC-eligible children who "walk in" for immunizations only and are not established patients in the practice. For established VFC-eligible patients and other VFC-eligible patients that the provider chooses to immunize, VFC immunization cannot be denied due to the inability to pay an administration fee.

Qu**estion:**
Please define the term "waive" in the context of this section of Module 3 of the VFC Operations Guide:
Not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

1. ***The only fee that must be waived is the administration fee. Other visit or office fees may be charged as applicable.***

Answer:
The term "waive" in this context is based on the first entry of "waive" as defined in the online version of Merriam-Webster dictionary #1). 1 give up, forsake. So, if the parent cannot pay the administration fee for a VFC vaccine, the provider must give up or forsake the VFC administration fee.

Question:
Can providers send a bill in order to collect the vaccine administration fee after the date of service (for vaccines provided to non-Medicaid VFC-eligible children)?
Answer:
There are no restrictions against sending a bill for the vaccine administration fee after the point of service. However, the provider cannot send the bill for the vaccine administration fee to collections if the parent cannot afford to pay (i.e., if the parent does not pay the bill). The provider can send the office visit fee or any other visit fee (e.g., labs) to collections if unpaid, but not the vaccine administration fee. The federal requirement restricts the provider from seeking payment if the parent cannot afford it. But this is not a restriction from sending a statement or bill after the point of service. If the parent cannot pay the administration fee for a VFC vaccine, the provider must waive it.

Section Three: VFC Eligibility

Question:
How can you determine if a health benefits organization is a health insurance company when determining a child's VFC eligibility?
Answer:
Health insurance is subject to the Employee Retirement Income Security Act of 1974 (ERISA) or is regulated by a state's Insurance Commissioner as insurance. ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans. Contact the state Insurance Commissioner to determine if an organization is a health insurance company.

Question:
For providers who offer a medical concierge service (i.e., provision of special medical services at a set member fee), is the service considered health insurance?
Answer:
Health insurance is defined as a plan subject to ERISA or regulated by the state's Insurance Commissioner as insurance (see Q&A above). If the service does not fall in either of these two categories, the service is not considered a form of insurance for the purposes of the VFC program.

Question:
If a family has a medical savings account or health savings account does that account affect a child's VFC eligibility?
Answer:
Individuals covered by medical savings accounts or health savings accounts must also have high deductible health plan coverage. Therefore, such individuals are insured.

Question:
If a child presents for vaccines and does not have health insurance but the parent plans to insure the child, would this child be eligible for VFC vaccine?
Answer:
If the child has no health insurance on the day he/she presents at the office for immunizations, the child would be VFC eligible because he/she is uninsured. VFC eligibility screening and documentation of eligibility status must take place with each visit.

Question:
If a child is eligible for insurance and the parents choose not to insure the child, would the child be eligible for VFC vaccine?
Answer:
If the child has no health insurance on the day he/she presents at the office for immunizations, regardless of the reason, the child would be VFC eligible because he/she is uninsured.

Question:
Can VFC vaccines be administered to the underserved population?

Answer:
VFC does not have a category specifically for the underserved. The term "underserved" refers to a geographic location such as a county or a census tract or a population living in a specific geographic location that has been designated by HRSA as medically underserved. For further information on medically underserved areas or population, please visit the Health Resources and Services Administration (HRSA) website at
http://www.hrsa.gov/index.html. It is common for VFC- eligible children to live in medically underserved areas or to be members of medically underserved populations.

Question:
If a child is eligible for a Title V program that pays for medical care for that child, is the child VFC eligible?
Answer:
Title V is not a type of health insurance so it has no effect on VFC eligibility of a child. To be eligible for VFC a child has to meet the age and eligibility criteria of the VFC program.

Question:
If a VFC-eligible child starts a vaccine series (such as hepatitis B) at age 18, can the series be completed using VFC vaccine after the child turns 19?
Answer:
No. Children are eligible to participate in the VFC program only through age 18 years regardless of the child's immunization status (series completed or series not completed) when they age out of VFC.

Question:
Are all children enrolled in Medicaid programs automatically VFC eligible?
Answer:
Yes, all children from birth through 18 years of age who are covered by Medicaid are considered VFC eligible because of their Medicaid status.

Question:
Are all children who have Medicaid as a secondary insurance covered by VFC?
Answer:
Yes, all children who have Medicaid as a secondary insurance are covered by VFC. The state Medicaid agency will pay the claim for the administration fee and seek reimbursement from the primary insurance.

Question:
How should providers bill administration fees for VFC vaccines administered to children who are covered by Medicaid and have another form of health coverage?
Answer:
Generally, providers are required to bill third parties before Medicaid will make payment (we refer to this as cost avoidance). However, there are a few exceptions to the cost avoidance rules. In the case of preventive pediatric services including EPSDT, if the Medicaid agency is billed, it is required to make payment and then seek reimbursement from the third party (CMS refers to this as pay & chase) - see 1902(a)(25)(E) of the Social Security Act. The Medicaid agency is to seek recovery as long as it is cost effective to do so, i.e., where the amount of reimbursement the State can reasonably expect to

recover exceeds the cost of recovery (see 1902(a)(25)(B)). Since child immunizations fall under this exception, the provider has several options for billing the administration fee:
The provider could administer VFC vaccine, and then bill the maximum regional charge for the vaccine administration to the Medicaid agency and Medicaid would be responsible for seeking reimbursement from the primary insurance.

The provider could administer private stock vaccine and bill the primary insurance the usual and customary charge for both the vaccine and the vaccine administration fee.
If the primary insurance is billed first and the insurance denies the claim, the provider could replace the private stock vaccine used with VFC vaccine then bill the maximum regional charge for the vaccine administration fee to Medicaid. The Medicaid agency should bypass their cost avoidance edit allowing the claim to be considered for payment.

Also, if the third party payer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee up to the amount Medicaid pays for the administration fee.

Question:
What is the VFC-eligibility status for children that have out-of-state Medicaid coverage and a bordering state agreement is not in place?
Answer:
The child is VFC eligible. The vaccine administration fee would be paid by different parities in varying circumstances.

1. If a service, that is not an emergency, is provided to a non-resident and if the provider doesn't have an arrangement with the state the Medicaid recipient is form, that Medicaid recipient is responsible for payment, which in this case would by the vaccine administration fee. The provider can choose to waive the fee, and must according to the VFC program requirement that VFC vaccine cannot be refused due to inability to pay the vaccine administration fee
2. If the recipient is re-locating to a new state and is applying for Medicaid, and the application is approved, coverage could go back to the date of the application. Therefore, if a child needed a vaccine for school and his parents had already applied for Medicaid, if their application was accepted, the vaccine administration fee could be billed for and paid by Medicaid and not the parent.

Section Four: Vaccine Storage and Handling

Question:
Where can I get more information on vaccine storage and handling?
Answer:
CDC's Vaccine Storage and Handling Toolkit is available on-line. The link to download the toolkit is http://www.cdc.gov/vaccines/recs/storage/default.htm

Question:
What is the impact of a power outage on vaccine and what should be done with vaccine?
Answer:
General procedures for power outages are described in the Vaccine Storage and Handling Toolkit. (http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf)
All providers should have an emergency vaccine retrieval and storage plan prepared in advance to guide them in the event of a power outage or other emergency. This should include plans for alternative storage and transport of vaccines.

Please note the following key messages for immunization providers:
In any type of power outage:

1. Do not open freezers and refrigerators until power is restored, except to transport vaccine to an alternative storage location.

2. Monitor temperatures and duration of power outage; don't discard vaccine; don't administer affected vaccines until you have discussed with public health authorities

3. Do NOT allow the vaccines to remain in a nonfunctioning unit for an extended period of time. If at any time you are unsure how long the power interruption will last, or you determine that the power will not be restored in time to maintain internal temperatures within the recommended ranges, activate the Emergency Vaccine Retrieval and Storage Plan

Question: Are "Dorm Style" refrigerators acceptable storage units for VFC vaccines?
Answer: No. Dormitory-style refrigerators should not be used to store VFC vaccine at any time. As of January 1 2013, VFC providers may **not** use dormitory-style refrigerators for storage of VFC vaccine.

Question: Some of our providers have small compact storage units that were designed to hold medical biologicals. Are these storage units acceptable for permanent storage of VFC vaccine?
Answer: Yes, these types of vaccine storage units are acceptable if they meet the following conditions:

1. The refrigerator and freezer compartments each have a separate external door, or
2. Units are stand-alone refrigerators and freezers

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

1. Be able to maintain required vaccine storage temperatures year-round;
2. Be large enough to hold the year's largest inventory;
3. At a minimum, have a working certified and calibrated digital data logger (DDL) thermometer inside each storage compartment. A Certificate of Traceability and Calibration Testing (also known as Report of Calibration) accompanies DDL thermometers that have undergone this calibration against a reference standard by an ILAC MRA signatory body. DDL thermometer calibration must be tested annually or according to manufacturer recommendations by a laboratory with accreditation from an ILAC MRA signatory body. Laboratories that have attained this accreditation meet the requirements for traceability. Providers are responsible for maintaining Certificates of Traceability and Calibration Testing (also known as Report of Calibration). Be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.)

Question:
It appears that some manufacturers' package inserts and CDC's storage and handling recommendations for refrigerated vaccines differ by one degree on the bottom of the refrigerated range. What range should the field staff use as their guide?
Answer:
Merck, GSK and Wyeth's package inserts recommend storage temperatures for their products to be 2° - 8°C (36° - 46°F). On the other hand, Sanofi's package inserts state that their products should be stored at 2° - 8°C (36° - 46°F). I have spoken with both the manufacturers and FDA on this matter. This is a non-issue with the manufacturers. In addition, the FDA (CBER's Office of Vaccine Research and Review (OVRR)) does not have any official position on this rounding issue. However, it is the opinion of OVRR that four-tenths of a degree should not cause any problem with the quality of vaccines and 35°F is acceptable. As you know, the vaccines should not be exposed to freezing temperatures, particularly those vaccines containing aluminum adjuvants.

The take home message is that the recommended temperature ranges are effective in keeping vaccine storage away from the dreaded 0°C (32°F).

Celsius °C	**Fahrenheit °F**
0 °C	32.0 °F
1 °C	33.8 °F
2 °C	35.6 °F
3 °C	37.4 °F
4 °C	39.2 °F
5 °C	41.0 °F
6 °C	42.8 °F
7 °C	44.6 °F
8 °C	46.4 °F

Question:
Some of our providers have been removing VFC vaccine that comes in manufacturer prefilled syringes from the original packaging to store in plastic containers if storage space is a concern. What is CDC's position on this?
Answer:
CDC's position is to have providers store vaccine in their original containers to help protect the vaccine from damage due to storage errors, as well as, to decrease the possibility of administration errors from inadvertently confusing similarly packaged vaccines.

Section Five: VFC Provider Enrollment

Question:
What should we do if a VFC-enrolled primary care provider does not want to order or offer one specific VFC vaccine based on his or her medical judgment?

Answer: The VFC statue, at section 1928(c)(2)(B)(i) of the Social Security Act (42 U.S.C. 1396s(c)(2)(B)(i)), states within the provider agreement section that the provider agrees as follows:

"Subject to clause (ii) the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by the…[ACIP], except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate." CDC interprets this provision to mean a medical judgment based on the situation of an individual VFC patient. Except as noted in the next Q and A regarding varicella vaccine, only specialty providers may choose, at the discretion of the awardee, to offer only specific VFC vaccines and their choice is based on the scope of their medical practices.

Other VFC providers must offer the full list of VFC vaccines according to the schedule determined by the ACIP in its VFC resolutions, except when in the provider's medical judgment, subject to accepted medical practice, the circumstances of an individual VFC patient makes such vaccination medically inappropriate.

Question:
Our state has large rural areas and many rural providers do not have the appropriate storage units to stock varicella vaccine and may be the only medical provider for several hundred miles. Are these providers non-compliant with the provider agreement for the VFC program because they are not offering a specific VFC vaccine?
Answer:
Certain vaccines, such as varicella vaccine, require special storage and it would be accepted medical practice not to order or store those vaccines if the provider did not have the appropriate storage facilities. CDC strongly encourages awardees to assist providers in finding ways to obtain vaccine storage that will allow provision of all VFC vaccines.

Question: When enrolling inpatient facilities such as birthing hospitals or juvenile inpatient treatment facilities in the VFC program, is it necessary to list all providers (e.g., residents, interns) authorized to administer vaccines under the supervision of the VFC provider who signs the enrollment form?
Answer: No. Due to the potentially large number of individuals that would be listed on the form and the difficulty in maintaining the accuracy of the list, it is not necessary to list these individuals on the enrollment form for birthing hospitals.

Question:
Can a pharmacist become a VFC program registered provider?
Answer:
Yes, in accordance with state law. If a pharmacist is granted the authority to administer vaccine by state law (whether by prescription, protocol, or prescribing authority), the pharmacist is eligible to become a VFC program registered provider within the state.
In jurisdictions where pharmacists are *not* authorized to administer vaccines except under the direct supervision of a physician, then the supervising physician must co-sign the provider enrollment agreement along with the pharmacist in order for the pharmacist to be enrolled as a VFC registered provider.

Question:
Must specialty providers offer all age-appropriate VFC vaccines to their VFC-eligible patients in order to enroll in the VFC program?
Answer:
No. Specialty providers enrolled in the VFC program, at the discretion of the awardee may limit their VFC practice to particular relevant vaccines. Specialty providers would include birthing hospitals, juvenile detention centers or juvenile inpatient treatment facilities, OB/GYN practices, family planning and STD clinics, and pharmacists/ pharmacies.

Section Six: Accountability

Question:
Should awardees include unused influenza doses that are returned at the end of the flu season as expired for CDC reporting purposes?
Answer:
No, influenza vaccine that is returned at the end of the flu season because of lack of demand should not be included in the calculations for reporting of expired or lost due to improper storage or handling. Influenza vaccine lost during the flu season due to improper storage or handling should be included in the calculations.

Reliable Sources of Immunization Information: Where Parents Can Go to Find Answers!

Websites

American Academy of Pediatrics (AAP)
www.aap.org/immunization

Centers for Disease Control and Prevention (CDC)
FOR PARENTS: www.cdc.gov/vaccines/parents
FOR HEALTHCARE PROVIDERS: www.cdc.gov/vaccines

History of Vaccines
www.historyofvaccines.org

Immunization Action Coalition (IAC)
FOR THE PUBLIC: www.vaccineinformation.org
FOR HEALTHCARE PROVIDERS: www.immunize.org

U.S. Dept. of Health and Human Services (HHS)
www.vaccines.gov

Vaccinate Your Family (formerly Every Child by Two)
www.vaccinateyourfamily.org

Vaccine Education Center (VEC), Children's Hospital of Philadelphia
www.chop.edu/centers-programs/vaccine-education-center

Vaxopedia
www.vaxopedia.org/about/

Voices for Vaccines (VFV)
FOR PARENTS, OTHER ADULTS, AND HEALTHCARE PROVIDERS:
www.voicesforvaccines.org

Apps for Mobile Devices

Child Health Tracker Developed by the American Academy of Pediatrics, this "tracker" gives parents the power of on-demand access to guidance on vaccinations and milestones they should be expecting with each birthday. Also included are tools like parent handouts for each well child visit. Available at a nominal cost from the American Academy of Pediatrics.

Vaccines on the Go: What You Should Know – This app provides parents with reliable information about the science, safety, and importance of vaccines and the diseases they prevent. A free app from the Vaccine Education Center at the Children's Hospital of Philadelphia. Available for Android and Apple devices.

TravWell – Use this app to build a trip to get destination-specific vaccine recommendations, a checklist of what is needed to prepare for travel and much more. A free app from Centers for Disease Control and Prevention.

Books for Parents

Baby 411 by Denise Fields and Ari Brown, MD, Windsor Peak Press, 7th edition, 2015. Available from your favorite local or online bookstore.

Mama Doc Medicine: Finding Calm and Confidence in Parenting, Child Health, and World-Life Balance by Wendy Sue Swanson, MD (aka "Seattle Mama Doc"), 2014. Available from American Academy of Pediatrics at http://shop.aap.org/for-parents.

Parents Guide to Childhood Immunization from Centers for Disease Control and Prevention. Available at www.cdc.gov/vaccines/parents/tools/parents-guide/index.html to download or order.

Vaccine-Preventable Diseases: The Forgotten Story by Texas Children's Hospital vaccine experts R. Cunningham, et al. Available at www.tchorderprocessing.com to order.

Vaccines and Your Child, Separating Fact from Fiction by Paul Offit, MD, and Charlotte Moser, Columbia University Press, 2011. Available at your favorite local or online bookstore.

Videos

IAC's Video Library – Go to the Immunization Action Coalition's website for parents and the public, www.vaccineinformation.org/videos, for hundreds of video clips about vaccines and vaccine-preventable diseases.

Shot by Shot Video Collection – Go to www.shotbyshot.org to read people's stories of vaccine-preventable diseases shared on the California Immunization Coalition website.

Phone Numbers

CDC–INFO Contact Center – Operated by the Centers for Disease Control and Prevention, this number is for both members of the general public and healthcare professionals who have questions about immunization and vaccine-preventable diseases. Call (800) CDC-INFO or (800) 232-4636. TTY: (888) 232-6348. CDC-INFO's operating hours are Monday through Friday from 8:00 A.M. to 8:00 P.M. (ET).

immunization action coalition
IAC
immunize.org

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p4012.pdf • Item #P4012 (5/19)

Skills Checklist for Vaccine Administration

During the COVID-19 pandemic, the CDC recommends additional infection control measures for vaccination (see www.cdc.gov/vaccines/pandemic-guidance/index.html).

The Skills Checklist is a self-assessment tool for healthcare staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each area. Score yourself in the Self-Assessment column. If you check **Needs to Improve**, you indicate further study, practice, or change is needed. When you check **Meets or Exceeds**, you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it to assist with performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they administer vaccines to several patients, and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (see bottom of page 3) to help them achieve the level of competence you expect; circle desired actions or write in others.

The video "Immunization Techniques: Best Practices with Infants, Children, and Adults" helps ensure that staff administer vaccines correctly. (View at www.youtube.com/watch?v=WsZ6NEijlfI or order online at www.immunize.org/dvd.) Another helpful resource is CDC's Vaccine Administration eLearn course, available at www.cdc.gov/vaccines/hcp/admin/resource-library.html.

		Self-Assessment		Supervisor Review		
COMPETENCY	**CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES**	**NEEDS TO IMPROVE**	**MEETS OR EXCEEDS**	**NEEDS TO IMPROVE**	**MEETS OR EXCEEDS**	**PLAN OF ACTION**
A **Patient/Parent Education**	1. Welcomes patient/family and establishes rapport.					
	2. Explains what vaccines will be given and which type(s) of injection(s) will be done.					
	3. Answers questions and accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received Vaccine Information Statements (VISs) for indicated vaccines and has had time to read them and ask questions.					
	5. Screens for contraindications (if within employee's scope of work).					
	6. Reviews comfort measures and aftercare instructions with patient/parents, and invites questions.					
B **Medical and Office Protocols**	1. Identifies the location of the medical protocols (e.g., immunization protocol, emergency protocol, reporting adverse events to the Vaccine Adverse Event Reporting system [VAERS], reference material).					
	2. Identifies the location of epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
	5. Demonstrates knowledge of proper vaccine handling (e.g., maintains and monitors vaccine at recommended temperature and protects from light).					

CONTINUED ON THE NEXT PAGE ▶

Adapted from California Department of Public Health, Immunization Branch

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VACCINE MANAGEMENT PLAN

Clinic Name_____

PIN_____

Contact Information		
	Name	**Phone Number**
Clinic		
Primary Vaccine Coordinator		
Alternate Vaccine Coordinator		
Alternate Vaccine Coordinator		
VFC and Immunization Program		
Regional VFC Representative		
Arkansas Immunization Program		501-537-8969
VFC Program Coordinator		501-661-2170
Vaccine Management Team		501-661-2169
WebIZ Team		800-574-4040
Maintenance and Repair		
Storage Unit and Digital Data Logger Maintenance/Repair		
Utility/Power Company		
Generator Maintenance/Repair		
Additional Staff		

Routine Vaccine Storage and Handling Plan

Vaccine Coordinator Duties and Training

Designate a primary Vaccine Coordinator and at least one alternate Vaccine Coordinator. The alternate Vaccine Coordinator(s) will assume the responsibility of primary Vaccine Coordinator during the primary Vaccine Coordinator's absence.

The Vaccine Coordinator or alternate will

- Complete vaccine inventory reconciliation monthly.
- Place vaccine orders monthly.
- Oversee the proper receipt and storage of vaccine deliveries.
- Keep the vaccine storage unit organized and rotate vaccines as needed.
- Remove expired vaccines from the vaccine storage unit.
- Ensure that storage unit temperatures are reviewed and documented per policy.
- Respond to temperature excursions promptly and ensure potentially compromised vaccines are not administered.
- Maintain all appropriate vaccine storage and handling documentation.
- Update clinic staff on vaccine recommendation changes, as they occur.
- Oversee the packing of vaccines for transport to off-site clinics.
- Notify the VFC Program immediately of any changes in key immunization staff.

Required Training and Documentation

- Annually, the primary and alternate Vaccine Coordinators will view the updated "You Call the Shots: VFC" and "You Call the Shots: Storage and Handling" modules.
  - The "You Call the Shots" modules are available at https://www.cdc.gov/vaccines/ed/youcalltheshots.html.
- Document all storage and handling trainings on the Storage and Handling Annual Education Log in the Vaccine Management Plan.

Vaccine Storage Unit Requirements

Vaccine Storage Unit Requirements and Set-up

1) Storage Unit

- Use one of the following types of storage units for storage of vaccine: pharmaceutical grade, freezer-less refrigerators, standalone freezers, and either the refrigerator or freezer portion of a combination household style storage unit. Make sure a combination household style storage unit has separate exterior doors that seal tightly and properly.
- Ensure that the storage unit is able to maintain the required temperature range throughout the year.

- Ensure that the storage unit has enough room to store the year's largest inventory without crowding (i.e. mass flu/school clinics).
- Ensure that the storage unit has enough room to store water bottles (in the refrigerator) and frozen coolant packs/water bottles (in the freezer) to stabilize the temperatures. Does not apply to pharmaceutical storage units.

- Dedicate the storage unit to the storage of vaccines. Never store food or beverages in a vaccine storage unit.
- NEVER use a dorm-style unit to store vaccines, even temporarily.

2) Digital Data Logger Thermometer

- Place a digital data logger that has a detachable probe kept in a bottle containing a thermal-buffered material, such as glycol, in all vaccine storage units.
- In non-pharmaceutical storage units, place the bottle of thermal-buffered material upright in the center of the vaccine storage unit.
- In pharmaceutical storage units, place the bottle of thermal-buffered material in the area of the storage unit designated for the thermometer equipment. The temperature probe does not have to be located in the center of the storage unit unless there is no manufacturer-designated area.
- Ensure the data logger is certified and calibrated at least every 2 years or replace with a new data logger.
- Ensure that a certified and calibrated back-up data logger is available, when needed.

3) Vaccine Storage Unit Set-up

- Ensure that the storage unit is level and placed at least 4 inches from the wall.
- Plug the storage unit directly into an outlet dedicated to only that unit and, preferably, connected to a generator.
- Never plug a vaccine storage unit into an extension cord, power strip or an outlet with a built-in circuit switch/reset button (GFCI outlet).
- Place a "Do Not Unplug" sign by the storage unit plug outlet and, if possible, a plug guard or cover over the plug.
- Place a "Do Not Adjust Temperature" sign on the storage unit.
- Label all storage unit circuit breakers to alert people not to turn off power to the storage units.
- Set back-up generators to self-test weekly. Manually test the generator quarterly and schedule routine generator maintenance at least annually.
- Document routine maintenance tasks and repairs and place in the Equipment Logbook.

4) Prior to Vaccine Storage

- Set the vaccine storage refrigerators at a temperature between 36°F and 46°F (2°C and 8°C), with an ideal average temperature of 40°F (5°C).
- Set the vaccine storage freezers at a temperature between -58°F and +5°F (-50°C and -15°C).
- To stabilize temperatures in household storage units, place cold bottles of water labeled "Do Not Drink" in the following areas of the refrigerator unit where vaccine storage is prohibited: on the floor, in the shelves of the door and on the top shelf under the cooling vent. Do not block the air vent(s). Place frozen coolant packs or frozen water bottles

labeled “Do Not Drink” in the freezer along the back, beside the walls and in the door. Water bottles will be cold and coolant packs will be frozen prior to putting them in the refrigerator/freezer with vaccine so they don’t alter the temperatures of the storage unit.

Note: Place frozen coolant packs or water bottles in the door of the unit securely so they cannot dislodge and prevent the unit door from closing. Do not overfill the storage unit doors.

- Once storage unit temperatures stabilize, review the temperatures and document twice a day: at the beginning and end of the clinic day.
- The storage unit temperatures will be within recommended range at least 5 days prior to vaccine storage.

5) Storage Unit Maintenance

- Check storage unit door seals regularly for signs of wear and tear.
- Ensure that the door of the storage unit opens and closes smoothly and fits squarely against the body of the storage unit.
- Ensure that the inside of the vaccine storage unit is cleaned regularly and the storage unit coils and motor remain free from dust.
- Defrost manual-defrost freezers if ice buildup is noted. While defrosting the storage unit, store vaccines temporarily in another storage unit with appropriate storage temperatures.

Vaccine Storage Practices

- Maintain vaccine storage refrigerators at a temperature between 36°F and 46°F (2°C and 8°C), with an ideal average temperature of 40°F (5°C).
- Maintain vaccine storage freezers at a temperature between -58°F and +5°F (-50°C and -15°C).
- Maintain the room temperature where the vaccine storage unit is located between 68°F and 77°F.
- Do not place vaccines against the walls, on the floor of the unit, or under the vent on the top shelf of the storage unit. Store refrigerated vaccines far enough away from the air vent to avoid freezing the vaccine.
- NEVER store vaccines in the door of the storage unit.
- Do not pack storage units too tightly. Allow space between rows of vaccines to promote cold air circulation.
- Store vaccines with similar names or similar packaging separately in the unit to lessen the risk of administration errors.
- Store vaccines in well vented bins or trays.
- Do not store vaccines in vegetable bins or drawers.
- Place vaccines with the soonest expiration dates in front of other vaccines of the same type that have later expiration dates.
- Do not keep blood, enteric, or other lab specimens in the vaccine refrigerator or freezer.
- Protect the following vaccines from light: Varivax, Zostavax, ProQuad, MMR ll, Hiberix, Gardasil, Afluria, Fluarix, FluLaval, Fluvirin, MenHibrix, Menveo, Rotarix, and RotaTeq.
- Store vaccines in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light.

- Store vaccine diluents that contain antigen or that are packaged with their vaccines {e.g., DTaP-IPV/Hib and MenACWY (Menveo)} in the refrigerator next to their corresponding vaccines.
- Never store diluents in the freezer.
- Always store Varicella and Varicella-containing vaccines in the freezer.
- Store MMR vaccine in the freezer, if possible. If unable to store MMR vaccine in the freezer, store MMR vaccine on the top shelf of the refrigerator near the air vent. Do not block the air vent.
- Store all other routinely administered vaccines in the vaccine refrigerator.
- Store MMR and Varicella diluents either at room temperature or in the refrigerator, never in the freezer.
- Notify the VFC Program if there is vaccine in the storage unit that will expire within 90 days and will not be used.

Vaccine Temperature Monitoring and Responding to Temperature Excursions

Daily Temperature Monitoring

- Review and document vaccine storage unit temperatures at least twice a day (beginning and end of day).
- Review and document the vaccine storage unit minimum and maximum temperatures at least once a day.
- Maintain copies of all Refrigerator/Freezer Temperature Recording Forms for 3 years.

Responding to Temperature Excursions

- Separate vaccines exposed to inappropriate temperatures from other vaccines, label the vaccines “Do Not Use”, and store at recommended temperatures until vaccine viability is determined.
- Place any vaccine shipments exposed to out-of-range temperatures and/or delayed shipments in the vaccine storage unit at appropriate temperatures and mark “Do Not Use”.
- Move vaccines from a storage unit that will not maintain appropriate temperatures to another storage unit with stable temperatures.
- Report any temperature excursion immediately to the primary or alternate Vaccine Coordinator.
- The Vaccine Coordinator will report all temperature excursions to the VFC Program at 1-800-574-4040 Option 3.
- Do not use or discard any VFC or SCHIP vaccines exposed to out-of-range temperatures until instructed to do so by the VFC Program.
- Document all temperature excursions and actions taken.

Responding to a Power Outage

- During a power outage, never open the storage unit door until the power is restored or it is determined that the vaccine will be moved to an alternate storage facility.

- If you are unsure how long a power outage will last, or you determine power will not be restored in time to maintain proper temperatures inside a vaccine storage unit, implement the Emergency Vaccine Storage, Handling, and Transport Plan.
- Once power has been restored to a storage unit, document the following:
    a) The room temperature where the storage unit is located
    b) The length of time the power was off
    c) The minimum and maximum temperatures reached during the power outage

    Notify the VFC Program if a vaccine storage unit temperature goes outside of the recommended range during a power outage to determine if the vaccine can be used.

Inventory Management

Vaccine Inventory and Reconciliation

- Count all vaccine doses at least once a month to ensure the number of physical doses on hand matches the number of doses indicated in WebIZ.
- Complete an Inventory Reconciliation in WebIZ at least once a month and no more than 14 days prior to ordering vaccine.
- Inventory Reconciliation instructions are available on the WebIZ Home Page.

Vaccine Stock Rotation and Removal

- Rotate vaccine stock at least once a week and with each vaccine shipment to ensure that shorter-dated vaccines are placed in front and used first.
- Check expiration dates weekly and immediately remove any expired vaccines and diluents. Mark expired vaccines “Do Not Use” and remove from the vaccine storage unit.

Vaccine Ordering

- Place routine vaccine orders monthly.
- Contact the Vaccine Management Team to order non-routinely recommended vaccines, such as Td, PPSV23 and Meningococcal B, and to place an emergency vaccine order.

Receiving Vaccine Shipments

- Upon arrival, examine the shipping container for signs of physical damage.
- Verify that the vaccine shipment was shipped to the correct address/facility.
- Unpack and examine vaccine deliveries immediately.
- Ensure that the vaccine diluent was received with the vaccine.

    Note: Vaccine diluent may be shipped in the box lid of the vaccine transport container.
- Place the vaccine received into the storage unit.
- Never place an unopened vaccine shipment box in a vaccine storage unit.
- Ensure the packing slip matches the vaccines received.
- Check the expiration dates of received vaccines and diluents to ensure that no expired or short-dated vaccines are received.
- Verify that the cold chain monitor included with the vaccine shipment (if applicable) indicates that the vaccine temperature did not go out of range during shipment.

Note: Some vaccine manufacturers do not include a cold chain monitor with vaccine shipments.

- Check all inserts included with vaccine shipments. Some manufacturers include important information on vaccine shipments, such as the allowed shipment timeframe, in the shipment container with the vaccine.
- Notify the Immunization Program at 1-800-574-4040 if vaccine viability is questionable when vaccine is received.
- Accept the vaccine shipment in WebIZ to add the vaccines received into the WebIZ inventory.
- Maintain all vaccine packing slips for 3 years.

Vaccine Separation

- Separate and label vaccines according to funding source: VFC, Private, and SCHIP (if applicable).

- Physically separate vaccines by vaccine type and funding source in a storage unit in one or more of the following ways:

- Mark the vaccine boxes/vials with the appropriate funding source.
- Store the vaccines in the same storage unit in separate containers and/or separate shelves with the funding source clearly marked on the container/shelf.
- Store vaccine in separate storage units and mark the storage unit with the appropriate funding source.

Vaccine Borrowing

- Borrowing vaccine from VFC vaccine stock will only occur in rare, unplanned situations. For example, a delayed vaccine shipment, vaccine spoiled in-transit to the clinic, or new staff that calculated the ordering time incorrectly.
- Ensure that borrowing from VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child.
- Repay borrowed VFC doses as soon as possible; not to exceed 90 days.
- Never swap short-dated VFC vaccine with vaccine from another funding source to prevent the vaccine from expiring.

VFC Vaccine Borrowing Reports

- Review the VFC Borrowing Report at least once a week.
- Document when a dose of borrowed VFC vaccine is replaced by completing the “Date Dose Returned to Appropriate Stock” and “Returned by” sections of the Vaccine Borrowing Report.
- Maintain all Vaccine Borrowing Reports for 3 years.

Vaccine Transfers

- All vaccine transfers must be approved by the VFC Program.

- Contact your VFC Representative if vaccine needs to be moved to another facility.
- Only transfer vaccines when absolutely necessary.
- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
- Transport diluents that contain antigen, such as Pentacel and Menveo diluent, with the corresponding vaccines at refrigerator temperature.
- If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) are transported with refrigerated vaccines, refrigerate the diluents in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.
- Never freeze diluents.
- Enter all outgoing vaccine transfers into the WebIZ.

- When receiving incoming vaccine transfers, verify that the vaccine received is the same vaccine entered on the WebIZ transfer.

- Once verified, accept all vaccine transfers in WebIZ. Accepting the WebIZ transfer will add the vaccine to the WebIZ inventory.

- Place all vaccines received into the storage unit immediately.

Expired and Spoiled Vaccines

- Vaccine expiration dates including only a month and year expire at midnight on the last day of the indicated month.
- Vaccine expiration dates including a month, day and year may be used through the day included in the expiration date.
- Always remove expired and spoiled vaccines and diluents from storage units containing viable vaccines to prevent inadvertent administration.
- Label all expired and spoiled vaccine “Do Not Use”.

Expired and Spoiled and Vaccine Returns

- Return all expired and spoiled vaccines as soon as possible.
- Return expired and spoiled vaccines no later than the 20th of each month.
- Do not send any <u>open</u> vaccine vials or syringes to McKesson. Discard all opened vaccine vials and syringes that are expired or spoiled in a medical waste container.
  Note: Open boxes of vaccines can be returned but not vials or syringes with the caps removed.
- Enter vaccine returns using the Vaccine Return module in WebIZ. Vaccine return instructions are available in the WebIZ Reports module under Arkansas WebIZ Training Material and Documents.

VFC/Storage and Handling Training

DATE	TITLE OF TRAINING	NAME AND TITLE OF EMPLOYEE

Emergency Vaccine Storage, Handling and Transport Plan

Emergency Contact Information		
	Name	Phone Number
Primary Vaccine Coordinator		
Alternate Vaccine Coordinator		
Regional VFC Representative		
ADH Immunization Program		800-574-4040 or 501-537-8969
VFC Program Coordinator		501-537-8969
Vaccine Management Team		800-574-4040
Contact for 24 hour access to Clinic		
Storage Unit Maintenance and Repair		
Storage Unit and Digital Data Logger		
Local Utility/Power Company		
Generator Maintenance/Repair		
In Case of Emergency, move the vaccines to the following facility		
Facility Name:		
Facility Address:		
Contact Person with 24 hour access at facility Name _____Phone Number _____		

Contact the VFC Program to determine if vaccine can be used after an emergency if vaccines were exposed to out-of-range temperatures.

Transporting Vaccines and Diluents in an Emergency

- Establish a working agreement with at least one alternative storage facility with a back-up generator where vaccines can be appropriately stored and monitored during a power outage.
- Do not open the storage unit door during a power outage unless vaccine is being moved to an alternate storage facility or site. Open doors only after completing all preparations for packing and moving vaccines.

- If unsure of how long a power outage will last, or it is determined that power will not be restored in time to maintain proper temperature inside the vaccine storage unit, contact the alternate vaccine storage site
- Verify with the alternate storage facility that their electricity is on or that the generator is working and they can accept the vaccines for storage.
- Once the alternate storage facility is contacted and transport supplies are gathered, pack the vaccines in the transport container following CDC guidelines.
- Transport vaccines in a hard-sided cooler with at least 2-inch walls, a thick Styrofoam vaccine shipping container or a specialized vaccine transport cooler (e.g., AcuTemp vaccine courier system).

- Always use a digital data logger to monitor temperatures during vaccine transport.

- Place a copy of the vaccine inventory being transported in the transport container with the vaccines.
- Move transport containers directly to a preheated or precooled vehicle.

- Only transport vaccines inside the passenger compartment of a vehicle, not in the trunk.

- Avoid leaving containers in areas where they are exposed to direct sunlight.

- Upon arrival at the alternate storage facility, confirm their vaccine storage unit temperatures are within recommended ranges.

- Record the date, time, and temperature in the transport container upon arrival at the alternate storage facility. The temperature should always be checked prior to opening the transport cooler, if possible.

- Store vaccines immediately upon arrival at the alternate storage facility.
- Once power is restored at the clinic and the storage unit temperatures are stabilized, transport the vaccine back to the clinic and place in the vaccine storage unit.

- Diluents that contain antigen, such as Pentacel and Menveo diluent, should be transported with the corresponding vaccines at a refrigerator temperature in the transport container.

- For diluents stored at room temperature, place the diluent in a refrigerator storage unit prior to transport to cool the diluent before placing the diluent in the transport container.

Diluents

- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
  - Note: Placing room temperature diluent in the transport container can raise the temperature of the container.
- Place an insulating barrier (e.g., bubble wrap) between the diluents and conditioned water bottles.
- Never freeze diluents, not even during transport.

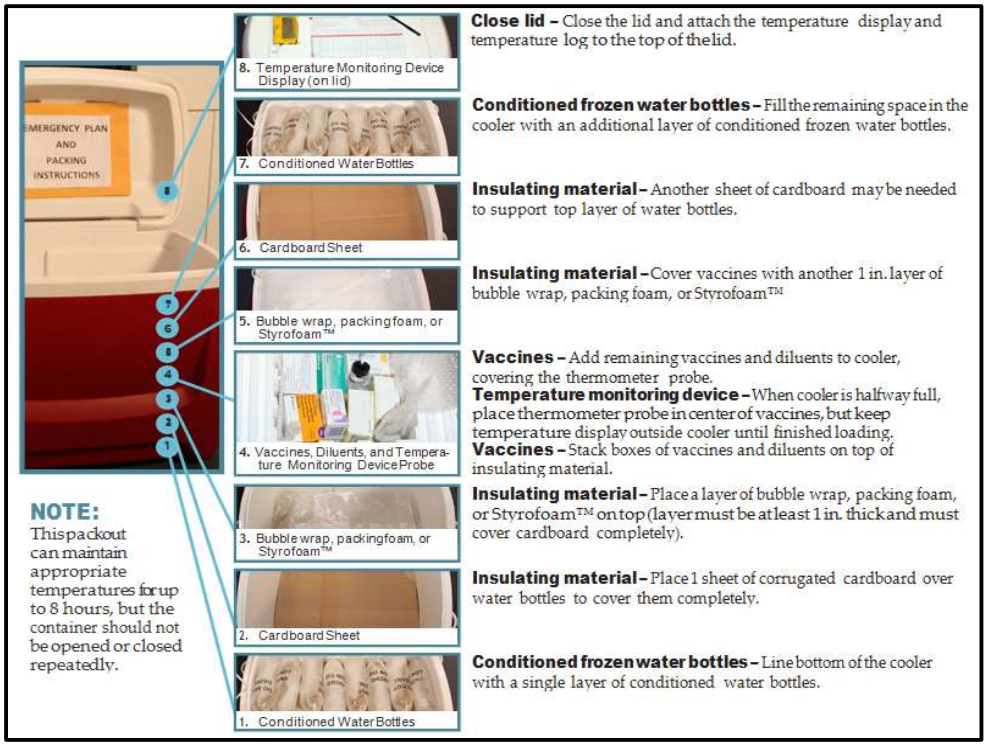
Refrigerated Vaccines

- Transport and store refrigerated vaccines at 36-46°F at all times.
- "Condition" frozen water bottles prior to use in hard-sided and Styrofoam coolers. To condition water bottles, place them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming on the inside near the surface of the bottle. The water bottle is properly conditioned if the ice block inside spins freely when the bottle is rotated. **Frozen water bottles that are not conditioned can freeze vaccine.**
- Pack hard-sided coolers and thick Styrofoam shipping containers as follows:

1) Place a layer of "conditioned" water bottles in the bottom of the transport container.
2) Place a piece of corrugated cardboard (cut to fit the interior dimensions of the cooler) over the water bottles.
3) Place at least a 1-inch layer of insulating cushioning material over the cardboard (bubble wrap, packing foam, or Styrofoam). Do not use packing peanuts, paper towels or any thin material as insulation material.
4) Place the vaccine on the insulating material. Refrigerated vaccines should never be placed directly on frozen water bottles.
5) Place the buffered temperature probe from a digital data logger in the middle of the vaccine.
6) Place at least a 1-inch layer of insulating cushioning material over the vaccine.
7) Place a piece of corrugated cardboard over the insulating material.
8) Place a layer of conditioned water bottles on top of the piece of cardboard.
9) Secure the digital data logger display to the outside of the container to decrease the number of times the container door is opened.

- Pack specialized vaccine transport coolers (e.g., Acutemp vaccine courier system) as instructed by the manufacturer.

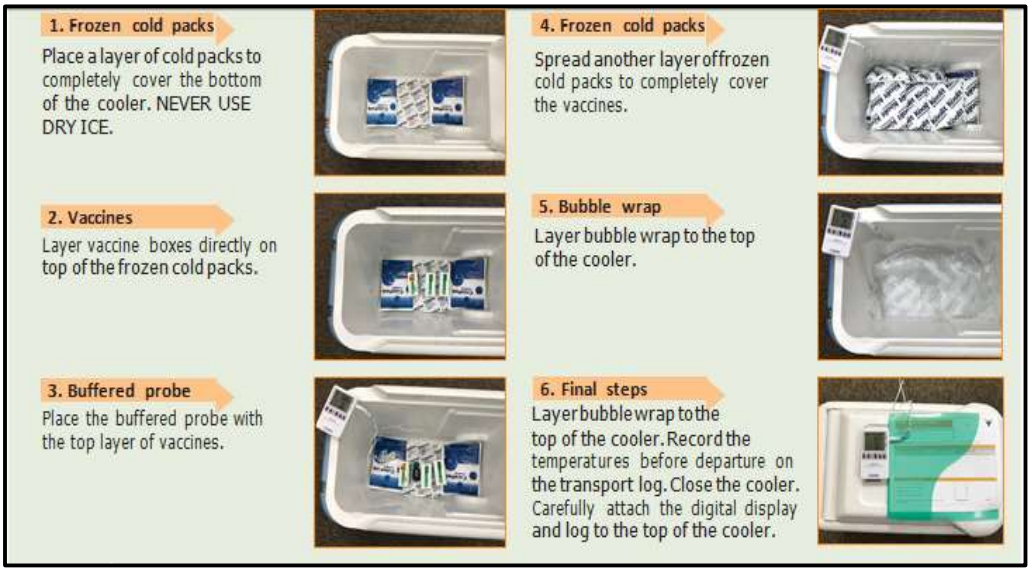
Refrigerated Vaccine Pack out



Frozen Vaccines

- Transport frozen vaccines in a portable freezer unit that maintains the temperature between -58°F and +5°F, if at all possible.
- If a portable freezer unit is not available, transport frozen vaccines using a qualified container and pack-out.

Frozen Vaccine Pack-out



VACCINE MANUFACTURER CONTACT LIST

Manufacturer	Telephone Number	Vaccine Product(s)
GlaxoSmithKline (GSK)	866-475-8222	Infanrix, Pediarix, Kinrix, Havrix, Engerix-B, Twinrix, Hiberix, Fluarix, Menveo, Rotarix, Boostrix, Bexsero
Massachusetts Biological Labs	800-457-4626	Td
MedImmune	877-633-4411	LAIV- FluMist
Merck & Co., Inc.	877-829-6372	Vaqta, Recombivax-B, Gardasil, MMR, PedvaxHib, Pneumovax, ProQuad, Rotateq, Varivax, Zostavax
Novartis	877-683-4732	RabAvert
Pfizer/Wyeth	800-438-1985	Trumenba, Prevnar13
Protein Sciences	800-488-7099	FluBlok
Sanofi Pasteur	800-822-2463	Daptacel, Tenivac, Adacel, Fluzone, Imovax, Menactra, ActHib, Pentacel, Quadracel, IPOL
Seqirus	855-358-8966	Afluria, Fluad, Flucelvax, Fluvirin, Rapivab

VACCINE MANAGEMENT PLAN UPDATES Annually and As Needed Due To Changes	
Date	Updated By:

Clinic Policy Templates

Clinic AR Primary and Alternate Vaccine Coordinator

Policy:

Each VFC Provider will designate a Primary and Back up Vaccine Coordinator who will be responsible for vaccine management.

Procedure:

1. _____ Clinic will designate a staff member(s) as the primary vaccine inventory manager/coordinator. A back-up person will be cross-trained in case of the primary vaccine inventory manager's absence.
2. The Inventory Manager/Coordinator will be responsible for shipping, storing and receiving vaccine according to recommendations found in the most current addition of *The Epidemiology and Prevention of Vaccine Preventable Diseases (Pink Book)* and instructions found in WebIZ.
3. Vaccine Inventory Manager/Coordinator is responsible for:
   a. Maintaining and adjusting the temperatures of a vaccine storage unit.
   b. Documenting on temperature logs for each storage unit.
   c. Documenting adjustments in temps and communications with the Immunization Section and any concerns with vaccine temperatures, balances, wastage, etc.
   d. Any inventory concerns will be communicated to the Vaccine Management Team at 800.574.4040 as soon as possible.
4. Significant changes in population size served must be submitted to the Immunization Section via an updated *Provider Profile* (see pages 8-9).
5. The Vaccine Inventory Manager/Coordinator is responsible for training staff and keeping a record of that training.
6. Other resources for Providers including notices of immunization changes, newsletters and other helpful information can be subscribed to via: http://www.cdc.gov/vaccines/

Education for Vaccine Personnel

Policy:

Ongoing education and information is available to staff administering vaccinations.

Procedure:

1. Current copies of *Epidemiology and Prevention for Vaccine-Preventable Diseases (The Pink Book)* will be available for the staff.

2. Online copies of *The Pink Book* are available at http://www.cdc.gov/vaccines/pubs/pinkbook/index.html. Please save as a favorite to the desktop.

3. Policy and procedure for the vaccination program will be reviewed annually and updated as needed.

4. Other in-service is available to the staff through CDC web services, literature, in-house staff and the Arkansas Department of Health.

5. Staff are required to view the following videos annually and print the certificate to be available during the VFC Site Visit:

   Immunization: You Call The Shots - VACCINES FOR CHILDREN PROGRAM

   Link: http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp

   Immunization: You Call The Shots - STORAGE AND HANDLING

   Link: http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

Clinic AR Immunization Registry/WebIZ Software Administrator

Policy:

The WebIZ requires local staff to maintain accurate and safe access for the clinic.

Procedure:

1. _____ Clinic will designate one staff member as the WebIZ Software Administrator.

2. A back-up person will be cross-trained in case the primary administrator is absent.

3. WebIZ Software Administrator will be trained initially by WebIZ Personnel or VFC Representative. That administrator will then be responsible for the training of any additional clinic personnel.

4. The WebIZ Software Administrator will consult Little Rock Personnel for any questions at either the helpdesk email or telephone number provided on the Web IZ Home Page.

5. New employees will be added to the appropriate Web IZ user categories according to Clinic needs.

6. Employees no longer employed will be removed from WebIZ immediately to prevent access to vaccine information.

Regulations Concerning Vaccine Information Statements (VIS)

Policy:

_____ Clinic will provide Vaccine Information Statements and maintain records in accordance with the National Childhood Vaccine Injury Act.

Parents/Responsible persons will be given a copy of the VIS to read prior to the immunization and a copy will be available for the parent/responsible person to take with them out of the clinic.

Procedure:

1. On the internet, click onto CDC.gov and go to the Vaccine Information Statement site.
2. Choose the appropriate VIS for the language spoken and vaccine being given.
3. Multiple copies can be kept for clinic convenience. Care will be taken to destroy out of date copies and replace them with in-date copies as they become available.
4. Record the name of the VIS, date of the VIS, and the date the VIS was given to the parent/responsible party in the Medical Record.
5. Immunizations recorded directly into the WebIZ automatically contain this information.

How to Obtain a Current Vaccine Information Statement (VIS)

Policy:

The _____ Clinic will obtain current and language appropriate VIS in accordance with regulation.

Procedure:

1. Go to http://www.cdc.gov/vaccines/hcp/vis/current-vis.html to subscribe to automatic updates

2. Save another VIS location to your favorites: http://www.immunize.org/vis/

3. Print the required VIS in the appropriate language.

4. WebIZ maintains all current VIS in the Reports Section under “Forms/Informational Documents”. VIS may be printed from this area of WebIZ.

Mandatory Information for Immunizations in the Medical Records

Policy:

The _____ Clinic shall make a notation in each patient's permanent medical record at the time vaccine is given.

Procedure:

1. Verify the Clinic Information is contained in the Immunization Record.
2. Choose and record the appropriate VIS for the language spoken and vaccine being given.
3. Record the name, address and title of the individual who administers the vaccine.
4. Record the date the vaccine is administered.
5. Record the vaccine manufacturer, lot number and expiration date of the vaccine used.
6. Record the date the Vaccine Information Statement was provided.

Mandatory Recording of Immunizations into WebIZ

Policy:

The _____ Clinic will record each immunization into the WebIZ, the State immunization registry/information system, according to the laws of the State of Arkansas (found at: https://www.healthy.arkansas.gov/images/uploads/rules/ImmunizationReporting.pdf.)

Procedure:

Record the immunizations according to the WebIZ instructions.