VACCINES FOR CHILDREN

Provider Guide

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VFC PROGRAM 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 Arkansas VFC Program 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 Advisory Committee on Immunization Practices (ACIP)
- Saves parents and enrolled providers out-or-pocket expenses for vaccines.
- Eliminates or reduces vaccine cost as a barrier to vaccinate eligible children.
- Reduces the practice of revering children for vaccinations.

Vaccines Available Through the VFC Program

Vaccine procured through the VFC program must be administered according to the guidelines outlined by the ACIP in VFC resolutions. VFC vaccine also may be administered in accordance with State school attendance laws. The current VFC vaccine list can be found at VFC-ACIP Resolution.

Diphtheria	Mumps
Haemophilus Influenzae Type B (Hib)	Pertussis (whooping cough)
Hepatitis A	Pneumococcal Disease
Hepatitis B	Polio
Human Papillomavirus (HPV)	Rotavirus
Influenza (flu)	Rubella (German measles)
Measles	Tetanus (lockjaw)
Meningococcal Disease	Varicella (chickenpox)
COVID-19	RSV

VFC Provider Agreement

Provider Enrollment form is a legally binding agreement that must be **completed every year.** When you electronically accept the conditions, 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 vaccines 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 *(MD, DO, NP, PA, pharmacist)* or equivalent, to represent all physicians.
The VFC Provider Agreement is completed through the Clinic Tools module in WebIZ. Please note the following important information:

- **New VFC Enrollments** must be completed withing the 90-day time frame. Failure to submit required enrollment documentation will result in a rejected VFC enrollment and must start from the beginning.
- All VFC documents must be retained for three (3) years prior to discarding.
- Annual VFC enrollments must be submitted at the beginning of each Fiscal Year (July 1st through June 30th of the following year).
    - VFC open enrollment for recertification begins on July 1st and closes on August 30th.
    - You Call the Shots Training must be current prior to approval.
        - CDC Vaccines for Children
        - Storage and Handling

NOTE: Failure to comply with VFC Program regulations may result in the ordering of vaccine suspension or the removal of your facility from the VFC program.

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 Profile. Annually thereafter, the VFC Provider Profile form must be completed using data from the previous 12 months. The Provider Profile data should be obtained from the clinic electronic medical record or from the Arkansas Immunization Information System (IIS), all vaccination information must be 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 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 the number of children seen by clinic). The VFC Provider Profile is completed through the Clinic Tools module in WebIZ with the VFC Provider Agreement.

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 or more 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
- Underinsured is defined as children who have private health insurance, but the coverage does not include vaccines, 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 eligible to receive VFC vaccines).

ONLY APPLICABLE to Federal Qualified Health Centers (FQHC), Rural Health Centers (RHC), and Local Health Units.

Underinsured children are eligible to receive VFC vaccine only through a Federal Qualified Health Center (FQHC), Rural Health Clinic (RHC), or a Local Health Unit (LHU). Underinsured children should be referred to an FQHC, RHC, or LHU.

- FQHCs and RHCs for VFC purposes 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 Community Health Center (CHC)/FQHC.

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 Arkansas Immunization Information System, WebIZ, with each immunization encounter. VFC vaccine must be administered only to children who are VFC eligible. State Children's Health Insurance Program (SCHIP) vaccine must 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 requirements will be monitored by an AR VFC Representative during the VFC site visit by selecting random patients.

We highly recommend that VFC Providers post a Vaccine Eligibility Reminder Sign on the storage unit(s) or print out a copy and disseminate amongst staff responsible for determining VFC eligibility. VFC Providers must be aware that some children may have more than one eligibility category. In this case, 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.

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 (3) cost associated with each immunization:

- The cost of the vaccine
- The cost of administering vaccine
- The cost of the office visit

Because some children may qualify for VFC and have private insurance, ensure that billing can determine when VFC vaccine is given. Clinics cannot bill for the cost of VFC vaccine, only the administration fee. Charging for the cost of VFC vaccine can be considered fraud and abuse. During the site visit, the provider must be able to explain or demonstrate how much the practice will charge.

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. A patient may be sent only one bill for administration fee reimbursement. 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/SCHIP 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. Pharmacies must vaccinate all "walk-in" patients that are VFC-eligible.

For VFC-eligible Medicaid patients, providers must document the correct Current Procedural Terminology (CPT) code(s) when billing Medicaid for the administration fee on the claim form for each immunization administered to receive reimbursement for the administration. An office visit or an Early and Periodic Screening Diagnostic and Treatment (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.

State Law and Standing Ordering for Immunization Services

Laws permitting non-physician health professionals to administer vaccines by state and specialty. For more information click here.

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 WebIZ 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. 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).

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 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, 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.

RSV Monoclonal Antibody Products

- Starting July 1, 2025, VFC Providers *that serve and plan to vaccinate* any privately insured, non-VFC eligible population, must maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. This will include Nirsevimab and any other RSV monoclonal antibody product that may be added to the VFC program. **Routine borrowing of VFC vaccines and monoclonal antibody products for use among privately insured, non-VFC-eligible patients is not permitted**.

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:

- In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate.
- The requirements contradict state law, including laws pertaining to religion 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 vaccines 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 VFC-ACIP Vaccine Resolutions.

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 CDC Immunization Schedules.

Consider signing up for automatic notifications updates at "About CDC's Emails Subscription Service"

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 vaccines may be stocked by the clinic or ordered as needed through the AR WebIZ Vaccine Ordering Module.

Medical Exemptions

A physician statement outlining medical reasons for an exemption for a specific immunization is to be submitted to the Medical Director of the Immunization Section. The Medical Director will decide whether to grant a medical exemption based on the CDC guidelines.

NOTE: Incomplete forms will be returned for completion. A new exemption form must be completed every school year.

Philosophical Exemption

Philosophical exemptions can be granted for children on the grounds that such immunization conflicts with religious and or philosophical tenets or beliefs.

NOTE: The form requires a signature and a seal from a Notary Public. Incomplete forms will be returned for completion. A new Exemption Form Must Be Completed Every School Year.

- Exemption Form can be found at the Arkansas Department of Health Website or you can email the Arkansas Department of Health (ADH) at Immunization.section@arkansas.gov.
- Arkansas Immunization Requirements for colleges, schools, and daycares can be found at "Arkansas State Board of Health".

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 (VIS), and mandated the reporting of certain adverse events following vaccination. Federal law requires that 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 Vaccine Information Statement is provided.

Vaccine Information Statement (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 the VISs for routine vaccines given from birth through six years: DTaP, IPV, Hib, PCV, and Hepatitis B.
- When possible, provide the VIS in the person's native or preferred language. Translated VISs are available at no charge on the Immunization Action Coalition website.
- Providers should have a process in place to frequently check for VIS updated forms on the "CDC VIS" webpage. VIS forms can be downloaded as PDFs or printed.

Consider signing up for automatic notifications updates at

"About Centers for CDC's Emails Subscription Service"

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 the "VAERS" Website. A VAERS form is also available on WebIZ.

Prepare 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, "Clinical Resources Managing Vaccine Reactions".

Arkansas Immunization Information System/ 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 (3) years and made readily available to public health officials, including the AR Department of Human services upon request.

Recording Changes

VFC enrolled providers may be notified of changes to the VFC program via email, fax, phone call, 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. Facility Vaccine Coordinator changes may be submitted in the Clinic Tools module in WebIZ.

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 in the CDC "Vaccine Storage and Handling Toolkit" webpage.

Minimum elements required for VFC providers' participation are outlined below:

- Designate one staff member to be the primary vaccine manager and at least one back-up vaccine manager who can perform the same responsibilities if the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office; *therefore, we highly recommend that a full-time employee of the facility is designated as the primary or back-up vaccine manager.*
- 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 and if applicable the Min/Max should be recorded ones a day.
- Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency, following the office's Vaccine Storage and Handling Plan. ***A simple log sheet with the staff members' name and date of training must be kept and displayed as documentation. A sample form is available in the Vaccine Management Plan template provided by the VFC Program.***
- Unless otherwise noted, the Primary Vaccine and/or Back-up Coordinator 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 their own (must be approved by the VFC Program). Both plans should be reviewed and updated as necessary and at a 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.
- 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 a stand-alone unit is the 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-along 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.

VFC Requirements for Inventory of COVID-19 and Nirsevimab

RSV Monoclonal Antibody Products

- Starting July 1, 2025, VFC Providers *that serve and plan to vaccinate* any privately insured, non-VFC eligible population, must maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. This will include Nirsevimab and any other RSV monoclonal antibody product that may be added to the VFC program. Routine borrowing of VFC vaccines and monoclonal antibody products for use among privately insured, non-VFC-eligible patients is not permitted.
    - **For example**: If the provider vaccinates privately insured and non-VFC eligible population with routine vaccines, the Provider can choose not to administer the RSV monoclonal antibody (seasonal) and refer them to the Local Health Unit", as long as they don't use their VFC RSV vaccine to vaccinate the privately insured".

COVID-19 Vaccines

- Given the unique considerations of COVID-19 vaccination, it may not be practical for all VFC providers to stock this vaccine for VFC-eligible patients. In such cases, VFC Providers must identify accessible locations where VFC-eligible children can be referred for COVID-19 vaccination.

Note: When purchasing a new vaccine storage, it is highly recommended to consider purchasing a stand-

alone or a pharmaceutical grade storage unit.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the clinic's Primary Vaccine and/or the Back-up vaccine Coordinator. If delegated to the Back-up Coordinator, 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 them 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, providers must 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 Primary Vaccine and Back-up Coordinator. If other staff must monitor temperatures, they must be trained in how to respond, 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 workday ensuring that refrigerator temperatures are between 36° and 46° F (2° and 8°C), freezer temperatures are between -58° and +5° F (-50° and -15°C), and ultracold freezer temperatures are between -130° F and -76° F (-90° C and -60° C), if applicable. The minimum and maximum temperatures of the digital data logger should be cleared each day after documentation. Monitoring and recording are 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.
- Contact the vaccine manufacturer(s) for a vaccine viability determination if a temperature excursion occurs. Obtain vaccine manufacturer information regarding the temperature excursion and vaccine viability results.
- Must maintain an ongoing file of temperature logs and excursion information for 3 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 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 the 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 temperatures, 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 stop 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. Vaccine orders may only be placed the ***1st through the 20th of each month***. **Orders received beyond this timeframe will be rejected. 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 for 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 VFC 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. These vaccines must be disposed of in a biological waste container.

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.

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. Vaccines should not be placed in the storage unit in the transport container. If a vaccine shipment is compromised, temperature monitors are out-of-range, or a warm indicator is activated, they should contact the **Vaccine Management Team immediately at (800) 574-4040.**

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 during an AR VFC site visit. Failure to allow a site visit or complete a follow-up visit may result in a temporary vaccine ordering suspension until follow-up has been completed and all matters have been resolved.

The intention of the site visit is to offer VFC providers support, guidance, and to ensure the federal and state requirements are 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 in developing an action plan to improve them.

Clinic VFC Primary and Back-up Coordinators must complete 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 Representatives must verify training completion during VFC compliance sitevisits.

At a minimum, the VFC Primary and Back-up Coordinators must complete the "CDC Vaccines for Children- 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 three (3) years. The VFC Reviewer will request a copy of the completion certificates during the VFC Provider Compliance Site Visit.

In the event a new person is appointed to replace the VFC Primary Coordinator, AR VFC Representative must be notified no later than 15 days after the new VFC manager is appointed. The new VFC Primary Coordinator must submit to the AR VFC Representative 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, they must contact the VFC Program at 501-661-2170. The Provider is responsible for returning all VFC vaccine received. The VFC Representative will furnish the provider with information on returning any expired VFC-provided vaccine or assist with transferring viable vaccine doses to another VFC Provider. If the agreement is terminated, then the provider will properly return any expired 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.
- Failure to submit VFC enrollment recertification.
- Failure to maintain required VFC documentation.
- Failure to respond to the VFC Representatives in a timely manner.
- Incomplete site reviews (including follow-up reviews.)

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 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 vaccines 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 fully account for the 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 an external agency (e.g., Medicaid) for further fraud and abuse investigation.

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.

VFC Primary and Back-up Vaccine Coordinators

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

VFC 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.

- 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
- Attendance at a regional immunization training session.

Primary Vaccine Coordinator:

- Is responsible for ensuring that all staff receives training on VFC guidelines and proper storage/handling and vaccine administration.
- Upon hire and repeating annually, immunization staff (other than Primary and Back-up Coordinators) should take the following online Center for Disease Control and Prevention (CDC) training modules.
    - Vaccines for Children (VFC) Vaccine
    - Storage and Handling

Note: New CDC CE Activities Will Be Listed on CDC TRAIN Starting January 1, 2024.
To improve your learning experience, CDC's continuing education (CE) process is moving from Training and Continuing Education Online (TCEO) to CDC TRAIN. Beginning on January 1, 2024, *new* activities that offer CE from CDC will be listed in CDC TRAIN. If you do not already have a CDC TRAIN account, please create one.

TCEO has been the primary system that provides access to CDC educational activities for CE. The move to one system will improve efficiency and make it easier for learners to access non-credit and for-credit activities, and earn CE in one place – CDC TRAIN!

Additional information is available at CDC Continuing Education Update. Instructions will also be available on both platforms, and a learner support team will be available to answer questions.

CDC training modules offer continuing education credits at no charge. It is highly recommended for Certificate(s) of completion to be saved electronically, printed, and filed with VFC records.

Oversight Responsibilities

- Notify the Immunization Program immediately of any changes in key staff (Primary or Back-up Vaccine Coordinator).
- Check and record temperatures twice daily at the beginning and end of each clinic day for every vaccine storage unit. Use certified, calibrated thermometers.
- Assure refrigerator temperatures are within the acceptable range of 35° F and 46° F.
- Maintain freezer temperatures between 5° F and -50° F.
- If applicable, maintain ultracold freezer temperatures between -130° F and -76° F (-90° C and -60° C)
- Ultracold freezer temperatures are between -130° F and -76° F (-90° C and -60° C), if applicable. The minimum and maximum temperatures of the digital data logger should be cleared each day after documentation. Monitoring and recording are required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action if temperatures are not within appropriate ranges.
    - Isolate/Quarantine vaccine.
    - Mark, DO NOT USE.
    - Immediately notify the vaccine manufacturer(s)
- With the receipt of any vaccine:
    - Ensure the packaging slip matches the contents.
    - Verify the internal temperature of the shipping container is at the appropriate temperature range for the vaccine contained.

    - Store vaccine inventory in an appropriate refrigerator/freezer.
    - Enter the received vaccine into WebIZ making sure the entry matches the packing slip.
- Rotate inventory to assure vaccines with the shortest expiration dates are used first.
- Remove expired vaccine from storage units upon expiration date.
- Provide training for staff during orientation, annually, and as needed on the following:
    - Proper handling of vaccine.
    - Managing vaccine inventory.
    - Storing vaccines appropriately.
    - Stabilizing temperatures.
    - Safeguarding the electrical supply for vaccine storage units.
    - Vaccine accountability including the NO borrowing policy between VFC and privately purchased vaccine.
    - Proper documentation in WebIZ.
    - Emergency procedures related to the safe keeping of vaccine.
- Perform reminder/recall for children and adolescents who are not up to date on all recommended vaccines.

VACCINE ELIGIBILTY REMINDER

Always check current VFC eligibility prior to obtaining vaccine from the refrigerator/freezer! Document the eligibility status in your Electronic Health Record (EHR) and WebIZ. Choose the correct vaccine lot number designated as "Private or "Public (VFC or SCHIP)" 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.

Special Circumstances: Non-U.S. citizen children are VFC eligible, if they meet the basic VFC eligibility criteria (≤18 years and AI/AN, Medicaid eligible, uninsured, or underinsured). Additionally, while citizenship is not a requirement for VFC eligibility, VFC vaccines are not intended to be used for children who are simply visiting the United States, temporarily traveling in the United States or tourist.

VFC Eligibility Reminder

0 THROUGH 18 YEARS	
Insurance Status	**Eligibility-Vaccine**
Medicaid Part A →	VFC Eligible
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 through a FQHC, RHC or Local Health Unit **only**. • Private providers should **refer** patient to a provider who can administer to under insured for no or low-cost vaccines. Private stock may be used if parent desires.
Insurance Pays for Immunization	**NOT VFC ELIGIBLE** Use Private Vaccine or

SCHIP-Medicaid Part B (**Category 01**) →	**NOT VFC ELIGIBLE** SCHIP (Medicaid Part B) Stock
19 Years of age or older are not VFC Eligible and must use PRIVATE STOCK.	

ARKANSAS DEPARTMENT OF HUMAN SERVICES

Healthy Kids are Happy Kids!

ARKids First is a health insurance program that provides coverage for thousands of children across the state. It covers well-child checkups, eye exams, dental checkups and more. It is insurance that is growing healthy kids in Arkansas, and it might be the answer for health coverage for your children.

ARKids First covers many of the preventive services and medical care your child may need, including important childhood immunizations and well-child checkups. Not sure which vaccines your child should be getting? Check out the CDC's immunization schedule here.

The ARKids program provides a full package of benefits under two coverage options based on family income: There is no charge when your child participates in ARKids A. For ARKids B, there are co-payments required for some services.

Your children's health is important to you and to us, so check out the links for more information. If you have questions, please call the ARKids hotline; 1-888-474-8275 Monday through Friday between 8:00 a.m. and 4:30 p.m.

VACCINES WITH DILUENTS: How to Use Them

Be sure to reconstitute (mix) the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder in one vial must be mixed with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.
- Never freeze diluents.

Vaccine product name	Manufacturer	Lyophilized (powder) vaccine	Liquid diluent (may contain vaccine)	Time allowed between mixing and use[a]	Diluent storage environment
Abrysvo	Pfizer	RSV	Sterile water	4 hrs	Refrigerator or room temp
ActHIB (Hib)	Sanofi	Hib	Sodium chloride 0.4%	24 hrs	Refrigerator
Arexvy	GSK	RSV	AS01E adjuvant suspension	4 hrs	Refrigerator
COVID-19, Pfizer-BioNTech, 6 mos through 4 yrs formulation	Pfizer-BioNTech	see footnote[b]	Sodium chloride 0.9%	12 hrs	Refrigerator or room temp
Dengvaxia (DEN4CYD)	Sanofi	Dengue	Sodium chloride 0.4%	30 min	Refrigerator
Hiberix (Hib)	GSK	Hib	Sodium chloride 0.9%	Immediately[c]	Refrigerator or room temp
Imovax (RAB_{HDCV})	Sanofi	Rabies	Sterile water	Immediately[c]	Refrigerator
Ixchiq	Valneva	Chikungunya	Sterile water	Immediately[c]	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menveo[d] (MenACWY)	GSK	MenA	MenCWY component	8 hrs	Refrigerator
Penbraya (MenABCWY)	Pfizer	MenACWY	MenB component	4 hrs	Refrigerator
Penmenvy (MenABCWY)	GSK	MenACWY	MenB component	Immediately[c]	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi	Hib	DTaP-IPV component	Immediately[c]	Refrigerator
Priorix (MMR)	GSK	MMR	Sterile water	8 hrs	Refrigerator or room temp
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB_{PCECV})	GSK	Rabies	Sterile water	Immediately[c]	Refrigerator
Rotarix[d] (RV1)	GSK	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GSK	RZV	AS01B adjuvant suspension	6 hrs	Refrigerator
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
Vaxchora (CVD 103-HgR)	Bavarian Nordic	Cholera	Buffer solution plus bottled water	see footnote[e]	Refrigerator
YF-VAX (YF)	Sanofi	YF	Sodium chloride 0.9%	60 min	Refrigerator or room temp

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

1. For single-dose vaccine products (exceptions: Rotarix, Vaxchora), select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine. For Rotarix and Vaxchora, see the package insert.
2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that:
    - they are the correct two products to mix together,
    - the diluent is the correct volume, and
    - neither the vaccine nor the diluent has expired.
3. Reconstitute (i.e., mix) vaccine before use by:
    - removing the protective caps and wiping each stopper with an alcohol swab,
    - inserting needle of syringe into diluent vial and withdrawing contents, and
    - injecting diluent into lyophilized vaccine vial and rotating or inverting to thoroughly dissolve the lyophilized powder.
4. Check the appearance of the reconstituted vaccine.
    - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
    - If there is discoloration, particulate matter, obvious lack of resuspension, or the vaccine cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.
5. If reconstituted vaccine is not used immediately or comes in a multidose vial, be sure to:
    - clearly mark the vial with the date and time the vaccine was reconstituted,
    - maintain the product at 2°–8°C (36°–46°F); do not freeze, and
    - use only within the time indicated on chart above.

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a. If the reconstituted vaccine is not used within this time period, it must be discarded.
b. The Pfizer-BioNTech COVID-19 formulation for children ages 6 mos through 4 yrs is a liquid concentrate that requires dilution.
c. For purposes of this guidance, Immunize.org defines “immediately” as within 30 minutes or less.
d. Rotarix and Menveo vaccines are available as either a liquid formulation that does not require dilution or as a lyophilized vaccine that requires reconstitution. Both formulations of the Rotarix vaccine are administered by mouth; they should not be administered as an injection.

e. Vaxchora dilution: 30 minutes if sucrose or unflavored stevia added; 4 hours if sucrose or unflavored stevia have not been added.

VACCINE ABBREVIATIONS	
Hib = Haemophilus influenzae type b	**RSV** = Respiratory syncytial virus
MenA = Meningococcal serogroup A	**RV1** = Rotavirus vaccine, monovalent
MenACWY = Meningococcal serogroups A, C, W, Y	**RZV** = Zoster vaccine, recombinant
MMR = Measles, mumps, & rubella	**YF** = Yellow fever
MMRV = MMR + varicella	

Click here to download: Vaccines with Diluents: How to Use Them

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p3040.pdf
Item #P3040 (3/17/2025)
Scan for PDF

VFC ELIGIBILITY AND FUNDING SOURCES

User Defined Table 0064 – Financial Class-Vaccines for Children

WebIZ supports the following VFC Relationship codes. Use in PV1-20 for patient VFC Eligibility and in OBX-5 for VFC Eligibility at the dose administered level (i.e., vaccine). The IIS prevents both vaccine- and patient-level financial eligibility from being set for patients who are not eligible for those categories based on their age. These are the recommended values from the CDC per http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf

- **NOTE**: V06 and V07 have been deprecated and are not supported. These codes are essential for future automatic vaccine inventory dose decrementing with HL7.

Value	Description	Comment	VFC Eligibility Mapping for CEHR Workflow
V00	VFC Eligibility not Determined/Unknown	Maps to V01-Will always be not VFC Eligible	**Do Not Use** This should not be an option for staff to use. Eligibility should be known.
V01	Not VFC Eligible	Client does not qualify for VFC because they do not have one of the statuses below.	**Not VFC Eligible** Use one of the statuses below whenever possible to ensure dose decrementing.
V02	VFC Eligible – Medicaid/Medicaid Managed Care	Client is currently on Medicaid or Medicaid managed care and < 19 years old, and the vaccine administered is eligible for VFC funding.	Covered under Medicaid- **VFC Eligible**
V03	VFC Eligible – Uninsured	Client does not have private insurance coverage and < 19 years old, and the vaccine administered is eligible for VFC Funding.	Self-Pay **- VFC Eligible**
V04	VFC Eligible – American Indian/Alaskan Native	Client is a member of a federally recognized tribe and < 19 years old, and the vaccine administered is eligible for VFC Funding.	American Indian/Alaskan Native- **VFC Eligible**

V05	VFC Eligible – Federally Qualified Health Center Patient (under-insured)	Client has insurance that partially covers vaccines received on the visit and so is eligible for VFC vaccines not covered by insurance at a Federally Qualified Health Center. The client must be receiving the immunizations at the FQHC and be under 19 years old, and the vaccine administered is eligible for VFC Funding.	FQHC/CHC/RHC/LHU Only- **VFC Eligible** This should not be an available option for the staff if they are not one of the federally subsidized clinics.
Value	**Description**	**Comment**	**VFC Eligibility Mapping for CEHR Workflow**
V22	(S)CHIP	Client has Medicaid Part B and is eligible for the SCHIP program, a separate state health insurance that is NOT a Medicaid expansion program.	Covered under SCHIP- **Not VFC Eligible**
V23	317	Client is eligible to receive 317-funded vaccines received through the state immunization program and the vaccine administered is eligible for 317 funding.	Federal Vaccine Programs- **Not VFC Eligible** Do not confuse this with VFC. This is an adult program.
V24	Medicare	Client is enrolled in Medicare	Covered under Medicare- **Not VFC Eligible**
V25	State specific code	Client is eligible for specific state vaccine program	**Do not use-** This should not be an active choice. Arkansas does not currently have any of these programs.

Value Set Name – Immunization Funding Source

The Immunization Information System supports the Immunization Funding Source codes listed in Table 9-19. Use in OBX-5 when OBX-3 has a value of 30963-3. The Immunization Information System will insert the data on the vaccination edit screen under funding source for the associated vaccine. Please note, these are the recommended values from the CDC per http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf

Value	Description	Comment
PHC70	Private	Vaccine stock used was privately funded
VXC50	Public	Vaccine stock used was publicly funded (317)
Value	**Description**	**Comment**
VXC51	Public VFC	Vaccine stock used was publicly funded by the VFC program (VFC)
VXC52	Public non-VFC	Vaccine stock used was publicly funded by a non-VFC program (SCHIP)

I have attached the tables for the VFC eligibility and funding source tables. The three options highlighted below are the suggested changes. This is what will help make your workflow improved:

VFC Eligibility and Funding Source

VFC Eligibility	Funding Source	Funding Source in GUI Table
V01	PHC70	Private Vaccine
V02, V03, V04, V05,	VXC51	(Public VFC) VFC
V22	VXC52	(Public Non-VFC) SCHIP
V23, V24, V25	VXC50	(Public)State Funded Vaccine non VFC/ non-SCHIP
For any questions or concerns, contact:		

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DATA LOGGER INFORMATION AND CALIBRATION CERTIFICATE

VFC Providers are required to monitor vaccine temperatures using a data logger. In 2018, the Arkansas Department of Health moved to Digital Data Loggers (DDL) for vaccine storage units has saved thousands of dollars' worth of vaccine. Installing data loggers and upgrading to pharmacy grade and stand-alone storage units significantly decreased vaccine loss.

VFC Thermometer Requirements

Providers are required to always use a VFC-compliant DDL in each vaccine storage unit. Practices also must have at least one VFC-compliant back-up thermometer for use when primary thermometers fail or are being recalibrated.

To meet specifications, thermometers must:

- Be accurate within +/-1°F (+/-0.5°C).
- Be digital, with the digital display placed outside the unit to allow readings without opening the door.
- Have a buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g., glycol, ethanol, glycerin); a vial filled with loose media (e.g., sand, glass beads); or a solid block of material (e.g., Teflon®, aluminum).
- Display current, minimum, and maximum temperatures.
- Have a visual or audible alarm to signal out-of-range temperatures.
- Have a valid Certificate of Traceability and Calibration Testing. Arkansas allows up to 2 years between calibrations. **Non-calibrated thermometers can be off significantly than the actual temperatures.** A sample Certificate of Calibration is in the Appendix of this manual.

There is a lot of confusion as companies and sales reps begin to push these devices out to providers. Companies and sales reps may or may not be accurate or even knowledgeable of VFC requirements. This guide is to help clarify some of the information you are receiving.

Points To Remember When Purchasing

- Some DDLs are expensive to recalibrate, and you must send them back to the company every 2 years for recalibration. If you have access to a bio-med department or company that can do this for you, we have a form they can fill in and sign.
- Make sure they are calibrated within +/- 1.0F or +/- 0.5 C or they are not accurate enough.
- Make sure if you send the unit to the company that you know how much they charge you and how long it will take them to return the unit. Always have a backup device available.
- You may need to change out the unit rather than recalibrate the old one and send it back.
- Consider having an audio alarm and a notification via text or email.
- Check the DDL's power systems, upload capability, and storage capacity.
- Some DDLs plug into the wall so make sure you have enough plugs.
- Battery power is better, however, make sure the batteries can be changed, and the unit does not need to be sent back to the factory.

Types of DDLs:

- USB based DDLs have local alarms and must plug into a computer with a USB Port. It is highly recommended for providers to download the DDL weekly and review the report for any potential excursions. A temperature paper log must be maintained and placed by or on the storage unit. Temperatures must be manually recorded twice a day (beginning and ending shifts) and document the min/max once a day, even when the DDL is in use.
- WIFI/Cellular/Bluetooth -will alarm you by phone, text, or email when the temps are out of range. Staff can sign in remotely from any computer or device. Paper logs are not required if staff can sign in electronically, for example PharmaWatch.

Other considerations:

- DDLs must have a digital readout visible when the storage unit is closed.
- Download data every day when possible. If you accidentally freeze vaccine on Monday, give shots throughout the week and download on Friday, you have given compromised vaccine and may need to revaccinate.
- Make sure the company can train or has training videos. DDLs are not necessarily intuitive.
- Consider buying directly from the company. This helps ensure you get the information and training you need to do a complete set up and you may get a better price.

The provider may purchase any DDL that meets January 1, 2018, VFC specifications:	
USB port and WIFI versions	www.saberteck.com
USB downloads	www.deltatrak.com
USB port and WIFI versions	www.fishersci.com-
Cloud based system	www.sensoscientific.com/vaccine-vfc
USB port, Cloud and WIFI versions	www.vfcdataloggers.com
USB port, Cloud and WIFI versions	www.control3.com/6400.htm
USB port	www.berlingerusa.com/sitemonitoring/
Cloud based system that alerts via email, text, and phone when temps are out of range	www.pharmawatch.com

This is not an exhaustive list.

STORAGE UNIT REQUIREMENTS

Provider Responsibilities

- Stand-alone refrigerators and freezers should be used to store VFC vaccines.
- 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.
- Ensure there is a digital data logger for each vaccine storage unit storing federal vaccine.
- 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.
- Assess and record minimum and maximum temperatures each clinic morning and clear the minimum and maximum temperature readings each morning (required).
- As currently required, report all vaccine excursions to the VFC Program.
- Document information about the excursion and what steps were taken to correct any issues.

NOTE: CDC is considering denying the use of combination storage units for vaccine storage in the future. When purchasing a new storage unit, choose a standalone or pharmaceutical grade unit.

Storage and Handling Data Logger Frequently Asked Questions and Answers:

Question: What is a data logger vaccine storage monitor?
Answer: 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.

Question: How is data logger technology different and better than traditional thermometers?
Answer: 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 acceptable ranges for extended periods of time which can compromise vaccines.

VACCINE RETURN INSTRUCTIONS

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. "**Replacement Doses**" should **never** be used.

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.
    a. *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 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 question about the provider return process, please submit a ticket to the WebIZ Help Desk at https://adhimmiregistry.hesk.com/

OFF-SITE VACCINATION CLINICS

Some providers may conduct temporary, mobile, off-site, or satellite clinics if approved by the Immunization Program. These opportunities can improve access and vaccination coverage for VFC-eligible children. However, these situations require additional program oversight and vaccine accountability.

Not only are these alternative provider locations required to adhere to all general program requirements, including screening and documenting VFC eligibility, but they must also maintain enhanced storage and handling practices, including:

- The number of VFC vaccines transported to a temporary, mobile, off-site, or satellite clinic should be based on anticipated number of VFC-eligible children to be served.
- Vaccines may be transported—not shipped—to a clinic site using vaccine transportation procedures outlined in CDC's Vaccine Storage and Handling Toolkit. This includes transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment, as well as monitoring and documenting temperatures using a DDL with a probe in buffered material.
- Upon arrival at the clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented every hour during the clinic using a DDL with a digital display and probe in buffered material.
- At the end of the clinic day, temperature data must be assessed prior to placing vaccines back into storage units to prevent administration of vaccines that may have been compromised.

If at any time, vaccines are exposed to temperature excursions, they must be labeled "do not use" until the vaccine manufacturer(s) are contacted regarding vaccine viability.
Enhanced oversight for community vaccinators or providers conducting temporary, mobile, off-site, or satellite clinics also includes:

- Vaccine ordering—while CDC recommends vaccines be delivered directly to provider facilities, this may not be possible for temporary, mobile, off-site, satellite and community vaccination clinics. To protect the cold chain and vaccine viability, vaccines must be ordered and shipped

directly from CDC to a location within the awardee's jurisdiction when direct delivery is not possible. Vaccines may also only be administered within the jurisdiction.
- Vaccine transport records that detail the type of vaccine(s), quantity being transported, and temperature monitoring should be maintained by providers for temporary, mobile, offsite, or satellite clinics.

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

CDC recommendations and best practices for vaccine handling during a temporary, mobile, off-site, or satellite clinic include:

- Do not draw up vaccines before arriving at the clinic site. Drawing doses days or even hours before a clinic's operational hours are **not acceptable**. CDC strongly recommends not pre-drawing doses before they are needed.
- If possible, use manufacturer-filled syringes, as an alternative to pre-drawing vaccines.
- Each person administering vaccines should pre-draw no more than one multidose vial (MDV) at one time.
- Monitor patients flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in pre-drawn syringes at the end of the workday.

Additional information on handling and preparing vaccine can be found in CDC's *Vaccine Storage and Handling Toolkit* and on CDC's vaccine administration website.

NOTE: It is not recommended to transport Varivax or MMRV to off-stie clinics. Please contact the VFC Program for prior approval to transfer these vaccines off-site.

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 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 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 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) if 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.

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 ACIP's VFC-recommended vaccines are part of the EPSDT benefit package for Medicaid children under age 21. Immunizations through the age of 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 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.

Question: 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 cap will 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 with 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 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.

Question: 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.
    - 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 administrationfee.

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 service 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 have a 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 must 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 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 if 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 parties in varying circumstances.

- 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.
- If the recipient is moved 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 (https://www.cdc.gov/vaccines/hcp/admin/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. 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 for the pharmacist to be enrolled as a VFC registered provider.

Question: Are specialty providers required to offer all age-appropriate VFC vaccines to their VFC-eligible patients 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 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.

APPENDIX

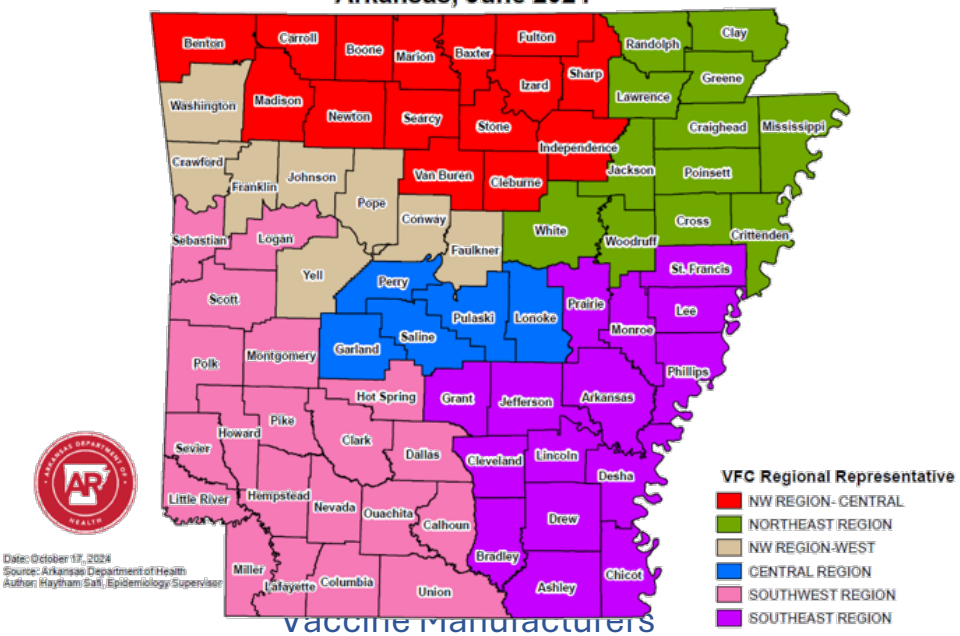
Vaccines For Children Program Contacts

Dorie Owen **Northwest Region- Central** Office: 870.448.3374 Cell: 479.287.8674 Fax: 870.448.3783 dorie.owen@arkansas.gov Searcy County LHU 742 Airport Rd. Marshall, AR 72650	**Allison Pinkley** **Northeast Region** Office: 870.933.4585 Cell: 870.219.7597 Fax: 870.933.6416 allison.pinkley@arkansas.gov Craighead County LHU 611 E. Washington Jonesboro, AR 72401	**Carolyn Robinson** **Northwest Region-West** Office: 870.446.2216 Cell: 479.790.8250 Fax: 479.964.0928 carolyn.f.robinson@arkansas.gov Newton County LHU 506 West Court St Jasper, AR 72802
Alicia Clark **Central Region** Office: 501.624.3394 Cell: 501.249.8485 Fax: 870.460.6210 alicia.clark@arkansas.gov Garland County LHU 1425 Malvern Ave Hot Spring, AR 71901	**Susan Carter** **Southwest Region** Office: 479.394.1597 Cell: 870.807.0601 Fax: 479.394.6610 susan.carter@arkansas.gov Polk County LHU 702 Hornbeck Ave Mena, AR 71953	**Jamie Henderson** **Southeast Region** Office: 870.367.6234 Cell: 870.224.1439 Fax: 870.460.6210 jamie.henderson@arkansas.gov Drew County LHU 940 Scogin Drive

Vaccines for Children Coordinator:
Nora Fawcett
Office: 501.661.2170
Fax:501.661.2300
4815 West Markham St., Lot 48
Little Rock, AR 72205

***** PRIVATE CLINICS *****

Vaccines for Children (VFC) Regional Representative by County
Arkansas, June 2024



Vaccine Manufacturers

MANUFACTURER CONTACT INFORMATION		
AstraZeneca	**1-800-221-1638**	
- Live-attenuated influenza (FluMist Quadrivalent)		
Bavarian Nordic	**1-800-675-9596**	info@bavarian-nordic.com
- Smallpox and Monkeypox (Jynneos)		
BioNTech	**1-877-VAX-CO19 (1-877-829-2619)**	
- COVID-19 vaccine (Comirnaty, with Pfizer)		
CSL Seqirus	**1-855-358-8966**	customerservice.us@seqirus.com
- Adjuvanted inactivated influenza (Fluad); Cell culture-based inactivated influenza (Flucelvax Quadrivalent); Inactivated influenza (Afluria Quadrivalent);		
Dynavax	**1-510-848-5100 or 1-877-848-5100**	contact@dynavax.com
- Hepatitis B Vaccine, Recombinant, Adjuvanted (Heplisav-B)		
GSK	**1-866-475-8222**	
- DTaP (Infanrix); DTaP+IPV (Kinrix); DTaP+Hepatitis B+IPV (Pediarix); Hepatitis A (Havrix); Hepatitis B (Engerix-B); Hepatitis A+Hepatitis B (Twinrix); Hib (Hiberix); Hib; Inactivated influenza (Fluarix Quadrivalent and FluLaval Quadrivalent); Meningococcal-MCV4 (Menveo); MMR (Priorix); Meningococcal serogroup B vaccine (Bexsero); Rabies (RabAvert); Rotavirus (Rotarix); Tdap (Boostrix); Zoster Vaccine Recombinant Adjuvanted (Shingrix)		
MassBiologics	**1-800-457-4626**	information@massbiologics.org
- Td		
Merck	**1-877-829-6372**	
- Ebola Zaire Vaccine, Live (ERVEBO); Hib (PedvaxHIB); Hepatitis A (VAQTA); Hepatitis B (Recombivax-HB); HPV (Gardasil 9); Measles, Mumps, and Rubella (M-M-R II); MMR+Varicella (ProQuad); Pneumococcal-PCV15 (Vaxneuvance); Pneumococcal-PPSV23 (Pneumovax 23); Rotavirus (RotaTeq); Varicella (Varivax); Zoster (Zostavax); BCG Vaccine U.S.P.		
Moderna	**1-866-MODERNA (1-866-663-3762)**	ModernaPV@modernatx.com
- COVID-19 vaccine (Spikevax)		
Novavax	**1-844-NOVAVAX (668-2829)** (8am- 8pm EST)	
- COVID-19 vaccine		
Pfizer	**1-800-505-4426 or 1-877-VAX-CO19 or 1-877-829-2619)**	
- COVID-19 vaccine (Comirnaty, with BioNTech); Meningococcal serogroup B vaccine (Trumenba); Meningococcal ABCWY (Penbraya); Pneumococcal-PCV13 (Prevnar 13); Pneumococcal-PCV20 (Prevnar 20); Tick-borne encephalitis vaccine (Ticovac)		
Sanofi U.S.	**1-800-VACCINE (1-800-822-2463)**	
- DTaP (Daptacel); DTaP+Hib+IPV (Pentacel); DTaP+IPV (Quadracel); DT (pediatric); Hib (ActHIB); High-dose inactivated influenza (Fluzone High-Dose); Inactivated influenza (Fluzone Quadrivalent); Meningococcal conjugate vaccines (Menactra, MenQuadfi); Poliovirus, inactivated (IPOL); Rabies (Imovax); Recombinant influenza (Flublok Quadrivalent); Td (TENIVAC); Tdap (Adacel); Typhoid Vi, inactivated, injectable (TYPHIM Vi); Yellow Fever (YF-Vax)		
VBI Vaccines	**1-617-830-3031**	info@vbivaccines.com
- Hepatitis B recombinant (PreHevbrio)		

2025-2026
VACCINES FOR CHILDREN (VFC) PROGRAM
PROVIDER AGREEMENT

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 the 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. 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 VFC 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) Always store 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 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 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. It also includes VFC eligible newborn infants at the birthing facility. "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 Arkansas Department of Health (ADH) the administration of any childhood immunization to any person under twenty-two years of age. Per Arkansas Code Annotated §§ 20-15-1201-1203, adult immunization records may be reported to the registry by the immunization provider. 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.

Vaccines For Children Program Provider Profile Form

All healthcare 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 provider/facility changes during the calendar year.

Date: _____ Provider Identification Number: _____

CLINIC HOURS- THESE ARE THE TIMES YOUR VACCINES CAN BE SAFELY DELIVERED:						
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Closed for lunch between:						

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

PROVIDER TYPE (select only one provider type)

Please review the provider type definitions to assist with provider type selection.

☐ Addiction Treatment Center	☐ Pharmacy	☐ Rural Health Clinic
☐ Birthing Hospital or Birthing Center	☐ Private Practice (e.g., family practice, pediatric, primary care)	☐ School-Based Clinic (permanent clinic location)
☐ Community Health Center		
☐ Community Vaccinator (non-health department)	☐ Private Practice (e.g., family practice, pediatric, primary care) as agent for FQHC/RHC-deputized	☐ STD/HIV Clinic (non-health department)
☐ Correctional Facility		☐ Teen Health Center (non-health department
☐ Family Planning Clinic (non-health department)	☐ Public Health Department Clinic (state/local)	☐ Urgent Care Center
☐ Federally Qualified Health Center	☐ Public Health Department Clinic (state/local) as agent for FQHC/RHC-deputized	☐ Women, Infants, and Children (WIC) Clinic
☐ Hospital		☐ Other (specify):
☐ Indian Health Service, Tribal, or Urban Clinic	☐ Refugee Health Clinic	
☐ Juvenile Detention Center		
☐ Migrant Health Center		
☐ Mobile Provider		

If applicable, please indicate the Specialty of provider/practice (Select all that apply):

☐ Family Medicine	☐ Pediatrics	☐ N/A
☐ Internal Medicine	☐ Preventive Medicine	
☐ OB/GYN	☐ Other (specify):	

Is this provider site part of a hospital/healthcare system?

☐ YES ☐ NO ☐ N/A or don't know

Facility Type (select one):

☐ Private Facility (privately funded entity; non-governmental
☐ Public Facility (publicly founded or government entity
☐ Combination (funded with public and private funds)

Is this facility a mobile facility, or does this facility have mobile units? *

☐ YES ☐ NO

*A mobile unit is a dedicated vehicle with a primary purpose of providing medical services (e.g., immunization services).

VACCINES OFFERED

Is this provider a Specialty Provider? * Please note: The immunization Program must review and approve any provider who identifies as a Specialty Provider.

☐YES ☐NO

Vaccines Offered (select one):

☐All ACIP recommended vaccines for children 0 through 18 years of age

☐Select vaccines only (This option is available only for facilities designated as **Specialty Providers** by the Immunization 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, family planning, etc.) 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 Immunization Program has the authority to designate VFC providers as specialty providers. At the discretion of the Immunization Program, certain enrolled providers such as or community vaccinators may offer a limited selection of vaccines.

Select Vaccines Offered by Specialty Provider:

☐COVID-19	☐Influenza	☐Rotavirus
☐DTaP	☐Meningococcal Conjugate	☐Td
☐Hepatitis A	☐MMR	☐Tdap
☐Hepatitis B	☐Pneumococcal Conjugate	☐Varicella
☐HIB	☐Pneumococcal Polysaccharide	☐Other (specify):
☐HPV	☐Polio	

PROVIDER POPULATION

Provider population based on patients seen during the previous 12 months. Report the number of children by age group who received vaccinations at your facility. Count a child only once based on the age/eligibility categories at the last immunization visit, regardless of the number of visits made. The following table details the number of children who received VFC vaccine and non-VFC vaccine, by eligibility category.

VFC Vaccine Eligibility Categories	# of Children by age category who received VFC vaccines			
	<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 by age category who received non-VFC vaccines			
	<1 Year	1-6 Years	7-18 Years	Total
Insured (private pay/health insurance covers vaccines)				
Children's Health Insurance Program (CHIP)[2]				
Total VFC:				
Total Patients (must equal sum of Total VFC + Total Non-VFC)				

[1]Underinsured includes children with health insurance that does not cover vaccines or only covers specific vaccine types. Children are eligible only for vaccines that are not covered by their 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 underinsured children.

[2]CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). Children enrolled in CHIP are considered insured and are not eligible for vaccines through the VFC program. Each state determines how CHIP vaccine is purchased and administered by participating providers.

TYPE OF DATA USED TO DETMINE PROVIDER POPULATION (choose all that apply):		
☐ Benchmarking	☐ IIS	☐ Provider Encounter Data
☐ Medicaid Claims Data	☐ Doses Administered	☐ Billing system
☐ Other (must describe):		

PROVIDER TYPE DEFINITIONS

Addiction Treatment Center

Provides counseling, behavioral therapy, medication, case management, and other types of services to people with substance use disorders. This provider type is used for addiction treatment centers where on-site vaccination services are provided.

Birthing Hospital or Birthing Center

This provider type is used for birthing centers or birthing hospitals where on-site vaccination services are provided.

Community Health Center

Community-based and patient-directed organizations that serve populations with limited access to health care. This provider type is used for community health centers that provide vaccination services.

Community Vaccinator (non-health department)

This provider type is used for community-wide vaccinators that are external to health departments and conduct vaccination clinics in satellite, temporary, or offsite locations exclusively.

Correctional Facility

This provider type is used for juvenile correctional facilities as well as adult correctional facilities where juveniles are confined, and on-site vaccination services are provided. Unlike juvenile detention centers, correctional facilities are long-term in nature; youths are confined in secure correctional facilities for periods generally ranging from a few months to a year or more.

Family Planning Clinic (non-health department)

Provides contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and/or mental health). This provider type is used for family planning clinics where vaccination services are provided. NOTE: Non-health department clinics that offer only STD/HIV screening and treatment services should be categorized as "STD/HIV Clinic (non-health department)."

Federally Qualified Health Center

Community-based health care provider that receives funds from the HRSA Health Center Program to provide primary care services in underserved areas. This provider type is used for federally qualified health centers (FQHCs) that provide vaccination services. NOTE: For tribal or urban Indian health clinics enrolled as FQHCs, use the "Indian Health Service, Tribal, or Urban Clinic" designation.

Hospital

This provider type is used for all hospitals, excluding birthing hospitals, where on-site vaccination services are provided. NOTE: For birthing hospitals, use the "Birthing Hospital or Birthing Center" designation.
Indian Health Service, Tribal, or Urban Clinic
This provider type is used to for Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated Federally Qualified Health Centers and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

Indian Health Service, Tribal, or Urban Clinic

This provider type is used to for Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated Federally Qualified Health Centers and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

Juvenile Detention Center

Juvenile detention is defined as the temporary and safe custody of juveniles who are accused of conduct subject to the jurisdiction of the court who require a restricted environment for their own or the community's protection while pending legal action. This provider type is used for juvenile detention centers where on-site vaccination services are provided.

Migrant Health Center

Provides health services to migratory and seasonal agricultural workers and their families. This provider type is used for migrant health centers that provide vaccination services.

Mobile Provider

This provider type is used for providers who exclusively store and administer vaccines out of a mobile facility. This designation should NOT be used for providers who have a mobile unit associated with their facility, but the unit is not the primary site for vaccine administration.

Pharmacy

This provider type is used for stand-alone retail pharmacies (e.g., CVS, Duane Reade, Walgreens) or a retail pharmacy within a hospital or health system where on-site vaccination services are provided. This category also includes retail pharmacies that conduct community vaccination clinics at offsite or mobile locations.

Private Practice (e.g., family practice, pediatric, primary care)

This provider type is used for private practice locations, including solo, group, or HMO practitioners, that provide vaccination services.

Private Practice (e.g., family practice, pediatric, primary care) as agent for FQHC/RHC-deputized

A deputized provider has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) as an agent to vaccinate underinsured children. This provider type is used for deputized private practices, including solo, group, or HMO practitioners, that provide vaccination services.

Public Health Department Clinic (state/local)

This provider type is used for state or local public health department clinics that provide vaccination services. This category includes public health department-run STD/HIV clinics, family planning clinics, and teen health centers.

Public Health Department Clinic (state/local) as agent for FQHC/RHC-deputized

A deputized provider has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) as an agent to vaccinate underinsured children. This provider type is used for deputized state or local public health department clinics that provide vaccination services.

Refugee Health Clinic

Designated to improve the health care and monitor medical conditions of refugees who have relocated to the United States. This provider type is used for refugee health clinics that provide vaccination services. NOTE: If vaccination services are provided in a location that is co-located in a physical facility with a refugee health clinic but are not administered by refugee health staff, select the category of the provider with oversight of vaccination services.

Rural Health Clinic

Located in a non-urbanized Health Professional Shortage Area, Medically Underserved Area, or governor-designated and secretary-certified shortage area. This provider type is used for rural health clinics that provide vaccination services.

School-Based Clinic (permanent clinic location)

This provider type is used to for permanent school-based clinics that provide vaccination services. NOTE: Non-permanent school-based clinics should be categorized as "Community Vaccinator (non-health department)."

STD/HIV Clinic (non-health department)

Provides timely STD/HIV diagnosis, testing with on-site treatment, and partner services. This provider type is used for STD/HIV clinics NOT located within a health department where on-site vaccination services are provided. NOTE: this category should be used by non-HD clinics that exclusively offer STD/HIV screening and treatment services.

Teen Health Center (non-health department)

This provider type is used for teen health centers that are NOT public health department-sponsored and provide on-site vaccination services.

Urgent Care Center

Provides immediate medical outpatient care for the treatment of acute and chronic illness and injury. This provider type should be used for urgent care centers or walk-in clinics where on-site vaccination services are provided.

Women, Infants, and Children (WIC) Clinic

Serves low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 5 who are at nutritional risk by providing nutritious foods to supplement diets, information on healthy eating including breastfeeding promotion and support, and referrals to health care. This provider type is used for WIC clinics that also provide vaccination services. NOTE: If vaccination services are provided in a location that is co-located in a physical facility with a WIC clinic but are not administered by WIC staff, select the category of the provider with oversight of vaccination services.

Other

This provider type is used for any provider type not captured in one of the other provider type options (e.g., CVS Minute Clinic or Walgreens Take-Care Clinic).

PROVIDER SPECIALTIES DEFINITIONS

Family Medicine

Manages common illnesses and conditions for people of all ages, focusing on overall health and well-being throughout the lifespan.

Internal Medicine

Deals with the prevention, diagnosis, and nonsurgical treatment of diseases and disorders of the internal organs/structures in adults.

OB/GYN

Obstetrician-gynecologist. Provides specialized services for women's health.

Pediatrics

Involves disease/disorder prevention, diagnosis, and treatment associated with the physical and developmental health of children from birth to young adulthood.

Preventive Medicine

Focuses on the health of individuals and communities with the goal of promoting health and well-being and preventing disease, disability, and death.

Vaccine Storage Quick Reference

REMEMBER: Improperly stored or outdated vaccines won't protect your patients!

- This reference includes vaccines approved or authorized in the United States. It does not include travel vaccines. For additional details, refer to vaccine package inserts (www.immunize.org/official-guidance/fda/pkg-inserts).
- If you have a concern about the condition of any vaccine upon arrival or while it is in storage, **take action!** Follow the steps on Immunize.org's "Vaccine Storage Emergency Response Worksheet" and document the situation on the "Vaccine Storage Troubleshooting Record" (see *Additional Resources* #1 and #2).

STORE VACCINES AT APPROPRIATE TEMPERATURES

Refrigerator (most vaccines)

▶ **Maintain between 2°C and 8°C (36°F and 46°F) *Aim for 5°C (41°F)***

- Any combination vaccine containing only refrigerated components listed below
- COVID-19 2024–2025 formulations:
  - Comirnaty (age 12+ yrs)
  - Novavax EUA
- Dengue (Dengvaxia)
- DTaP, Tdap, Td (all)
- Hepatitis A (all)
- Hepatitis B (all)
- *H. influenzae* type b (Hib, all)
- Human papillomavirus (HPV)
- Influenza (all)
- MMR (MMR II, Priorix)*
- Meningococcal (all)
- Pneumococcal (all)
- Polio (IPV)
- Rabies (all)
- RSV (Arexvy, Abrysvo)
- RSV monoclonal antibody
- Rotavirus (all)
- Zoster/Shingles (Shingrix)

Vaccine diluents: All may be stored in the refrigerator; certain diluents may be stored at room temperature (see *Additional Resources* #3).

Freezer

▶ **Maintain between -50°C and -15°C (-58°F and 5°F)**

- COVID-19 2024–2025 Moderna formulations
- MMR (MMR II only)*
- MMRV
- Mpox (Jynneos)
- RSV (mResvia)
- Varicella

Vaccine diluents: Do not freeze.

Ultra-Cold Freezer

▶ **Maintain between -90°C and -60°C (-130°F and -76°F)**

- COVID-19 2024–2025: Pfizer-BioNTech EUA (age 6 mos through 11 yrs)

Special Cases

Certain vaccines may be frozen until their expiration date *or* may be stored in a refrigerator for several weeks before use. Once thawed, DO NOT REFREEZE.

Refrigeration time (use within allowable time or until expiration, whichever is first):

- COVID-19 2024-2025 formulations:
  - All Moderna formulations — *up to 60 days in refrigerator*
  - Pfizer-BioNTech EUA (age 6 mos through 11 yrs) — *up to 10 weeks in refrigerator*
- Mpox (Jynneos) — *up to 8 weeks in refrigerator*

* MMR: MMR II (Merck) may be stored until expiration in a freezer or refrigerator. Store Priorix (GSK) only in the refrigerator.

ADDITIONAL RESOURCES

Immunize.org:

1. "Vaccine Storage Emergency Response Worksheet" – guidance for vaccines exposed to improper storage conditions, such as a power failure (www.immunize.org/catg.d/p3051.pdf)
2. "Vaccine Storage Troubleshooting Record" – form to document an improper vaccine storage incident and actions taken to resolve it (www.immunize.org/catg.d/p3041.pdf)
3. "Vaccines with Diluents: How to Use Them" (www.immunize.org/catg.d/p3040.pdf)
4. Warning Sign: "Do Not Unplug Refrigerator or Freezer" (www.immunize.org/catg.d/p2090.pdf)
5. Warning Sign: "Do Not Turn Off Circuit Breaker" (www.immunize.org/catg.d/p2091.pdf)

CDC:

6. "Vaccine Storage and Handling Toolkit" (www.cdc.gov/vaccines/hcp/storage-handling)
7. Resources for organizing and labeling vaccines in your storage units (www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)

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

Websites

American Academy of Pediatrics (AAP)
www.healthychildren.org

Centers for Disease Control & Prevention (CDC)
For parents: www.cdc.gov/vaccines/parents
For healthcare providers: www.cdc.gov/vaccines

Immunize.org's websites
For the public: www.vaccineinformation.org
For healthcare providers: www.immunize.org

Vaccinate Your Family
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
www.voicesforvaccines.org

Use www.vaccines.gov to find influenza and COVID-19 vaccines near you.

Apps for Mobile Devices

CDC Mobile App – This app provides 24 hour, 7 days a week access to timely CDC vital health information. With direct links to social media, text and email, this app lets you immediately share information with friends and family. Available for Android and Apple devices.

Vaccines on the Go: What You Should Know – This app provides reliable information about the science, safety, and importance of vaccines and about the diseases they prevent. The app links to videos and resources as well as offering an opportunity to email vaccine-related questions directly to the experts at VEC. Created by VEC and available for Android and Apple devices.

Voices for Vaccines App – A free app, created by the Task Force for Global Health, helps debunk misinformation, guide vaccine conversations, and inspire advocacy. Available for Android and Apple devices.

Books for Parents
(available from your favorite book seller)

Baby 411: Your Baby, Birth to Age 1 by Denise Fields and Ari Brown, MD, Windsor Peak Press, 10th edition, 2022. See baby411.com/

Immunization Information: The Benefits and the Risks by Martin Myers, MD., Houndstooth Press, 2021.

Vaccines and Your Child, Separating Fact from Fiction by Paul Offit, MD and Charlotte Moser, 2011. See excerpts in https://media.chop.edu/data/files/pdfs/vaccine-education-center-vaccine-safety-eng.pdf

Video Suites

Immunize.org's Video Library – This website has hundreds of video clips about vaccines and vaccine-preventable diseases. Complied by Immunize.org. https://vaccineinformation.org/videos

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

Vaccine Education Center (VEC), Children's Hospital of Philadelphia Videos

Go to www.chop.edu/centers-programs/vaccine-education-center/resources/vaccine-videos-and-dvds for videos such as "Vaccine Conversations," "Dr. Offit Answers Your Questions @ Vaccines," "Doctors Talk Diseases," "My COVID-19 Vaccine Experience," "Perspectives on COVID-19 Vaccine for Kids," and the Vaccine Makers Project animations.

Getting Answers

CDC–INFO Contact Center – Operated by the CDC, this number is for anyone with questions about immunization and vaccine-preventable disease. At any time, email CDC via an online form at wwwn.cdc.gov/dcs/ContactUs/Form. Or, call (800) CDC-INFO or (800) 232-4636. TTY: (888) 232-6348; Monday through Friday from 8:00 a.m. to 8:00 p.m. (ET).

Vaccine Education Center (VEC), Children's Hospital of Philadelphia – Parents and healthcare professionals can email their questions to VEC directly at vacinfo@chop.edu.

Arkansas Vaccines for Children Program Calibration Certificate

This form is for Clinics/ Hospitals with self-calibration certificates. This Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-I and 9001.

Clinic ID Name:_____ VFC Pin #: _____

Clinic Address: _____ Clinic

Director: _____

Calibration Tool Maker:_____ Calibration Tool Model: _____

Calibration Tool Serial #: _____

..... REFRIGERATOR-IDENTIFICATION NUMBER .....

Temperature Range:	
Temperature Measured:	
Actual Temperature:	
Uncertainty:	
Unit in Tolerance:	Yes ☐ No ☐
Unit of Measure:	
Date of Calibration:	
Customer Specified Due Date:	

..... FREEZER-IDENTIFICATION NUMBER .....

Temperature Range:	
Temperature Measured Actual Temperature:	
Uncertainty:	
Unit in Tolerance:	Yes ☐ No ☐
Unit of Measure:	
Date of Calibration:	
Customer Specified Due Date:	
Service Technician Name:	
Service Technician Signature	

CUSTOMER NAME: _____

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 medicine, 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 heart, lung (including asthma), kidney, liver, nervous system, or metabolic disease (e.g., diabetes), a blood disorder, no spleen, a cochlear implant, or a spinal fluid leak? Are they taking regular aspirin or salicylate medication?	☐	☐	☐
5. For children age 2 through 4 years: Has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6. For babies: Have you ever been told the child had intussusception?	☐	☐	☐
7. Has the child, a sibling, or a parent had a seizure; has the child had a brain or other nervous system problem?	☐	☐	☐
8. Has the child ever been diagnosed with a heart condition (myocarditis or pericarditis) or have they had Multisystem Inflammatory Syndrome (MIS-C) after an infection with the virus that causes COVID-19?	☐	☐	☐
9. Does the child have an immune-system problem such as cancer, leukemia, HIV/AIDS?	☐	☐	☐
10. In the past 6 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs to treat rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments?	☐	☐	☐
11. Does the child's parent or sibling have an immune system problem?	☐	☐	☐
12. In the past year, has the child received immune (gamma) globulin, blood/blood products, or an antiviral drug?	☐	☐	☐
13. Is the child/teen pregnant?	☐	☐	☐
14. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐
15. Has the child ever felt dizzy or faint before, during, or after a shot?	☐	☐	☐
16. Is the child anxious about getting a shot today?	☐	☐	☐

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.

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p4060.pdf

Item #P4060 (12/15/2023)

Skills Checklist for Vaccine Administration

This "Skills Checklist" is an assessment tool for healthcare staff who administer immunizations. To complete it, staff should review the competency areas below and the clinical skills, techniques and procedures outlined for each area.

Staff: Enter a score in the **Self-Assessment** column. If "Needs to Improve" is checked, it indicates further study, practice, or change is needed. When "Meets or Exceeds" is checked, it indicates belief that performance is 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.

CDC's Web-based Training Courses

- *You Call the Shots:* updated regularly to include the latest guidelines and recommendations in vaccine practice; available at www.cdc.gov/vaccines/ed/youcalltheshots.html.
- Vaccine Administration eLearn: available at www.cdc.gov/vaccines/hcp/admin/resource-library.html

AREA	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	SELF ASSESSMENT		SUPERVISOR REVIEW		PLAN OF ACTION
		needs to improve	meets or exceeds	needs to improve	meets or exceeds	
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) and appropriate materials for indicated vaccines and has had time to read them and ask questions.					
	5. Screens for contraindications and precautions (if within employee's scope of work).					
	6. Reviews comfort measures and aftercare instructions with patient/parents, and invites questions.					
Medical & Office Protocols	1. Identifies the location of protocols for providing immunizations, infection prevention, emergency situations, and for reporting adverse events to the Vaccine Adverse Event Reporting system (VAERS).					
	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).					

Adapted from California Department of Public Health, Immunization Branch

continued on the next page ▶

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Adapted from California Department of Public Health, Immunization Branch

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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 after vaccination.

Administering any medicine, including vaccines, can cause an adverse reaction. Always verify container labels to ensure the correct product is being administered. To reduce the risk an adverse reaction, screen patients for vaccine contraindications and precautions before 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 range from minor (e.g., soreness, itching) to serious (e.g., anaphylaxis). Be prepared.

Vaccinators should know how to recognize allergic reactions, including anaphylaxis. Have a plan and supplies ready to provide appropriate medical care if an event occurs.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Injection site	Soreness, redness, itching, or swelling	Apply a wet cloth to the injection site. Consider giving medication to reduce pain (e.g., Tylenol) or itching (e.g., Benadryl) if needed.
	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)	Anxiety before injection	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 patient under close observation until full recovery.
	Fall, without loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient for injury before trying to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover promptly.
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 next page for details on treating anaphylaxis.

Supply List for Managing Anaphylaxis

FIRST-LINE medication

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

OPTIONAL medications: H_1 antihistamines

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

Additional emergency supplies

- ☐ Syringes (1 and 3 mL) and needles (22 and 25 g, 1", 1¼", 1½", and 2") if needed for epinephrine
- ☐ Alcohol wipes
- ☐ Stethoscope
- ☐ Blood pressure measuring device (with a variety of cuff sizes as needed)
- ☐ Light with extra batteries (for examination of the mouth and throat)
- ☐ A timing device, such as wristwatch, for measuring pulse
- ☐ Cell phone or access to onsite phone
- ☐ CPR rescue mask with one-way valve
- ☐ Oxygen (if available)

See also "Supplies You May Need at an Immunization Clinic" at www.immunize.org/catg.d/p3046.pdf.

REFERENCES

American Academy of Pediatrics. Red Book: 2021–2024 Report of the Committee on Infectious Diseases. 32nd edition, p. 64–67.

Campbell RL, Kelso JM, Anaphylaxis: Emergency treatment, updated August 4, 2022 in UpToDate, www.uptodate.com/contents/anaphylaxis-emergency-treatment

Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guide-lines 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 managing anaphylaxis in children and teens

1. If itching and swelling are limited to the injection site, observe patient closely for the development of generalized symptoms.

2. If symptoms are generalized, alert the lead clinical healthcare professional on-site and call 911. A healthcare professional should assess the airway, breathing, circulation, and level of consciousness of the patient. Monitor vital signs at 5-minute intervals.

3. **DRUG DOSING INFORMATION: The 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.** Use **epinephrine** in a 1 mg/mL aqueous solution (1:1000 concentration). See page 3 to determine correct dose to be used based on child's weight. If using an autoinjector, 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 formulation, 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 intervals 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) for relief of itching or hives.

   Administer **diphenhydramine** orally, standard dose of 1–2 mg/kg every 4–6 hours. See dosing chart on page 3.

4. Monitor the patient closely every 5 minutes. 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.

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 medi-cation, 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 https//www.vaers.hhs.gov/reportevent.html.

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.

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated at 5–15 minute intervals up to 3 times while waiting for EMS to arrive.

First-Line Treatment: Epinephrine				Epinephrine Dose	
	Age group	Range of weight (lb)	Range of weight (kg)*	1 mg/mL aqueous solution (1:1000 concentration); intramuscular. Minimum dose: 0.05 mL	Epinephrine autoinjector (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 approved for use in 7.5 to 14 kg infants and children

▶ **commonly known as Benadryl**

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

Optional Treatment: Diphenhydramine				Diphenhydramine dose calculations based on 1 mg/kg†
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL Capsules or 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: 2021–2024, 32nd 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.

This policy and procedure shall remain in effect for all patients of the _____ (NAME OF PRACTICE OR CLINIC)

effective _____ (DATE) until rescinded or until _____ (DATE).

Medical Director _____ (PRINT NAME) / _____ (SIGNATURE) _____ (DATE)

Supplies You May Need at an Immunization Clinic[1]

A. Vaccines you intend to give[2]

- For a list of vaccines commonly given in the U.S., refer to www.cdc.gov/vaccines/vpd/vaccines-list.html. Select the vaccines you need based on the age of the patients you expect at your clinic.
- For instructions on how to pack and transport vaccines, go to www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

B. Patient Resources

Vaccine Information Statements (VISs)[2]
Most current version associated with each vaccine used in the clinic *(available in English and over 40 languages at www.immunize.org/vis)*

After the shots . . . what to do if your child has discomfort
Includes information on medicines to reduce pain and fever *(available at www.immunize.org/catg.d/p4015.pdf)*

C. Routine Clinic Supplies[2]

- ☐ Appropriate storage units and monitoring equipment to maintain vaccine cold chain (see www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
- ☐ Needle disposal "sharps" containers
- ☐ 1 mL, 3 mL syringes
- ☐ 22 and 25g needles
  - ☐ ⅝"; ☐ 1"; ☐ 1¼"; ☐ 1½"; ☐ 2" (see *Administering Vaccines: Dose, Route, Site, and Needle Size* at www.immunize.org/catg.d/p3085.pdf)
- ☐ Medical gloves (optional for administration of vaccine)
- ☐ Alcohol wipes
- ☐ Spot band aids ☐ Rectangular band aids
- ☐ 1" sterile gauze pads or cotton balls
- ☐ Temperature monitoring devices (preferably continuous digital data loggers) for all vaccine storage units
- ☐ Emergency transport container
- ☐ Paper towels
- ☐ Hand sanitizer
- ☐ Sanitizing products for surfaces
- ☐ Face masks or respirators if protection from respiratory viruses is desired

D. Medical Emergency Supplies[2]

- ☐ *Medical Management of Vaccine Reactions in Children and Teens in a Community Setting* www.immunize.org/catg.d/p3082a.pdf
- ☐ *Medical Management of Vaccine Reactions in Adults in a Community Setting* www.immunize.org/catg.d/p3082.pdf

First-line medication

- ☐ Epinephrine 1 mg/mL solution (1:1000 concentration) in autoinjector or various vials or ampules. At least three epinephrine doses should be available onsite.

Other medications: H_1 antihistamines are for itching and hives only and not for managing anaphylaxis. Oral antihistamines should not be administered if airway is compromised.

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

Other supplies for emergencies:

- ☐ Syringes (1 and 3 mL) and needles (22 and 25g, 1", 1½", and 2") for epinephrine or diphenhydramine
- ☐ Alcohol wipes
- ☐ Stethoscope
- ☐ Blood pressure measuring device (with a variety of cuff sizes as needed)
- ☐ Light with extra batteries (for examination of mouth and throat)
- ☐ A timing device, such as wristwatch, for measuring pulse
- ☐ Cell phone or access to onsite phone
- ☐ CPR rescue mask with one-way valve
- ☐ Oxygen (if available)

E. Office Supplies

- ☐ Calendar
- ☐ Pens
- ☐ File folders
- ☐ Scissors
- ☐ Pad of paper
- ☐ Stapler/staples
- ☐ Tape
- ☐ Paper clips
- ☐ Sticky notes
- ☐ Wastebaskets/trash bags

F. Documents and Forms

- ☐ Current immunization schedules for children, adolescents, and adults www.immunize.org/cdc/schedules
  - ☐ *Summary of Recommendations for Child/Teen Immunization* www.immunize.org/catg.d/p2010.pdf
  - ☐ *Summary of Recommendations for Adult Immunization* www.immunize.org/catg.d/p2011.pdf
- ☐ Vaccine standing orders and protocols www.immunize.org/standing-orders
- ☐ Internet access or hotspot to IIS or EMR to access/update immunization records
- ☐ Immunization record cards for patients (pediatric and adult) shop.immunize.org/collections/immunization-record-cards
- ☐ Vaccination administration record sheets (e.g., medical records, if needed); for children and teens: www.immunize.org/catg.d/p2022.pdf; for adults: www.immunize.org/catg.d/p2023.pdf
- ☐ *Screening Checklist for Contraindications to Vaccines for Children and Teens* www.immunize.org/catg.d/p4060.pdf
- ☐ *Screening Checklist for Contraindications to Vaccines for Adults* www.immunize.org/catg.d/p4065.pdf
- ☐ Vaccine Adverse Events Reporting System (VAERS) information https://vaers.hhs.gov
- ☐ Temperature logs and other materials to help manage vaccine storage and handling www.immunize.org/handouts/vaccine-storage-handling.asp
- ☐ Billing forms, if needed
- ☐ Laptop computer, tablet, or smartphone
- ☐ Release of information forms
- ☐ Schedules, including dates and times, of future immunization clinics

1. See also "Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics" at www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/
2. Always check the expiration dates of all vaccines, medications, and medical supplies while packing and before using! In addition, be sure to check that you have the most current versions of the VISs. For a listing of current dates of VISs, visit www.immunize.org/vis.

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p3046.pdf
Item #P3046 (4/19/2023)
Scan for PDF

YOU CALL THE SHOTS

Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

Below are supplies that may be needed to conduct a satellite, temporary, or off-site vaccination clinic. The list may not be comprehensive. Your state or local public health immunization program may also have a checklist.

For large-scale clinics held at large facilities, such as stadiums and arenas, or over multiple days, additional supplies will be needed. Contact your state or local public health preparedness program and work with the clinic medical director for additional guidance and assistance.

Quantity of supplies needed will vary significantly between smaller, one-day clinics held in schools, churches, or pharmacies and large-scale clinics held in arenas or held over multiple days.

VACCINES

Refrigerated vaccines

Select the vaccine(s) that will be offered at the clinic.

- ☐ Diphtheria, tetanus, and pertussis (DTaP)
- ☐ DTaP-HepB-IPV (Pediarix)
- ☐ DTaP-IPV/Hib* (Pentacel)
- ☐ DTaP-IPV (Kinrix, Quadracel)
- ☐ *Haemophilus influenzae* type b* (Hib)
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ HepA-HepB (Twinrix)
- ☐ Human papillomavirus (9vHPV)
- ☐ Influenza, injectable (IIV) (in season)
- ☐ Influenza, live attenuated intranasal (LAIV) (in season)
- ☐ Measles, mumps, rubella* (MMR)
- ☐ Meningococcal ACWY* (MenACWY)
- ☐ Meningococcal B (MenB)
- ☐ Pneumococcal conjugate (PCV13)
- ☐ Pneumococcal polysaccharide (PPSV23)
- ☐ Polio, inactivated (IPV)
- ☐ Rotavirus* (RV)
- ☐ Tetanus-diphtheria, adult (Td)
- ☐ Tetanus, diphtheria, and pertussis (Tdap)
- ☐ Zoster, recombinant (RZV, Shingrix*)

Frozen vaccines

(Frozen vaccines may only be administered at satellite, temporary, and off-site clinics if they can be safely shipped to and monitored at the site. They should never be transported from one location to another.)

- ☐ Measles, mumps, rubella, varicella* (MMRV, ProQuad)
- ☐ Varicella*

*Diluent for ActHIB, Hiberix, Menveo, Pentacel, Rotarix, and Shingrix comes packaged in the same container as the lyophilized component. Diluent for MMR, MMRV, and varicella comes from the manufacturer packaged with the vaccine in separate containers.

CLINICAL SUPPLIES

Administration supplies

- ☐ Adhesive bandages
- ☐ Appropriate needles (length, guage) for the route of administration (Subcut, IM) and the expected patient population
- ☐ Sterile alcohol prep pads
- ☐ Syringes (1 or 3 cc)

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Clinic supplies

- ☐ Alcohol-based hand sanitizer (at least 60% alcohol)
- ☐ Digital data logger for each storage unit/container
- ☐ Disposable table covers
- ☐ Gauze pads
- ☐ Medical gloves
- ☐ Partition screens
- ☐ Paper towels
- ☐ Sanitizing products for vaccination and preparation surfaces
- ☐ Sharps containers
- ☐ Table and chairs for patient and vaccination provider at each vaccination station
- ☐ Vaccine storage units (onsite) or portable refrigerators or packouts (for transport) that can maintain the appropriate vaccine cold chain
- ☐ Wastebaskets

Clinic documentation

- ☐ Billing forms, if needed
- ☐ Immunization record cards
- ☐ Immunization schedule for targeted audience(s)
- ☐ Internet access or hotspot
- ☐ Forms to record vaccine administration (this may be done by computer)
- ☐ Laptops, computers, tablets, or smartphones, as well as printers and 2D barcode readers (if using), including multiple plug outlet strips and extension cords
- ☐ Screening checklist for contraindications to vaccines for children, teens, and adults
- ☐ Vaccination standing orders and protocols, as necessary
- ☐ Vaccine information statements (VISs) for each vaccine being offered and in multiple languages as appropriate (in some instances, an emergency use authorization [EUA] form may be required)
- ☐ Vaccine storage temperature log(s)

Office supplies

- ☐ Clipboards
- ☐ Notepads
- ☐ Pens
- ☐ Printer paper
- ☐ Printers, if applicable
- ☐ Rope, cones, and/or tape as needed to direct traffic flow
- ☐ Signage for clinic hours, future clinics, clinic flow, and easels or other equipment for displaying
- ☐ Trash bags
- ☐ Walkie-talkies or similar devices, depending on size of the clinic

MEDICAL EMERGENCY SUPPLIES

If possible, it is preferable that emergency medical services (EMS) staff be available during the clinic. Clinical staff providing vaccine should be trained in CPR and able to respond to medical emergencies.

At a minimum, there should be:

- ☐ Antihistamines (diphenhydramine [Benadryl], hydroxyzine [Atarax, Vistaril], and syringes if needed)
- ☐ Cell phone or land line to call 911
- ☐ Epinephrine in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules (Epi-pens)
- ☐ First aid kit

Additional supplies may include:

- ☐ Blood pressure measuring device
- ☐ Light source to examine mouth and throat
- ☐ Oxygen
- ☐ Stethoscope
- ☐ Timing device for measuring pulse
- ☐ Tongue depressors
- ☐ Tourniquet

Additional supplies needed during the COVID-19 pandemic

During the COVID-19 pandemic, additional supplies are needed to protect both staff and patients, including:

- Additional hand sanitizer with at least 60% alcohol for hand hygiene
- Additional cleaning equipment for more frequent cleanings, using EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2
- Additional signage, tape, ropes, and cones to encourage physical distancing and provide one-way flow through the clinic
- Face coverings for patients who arrive without one
- Hand soap, as appropriate
- Personal protective equipment (PPE) for staff. Gloves should be worn by anyone administering intranasal or oral vaccine. Depending on level of community transmission, eye protection may also be recommended.
- Thermometers for checking patient temperature before entering the clinic, if required
- Tissues

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CLINIC AR IMMUNIZATION REGISTRY/WEBIZ SOFTWARE ADMINISTRATOR

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 must be cross trained to assist during the Primary Administrator's absence.
3. WebIZ Software Administrator will be trained initially by a WebIZ Personnel or VFC Representative. The 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 WebIZ homepage.
5. New employees will be added to the appropriate WebIZ user categories according to clinical needs.
6. Employees no longer employed will be removed from WebIZ immediately to prevent access to vaccine information.

CLINIC AR PRIMARY AND ALTERNATE VACCINE COORDINATOR

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

Procedure:

1. _____Clinic must designate a staff member(s) as the Primary Vaccine Inventory Manager Coordinator. A Back-up person must be appointed and cross trained to assist during 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 Disease (Pink Book) and instructions found in WebIZ.

3. The Vaccine Inventory Manager Coordinator is responsible for:
    a. Maintaining and adjusting the temperatures of a vaccine(s) storage unit.
    b. Documenting temperature logs for each storage unit twice a day (AM and PM).
    c. Documenting adjustments in temperatures 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 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 staffand 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 http://www.cdc.gov/vaccines/

EDUCATON FOR VACCINE PERSONNEL

Ongoing education and information are available to staff administering vaccinations.

Procedure:

1. Current Copies of The Epidemiology and Prevention of Vaccine PreventableDisease (Pink Book) are available online for staff.
2. The VFC Vaccination Program's policy and procedure will be reviewed annuallyand updated as needed.
3. Other in-service training is available through the CDC website, literature, and the Arkansas Department of Health.
4. The VFC Primary and Back-up Vaccine Coordinators are required to takethe Immunization Training via the CDC website:
    a. You Call the Shots "Vaccines for Children Program" http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp
    b. You Call the Shots "Storage and Handling" http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

HOW TO OBTAIN A CURRENT VACCINE INFORMATION STATEMENT (VIS)

The_____Clinic will obtain current and language appropriate VIS in accordance with regulations.

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 IMMUNIZATION IN THE MEDICAL RECORDS

The_____Clinic shall make a notation on each patient's permanent medical record at the time the vaccine is given.

Procedure:

1. You must verify the clinic information contained in the Immunization Record.
2. Choose and record the appropriate Vaccine Information Statement for thelanguage spoken and vaccine being administered.
3. Record the name, address and title of the individual who administered the vaccine.
4. Record the date the vaccine is administered.
5. Record the vaccine manufacturer, lot number and expiration date of thevaccine administered.
6. Record the date the Vaccine Information Statement was provided.

REGULATIONS CONCERNING VACCINE INFORMATION STATEMENTS (VIS)

_____Clinic will provide Vaccine Information Statements (VIS) and maintain records in accordance with the National Childhood Vaccine Injury Act.

Parents/Responsible person will be provided with a copy of the VIS to read prior to the child's vaccine administration. and a copy will be available for the parent/responsible person to take with them out of the clinic.

Procedure:

1. Click here to obtain a current VIS information or click on your internet browser, type Vaccine Information Statement | Current VISs | CDC on the "search button".
2. Choose the appropriate VIS for the vaccine being administered.
3. It is highly recommended to make multiple copies for clinical convenience and organize VISs accordingly in a file cabinet.
4. Outdated VIS information must be discarded appropriately and replaced with the update copies as they become available.
    a. The date for a new VIS's required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately. A provider might be reluctant to discard existing stocks of a VIS when a new edition is published. This will become less an issue as providers and patients begin to rely more on electronic, rather than paper, versions of VISs. As a rule, when changes to a VIS concern the safety of the vaccine (e.g., contraindications or precautions, or adverse events), it is essential that the new edition be used immediately upon publication. Click here for VIS frequently asked Questions.
5. Record the name of the VIS, date of the VIS, and the date the VIS was given to the parent/responsible party in the patient's medical record.
6. Immunization recorded directly into the WebIZ automatically contains this information.

MANDATORY RECORDING OF IMMUNIZATION INTO WEBIZ

The_____Clinic shall record each immunization into the WebIZ, the Arkansas State Immunization Registry/Information System in accordance with the law of the State of Arkansas found at https://www.healthy.arkansas.gov/images/uploads/rules/ImmunizationReporting.pdf

Procedure:

All immunizations must be recorded into the WebIZ system. Please see WebIZ instruction for guidance if needed.

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4. The VFC Primary and Back-up Vaccine Coordinators are required to take the Immunization Training via the CDC website:
    a. You Call the Shots "Vaccines for Children Program" http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp
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3. Record the name, address and title of the individual who administered the vaccine.
4. Record the date the vaccine is administered.
5. Record the vaccine manufacturer, lot number and expiration date of the vaccine administered.
6. Record the date the Vaccine Information Statement was provided.

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

Other – Describe:	13 Other

IMPORTANT: VFC program completed forms must be retained for 3 years and made readily 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's DOB	E Date Dose Administered	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

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 Management Plan

CLINIC NAME: _____ PIN #: _____

CONTACT INFORMATION		
Contact	**Name**	**Telephone Number**
Primary Vaccine Coordinator		
Back-Up Coordinator		
Alternate Vaccine Coordinator		
VFC and Immunization Program		
Regional VFC Representative		
ADH Immunization Program		(501) 537-8969
VFC Program Coordinator	Nora Fawcett Nora.Fawcett@arkansas.gov	(501) 661-2170
Vaccine Management Team		(501) 280-4096 or (501) 661-2159
WebIZ Team		(800) 574-4040
24- Hour Clinic Contact		
Location of Back-up Digital Data Logger:		
Dates of Calibration:		
Storage Unit Maintenance and Repair		
Storage Unit & Digital Data Logger Maintenance/Repair		
Local Utility/Power Company		
Generator Maintenance/Repair		
Medicaid Billing Issues		
Arkansas Department of Human Services-Division of Medical Services	Kimberly Wilmot Kimberly.Wilmot@dhs.Arkansas.gov	Phone: (501) 537-1666 Fax: (501) 682-8013
PHARMACIES ONLY	Marlene Battle marlene@arrx.org	Phone: (501) 372-5250

IN CASE OF EMERGENCY, MOVE VACCINES TO THE FACILITY LISTED BELOW

Facility Name: _____ Telephone #: _____

Facility Address: _____

Contact Person with 24-hours access at facility: _____

Contact the vaccine manufactures to determine if the vaccines can be used after an out-of-range emergency temperature exposure.

STORAGE AND HANDLING TRAINING

DATE	TITLE OF TRAINING	EMPLOYEE NAME	TITLE

*** ROUTINE VACCINE STORGE AND HANDLING PLAN ***

Vaccine Coordinator Duties and Training

Designate a Primary Vaccine Coordinator, and at least one Back-up Vaccine Coordinator for each facility. The alternate Vaccine Coordinator(s) will assume the responsibility of primary Vaccine Coordinator during the Primary Vaccine Coordinator's absence.

The Primary Vaccine Coordinator and Back-up Vaccine Coordinators are responsible for:

- Completing monthly vaccine inventory reconciliation.
- Placing monthly vaccine orders.
- Oversee the proper receipt and storage of vaccine deliveries.
- Maintaining a well-organized vaccine storage unit, which includes rotating 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.
- Immediately notify the VFC Program of any changes in key immunization staff and update the VFC Management Plan.

Required Training and Documentation:

- Annually, the Primary Vaccine Coordinator and Back-up Vaccine Coordinators are required to take **CDC's "You Call the Shots Trainings"**
    - Vaccines for Children Program (VFC)- Module Sixteen
    - Storage and Handling- Module Ten
- First create an account with the "CDC TRAIN" if you do not have an account prior to taking trainings. Once the account has been created you will be able to complete the required training courses and access the training certificates.
    - Select the "Course Catalog" tab
    - Type the name of the training, on "Search TRAIN"

The "You Call the Shots" training certificates are required to be uploaded into the WebIZ system during your VFC Enrollment. A copy should also be printed and placed in the provider's VFC folder. All VFC documentation should be readily available upon the State's request.

*** VACCINE STORAGE UNIT REQUIREMENTS ***

Vaccine Storage Unit Requirement and Set-Up

1. **Storage Unit**
    - Storage units must have enough room to store the largest inventory a provider location might have at the busiest point in the year without crowding. Storage Unit(s) must be one of the following (select all that apply):
        - Purpose-built
        - Pharmaceutical
        - Medical Grade
        - Standalone Unit

NOTE: After July 1, 2024, new providers will not be allowed to use the freezer compartment of a household combination unit. The use of dormitory or bar-style refrigerator/freezers is always prohibited for VFC program provider locations.

- Protect your vaccine and your patients by ensuring:
    - That the storage unit can maintain the required temperature range throughout the year.
    - That the storage unit has enough room to store the year's largest inventory without crowding (i.e., mass flu/school clinics).
    - 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.
    - That no food or beverages are stored in a vaccine storage unit.
    - The use of dormitory or bar-style refrigerator/freezers is always prohibited for VFC program provider locations.

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 storage unit designated for the thermometer equipment. The temperature probe does not have to be 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 it 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, connect it 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).
    - Ultracold freezer temperatures are between -130° F and -76° F (-90° C and -60° C), if applicable. The minimum and maximum temperatures of the digital data logger should be cleared each day after documentation. Monitoring and recording are required even if a continuous graphing/recording thermometer or a digital data logger is used.

- 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 ***

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), and ultracold freezer temperatures are between -130° F and -76° F (-90° C and -60° C), if applicable. The minimum and maximum temperatures of the digital data logger should be cleared each day after documentation. Monitoring and recording are required even if a continuous graphing/recording thermometer or a digital data logger is used.
- 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 TEMPERTRE 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 vaccine manufacturer(s) and send final temperature excursion information, including the vaccine viability determination by the manufacturer(s), to the regional VFC Program and VFC Representative.
- 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:
    - The room temperature where the storage unit is located.
    - The length of time the power was off.
    - The minimum and maximum temperatures reached during the power outage.

IMPORTANT: 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

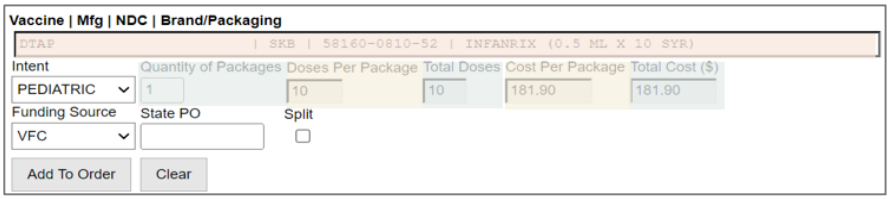
- Count all vaccine doses at least once a month to ensure the number of physical doses on hand matches the number of doses indicated in WebIZ.
- Complete an Inventory Reconciliation in WebIZ at least once a month and no more than 14 days prior to ordering vaccine.
- Inventory Reconciliation instructions 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 on the 1st through the 20th of each month. Orders placed beyond this timeframe will be rejected.
- 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.
- Order appropriately, timely, and accurately to maintain inventory and avoid stockpiling.
- Double check the vaccine quantities in WebIZ prior to clicking the "Add to Order" button.
    - Once the "Add to Order" button has been clicked, it will display the following:
        - Type of vaccine
        - Quantity of Packages
        - Doses Per Package
        - Total Doses
        - Cost Per Package
        - Total Cost



- Again, double check the final order prior to clicking "Submit to VFC".
    - When in doubt on the accuracy of your vaccine order, contact the ADH Vaccine Management Team for assistance.

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, Option 2 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 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, 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 open 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.

***** 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

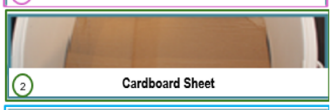
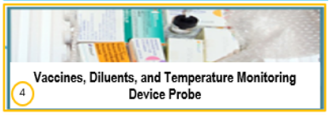
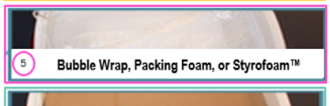
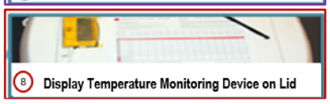
- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
    - *Note: Placing room temperature diluent in the transport container can raise the temperature of the container.*
- Place an insulation barrier (e.g., bubble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

Refrigerator 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.**
- If specialized vaccine transport coolers are not available for emergencies, pack hard-sided coolers and thick Styrofoam shipping containers as follows:
    - Place a layer of "conditioned" water bottles in the bottom of the transport container.
    - Place a piece of corrugated cardboard (cut to fit the interior dimensions of the cooler) over the water bottles.
    - 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.
    - Place the vaccine on the insulating material. Refrigerated vaccines should never be placed directly on frozen water bottles.
    - Place the buffered temperature probe from a digital data logger in the middle of the vaccine.
    - Place at least a 1-inch layer of insulating cushioning material over the vaccine.
    - Place a piece of corrugated cardboard over the insulating material.
    - Place a layer of conditioned water bottles on top of the piece of cardboard.
    - 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

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

	**Conditioned Frozen Water Bottles-** Line the bottom of the cooler with a single layer of conditioned water bottles.
	**Insulating Material-** Place 1 sheet of corrugated cardboard over the water bottles to cover them completely.
	**Insulating Material-** Place a layer of bubble wrap, packing foam, or Styrofoam ™ on top (layer must be at least 1-inch thick and must completely cover the cardboard.
	**Vaccines-** Add remaining vaccines and diluents to cooler, covering the thermometer probe. **Temperature Monitoring Device-** When cooler is halfway full, place thermometer probe in center of vaccines, but keep temperature display outside cooler until finished loading. **Vaccines-** Stack boxes of vaccines and diluents on top of insulating material.
	**Insulate Material-** Cover vaccines with another 1-inch layer of bubble wrap, packing foam, or Styrofoam ™
	**Insulate Material-** Another sheet of cardboard may be needed to support top layer of water bottles.
	**Conditioned Frozen Water Bottles-** Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.
	**Close Lid-** Close the lid and attach the temperature display and temperature log to the top of the lid.

Frozen Vaccines

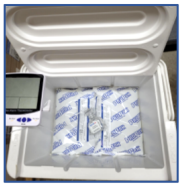
- Transport frozen vaccines in a portable freezer unit that maintains the temperature between -58°F and +5°F, if possible.
- If a portable freezer unit is not available, transport frozen vaccines using a qualified container and pack-out.

FROZEN VACCINE PACK-OUT

1. Frozen Cold Packs
Place a layer of cold packs to completely cover the bottom of the cooler. NEVER USE DRY ICE.

2. Vaccines
Layer vaccine boxes directly on top of the frozen cold packs.

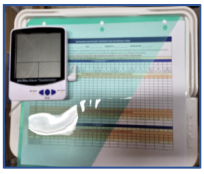
3. Buffered Probe
Place the buffered probe with the top layer of vaccines.



4. Frozen Cold Packs
Spread another layer of frozen cold packs to completely cover the vaccines.

5. Bubble Wrap
Layer bubble wrap to the top of the cooler.

6. Final Steps
Layer bubble wrap to the top of the cooler. Record the temperature before departure on the transport log. Close the cooler and carefully attach the digital display and temperature log on the top of the cooler.



IMPORTANT NOTICE:

- All VFC documents must be retained for three (3) years prior to discarding.
- Annual VFC enrollments must be submitted at the beginning of each Fiscal Year (July 1 through June 30 of the following year).
  - VFC open enrollment for recertification begins in July 1and closes on August 30. Failure to comply may result in the removal of your facility from the VFC program.
- New VFC Vaccine Providers can start ordering vaccines the same date their New Enrollment Site Review is completed.
- Facilities must be open with appropriate staff at least one weekday other than Monday, for at least four consecutive hours, to receive and immediately store vaccines.

VFC Requirement for Inventory of COVID-19 and Nirsevimab

Policy Regarding VFC Requirements for Inventory of COVID-19 Vaccine and Nirsevimab

- **RSV Monoclonal Antibody Products**

  Starting July 1, 2025, VFC Providers that serve and plan to vaccinate any privately insured, non-VFC eligible population, must maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. This will include Nirsevimab and any other RSV monoclonal antibody product that may be added to the VFC program. **Borrowing of VFC monoclonal antibody products for use among privately insured, non-VFC-eligible patients is not permitted. Failure to comply may result in a 30-day vaccine ordering suspension.**

  - For example: If the provider vaccinates privately insured and non-VFC eligible population with routine vaccines, the Provider can choose not to administer the RSV monoclonal antibody (seasonal) and refer them to the Local Health Unit", as long as they don't use their VFC RSV vaccine to vaccinate the privately insured".

- **COVID-19 Vaccines**

  Given the unique considerations of COVID-19 vaccination, it may not be practical for all VFC providers to stock this vaccine for VFC-eligible patients. In such cases, VFC Providers must identify accessible locations where VFC-eligible children can be referred for COVID-19 vaccination. The Local Health Unit Directory has been attached to assist VFC Providers when referring patients to local health units. The patient will need to contact the local health unit to schedule a vaccine appointment.

Special Consideration for COVID-19 Vaccine waiver has ended.

VACCINE MANAGEMENT PLAN UPDATES

DATE	UPDATED/REVIEWED BY *PRINT NAME*	SIGNATURE	TITLE

Temperature Recording Form

DAYS 1-15

REFRIGERATOR/FREEZER TEMPERATURE RECORDING FORM

CLINIC NAME:_____ **PIN #**:_____ **PROPERTY #**:_____ **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.

CONTACT THE VACCINE MANUFACTURER(S) ANY TIME VACCINES ARE EXPOSED TO OUT-OF-RANGE TEMPERATURES.

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		**1**		**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**		**10**		**11**		**12**		**13**		**14**		**15**	
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MAXIMUM TEMP																															

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DAYS 16-31

REFRIGERATOR/FREEZER TEMPERATURE RECORDING FORM

CLINIC NAME:_____ **PIN #:**_____ **PROPERTY #:**_____ **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.

CONTACT THE VACCINE MANUFACTURER(S) ANY TIME VACCINES ARE EXPOSED TO OUT-OF-RANGE TEMPERATURES.

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 ***																																	
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≥48	≥8.8	RECORD ACTUAL TEMPERTURE												**TAKE IMMEDIATE ACTION IF TEMPERATURE IS IN THE SHADED SECTION**											RECORD ACTUAL TEMPERTURE									
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