
# Kentucky VFC Program

# Provider Manual

Revised September 2025

Cabinet for Health and Family Services
Department for Public Health
Division of Epidemiology and Health Planning
Kentucky Immunization Branch
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Frankfort, KY 40621
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https://chfs.ky.gov/agencies/dph/dehp/Pages/immunization.aspx

# Introduction

The Vaccines for Children (VFC) Program is a federally funded entitlement program that ensures all children have access to life-saving vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP). This is accomplished by providing vaccines at no cost to VFC-eligible children through public and private providers enrolled in the program. The VFC Program is regulated by the Centers for Disease Control and Prevention (CDC) and the National Immunization Program (NIP). Funds for the VFC program are annually transferred from the Centers for Disease Control and Prevention (CDC) and awarded to immunization programs. About ninety percent of these funds are used for vaccine purchases. The remaining funds are used for program operational activities such as provider recruitment and enrollment, evaluation, vaccine ordering, and accountability.

The VFC program:

- Provides vaccines free of charge to eligible children.
- Covers all vaccines recommended by the ACIP.
- Reduces vaccine cost as a barrier to the vaccination of eligible children.
- Reduces the practice of referring children for vaccination and keeping children in their medical homes for comprehensive health care.

The Kentucky Immunization Program, a part of the Department for Public Health, manages the VFC program within the state. The Immunization Program manages the budget, distributes vaccines, enrolls and educates providers, and ensures compliance through provider site visits. The Program also works at the state and local levels by working closely with providers to help develop and implement systems to assess immunization levels statewide.

## VFC Program Benefits

- Provides cost-savings to states and territories through the bulk purchase of vaccines at lower prices using the CDC's contracts and eliminates state-to-state differences in price.
- Reduces referrals of children from private providers to local health departments for vaccination.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccines.
- Eliminates or reduces vaccine costs as a barrier to immunizing eligible children.

All enrolling provider locations must adhere to all requirements of the VFC program. These include:

- Having a primary and backup vaccine coordinator.
- Operating within the VFC requirements for storage and handling.
- Completing an enrollment site visit.
- Completed the onboarding process for the Immunization Information System (IIS)
    - For Kentucky, this is known as the Kentucky Immunization Registry (KYIR).

# Acronyms

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| ACIP | Advisory Committee on Immunization Practices |
| AI/AN | American Indian or Alaska Native |
| CDC | Centers for Disease Control and Prevention |
| DDL | Digital Data Logger |
| DHHS | Department of Health and Human Services |
| FQHC | Federally Qualified Health Center |
| EHR | Electronic Health Record |
| HL7 | Health-Level 7 (standards for electronic transmission of health data) |
| HRSA | Health Resources and Services Administration |
| IQIP | Immunization Quality Improvement for Providers |
| KDPH | Kentucky Department of Public Health |
| KIP | Kentucky Immunization Program |
| KYIR | Kentucky Immunization Registry |
| LHD | Local Health Department |
| PIN | Provider Identification Number |
| RHC | Rural Health Center |
| VAERS | Vaccine Adverse Event Reporting System |
| VFC | Vaccines for Children Program |
| VIS | Vaccine Information Statement |
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# Immunization Program Contact Information

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| **VFC Enrollment** | |
| Contact for enrollment questions, to report a facility change, or to update the Primary and Backup VFC Contacts. | Email: KYVaxProvider@ky.gov |
| **Vaccine Ordering & Accountability Section** | |
| Contact for vaccine ordering, inventory, reconciliation, returns, and supply issues. | Email: DPH.KVP@ky.gov |
| **Vaccine Storage & Handling** | |
| Contact for VFC vaccine storage and handling issues, temperature excursions | Email: VaxColdChain@ky.gov |
| **Vaccine Clinical Questions** | |
| Contact for questions on vaccine administration, schedule, or other clinical issues. | Email: Daphne.Spalding@ky.gov or Crystal.Back@ky.gov |
| **KYIR Helpdesk** | |
| Contact for general KYIR assistance, user accounts, password resets, and facility enrollment. | Email: KYIRHelpdesk@ky.gov<br>Phone: 502-564-0038<br>Available Monday – Friday 8:00 am – 4:00 pm EST |
| **KYIR Onboarding Team** | |
| Contact for issues with electronic connection between electronic medical record (EMR/EHR) and KYIR. | Email: CHFSOATSKIR@ky.gov |

## Kentucky Immunization Program

Main Phone: 502-564-4478 Fax: 502-564-4760

## KYIR Helpdesk

The KYIR Helpdesk is an important resource for VFC providers.
All VFC providers are assigned a unique Personal Identification Number (PIN), which should be referenced when contacting the Helpdesk.
Hours of Operation: Monday – Friday 8:00 am to 4:00 pm Eastern
Telephone: 502-564-0038
Email: KYIRHelpdesk@ky.gov

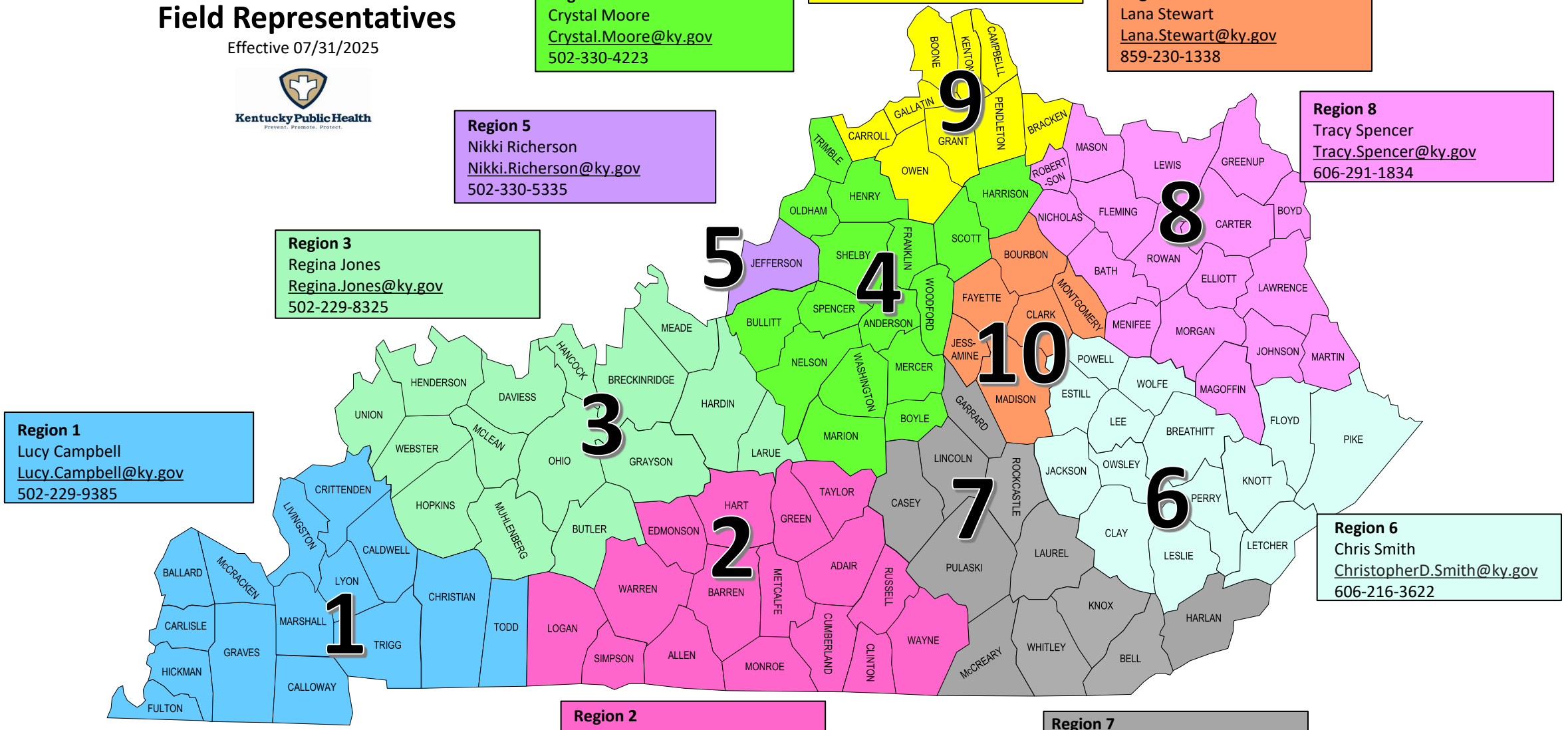
## Immunization Regional Field Representative

The Regional Field Representatives act as the primary liaison between the VFC program and prospective or enrolled providers. They provide a variety of support services for VFC providers, including approving sites for enrollment, conducting site visits, offering on-site training, and providing answers to all VFC-related questions.

# Kentucky Immunization Branch Field Representatives

Effective 07/31/2025

Kentucky Public Health
Prevent. Promote. Protect.

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**Region 10**
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859-230-1338

| VFC Program Requirements Summary | |
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| **Staff** | Key Clinic Staff includes a Medical Director, Primary Vaccine Coordinator, and a Backup Vaccine Coordinator. Required training must be completed prior to enrollment as well as annually. Any changes in key clinic staff must be submitted to the VFC Program within 10 business days. |
| **Provider Enrollment** | VFC Program Provider Agreements must be updated, including provider demographics, population profile, and key clinic staff contacts. |
| **Eligibility** | VFC Providers must have a knowledge of vaccine funding sources and use the eligibility screening to determine the correct funding source to be used prior to administering vaccines. |
| **Billing** | VFC Providers may bill only for the administration fee, not the cost of the vaccine. Medicaid should be billed for Medicaid-eligible children. Other VFC-eligible patients may be billed for the administration fee once and only within 90 days of administration. This fee is capped at $19.93 per vaccine for the state of Kentucky. Unpaid administration fees are not to be sent to collections or used to turn away VFC-eligible patients. |
| **Documentation** | Immunization records must be maintained in accordance with federal law. KY VFC Providers should ensure their vaccine administrations are documented in the Kentucky Immunization Registry (KYIR) through either manual entry or connection of their electronic medical record system. |
| **Vaccine Management Plan** | VFC Providers must develop and maintain current written standard operating procedures for routine and emergency vaccine management. The Vaccine Management Plan must be updated annually or when any of the plan information for the clinic changes. Current management plans must be kept on hand, near the storage units, and available during all site visits. |
| **Digital Data Logger Thermometers** | The VFC Program requires a digital data logger for each storage unit with current, valid certificates of calibration as the only acceptable method of monitoring temperatures. Providers must also have a digital data logger (with a valid calibration certificate) as a backup if needed. Providers are responsible for the recalibration fees for the digital data loggers. Temperature files for each unit and any backup in use must be uploaded to KYIR or sent to the assigned field rep every month. |
| **Daily Temperature Logs** | The minimum and maximum temperatures for the previous 24 hours must be checked at the start of each provider's workday and recorded on the paper temperature logs. The completed logs must be kept on file for reference for 3 years. |
| **Available Vaccines** | Vaccines available through the VFC Program include all ACIP-recommended vaccines in both single and combination presentations. |
| **Ordering** | Proper ordering and inventory management prevent vaccine waste and ensure that appropriate stock is available by vaccine type. A VFC Provider must place an order, at a minimum, once per calendar year to remain on the program. To place an order, there must be a currently balanced reconciliation for each storage unit within the past 13 days. |
| **Receiving** | Appropriately trained staff must be available and on-site to receive vaccine shipments. All vaccine orders are delivered in accordance with the reported clinic hours of operation. |

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| **Inventory Management** | Vaccines should be used on a "first in – first out" basis to ensure that vaccines are used before expiration. All vaccines should be maintained at the correct temperatures to ensure viability. Refrigerator temperatures should be within the 36° to 46° Fahrenheit (2° to 8° Celsius) range. Freezer temperatures should be at 5° Fahrenheit (-15° Celsius) or below.<br>Inventory reconciliations are required monthly (at a minimum) to monitor vaccine use, loss, and ordering needs. |
| **Borrowing** | Providers are required to maintain inventories of vaccines to administer to both private and publicly funded children that they serve. Borrowing is permitted only in rare, unplanned circumstances. |
| **Transfers** | Transfers of vaccines should be rare and not routinely occur. The Provider must contact and gain approval from their assigned Immunization Field Representative before the transfer is to take place. Only transfers that are within 1 hour will be approved. Immunization Field Representatives will handle transports greater than 1 hour. |
| **Expiration Dates and Returns** | VFC Providers must monitor vaccine expiration dates and notify their assigned Immunization Field Representative within 3 months of vaccine expiration. The short-dated vaccine may be transferred to another VFC Provider with Field Representative approval.<br>All expired VFC vaccines must be returned to the manufacturer through a return submitted in KYIR. Exceptions include opened multi-dose vials, which must be adjusted out of VFC inventory in KYIR. |
| **Mass Clinics** | Providers who conduct off-site and/or mass vaccination clinics with publicly funded vaccines must follow all VFC requirements in addition to enhanced storage and handling practices. All off-site clinics must have the approval of the assigned Immunization Field Representative. |
| **Temperature Excursions** | Once a vaccine has been exposed to temperatures outside the recommended temperature range, Providers must follow the temperature excursion protocol, which includes completing/submitting an incident report to the assigned Field Representative after contacting the manufacturers to determine vaccine viability. |
| **Wasted Vaccines** | VFC Providers must maintain vaccine inventory to minimize the risk of vaccine loss. All wasted or discarded vaccines must be documented in KYIR on monthly reconciliations. |
| **Restitution** | The KY Immunization Program reviews all vaccine loss to determine if it was avoidable or unavoidable. VFC Providers are responsible for the repayment of avoidable vaccine loss. The Provider may be required to replace the lost vaccine with a privately purchased vaccine on a "dose-for-dose" basis. |
| **Fraud and Abuse** | All VFC Providers must agree to operate based on requirements to avoid fraud and abuse. Failure to follow the requirements could lead to fraud and abuse of the VFC Program. |

# VFC Program Policies

This provider manual contains best practices, recommendations, policies, and requirements of the Kentucky VFC Program.
Providers enrolling in the VFC program agree to all conditions contained in the Provider Agreement and this manual.
The most current version will be posted on the Immunization Program webpage. When revisions are made, providers will be notified through an all-provider email with the revised section(s), and the revised version will be posted on the webpage.
It is the provider's responsibility to keep the most up-to-date version by discarding outdated sections and replacing them with current versions.

## VFC Providers

Any Kentucky healthcare provider serving children 0 through 18 years of age who meets the following criteria can enroll in the VFC program:

- Has a medical director or equivalent to sign the Provider Agreement who has a valid license to administer vaccines in Kentucky and the authority to ensure the facility and all providers listed on the agreement adhere to the requirements of the program.
- Agrees to all program requirements, including participating in site visits and education requirements, and providing all ACIP-recommended vaccines for the populations they serve.
- Has the capacity to order, manage, and store public vaccines, including proper vaccine storage and temperature monitoring capacity as described in this manual.
- Does not have providers or staff included on the Office of Inspector General List of Excluded Individuals and Entities (LEIE).
- Is on-site with appropriate staff available to receive vaccine at least one day a week other than Monday and Friday, and for at least four consecutive hours during that day.

VFC providers can be both public and private facilities, and those not registered as Medicaid providers. Healthcare provider locations serving VFC-eligible populations can include (but are not limited to):

- Pediatricians
- Family practitioners
- General practitioners
- Local health departments
- Specialty care providers can include (but are not limited to):
    - OB/GYNs
    - Specialty provider practices
        - Family Planning and Sexually Transmitted Disease Clinics
        - Birthing Hospitals
        - Long-Term Juvenile Correctional Facilities
    - School-located vaccination clinics *
    - Pharmacies *
    - Urgent Care Centers *

* These providers must agree to vaccinate all "walk-in" VFC-eligible children, in addition to meeting all general VFC requirements.

# Specialty Providers

Specialty providers who serve a unique client base and offer only specific pediatric vaccines are eligible for the VFC program. Specialty provider status is not applicable to most providers. Unless otherwise noted below, specialty providers must follow all requirements of the VFC program.

## Family Planning and Sexually Transmitted Disease Clinics

The CDC defines a family planning clinic as a provider whose main purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. Providers whose main services involve primary or acute care do not qualify as family planning clinics.

- Family planning clinics have the following unique VFC requirements:
  Vaccine offerings at family planning clinics are limited to those relevant to their client base, such as human papilloma virus (HPV) and hepatitis B.
- Family planning clinics can administer the VFC vaccine to an additional eligibility category:
  - Unaccompanied minors less than 19 years of age who present at family planning clinics for contraceptive services or sexually transmitted disease (STD) treatment, who do not know their insurance status or choose not to access their insurance due to the confidential nature of their visit.
    Family planning clinics must screen for this special eligibility category and document the VFC vaccine given to this population per the current Immunization Program instructions.
    ***Note***: The VFC Program does not regulate the issue of medical consent for the provision of medical care to minors. Clinics are responsible for providing care in conformance with Kentucky's medical consent laws as they pertain to minors.

## Birthing Hospitals

- A birthing hospital or birthing center is defined as a facility with more than one birth within the past year (January 1 – December 31 of the past year) or at least one registered maternity bed.
- Hepatitis B vaccine and RSV monoclonal antibody products are available for birthing hospitals for VFC-eligible newborns.

## Long-Term Juvenile Correctional Facilities

Incarcerated juveniles housed at long-term juvenile correctional facilities through 18 years of age who lose access to their health insurance due to their circumstances are considered uninsured and VFC-eligible. Providers at these sites can enroll to serve only the adolescents housed at their facility.

# Pharmacies

Pharmacies must adhere to state law when administering immunizations. Kentucky pharmacies are allowed to provide vaccines to children aged 5 through 18 years of age. Pharmacies can enroll in the VFC Program to serve Medicaid and other VFC-eligible children.

- Pharmacies must agree to vaccinate all "walk-in" VFC-eligible children and not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.

# Available Vaccines

Vaccines covered by the VFC program are recommended by ACIP to protect infants, children, and teenagers from 19 vaccine-preventable diseases.
For a complete list of the vaccines available through the VFC program, see the Vaccine List located on the Kentucky VFC webpage.

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

- Age for vaccine administration
- Number of doses and dosing intervals
- Precautions and contraindications to vaccination

For the purposes of the VFC program, the term “vaccine” is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program. VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine availability and use.

**Influenza vaccine**: VFC providers must stock and offer flu vaccines for patients six months of age and older. Flu vaccine ordering is completed during a “pre-book” process each year, typically completed in January.

- Pre-booked flu vaccine is automatically shipped to providers, often beginning in early September.
- Providers should pre-book enough flu vaccine for their patient population.

## Non-Routine VFC Vaccines

VFC providers must ensure that VFC-eligible children have access to non-routine vaccines as needed. All providers should establish a vaccine plan on how VFC patients will have access to the non-routine vaccines. This plan should be reviewed during VFC Compliance Site Visits. All staff working with the VFC vaccine need to be trained and knowledgeable about the plan.

The following non-routine vaccines may be ordered as needed, based on clinical decision-making and according to the following guidelines:

- PPSV23 (Pneumococcal 23-valent polysaccharide) Vaccine after PCV: This includes PPSV23 vaccine available for ordering single doses as needed for high-risk children ages 2 through 18.
- Meningococcal B (MenB) Vaccines: All VFC providers are highly encouraged to stock and offer MenB vaccine.
    - Providers with limited VFC-eligible patients may order this vaccine as needed. If a parent requests MenB vaccine, it must be provided.
- Abrysvo (Respiratory Syncytial Virus) Maternal RSV Vaccine: CDC recommends a single dose of Abrysvo RSV vaccine administered to pregnant persons who are 32 to 36 weeks’ gestation. The vaccine should be administered between September through January in most of the continental U.S. to prevent RSV-associated lower respiratory tract infection in infants less than 6 months. Abrysvo is not to be used on infants or young children. Abrysvo is a Pfizer product. The Merck brand of RSV vaccine, Arexvy, is NOT approved for administration to pregnant persons, infants, or young children.

- Dengue Tetravalent Vaccine, Live (Dengue) Vaccine: Dengue is approved for use in children ages 9 to 16 years with laboratory-confirmed previous dengue virus infection and living in areas where dengue is endemic. Endemic areas include some U.S. territories and freely associated states (Puerto Rico). The vaccine should not be used on individuals traveling to areas where dengue is present. The CDC will make the vaccine available if areas within the U.S. become endemic. Kentucky is not an endemic area. Providers are not required to have or stock Dengue. If this status changes, the CDC would enact protocol for vaccine distribution.

## Private Stock

With respect to the VFC program, if a VFC provider serves and plans to vaccinate privately insured (non-VFC-eligible) populations, they should stock a separate vaccine supply for the specific vaccines they plan to offer non-VFC-eligible patients. The CDC generally considers a "sufficient" supply to be a four-week inventory, based on the size of the practice's stated non-VFC patient population.

CDC is not requiring VFC providers to maintain a full stock of all ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance includes, but is not limited to, RSV monoclonal antibody products.

Example: VFC providers, including birthing hospitals, that serve both VFC-eligible and non-VFC-eligible patients indicated to receive RSV monoclonal antibody products are not required to maintain a separate stock of this product for any non-VFC-eligible patient they do not plan to immunize with this product.

<u>If a VFC provider does not carry privately purchased stock, they are not permitted to use VFC stock on non-VFC-eligible patients.</u>

If a VFC provider does have privately purchased vaccines in addition to public vaccines, they must clearly separate these two stocks of vaccines.

## COVID-19 Vaccine Stock

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, enrolled VFC providers who do not stock COVID-19 vaccines must be aware of accessible locations and be prepared to refer VFC-eligible children accordingly. The referral plan must be included and updated on the Vaccine Management Plan. These procedures are similar to those for non-routine VFC vaccines, such as Mpox and PPSV23.

# VFC Provider Agreement

The Provider Agreement lists the federal statutory requirements of the VFC program. It must be signed by the medical director or equivalent at your facility. By signing a Provider Agreement and accepting shipment of VFC vaccine, you agree to abide by the requirements of the VFC program.
All VFC providers must submit an updated Provider Agreement every 2 years. New providers submit during the enrollment process. Current providers complete a new Provider Agreement every two years during the re-enrollment process or upon the change in Medical Director signing the agreement.

## Enrollment – New Providers

All VFC enrollment activities take place within the Kentucky Immunization Registry; therefore, first-time enrollees not already registered in KYIR must first enroll their facility and staff with KYIR. Once logged into KYIR, you can initiate the enrollment process in KYIR.
New provider enrollment involves the following steps:

- Enrolling the facility with KYIR
- Submitting a signed VFC Provider Agreement, including a Provider Population Profile
- Completing the required provider training, including KYIR training and CDC You Call the Shots training certificates
- Obtaining and setting up VFC-compliant vaccine storage units and thermometers (data loggers)
- Submitting a completed vaccine management plan
- Primary and Backup vaccine coordinators obtain KYIR Inventory access by completing the required inventory management training
- Receiving an enrollment visit from a Regional Immunization Field Rep
- Submitting required documentation
- Completed Vaccine Management Plan
- Two consecutive days of DDL temperature readings for each vaccine storage unit
- Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit a current Notice of Award from the U.S. Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates participation.

VFC enrollment can be completed in two to four weeks, although the sequence and timing of enrollment activities may vary depending on your location and the availability of Immunization Program staff.
Final approval into the VFC program is dependent upon the on-site Enrollment Site Visit. After successfully passing the Enrollment Site Visit, the practice will be able to place its first VFC vaccine order in KYIR.
Training Requirements for Primary and Backup Vaccine Coordinators:

- KYIR Inventory Management Training – This training shows how to order VFC vaccine and manage your VFC vaccine inventory.
- CDC's You Call the Shots – Two modules must be completed annually: Vaccine Storage and Handling and Vaccines for Children. A certificate of completion must be submitted to the assigned Field Rep as proof.

## Required Documents for Enrollment

- Completed VFC Provider Agreement with the signature of the Medical Director.
  Provider Agreement must include a completed Provider Population Profile. The KY Immunization Program uses the number of VFC and non-VFC-eligible children in the practice to evaluate the appropriateness of VFC vaccine orders. Provider Profile numbers are required to be reviewed and updated at least annually.
    - To determine the patient population, a provider may use patient records and/or vaccine administration data submitted to KYIR. It is essential to be accurate when submitting patient population; this information determines the number of vaccines each provider will need in the coming year.
- Completed Vaccine Management Plan
- CDC You Call the Shots training certificates of completion for modules 10 & 16 for both the Primary and Backup vaccine coordinators.
- Two consecutive days of digital data logging (DDL) thermometer readings for each vaccine storage unit for review and approval.
- Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit the current Notice of Award from the US Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA).

Once all required enrollment documentation has been approved, the Regional Field Representative will schedule an Enrollment Site Visit. The enrollment visit is to review VFC requirements, such as screening and eligibility, storage units, digital data loggers, vaccine management plan, etc. Final approval into the VFC program is dependent on passing this visit. After successfully passing the Enrollment Site Visit, the provider will be able to place its first VFC vaccine order in KYIR.
The enrollment process must be completed within three (3) months. This includes the enrollment site visit and any follow-up to be completed by the provider for enrollment completion. If this is not completed within this timeframe, the enrollment site visit must be repeated.

Newly enrolled practices will be authorized to order only one box of each vaccine on their initial order. This is to ensure that all shipping information is correct, and doses are delivered correctly. Subsequent orders are limited based on the use of available vaccines and the provider population profile submitted to the program.

After the initial enrollment visit, a full VFC compliance visit will occur within 6 months. Regular compliance visits occur at a maximum of every 24 months, but in most cases, visits are yearly.

# Re-enrollment – Current Providers

Every other year, current VFC providers must re-enroll in the VFC program by completing a new Provider Agreement. The Immunization Program notifies providers when the re-enrollment period begins and provides instructions for completing the process. All Provider Agreements are reviewed and approved by the Immunization Program.

- Re-enrollment is completed in the Kentucky Immunization Registry (KYIR) via the Clinic Tools module.
- Re-enrollment begins every other February and must be completed by April. Providers will be notified when the enrollment is available for submission.

- Providers who have not completed re-enrollment by April will be placed on Pending status and will be unable to order vaccines until the re-enrollment is submitted.

## Provider Population Profile

An updated Provider Population Profile must be submitted annually. The Provider Population Profile is the number of VFC-eligible children and non-eligible children you served in the most recent 12 months by age and eligibility category. Each year, you must submit your Provider Profile derived from actual eligibility screening data from the previous year.
Be sure to document eligibility throughout the year in a way that can be easily tallied for your annual Provider Population Profile update.

## Key Clinic Staff

- Medical Director: The official registered health care provider who signed the Vaccines for Children Provider Agreement. They must be the practitioner authorized to administer pediatric vaccines under state law, who will be held accountable for compliance with the provider office's responsibilities and conditions outlined in the provider enrollment agreement.
- Primary Vaccine Coordinator: The primary coordinator should be a member of staff who is based at the provider location. Primary coordinators cannot be primary coordinator at multiple locations. They are responsible for providing oversight for all vaccine management within the clinic, including:
    - Maintaining the Vaccine Management Plan.
    - Monitoring storage and handling, and vaccine administration practices in the clinic.
    - Completing vaccine reconciliations and submitting orders, returns, and notifying the Regional Field Rep of any short-dated vaccines.
    - Completing and maintaining documentation of annual training of VFC requirements.
    - Documenting vaccine management training for designated staff and training new staff upon hire.
    - Storing all required documentation for three years as required.
- Backup Vaccine Coordinator: The backup coordinator is responsible for assuming VFC oversight duties in the absence of the primary vaccine coordinator.

Each enrolled location may appoint 1 additional backup coordinator if needed.

## VFC Provider Education Requirements

The Immunization Program is required to provide annual education to Vaccines for Children (VFC) providers on the basics of the VFC program and vaccine storage and handling.
All VFC providers have agreed to the following requirements:

- Designate fully trained on-site primary and backup Vaccine Coordinators.
- Ensure that the Vaccine Coordinators comply with VFC educational requirements, such as annual training, and make sure they demonstrate competency in their assigned roles.
- Train staff, including any new employees, on temperature monitoring, including the use of digital data loggers and corrective actions for out-of-range temperatures.
- Make sure that staff authorized to accept packages are trained to immediately notify the Vaccine Coordinator when vaccines are delivered.

- Immediately report to the VFC program via the Regional Field Representative of any changes in Vaccine Coordinator staffing. These changes are required to be submitted in the Clinic Tools module in KYIR within 10 days of the change occurring.

Both the Primary and Backup Vaccine Coordinators for each provider location should complete the following training:

- CDC's You Call the Shots – The Primary and Backup must complete these modules annually. These modules can be accessed at: Welcome to TCEO (cdc.gov).
    - Vaccines for Children, Module 16
    - Vaccine Storage and Handling, Module 10

Both must be completed for all new enrollees and may be completed for annual education. A certificate of completion must be submitted to the Regional Field Representative as proof of completion.

- KYIR Inventory Management Module Training – To receive inventory access in KYIR, this training must be completed by both the primary and backup vaccine coordinators.
  The training plan is available on TRAIN.

## Vaccine Coordinator Responsibilities

All providers must designate one Primary Vaccine Coordinator and one Backup Vaccine Coordinator per location. Vaccine coordinators are responsible for the day-to-day operation of the VFC program within the clinic. They must be fully trained on routine and emergency procedures for vaccine ordering, storage, handling, transport, and inventory management.
The Primary Coordinator is physically on-site during clinic hours and is responsible for the day-to-day operation of the VFC program and storage and handling.
The Backup Coordinator must be readily available to perform the same tasks whenever the Primary is not present.
If any responsibility is delegated to another staff member, the Coordinators must ensure adequate training occurs and remain accountable for those responsibilities.

Vaccine coordinators play an integral role in the vaccine cold chain. They are responsible for ensuring all vaccines in their clinic are stored and handled correctly.

- **Vaccine Oversight**
    - Understand VFC eligibility, screening documentation, and billing (administration fees).
    - Oversee proper receipt and storage of vaccine shipments.
    - Oversee proper vaccine transport.
    - Maintain all appropriate storage and handling documentation as set by the Centers for Disease Control and Prevention (CDC).
    - Maintain storage equipment in compliance with CDC standards and manufacturer's guidelines.
    - Maintain records, including VFC program documentation for a minimum of three (3) years.
    - Report and return expired vaccine within 30 days of expiration or spoilage.
    - Keep all staff trained on basic vaccine storage and handling practices and the importance of handling vaccines properly on an annual basis and when new staff is hired.

        - This includes not only those who administer vaccines, but also anyone who accepts vaccine deliveries or may have access to the unit(s) where vaccines are stored.
- **Vaccine Storage**
    - Store and label vaccines in the storage unit(s) following CDC guidelines.
    - Keep vaccines organized within the storage unit(s) and inspect storage unit(s) daily.
    - Check stock weekly and rotate stock at least weekly so vaccines with the earliest expiration are used first.
    - Remove any expired vaccine from the storage unit(s) immediately upon expiration so it is not administered to patients.
    - Work with the VFC program staff to transfer any vaccines close to expiration.
- **Temperature Monitoring**
    - Use a digital data logging thermometer with a current certificate of calibration for every vaccine storage unit in use.
    - Read and document minimum and maximum temperatures for the previous 24 hours on the temperature log upon clinic opening each day.
    - Download and review temperature monitoring data at least monthly.
    - Immediately respond to any possible temperature excursions.
- **Inventory Management**
    - Place vaccine orders, assuring an adequate stock of vaccines without under- or overstocking.
    - Label private stock separately from VFC-supplied stock.
    - Maintain a regular schedule to count vaccine inventory at least once a month.
    - Complete monthly inventory reconciliations in KYIR.

## Vaccine Management Plan

VFC providers must have written routine and emergency vaccine management plans.

Providers agree to complete and maintain a vaccine management plan that covers routine and emergency situations. The plan details proactive responses providers and staff must take to protect the vaccines and minimize vaccine loss due to negligence.

Vaccine Coordinators (Primary and Backup) are responsible for implementing the plan. The Medical Director (Provider of Record) is ultimately accountable for practice or clinic compliance.

- Review the plan with all staff involved in immunization services at least annually.
- Post a copy of the completed Vaccine Management Plan on or near your VFC vaccine storage units.
- Provide a copy of the plan to your Regional Field Representative.
- Update the plan as needed, review with new staff, and re-post upon any changes.

Providers can compose their own plan or use the fillable version supplied by the KY Immunization program.

A sample Vaccine Management Plan is provided in the reference section at the end of this manual.

## Provider Identification Number (PIN)

During the enrollment process, the VFC program will issue each location a unique Provider Identification Number (PIN). To expedite processing, please reference this number in **ALL** communications and correspondence with the Kentucky Immunization Program.

## Change Notification Requirement

Current providers must notify the Immunization Program immediately if:

- Their contact information, vaccine management personnel, or vaccine shipment instructions change.
- The medical director (or equivalent) who signed the Provider Agreement changes.
    - An updated signed copy of the VFC Provider Agreement must be submitted to change the medical director (or equivalent).
- The number of immunization patients at their facility changes significantly.
- The facility type changes.
- They add or acquire new VFC vaccine storage units and/or data logger thermometers.
- Their facility status changes (e.g., closure, moving, or merging with another facility).
- Changes to the address must be reported at least 10 business days before moving the VFC vaccine to the new location.
    - Once vaccine storage units are moved to a new location, two days of in-range temperatures will need to be submitted for review and approval before the vaccine is placed in these units. The transfer of vaccines to the new location must be approved by the Regional Field Representative.
    - Address changes or Facility Name changes must be submitted on the Provider Change of Information form (included at the end of this manual).

Notifications should be provided as soon as the change occurs. Failure to notify the VFC program of changes promptly may result in suspension from the VFC program.

A KYIR user account is required to be created or updated prior to submitting a primary or backup vaccine coordinator change in KYIR. Completion of the Inventory Training is required before access to the Inventory module in KYIR is granted.

## VFC Documentation Retention

Providers are required to maintain all records related to the VFC program for a minimum of three years and make these records available for review upon request.
These records include:

- Enrollment documentation
- Patient screening and eligibility documentation
- Billing records
- Medical records of immunizations
- Vaccine ordering and accountability records: packing slips, borrowing logs, wastage reports, etc.
- Vaccine purchase and accountability records (such as Borrowing forms and invoices for replacement of borrowed vaccines)
- Temperature logs and date file downloads, including any excursion follow-up documents
- Annual training documentations/certificates

## Termination

VFC providers may terminate the Provider Agreement at any time.
A provider location that is closing or withdrawing from the VFC program must provide at least 10 business days' written notice to allow time for the VFC vaccine to be relocated by the Regional Field Rep.
The Immunization Program may terminate the Provider Agreement due to:

- Failure to comply with program requirements. Providers who fail to implement appropriate and timely corrective action risk being suspended from the program.
- Failure to complete re-enrollment. A provider that does not renew the Provider Agreement will be removed from the program and required to reapply.
- Provider inactivity. A provider that has not placed a vaccine order in the past 12 months will be removed from the program and required to reapply.
- Fraud and abuse regarding the public vaccines, billing, and eligibility.
- Being listed on the “List of Excluded Individuals and Entities” (LEIE) from the Office of Inspector General.

Terminated providers agree to return unused public vaccine as directed by the Immunization Program. The provider is responsible for maintaining proper storage, temperature monitoring, and temperature logs until the vaccine is retrieved by the Regional Field Rep.

## Program Initiated Termination Policy

When responding to non-compliance issues, the KY Immunization Program considers the seriousness of the issue, whether it is repetitive, intentional, negligent, an error due to lack of knowledge, or whether extenuating circumstances are involved. We reserve the right to escalate non-compliance issues that are repetitive, serious, or substantial instances of fraud and abuse.
Typical Non-compliance Follow-Up: The KY Immunization Program uses the online CDC program PEAR (Provider Education, Assessment, and Reporting) to report and track VFC compliance. PEAR prescribes corrective actions for one-time, non-serious incidences of non-compliance. PEAR prescribes two types of corrective actions:

- On-site Actions can be completed at the time of the visit with no additional follow-up.
- Follow-Up Actions require the provider to correct the non-compliance issue and then perform additional tasks by a deadline in the future. Some follow-up actions may require a return visit from the Regional Field Rep.
- Escalated Follow-Up: Providers enter escalated follow-up if their non-compliance issue is repetitive (i.e. same issue occurred within the past two site visits), serious, or if a prescribed follow-up action is not completed within a given time frame. Escalated follow-up puts the provider on probation and involves agreed-upon, written corrective actions with firm deadlines and increased Immunization Program oversight. Failure to complete an escalated follow-up plan results in termination from the VFC program.
- Termination: Termination is the removal of a provider due to uncorrected, non-compliance issues; substantiated instances of fraud or abuse; or a permanent condition such as being included on the “List of Excluded Individuals and Entities” from the Office of Inspector General.

Terminated providers must return any unused public vaccine as directed by the Immunization Program. Once all vaccines have been accounted for, the Immunization Program issues a memo to the provider finalizing the termination. A terminated provider may be allowed to re-enroll if they complete the enrollment process, including an enrollment site visit, and demonstrate full VFC program compliance.

# Billing

There are two charges associated with immunization services – one for the vaccine and one for an administration fee.
The following are the billing requirements of the VFC program:

## Vaccine

Providers cannot charge patients, Medicaid, or private insurance for the VFC-supplied vaccine. At no time should billing occur for the cost of the VFC vaccine.

## Administration Fee

A provider may charge an administration fee when vaccinating VFC-eligible children. Administration fees are per vaccine, not per antigen.
*Note:* Providers may charge an office visit fee in addition to the vaccine administration fee.

### Billing Medicaid-Eligible VFC Administration

- Providers agree to accept the administration fee set by the state Medicaid agency for Medicaid patients.

### Billing Non-Medicaid-Eligible VFC Administration

- Providers can charge non-Medicaid VFC-eligible patients an administration fee up to $19.93 per vaccine (not per antigen in combination vaccines).
- VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee. Providers must establish a process to waive the fee if the patient or parent remains unable to pay the vaccine administration fee.
- Unpaid administration fees cannot be sent to collections, and providers cannot refuse to vaccinate an eligible child whose parent or guardian has unpaid vaccine administration fees.
- Providers who bill for the vaccine administration fee of a non-Medicaid VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.
- Providers should never bill two different “payers” (i.e., patient, Medicaid, insurance) for the same vaccine administration fee amount.

### Billing Rejection

For a child who was reported as fully insured at the time of service with a private vaccine administered and insurance billed, but the vaccine payment was rejected by insurance, the dose can be replaced by a VFC vaccine. This child would be considered VFC eligible as Underinsured at the time of service. Replacing doses for underinsured rejections must be completed within 6 months from the time of service or as soon as the rejection is received.

- Dose level eligibility must be changed in KYIR from Insured to Underinsured to create the borrowing instance for inventory reporting.
- A borrowing report must be completed and submitted to the Vaccine Accountability Section. For additional information or questions on this process, contact the Vaccine Accountability Section at DPH.KVP@ky.gov

# Patient Eligibility and Screening

VFC providers must screen all patients for VFC eligibility and document the results at every immunization visit. All VFC eligibility documentation must be retained for **three** years.

There are two steps to the eligibility screening. Both must occur at each immunization visit:

1. Determining the patient's eligibility status (screening)
2. Recording the screening results (documenting)

Screening and documentation must include the date of the visit and the child's specific eligibility category. VFC providers must use screening results to ensure that only VFC-eligible children receive the VFC vaccines and that administration fees are billed appropriately. Eligibility status must be readily available to staff administering vaccines before selecting which vaccine stock to use.

Children who have insurance that covers vaccines are not VFC-eligible even if the patient has a high deductible or copays. Additionally, children with insurance seeking vaccination services either from an out-of-network provider or outside the geographic coverage area of their policy are considered fully insured and are therefore not eligible to receive VFC vaccines.

## VFC Eligibility Categories

Children from birth through 18 years of age (under 19 years) who meet at least one of the following criteria are eligible to receive the VFC vaccine:

- **Medicaid-eligible:** For the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably. Children covered by private insurance who have Medicaid as a secondary insurer are eligible for the VFC vaccine (see table below).
  - Note: A child is VFC-eligible in Kentucky if they are insured by Medicaid in any state.
- **Uninsured**: A child who has no health insurance coverage. Self-reported status is accepted.
  - A child covered by a Health Care Sharing Ministries is considered "uninsured" in Kentucky. These plans are nonprofit alternatives to purchasing health insurance and are not recognized as insurance by the Kentucky Department of Insurance.
- **American Indian or Alaska Native (AI/AN):** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
- **Underinsured**:
  - Underinsured means the child has health insurance, but the insurance policy:
    - Does not cover any ACIP-recommended vaccines,
    - Does not cover all ACIP-recommended vaccines (i.e., underinsured for vaccines not covered),
    - Does not provide first-dollar coverage (which includes copays, coinsurance, or deductibles) for ACIP-recommended vaccines, or
    - Covers ACIP-recommended vaccines but has a fixed dollar limit (or cap) for payment. The child is considered underinsured once the family's policy reaches the fixed dollar amount.
  - *Note*: Underinsured children are only eligible to receive the VFC vaccine at Federally Qualified Health Centers [1](FQHC), Rural Health Clinics[2] (RHC), or Local Health Departments (LHD). If providers cannot verify vaccine insurance coverage, underinsured children are considered insured and not VFC eligible.
    - FQHCs, RHCs, or LHDs that serve underinsured children are REQUIRED to verify a child's underinsurance status. For patients eligible under more than one category, providers should select the category that requires the least out-of-pocket expense to the parent or guardian.

[1] An FQHC is a health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide health care to a medically underserved population.
[2] An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area.

| VFC Eligibility and Insurance Situations | | |
|---|---|---|
| **Child's Insurance Status** | **VFC Eligible?** | **VFC Eligibility Category** |
| Enrolled in Medicaid | Yes | Medicaid-eligible |
| Has private health insurance plan with Medicaid as secondary insurance | Yes | Medicaid-eligible |
| Has health insurance covering all vaccines, but has not yet met the plan's deductible or paid for other services received at the visit | No | Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met. |
| Has health insurance covering all vaccines but has not yet met the plan's deductible or paid for other services received at the visit and has Medicaid as secondary insurance. | Yes | Medicaid-eligible |
| Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on the amount that it will cover. | Yes | Insured until the fixed dollar limit is met<br>Underinsured after the fixed dollar limit is reached |
| Has an insurance plan that does not cover all ACIP-recommended vaccines. | Yes | Underinsured. Child can only receive vaccines not covered by their plan through the VFC program. |
| Has health insurance, but the plan does not cover any vaccines. | Yes | Underinsured. With the implementation of the Affordable Care Act (ACA), this situation should be rare. |
| Enrolled in a Health Care Sharing Ministry | Depends | Uninsured unless the plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan.<br>Insured if the plan is recognized by the state insurance department and covers vaccines.<br>Underinsured if the plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines. |
| Has no health insurance coverage | Yes | Uninsured |
| Has private health insurance that covers all vaccinations and is AI/AN | Yes | AI/AN. However, the provider should choose the eligibility category most cost-effective for the child and family. |
| Has Medicaid and is AI/AN | Yes | Medicaid-eligible or AI/AN. The provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family. |

# Special Eligibility Circumstances

This section covers special VFC eligibility situations. In general, when selecting between eligibility categories, select the option requiring the least out-of-pocket expense to the child's parent or guardian.

## Non-U.S. Citizen Children

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 tourists.

## Medicaid as Secondary Insurance

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

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

**Options include:**

**Option 1: The provider administers VFC vaccines and bills Medicaid for the administration fee.**

In most health situations, Medicaid is considered the "payer of last resort". This means that claims must be filed with and rejected by all other insurers before Medicaid will consider payment for the service. This is not true of the vaccine administration fee for Medicaid-eligible VFC children. Medicaid must pay the VFC provider the administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once a claim is submitted to Medicaid, the state Medicaid agency has the option to seek reimbursement for the administration fee from the primary insurer.

**Option 2: The provider administers private stock vaccines and bills the primary insurance carrier for both the cost of the vaccine and the administration fee.**

- If the primary insurer reimburses less than Medicaid for the administration fee, the provider can bill Medicaid for the balance, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of a vaccine and administration fee, the provider may replace the privately purchased vaccine with the VFC vaccine and bill Medicaid for the administration fee (only applies in that instance where the child has Medicaid as secondary insurance). The provider must document this in KYIR and on the VFC borrowing form.

## Temporary, Off-Site, or Satellite Clinics

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

## Bordering State

Some children may receive health care in a bordering state instead of their state of residency. If a provider administers VFC vaccines to a Medicaid VFC-eligible child from a neighboring state, the provider must be Medicaid-enrolled for the child's state of residency to receive administration fee reimbursement from that Medicaid program.

## Incarcerated Juveniles

Incarcerated juveniles through 18 years of age who lose access to their health insurance due to their circumstances are considered uninsured and VFC-eligible.

## Dual Eligibility – American Indian/Alaska Native

American Indians and Alaska Natives (AI/AN) can be eligible for the VFC vaccine under more than one category. The following table outlines the VFC eligibility status, vaccine stock, and vaccine billing for AI/AN populations seen at providers other than Indian Health Services (IHS), tribal, and urban Indian clinics.

| Population | Facility Type | Insurance Status | VFC Eligibility Category | Vaccine Stock to Use | Bill to: Vaccine | Bill to: Administration Fee[1] |
|---|---|---|---|---|---|---|
| AI/AN | Any (except IHS, tribal, urban Indian clinics) | Medicaid | Medicaid-eligible | VFC | No charge | Medicaid |
| AI/AN | Any (except IHS, tribal, and urban Indian clinics) | Uninsured | AI/AN | VFC | No charge | Patient |
| AI/AN | Private | Underinsured | AI/AN | VFC | No charge | Patient |
| AI/AN | FQHC/RHC | Underinsured | AI/AN Underinsured | VFC | No charge | Patient |
| AI/AN | Any (except IHS, tribal, and urban Indian clinics) | Insured | AI/AN[2] | Private | Insurer | Insurer[3] |
| | | | | VFC | No charge | Insurer |

[1]VFC vaccine administration fees billed to patients cannot exceed $19.93 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.
[2]Insured AI/AN children are not required to participate in the VFC Program. The decision whether to participate should be based on what is most cost-effective for the patient. AI/AN children with high-deductible insurance plans requiring the parent to pay out of pocket for vaccines should be considered VFC-eligible if the family has not yet reached its deductible.
[3]Private insurance can be billed with administration fees at the private rate. If the primary insurer denies payment for the vaccine, VFC stock can be used to replace the private stock used (See Borrowing in Section X). Patients may be balance billed unreimbursed VFC vaccine administration fees up to $19.93.

# Documenting Eligibility Screening

Eligibility screening results must be:

- Documented for all eligibility categories you can serve, including privately insured (not VFC eligible) and AI/AN.
- Documented at every immunization visit.
- Associated with the patient and the visit or immunization date.
- Documented through a process that informs clinicians what vaccine stock to use.
- Documented in a way that can be tallied to obtain annual Provider Profile numbers.
- Retained for three years.
- Made available to Immunization Program staff on request and during compliance site visits.
- VFC eligibility screening and documentation of eligibility status must take place with each immunization visit, up to 24 hours in advance.
- Eligibility should be recorded in the practice's Electronic Health Record (EHR) system that is connected to KYIR via an HL7 connection. If an EHR is not in use or connected to KYIR, eligibility should be recorded manually in KYIR and maintained in a paper chart.

## Patient Record documentation

Healthcare providers are required by law to record certain information in a patient's medical record. This record can be in electronic or paper form. Healthcare providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the patient includes:

1. Date of administration
2. Vaccine manufacturer
3. Vaccine lot number
   The best practice is to include the site and route of the vaccine administration.
4. Name and title of the person who administered the vaccine
5. Address of the clinic where the vaccine was given
6. Date the Vaccine Information Statement (VIS) or Immunization Information Statement (IIS) was given
7. VIS/IIS publication date
8. Eligibility

Providers who use their EHR/EMR connection to the KY Immunization Registry (KYIR) must ensure that all required fields are accurately reported in KYIR.

# VFC Site Visits

A compliance site visit is when a Regional Field Representative visits your clinics and assesses the implementation of the VFC program at your location. Compliance visits consist of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves the administration of a questionnaire, evaluating compliance with requirements, and providing education. The visit includes a formal review of vaccine management practices, as well as a review of patient records and other documentation to ensure appropriate vaccine eligibility screening and administration documentation is occurring.
All VFC providers receive a compliance site visit within 6 months of enrollment and at least every 24 months after that.

## Site Visit Preparation

Approximately one month before your visit, the Field Representative will contact you by telephone or email to schedule a CDC-required VFC compliance visit. Compliance visits are completed a maximum of every 24 months, but are often completed yearly.

## During the Site Visit

Site visits can take from one to four hours, depending on the size of the clinic and the issues that arise during the visit.
Providers must make the following available during the visit:

- The vaccine coordinators and any key staff involved in the VFC program.
- Temperature logs (Min and Max Temperature Logs) and temperature data from the vaccine storage units.
- Calibration certificates for all data loggers, including the backup.
- Completed and annually reviewed Vaccine Management Plan.
- VFC eligibility screening documentation for the previous year.
- Borrowing reports (if applicable)
- Paper stock or electronic source of VISs
- The circuit breakers for the vaccine storage units.
- The vaccine administration fee charged to non-Medicaid, VFC-eligible patients.
- Any VFC-related documentation requested during the visit.

Approximately one hour of the site visit is a conversation with the vaccine coordinator. The Field Representative will ask questions about the VFC program and provide a cost of public vaccines shipped to your facility over the last year. They will also inspect your vaccine storage units.
At the end of the visit, the Field Representative will provide verbal feedback on their findings and a follow-up plan detailing any corrective actions. Due dates are included in the follow-up plan and must be followed appropriately.

There are 2 types of corrective actions:

1. On-site actions that can be performed during the visit.
2. Follow-up actions that require correction and documentation submitted by a deadline in the future.

Repeated or serious non-compliance may result in an escalated follow-up.

Before ending the compliance visit, a provider representative (preferably the vaccine coordinator or the provider) and the site reviewer must sign an acknowledgment of receipt of the follow-up plan attesting that everyone understands any non-compliance issues and the actions necessary to address them.

## Site Visit Follow-Up

Providers must complete any follow-up actions by the deadline. The Field Representative will be in contact by telephone, email, or may return to your location for a follow-up visit.

## Other Types of Visits from the Immunization Program

- **Unannounced Storage and Handling Visits** – Throughout the year, the Immunization program performs unannounced visits that focus on vaccine storage and handling. Any active VFC provider may receive an unannounced visit. They take approximately 30 minutes and include an inspection of the vaccine storage units. These visits may be randomly selected; however, priority is given to providers with ongoing compliance issues.
- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance. Providers may request an education visit from the Immunization program at any time (subject to staff availability). Education can also be conducted by telephone or webinar.
- **Enrollment Visits** – Enrollment visits occur during the enrollment process for newly enrolling or re-enrolling providers. The purpose of this visit is to provide education on the VFC program requirements and verify that the facility has the appropriate resources to implement program requirements.
- **IQIP Visits** – Immunization Quality Improvement for Providers occurs in a 12-month cycle, including the initial site visit, a 2-month and, a 6-month check-in, and a 12-month follow-up. The Field Rep and provider staff collaborate to select two quality improvement (QI) strategies that can improve the administration of timely vaccines to patients. The Field Rep acting as a consultant will provide technical assistance (resources, training & guidance) throughout the 12-month cycle.

# Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory panel that recommends routine immunization practices for children and adults in the United States. The ACIP approves vaccines for use in the VFC program.

## VFC Resolutions

The ACIP approves new and amended recommendations for inclusion in the VFC program by passing a VFC Resolution. VFC Resolutions determine what vaccines are available through the VFC program, including dosage, schedule, and contraindications. The CDC publishes current VFC Resolutions on its VFC Resolution webpage.

Please note the following about VFC resolutions:

VFC Resolutions may not be identical to published ACIP recommendations.

An ACIP recommendation does not apply to the VFC program until the VFC Resolution is approved.

For newly recommended vaccines, a VFC Resolution must be approved before the CDC can negotiate a purchase contract with the manufacturer. There may be a delay between when the resolution is approved and when the vaccine is available.

The Immunization Program notifies VFC providers when new and amended ACIP recommendations and VFC Resolutions become available.

## ACIP Recommendations

VFC providers must offer all ACIP-recommended vaccines for the populations they serve unless:

- They deem in their medical judgment and in accordance with accepted medical practice that compliance with ACIP recommendations is medically inappropriate for the child.
- The particular requirement contradicts state law concerning religious or medical exemptions.

# National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act (NCVIA) provides a cost-effective arbitration and compensation system for vaccine injury claims and a system for reporting and tracking adverse events related to vaccinations. Healthcare professionals who provide immunization services must adhere to the following NCVIA requirements when administering vaccinations. These requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC program.

# Vaccine Information Statements (VIS)

Providers must present current VISs to patients at every vaccination before they administer the vaccine. Before administering VFC monoclonal antibody immunizing products (e.g., nirsevimab), providers should provide an Immunization Information Statement. Providers should not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not yet have a VIS or Immunization Information Statement available, a provider may use the manufacturer's package insert, written FAQs, or any other document to inform patients about the benefits and risks of that vaccine. Providers may also produce their own information materials for patients. Once a VIS is available, providers should use it. If the vaccine is under an Emergency Use Authorization (EUA), providers should make the EUA Fact Sheet for Recipients available for patients.

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of a vaccine. You must provide a current vaccine-specific VIS to your patient or your patient's legal guardian at each vaccination visit. The appropriate VIS must be given prior to vaccination and prior to each dose of a multi-dose series and regardless of the age of the patient.
VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on its VIS webpage.
Whether managed as electronic files or paper handouts, you must provide current VISs to your patients. It is your responsibility to ensure VISs are kept up to date.
It is recommended that paper versions be stored in one location and that one person be responsible for updating them.
VISs managed through an EHR may require IT assistance to keep them up to date.
The CDC VIS webpage offers a "Get email updates" function that notifies you by email when VISs are changed.
You can also download VISs directly from the CDC website as needed, so they are always up to date.

# Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines.

## Reportable Events – Required

The NCVIA requires healthcare providers to report to VAERS:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccines.
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

## Reportable Events – Voluntary

You may report any adverse event that occurs after the administration of a vaccine licensed in the US, even if you are unsure whether a vaccine was the cause.

# Vaccine Charting Requirements

The NCVIA requires vaccination records to be in a patient's permanent medical record and include the following information:

- Name of the vaccine
- Date of vaccine administration
- Vaccine manufacturer and lot number
- Name and title of the person giving the vaccine
- Address of the clinic where the vaccine was given
- Publication date of the VISs and the date it was provided to the patient

Several resources are available for charting records. The Immunization Action Coalition website provides free immunization charts (downloadable as PDFs) that capture all the information required by the NCVIA.

# Vaccine Ordering and Accountability

Providers order and manage the VFC vaccine in KYIR, the state immunization registry.
Managing private stock vaccines in KYIR is optional.
Primary and Backup Vaccine Coordinators at provider locations must complete the KYIR Inventory Training in order to gain access to the ordering and accountability module in KYIR. For training information, contact the KYIR Helpdesk at 502-564-0038 (KYIRHelpdesk@ky.gov).

## Reconciling Inventory

Inventory reconciliation is accounting for the vaccines or other items removed from inventory since the last accounting period. To complete a reconciliation in KYIR, go to Inventory -> Vaccines -> Reconciliation. For more guidance on reconciliation, visit the KYIR webpage, the guides available under the Reports module in KYIR, or contact KYIR for training at 502-564-0038 (KYIRHelpdesk@ky.gov).
When reconciling, you must:

- Complete a reconciliation once a month, at a minimum.
- Account for all doses.
- Select accurate reasons for any inventory adjustments.
- Complete returns for any expired doses to remove them from inventory.

## Ordering Vaccines

Submit order requests in KYIR by going to Inventory -> Vaccines -> Vaccine Orders.
Before placing a vaccine order, you must have a closed reconciliation within the last 13 calendar days.
Order vaccine by the carton, with the total dose order amount showing on the order screen in KYIR.
The Vaccine Accountability and Ordering Section (VAS) reviews orders to ensure they are:

- Not more than a two-month supply based on past usage (including current inventory).
- Not over-ordering a particular antigen when considering combination vaccines.

The Immunization Program may adjust orders that do not conform to the requirements listed above. VAS Staff will attempt to contact providers before adjusting orders, but will adjust and place orders if we do not hear back from the provider.

Providers must inform the VAS Staff of special circumstances, such as off-site clinics and campaigns where more vaccine is needed than usage history allows, by placing a note in the “Clinic Comments” section of the order request.

Any upcoming clinic closures within the next 30 days must be communicated to VAS staff by placing a note in the “Clinic Comments” section of the order request.

Providers must immediately inform the Immunization Program if the shipping address or delivery times change.

## Receiving Vaccine Shipments

Providers must be on-site with appropriate staff available to receive vaccine shipments at least one day a week other than Monday and Friday, and for at least four consecutive hours during that day.
Refrigerated vaccines will ship from McKesson. Varicella-containing vaccines that are stored frozen ship from Merck. The frozen vaccine will arrive at a different time than your refrigerated vaccine.
Follow the steps below when receiving vaccines:

- Inform the front desk and supply personnel when vaccine deliveries are expected.
- It is best practice to have all staff complete the CDC's You Call the Shots Vaccine Storage & Handling training.
- Never reject a vaccine delivery or discard a VFC vaccine shipment.
- DO NOT leave vaccine deliveries unattended. Check all deliveries immediately to determine that the vaccine quantities, diluents, lot numbers, and expiration dates match the packing list and your KYIR order.

If the event of a discrepancy or any of the issues below occurs, contact VAS staff immediately on the day of shipment delivery.

- The package is damaged or leaking.
- The shipping time was more than 48 hours for refrigerated vaccines and more than 96 hours for frozen vaccines. If the interval between shipment from the supplier and arrival at your facility is more than the allowed time, the vaccines could have been compromised during shipment.
- The temperature monitors are not showing within acceptable limits.
- If you believe your vaccine was compromised during shipment, immediately store the vaccine under appropriate conditions, separate it from other stock, and mark "DO NOT USE".

Ensure the Primary and/or Backup Vaccine Coordinator for your facility when shipments arrive.
Place vaccines in an approved storage that maintains proper temperatures as soon as possible.
Rotate stock to ensure short-dated expiration dates are used first.

## Accepting Shipments in KYIR

Orders submitted to the VFC Program through KYIR will result in an electronic shipment link where you can receive it automatically into the inventory on hand.
To receive a vaccine shipment in KYIR, go to Inventory -> Vaccines -> On-Hand. You'll see a blue hyperlink at the top of the page showing your current inventory. The blue text will refer to a "Pending VTrckS Shipment."

- Click on the link to initiate the receipt of the shipment.
- Each vaccine is separate from the list of shipped vaccines. Verify that the quantity shipped is in fact the quantity you received. Click Receive.
- If you have already manually entered the doses into your inventory in KYIR, click on Dismiss so that you do not double your inventory erroneously.
- Enter the date and time when you received the shipment. This date should be accurate so that your inventory count stays correct.
- Select the Inventory location where the vaccine is going to be stored.
- Verify that the Lot Number, Expiration Date, and Number of Doses are correct. Click Create.
- KYIR will check the NDC and lot numbers you already have in your inventory and try to match your shipment to what you already have.

- Check the Match Confidence Percentage. If and only if the vaccines are an exact match (100% match) then click “Add To This Inventory Line Item”; if it shows anything less than 100% click on the blue “Proceed With Create” at the top of the page.

## Seasonal Influenza Vaccine Orders

The Immunization Program pre-books seasonal influenza vaccine months in advance and distributes doses during the season as they become available.

The Immunization Program opens an Influenza Pre-book order form early each calendar year. It lists the vaccine offerings for the coming season and instructions for submitting the form.

The influenza vaccine pre-book must contain your order for the coming flu season and be returned by the submission deadline in order to reserve your vaccines for the season.

As influenza doses become available at the warehouse, we ship allocations to enrolled providers. Shipments typically begin on the first of September and last through December until all orders are fulfilled. You may not receive your entire pre-book request at once.

After pre-book orders are fulfilled, we often have extra doses available on a first-come, first-served basis.

Seasonal influenza vaccine expires June 30th of each year. DO NOT discard expired vaccines. It must be returned to McKesson following the procedure for all expired VFC vaccines.

Contact the Vaccine Accountability and Ordering Section with questions about influenza vaccine orders. (Email: DPH.KVP@ky.gov).

# Inventory Management

Proper vaccine inventory management is essential and ensures each provider location has the vaccines the patient needs. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

## Receiving Deliveries

All staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

- Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.
    - Examine the shipping container and vaccines for signs of physical damage.
    - Check the contents against the packing list to be sure they match.
        - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on the shipment date.
    - If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
    - Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
    - Immediately check the cold chain monitor, a device used to monitor vaccine temperatures during transport (if one was included), for any indication of a temperature excursion during transit.
- Notify the Vaccine Accountability Section immediately if there are any discrepancies or errors with the shipment. **All issues must be reported on the day of delivery.**

## Organizing and Rotating Stock

- Physically differentiate the VFC vaccine from private and other public stock vaccines.
- Check expiration dates weekly and immediately remove expired, spoiled, and wasted vaccines from the storage units.
- Organize vaccine packages so that short-dated vaccines are used first and only one package is actively used at a time.

## Short-dated Vaccine

Vaccines that will expire in the next 90 days will appear with a red clock icon in KYIR.
If a vaccine is within 3 months of expiring, you will not use it in that timeframe, and it has not experienced any temperature excursions, contact your Regional Field Rep to see if the doses can be used by another provider in your area.

- DO NOT TRANSFER short-dated vaccine to another provider location without prior approval from the Regional Field Rep.
- DO NOT TRANSFER opened, multi-dose vials, or any vaccines that have experienced a temperature excursion.

## Beyond-Use Dates

Some vaccines have a beyond-use date/time. The Beyond-Use date is different from the expiration date. The Beyond-use date (BUD) is the last date or time that a vaccine can be safely used after it has been moved from one storage state to another (e.g., frozen to refrigerated) or prepared for patient use. It is a new deadline after which the product should not be used. The BUD varies by product and type of transition. This is sometimes also called a beyond-use time if it falls on the same day at a different time of day.

Unlike the expiration date that is determined by the manufacturer, the BUD is determined by the health care provider using guidance provided by the manufacturer. The BUD replaces the manufacturer's expiration date but never extends it. Always use the earlier date between the two.

Not all vaccine products have a BUD. The package insert or Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers will specify if there is a BUD and how to calculate it. Always review this informational material to determine if a BUD applies.

Examples of BUD include:

- **Reconstituted vaccines** have a limited period for use once the vaccine is mixed with a diluent. If a reconstituted vaccine is not used immediately, follow manufacturer guidance for storage conditions and time limits.
- **Multidose vials** might have a specified period for use once they have been punctured with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after the first puncture with a needle. If the vial is first punctured on 06/01/2024, the BUD is 06/29/2024. The vaccine should not be used after the BUD.
    - Except for COVID-19 vaccines, vaccines in multidose vials (MDVs) that do not require reconstitution contain preservatives and can be used through the expiration date printed on the label as long as the vaccine is not contaminated, unless indicated otherwise by the manufacturer. For example, inactivated polio in an MDV can be used through the expiration date on the vial.
- **Manufacturer-shortened expiration dates** may apply when the vaccine is exposed to inappropriate storage conditions. The manufacturer might determine the vaccine can still be used, but will expire on an earlier date than the date on the label. The BUD should be noted on the vial label along with the initials of the person making the calculation.

## Expired Vaccines

An expired vaccine is nonviable and should never be administered to patients. The expiration date is the final day that the vaccine can be administered. Vaccines past the expiration date should never be used. Providers must check expiration dates weekly and immediately remove expired vaccines from storage units.

When the expiration date has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month and year, the product may only be used through the end of that day.

All VFC vaccines that have expired must be reported in KYIR so that they may be returned to the supplier. The return process must be completed in KYIR. A prepaid return shipping label will be emailed to the primary vaccine coordinator's email on file.

Expired vaccines must be returned within 6 months of the expiration date.

## Adjustments of Wasted Vaccine

Wasted vaccine is a nonviable product that cannot be returned to McKesson due to the packaging being breached (e.g., broken vial/syringe, vaccine drawn but not administered, open multi-dose vials).
Create an adjustment in KYIR to subtract the wasted dose.
Account for any wasted doses during your monthly inventory reconciliation in KYIR.
Do not use the Other reason unless instructed by Vaccine Accountability Staff.

## Private Stock Vaccine Management

Private stock vaccines must be stored, handled, and inventory managed in the same manner as VFC if any movement occurs or is expected to occur between inventories. Any vaccine that is used for VFC but originated in private stock (i.e., borrowing, replacement of VFC borrowing, restitution of VFC doses, etc.) must follow all VFC requirements.

# Vaccine Preparation

Vaccine preparation is the final step on the cold chain before administration. Handling vaccines with care is equally important as storing them properly.

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Draw up vaccines only at the time of administration.
    - Predrawn vaccines can result in waste if more are drawn up than needed.
    - Never transfer predrawn reconstituted vaccine back into a vial for storage.
- Before preparing the vaccines, always check the:
    - Vial to ensure it is the correct vaccine.
    - Expiration date or beyond-use date/time to ensure it has not passed.
- Always check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

## Different types of vaccine vials

- **Single-dose vial (SDV)**
  A single-dose vial contains one dose and should be used one time for one patient. SDVs do not contain preservatives to help prevent microorganism growth. Never combine leftover vaccine from one SDV with another to obtain a dose.
  Only open an SDV when ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused SDVs without a protective cap at the end of the workday.
- **Multidose vial (MDV)**
  A multidose vial contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered or punctured more than once. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached.
  MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a BUD noted in the package insert.
  **Never use partial doses from two or more vials to obtain a dose of vaccine.**
  Based on safe injection practices, CDC does NOT recommend the use of vial adapters, spikes, or other vial access devices when withdrawing vaccine from a multidose vial. Leaving a vial access device inserted into a vial septum provides a direct route for microorganisms to enter the vial and contaminate the fluid.
- **Manufacturer-Filled Syringe (MFS) or Pre-Filled Syringe (PFS)**
  A manufacturer-filled syringe (MFS) or pre-filled syringe (PFS) is prepared and sealed under sterile conditions by the manufacturer. Activate an MFS (i.e., remove the syringe cap or attach the needle) only when ready to use.

An MFS does not contain a preservative to help prevent the growth of microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded by the end of the workday.

## Reconstitution of Vaccine

Lyophilized (freeze-dried) vaccines are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as reconstitution before being administered.

Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and the chemical requirements of their corresponding vaccines. Refer to the manufacturer's package insert for guidance on storage and handling.

**Diluents are not interchangeable unless specified by the manufacturer.**

- Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it.

**Never use a stock vial of sterile water or normal saline to reconstitute vaccines.**

**Never administer a vaccine reconstituted with the wrong diluent.**

# Vaccine Accountability Policies

## Restitution Policy (January 1, 2017)

Vaccine quality is the shared responsibility of all parties from the time the vaccines are manufactured until administration. Accountability of vaccine inventory is an essential requirement when receiving vaccines from the Kentucky Immunization Program (KIP), The KIP Restitution Policy requires any enrolled provider deemed negligent to replace the lost vaccine on a dose-for-dose basis. VFC providers will have to replace vaccines at the current open market price. Receipt of purchase must be submitted to the Vaccine Accountability and Ordering Section (VAS) within 30 days. Documentation of administration to VFC-eligible children must be submitted within 90 days.

**Definitions**

- Expired vaccine – any vaccine with an expiration date that has passed.
- Spoiled vaccine – any vaccine that is stored or transported outside the limits of the approved cold chain procedures or any vaccine that has been pre-drawn and not used within acceptable time frames. Always consult with KIP before determining that the vaccine is spoiled.
- Lost vaccine – any vaccine ordered but not delivered promptly by the commercial carrier or delivery service that results in lost and/or spoiled vaccine.

A vaccine that is determined to be expired, spoiled, lost, or otherwise unusable is considered a “wasted vaccine.” There is a wide range of potential vaccine storage and handling issues that may result in wasted vaccines. The Kentucky Immunization Program will review each incident of wasted vaccine to determine whether restitution will be required. If restitution is required, the facility will not receive additional VFC vaccines of the type requiring payback until replenishment with replacement vaccine is demonstrated and the problem that caused the wastage has been corrected.

### Situations Requiring Restitution

The following situations are examples of negligence that would lead to a non-viable vaccine that may require restitution. This list is not exhaustive.

- Failure to rotate vaccine stock to use the vaccine with the shortest expiration date first.
- Failure to notify KIP a minimum of 90 days before the vaccine expiration date.
- Repeated waste of vaccine due to drawing up or preparing the vaccine before patient screening.
- Vaccine left out of the refrigerator or freezer, resulting in vaccine reaching unacceptable temperatures.
- Freezing vaccine that must be refrigerated.
- Refrigerating the vaccine that must be frozen.
- Excessive ordering of vaccines that results in the expiration of the vaccine before it can be used.
- Provider staff failing to review and/or appropriately interpret and/or document refrigerator and/or freezer temperatures daily.
- Vaccine that is considered spoiled due to temperature monitoring problems/errors.
- Unplugged refrigerator/freezer unit or electrical breaker switched off for extended periods.
- Failure to contact KIP when the refrigerator or freezer malfunctions, resulting in temperature fluctuations.
- Refrigerator or freezer malfunctions or power outages in which provider staff fail to follow their Emergency Vaccine Management Plan and/or fail to contact KIP.

- Planned power outages in which provider staff fails to implement precautions to maintain appropriate storage of the vaccine.
- Vaccine physically received but unaccounted for in KYIR inventory reporting.
- Transportation of vaccine inappropriately; unnecessary transportation of vaccine, transportation with KIP consent, and/or failure to appropriately maintain cold chain during transportation.
- Failure to notify KIP when the provider's office will be closed for non-emergency situations, i.e., holidays, trainings, parties, etc. KIP must be notified 30 days in advance of the planned closing to prevent the delivery of vaccines during this time.
- Substantial vaccine wastage resulting from repeated or unresolved incidents from the list below of "Situations That Do Not Require Restitution."

## Situations That Do Not Require Restitution

The following situations are examples of situations in which loss of vaccine would NOT require restitution. In these situations, the provider location is deemed not to be at fault. This list is not exhaustive.

- Vaccine is damaged, improperly stored during transit, or not delivered promptly by a commercial carrier or delivery service.
- Provider staff moved vaccines to their backup location as outlined in their Vaccine Management Plan, in anticipation of a power outage or due to refrigerator or freezer malfunction, and the backup location experienced a power outage or equipment malfunction.
- Power interruption or failure due to storms or other weather conditions.
- Unanticipated refrigerator or freezer failure that occurs overnight, during the weekend, or during a period of time when the provider staff is not present.
- A vial of vaccine that is accidentally dropped or broken by provider staff.
- Occasional instances of wasted vaccines due to provider staff error or last-minute patient refusal.
- Expired vaccine that the provider staff notified KIP about, and redistribution was made to another provider.
- Extraordinary situations not listed above that are deemed by KIP to be beyond the provider's control.

## Procedures for Vaccine Restitution

The Immunization Program considers each situation when determining whether a vaccine must be replaced. The factors considered include, but are not limited to, provider communications, program staff observations, temperature data, temperature logs, incident reports, inventory records including wastage and expired doses, eligibility screening documents, and borrowing reports.
If restitution is required, the Immunization program will notify the provider in writing, including a summary of the vaccine mismanagement incident, a list of vaccines to be replaced doses-for-dose, instructions to replace vaccine dose-for-dose, and requirements for documenting vaccine replacement.
Providers must reimburse public vaccine dose-for-dose with vaccine from private stock. Monetary payment directly to the Immunization Program is not allowed. Providers must enter and manage the replacement doses in KYIR within 90 days of notification of restitution. Providers will be required to provide copies of purchase invoices for private stock used to replace doses.

## Procedures to Minimize Vaccine Loss

VFC providers should implement and adhere to the following items to minimize vaccine loss:

- Provide adequate vaccine storage and monitor storage conditions.
- Do not over-order or stockpile vaccines.
- Never assume the vaccine is nonviable in the event of a storage problem or temperature excursion. Follow the temperature excursion protocol and notify the KY VFC program.
- Conduct a count and reconcile vaccine inventory at least monthly.
- Check vaccine expiration dates at least monthly.
- Rotate vaccine stock regularly; move the earliest expiration dates to the front.
- Report vaccines that will not be used and will expire within 2-3 months to the KY VFC program.

# Vaccine Borrowing

VFC-enrolled providers are expected to maintain a minimum of four weeks' inventory of vaccines to administer to privately insured and VFC-eligible children.
Providers are required to maintain a private vaccine inventory that is sufficient to serve their non-VFC eligible patient population as reported on the Provider Profile in the Provider Agreement.

Borrowing of vaccines between VFC and private vaccine inventories is not permitted unless specifically authorized in advance by the Vaccine Accountability and Ordering Section (VAS) and due to extraordinary circumstances.
If approved, borrowing must be documented "dose-by-dose" for each patient on the Vaccine Borrowing Form. Doses borrowed from VFC inventory must be replaced within 30 days. Replacement must be documented on the Borrowing Form and submitted to VAS.
Routine borrowing from VFC for Private Pay/Fully Insured patients is not allowed. Borrowing should only be done in extreme cases.

## Borrowing Cases

- If you have insufficient stock to vaccinate the VFC-eligible child with the VFC vaccine, use private stock. You will need to complete a borrowing report for this case. In your EMR/KYIR, please document vaccine administration accurately with the correct lot number, funding source, and patient eligibility. Then, complete a borrowing report with the correct borrowing reason code, and submit it to VAS.
- Replacement applies when the provider files insurance claims and the claim is denied due to a lapse in coverage.
    - This practice does not apply to patients with insurance that covers vaccines, but requires a copayment, co-insurance, or high deductible.
- If you have insufficient stock to vaccinate a private pay/insured child with a private vaccine, use what is available to you. You need to complete a borrowing report for this case if the VFC vaccine was used. In your EMR/KYIR, please document vaccine administration accurately with the correct lot number, funding source, and patient eligibility. Then, complete a borrowing report with the correct borrowing reason code, and submit it to the Vaccine Accountability and Ordering Section at DPH.KVP@ky.gov

***Note***: If you receive 317 funded vaccines, per federal guidelines, 317 funds are only to be used for the uninsured or underinsured or during an outbreak that has been approved by the Kentucky Immunization Program. If accidental borrowing occurs, please follow the procedure detailed above regarding the borrowing report.
**VFC doses and 317 doses cannot be used to borrow or "pay back" one another. These vaccines are from different funding sources and can only be replaced with private inventory.**

Record the borrowed and payback information in KYIR on each patient's immunization record.
The Borrowing Form can be found on KYIR in the Reports/Training section under Kentucky Forms and Resources. Send in an updated borrowing form within 90 days that contains the documentation of the paid-back dose with documented administration. Payback is dose-for-dose and is not interchangeable among vaccine types.
Completed forms must be retained as a VFC program record and made available to the Kentucky Immunization Program upon request.

# Fraud and Abuse

By submitting a signed Provider Agreement and accepting shipment of VFC vaccine, you agree to abide by the statutory requirements of the VFC program. These requirements are federal law, and as the administrator of the VFC program in Kentucky, the Immunization Program is charged with enforcement. Federal fraud and abuse laws apply to the VFC program. Good stewardship of federal entitlement program taxpayer funding is a top priority. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC program.
The Kentucky Immunization Program refers to the Centers for Medicare and Medicaid Services (CMS) any instances of fraud or abuse that appear intentional and result in financial benefits to the provider.

## Fraud and Abuse Policy (December 7, 2012)

The following information outlines the policy and procedures to prevent, detect, investigate, and resolve suspected fraud and abuse allegations for medical providers receiving vaccines from the Kentucky Immunization Program. The federal Vaccines for Children (VFC) program is the largest part of the KIP. The Vaccines for Children program is a federally funded program that provides vaccines at no cost to children who are Medicaid-eligible, uninsured, American Indian/Alaska Native, or who are underinsured and receiving immunizations at a Federally Qualified Health Center (FQHC), Rural Health Center (RHC), or a local health department delegated by a FQHC or RHC. The cost and number of vaccines provided by the VFC program and Adult/317 programs have increased dramatically over the past few years; thus, the KIP must have effective and enforceable policies and procedures against fraud and abuse to safeguard this significant investment.
Authority: KRS 205.8453(4) directs the Cabinet for Health and Family Services to institute other measures necessary or useful in controlling fraud and abuse. The Kentucky Department for Public Health is responsible for monitoring the utilization of services in the Kentucky Immunization Program and refers any concerns of fraud, abuse, and/or waste to the Office of Inspector General (OIG) as the designated Single State Agency for the Kentucky Medicaid Program. Referrals outlining the potential fraud, abuse, or waste will be forwarded to the OIG, Division of Audits & Investigations, Medicaid Preliminary Investigations (MPI) Branch. The MPI Branch will review complaints of potential fraud, abuse, and/or waste. The MPI Branch is responsible for referring any situations in which they have determined that

fraud, abuse, and/or waste may have occurred to an outside agency for further investigation and prosecution (i.e., the Kentucky Office of the Attorney General, Department of Insurance, U.S. Department of Health & Human Services, U.S. Office of the Attorney General, etc.).

The following definitions are consistent with "fraud" and "abuse" as defined in Medicaid regulations 42 CFR § 455.2:

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state 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 healthcare. Abuse also includes recipient practices that result in unnecessary costs to the Medicaid program.

Fraud and Abuse Examples

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

- Failing to comply with any part of the Provider Agreement
- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting the VFC vaccine
- Billing a patient or third party for the VFC vaccine
- Charging more than the established maximum regional fee for the administration of the VFC vaccine
- Waste of the VFC vaccine
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay the administration fee
- Failing to screen for and document eligibility status at each visit
- Failing to maintain VFC records for a minimum of three years
- Failing to fully account for the VFC-funded vaccine
- Failing to properly store and handle the VFC vaccine

## Preventing Fraud and Abuse

The following activities are part of the VFC program's daily operations to prevent instances of fraud and abuse:

- Upon enrollment into the VFC program, new immunization providers will receive an educational training session from the Regional Field Rep to explain the VFC program in detail. Providers will be educated about the purpose, eligibility requirements, and VFC program requirements.
- All providers who participate in the VFC program are required to submit a completed Provider Profile and signed Provider Enrollment form before they can receive the vaccine. Providers must update these forms as needed, annually for the Provider Profile and biannually for the Provider Enrollment, to continue to receive vaccines. The Provider Enrollment form outlines the requirements with which providers must comply to participate in the VFC program. By signing the Provider Enrollment form, providers certify that they will comply with the VFC program requirements.
- The Vaccine Accountability and Ordering staff reviews all incoming vaccine orders and reports of doses administered. VAS staff address any inconsistencies on these reports (e.g., ordering more

vaccine than is usually ordered, reports of wasted/expired vaccine) quickly, and adjustments are made as appropriate.

- Per the Provider Enrollment form, the provider may have to reimburse the Immunization Program dose for dose for any vaccines that are unaccounted, spoiled, expired, or deemed preventable losses. Providers are required to develop corrective action plans and submit proof of replacement.
- All VFC staff who interact with VFC-enrolled providers are thoroughly trained to prevent, identify, and resolve issues and instances of programmatic fraud and abuse, and non-compliance in a provider's office/clinic as part of their job responsibilities.
- Regional Field Representatives conduct additional site visits if providers have vaccine storage and handling problems or other issues, and follow up with the providers until improvements are made and maintained.
- Storage and handling training for primary and backup coordinators, which could include in-person training and/or CDC modules, is required annually.
- As a quality assurance measure, VFC staff will review the List of Excluded Individuals and Entities list located at http://exclusions.oig.hhs.gov/ before allowing new VFC providers on the program and yearly when updated enrollment forms are received. The list is used to identify parties excluded from participation in federal health care programs. Any VFC-enrolled provider that newly appears on the exclusion list will be immediately suspended from the VFC program, and any VFC vaccine in inventory will be retrieved by VFC staff.

## Detecting, Investigating, Reporting, and Resolving Fraud and Abuse

Instances of potential fraud and abuse are most often reported as complaints or referrals from outside sources regarding a provider who has inappropriately used vaccines or billed Medicaid or private insurers for the cost of VFC vaccines. Instances of potential fraud and abuse might also be detected during review of providers' vaccine orders, during VFC site visits, or during Immunization Quality Improvement for Providers (IQIP) site visits.

As determined by KIP staff, if an instance of fraud and abuse is determined to result from an excusable lack of knowledge or misunderstanding of the VFC program requirements, the Vaccine Accountability and Ordering Section (VAS) Coordinator will implement an Education and Corrective Action Plan and attempt to resolve the situation with KIP staff.

This determination will be made on a case-by-case basis depending on such factors as:

- Amount of money lost
- Inadvertent financial gain by the provider
- How the incident was identified
- Length of time the incident was occurring
- Provider's willingness to replace the lost VFC vaccine
- Willingness of the provider's staff to participate in the educational referrals and post-education follow-ups

In addition, a visit by the Regional Field Representative to the provider's office and follow-up will be required until the situation improves.

If an instance of fraud and abuse is determined to be intentional or is not able to be resolved by KIP staff, the following information will be collected:

- Medical Provider's name (Medicaid ID if known)
- Address

- Source of allegation
- Date allegation was reported to the program
- Description of suspected misconduct
- Specific VFC requirements violated, and value of vaccine involved, if available
- Success of educational intervention
- Disposition (e.g., closed, referred, or entered education process) of case and date of disposition

A suspected instance of fraud or abuse that is determined to be intentional or is not able to be resolved by KIP staff will be referred to the Center for Medicare & Medicaid Services (CMS), Kentucky Medicaid, and Centers for Disease Control and Prevention (CDC) contacts within five (5) working days. In addition to the above-mentioned information, Immunization Program staff will gather and provide any additional information requested by Medicaid/CDC.

If a VFC Provider's actions are determined to constitute fraud or abuse, the provider may be required to reimburse vaccine or other costs, terminated from the VFC program, and have his/her name added to the KIP excluded provider list, and/or may be referred for criminal prosecution. If a VFC provider's actions are determined not to constitute intentional fraud or abuse, the provider would receive education and follow-up from the Kentucky Immunization Program staff until the situation is resolved.

## Fraud and Abuse Contact

Email: DPH.KVP@ky.gov
Phone: (502) 564-4478, Monday through Friday from 8:00 am to 4:30 pm

# Vaccine Storage & Handling

Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Improperly stored vaccines, outside the recommended ranges, have reduced potency, creating limited protection for the patient. This results in the need for revaccination of patients and thousands of dollars in wasted vaccines.

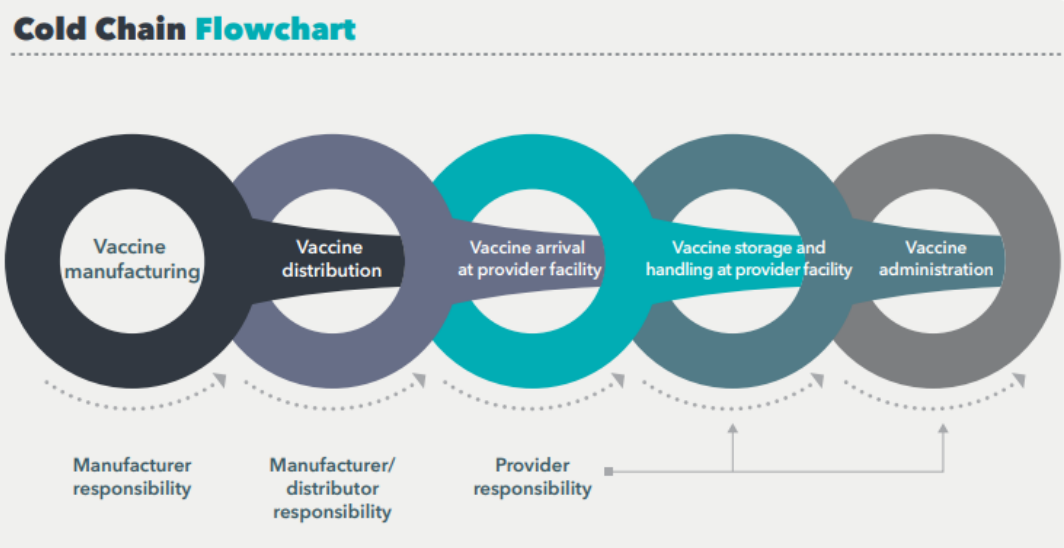
Both VFC Program requirements and Best Practices are provided in this section to assist providers in ensuring viable vaccines are administered to their patients.

Successful vaccine management is dependent on five factors:

1. Completed and up-to-date Vaccine Management Plan
2. Trained and knowledgeable Vaccine Coordinators and clinic staff
3. Dependable storage units with suitable capacity
4. Accurate temperature monitoring with calibrated, approved devices
5. Consistent adherence to protocols that protect vaccine viability

## Vaccine Cold Chain

The basis of appropriate storage and handling is the cold chain. The cold chain is a system of maintaining the vaccine's potency from the time of manufacture to the time of administration to the patient. Providers have an integral role in preserving vaccine potency.




Excessive hot or cold temperatures damage vaccines. Once vaccine potency is lost, it can never be regained, and the vaccine becomes ineffective at preventing disease. Visual inspection of vaccines is an unreliable method of assuring potency. Inactivated vaccines – even when exposed to freezing temperatures – may not appear frozen, giving no indication of reduced or lost potency.

## Vaccine Storage

- Refrigerated vaccines must be kept between 36°F and 46°F (2°C and 8°C). Aiming for 40°F (4.4°C) allows some temperature fluctuation without going out of range.
- Frozen vaccines must be kept between 5°F and -58°F (-15°C and -50°C). Aiming for 0°F (-17.7°C) allows for automatic defrost cycles. Freezers that require a manual defrost should be defrosted when the ice accumulation reaches ¼ inch.
- Ultra-cold frozen vaccines must be kept between -130°F and -76°F (-90°C and -60°C).
- Vaccines must be kept in their original box packaging with the lid of the box kept intact and reclosed each time it is accessed. This is due to some vaccines being light-sensitive. Storing vaccines in their original packaging also helps minimize administration errors.
- Vaccines should be stored in the middle of the storage unit, away from coils, walls, cooling vents, and the floor of the unit. Allow for 2 to 3 inches between the vaccines and the walls, and allow room for air to circulate between the vaccines.
- If the unit has glass or solid shelving, purchase plastic mesh baskets to promote air circulation in and around the vaccines.
- Label shelves and/or baskets clearly to identify where each type of vaccine is stored. Label VFC vaccines and keep them separate from privately purchased vaccines. The VFC Program has VFC stickers to denote VFC vaccines upon request.
- Store vaccines in similar packaging or names on different shelves. Adult and pediatric versions of the same vaccine should be stored on different shelves and labeled accordingly.
- Never store vaccine in the storage unit doors or in any bins or drawers.
- Never store food or beverages in the vaccine storage unit.
- Diluents packaged separately from their corresponding vaccines can be stored at room temperature or in the refrigerator. Diluents packaged with their vaccines should be stored in the refrigerator next to the vaccines. Never store diluent in the freezer.
- Always check to make sure the storage unit door is closed. Providers may opt to use door latches to ensure that the door is completely closed.
- Providers are required to review expiration dates of vaccines and rotate the stock weekly. Record the date of stock rotation on the daily temperature logs. Expired vaccines should never be stored in the storage units.
- If storage of medications or biologics is necessary in the refrigerator, store them below the vaccines and on a different shelf to prevent contamination of vaccines due to spills.

# Vaccine Protocols

The following protocols should be followed to ensure vaccine viability during all stages of storage and transport.

## Vaccine Order Deliveries

- Never refuse vaccine shipments due to damage to the exterior package or delayed delivery. Providers should accept all shipments and then notify the VFC Program of any issues.
- Deliveries should be arranged only when the clinic is open, and the vaccine coordinator is on duty. All staff must be aware of the importance of maintaining the cold chain and immediately notifying the vaccine coordinator of vaccine arrival.
- Never leave a vaccine shipping container unpacked and unattended. Store vaccine immediately in appropriate conditions. Log in to KYIR and click the link provided on your on-hand screen to accept the shipment into your inventory electronically.

### Follow the steps below when receiving vaccine shipments:

- Open all shipments immediately upon receiving
- Check the temperature indicators inside the shipment
- Compare the contents of the shipment to the packing list. Make sure to count the diluent doses to make sure there is a correct match to the number of vaccines in the shipment.
- Place the vaccines in the appropriate storage locations as quickly as possible upon opening the shipment.

## Reporting Procedures:

***Out of range temperature indicators inside the shipment:***

- Label the vaccines DO NOT USE and store them at appropriate temperatures
- Immediately contact the manufacturer to determine if the vaccines are viable
- Complete the VFC Incident Report and send it to your assigned Field Representative and fax it to the KY VFC Program at 502-564-4760
- If the vaccines are deemed viable per the manufacturer, you can remove the DO NOT USE label and use the vaccines as usual. If they are deemed not viable, the KY VFC Program will notify you on completing a return to send those doses back to the manufacturer.

***Damaged package or missing doses:***

Immediately contact the KY VFC Program at 502-564-4478 or the KYIR Helpdesk at 502-564-0038

***Provider Location change reporting:***

Whenever there are changes in provider, primary contact, unexpected or different office closures, or a change of address, notify the VFC program, preferably well in advance of the change, to assist in proper delivery of vaccine shipments. Failure to notify of a change in coordinators or an address change will result in provider suspension.

# Storage Units

The Kentucky VFC program requires stand-alone refrigerator and freezer units. They must be self-contained units that operate only as a refrigerator or freezer and are suitable for vaccine storage.

The unit must be large enough to hold the clinic's largest inventory. This includes times of high inventory, such as during flu season, back-to-school, and prior to holidays, when vaccine shipments are halted.

CDC recommends the following units, starting with the most preferable, for storing VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units.
- Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines).
- Stand-alone refrigerator and freezer units. These can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.

Calculate the largest number of doses on hand for the storage unit to determine the size of the unit needed. Include seasonal flu doses and private stock if all are to be stored in the same unit.

| Refrigerator | | Freezer | |
|---|---|---|---|
| Maximum Doses | Minimum $Ft^3$ Required | Maximum Doses | Minimum $Ft^3$ Required |
| 1001-2000 | 40 | 501-600 | 7-14.8 |
| 900-1000 | 36 | 201-500 | 5-5.6 |
| 801-900 | 21-23 | 0-200 | 3.5-4.9 |
| 701-800 | 17-19.5 | | |
| 401-700 | 11-16.7 | | |
| 100-400 | 4.9-6.1 | | |

- Acceptable units vary in size from compact, under-the-counter style to large, stand-alone pharmaceutical-grade units. Combination units will be approved only if they are pharmaceutical grade and have documentation of being such. The VFC Program will never approve dormitory-style units for use.
    - Pharmaceutical Purpose-Built Units – These are designed for the storage of biologics, including vaccines, and they maintain temperatures more consistently. Units vary in size from compact, under-the-counter style units to large stand-alone units or doorless vending-style units.
        - Some purpose-built pharmaceutical units may be a refrigerator/freezer combination with separate temperature controls in each section.
        - Doorless vending-style units:
            - Must have the ability to separate public and private stock.
            - For certain units, it may be recommended that the vaccine be stored outside of the packaging. Follow the manufacturer's guide for storage. Keep all cartons that correspond to the vaccines on hand in case of transfer or moving to a backup storage location.

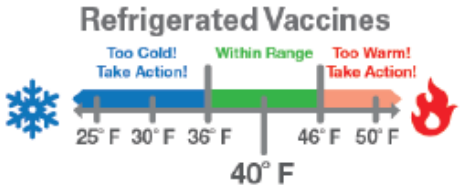
        - They may have built-in data loggers that track temperatures and provide min/max temperatures.
            - These probes or sensors must have current Certificates of Calibration.
            - A backup digital data logger is still required in case of transport.
            - Many of these units do not allow for or need the inclusion of water bottles for thermal ballast.
    - Commercial-Grade (Stand-Alone) Units – These are not built for vaccine storage and are instead intended for commercial food use. They can be acceptable if they can maintain stable in-range temperatures.
        - These units may have a temperature display on the unit, but this display reflects the air temperature rather than the required temperature data via a buffered probe. Any temperature display on these units is not to be used for temperature documentation. They do not reflect data logging thermometer standards with probes, calibrations, etc.
    - Household-Grade (Stand-Alone) Units – These units are dedicated refrigerator or freezer storage units manufactured for household use. They are not built for vaccine storage but are intended for household food use. They can be acceptable if they can maintain stable in-range temperatures.
        - Avoid storing vaccines or diluents in any part of the unit that may not provide stable temperatures or sufficient airflow: directly under cooling vents (top shelf and back), the door, or the bottom shelf or bins. Water bottles should be placed on the top shelf, floor, door, and all areas where vaccines should not be stored.

- Units must be dedicated to vaccine storage: NO food or drink is to be stored in the storage units.
- Storage units are assessed at site visits and with monthly temperature log submissions. The VFC program may indicate a need to replace units due to unstable temperatures, units too small for inventory needs, etc.
- Thermal ballast, such as water bottles, in the refrigerator and freezer, is recommended as best practice to help maintain appropriate temperatures inside the storage unit. The doors and top, and bottom shelves are ideal locations for water bottles. Thermal ballast may occupy up to 25% of the storage space in the unit.
    - Water bottles are recommended for household-grade units and are not recommended for use with the majority of pharmaceutical-grade and purpose-grade units. For such units, follow the manufacturer’s guidance.
- Back-up storage units must meet the same requirements as the primary units. However, the use of the refrigerator portion of a combination unit may be allowed for temporary storage. Back-up units shall not be used longer than two weeks. The freezer section of a combination unit is never approved for vaccine storage.
- Place the storage unit in a well-ventilated room with good air circulation around the unit. It must be plugged directly into the wall outlet without the use of extension cords.
    - Check the manufacturer's owner’s manual for additional guidance on placement and spacing.

  - Avoid outlets with built-in circuit switches or those activated by a wall switch. An outlet cover can be used to prevent inadvertently unplugging the unit.
- The outlet AND the circuit breaker in the breaker box must be labeled with warning signs such as “Do Not Unplug” and “Do Not Turn Off”.
- The unit must demonstrate two consecutive days of in-range temperatures before being used for vaccine storage. This applies if the unit is new or if the provider has an address change. The designated Field Representative will approve the storage unit if it is satisfactory for vaccine storage. Providers will need to supply the Field Representative with a copy of the purchase order for the unit and a temperature log of 2 consecutive days of in-range temperatures.

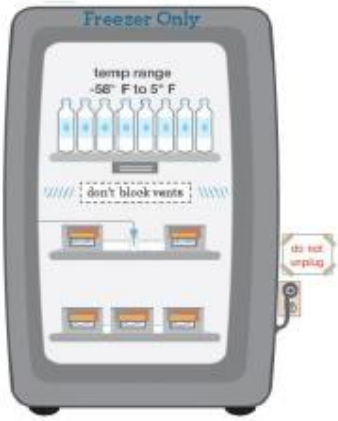
## Refrigerator Specifications

- Any storage unit must meet the following requirements to be approved:
  - Maintain consistent temperatures between 36°F and 46°F (2°C to 8°C).
  - Be a stand-alone unit at a commercial or pharmaceutical grade.
  - Possess the capacity to store all the practice's vaccines along with sufficient water bottles to stabilize temperatures.
  - Defrost automatically.
  - The door should seal tightly and close properly.
  - It is used primarily for vaccine storage.


## Freezer Specifications

- Any storage unit must meet the following requirements to be approved:
  - Maintain consistent temperatures between -58°F and 5°F (-50°C to -15°C).
  - Be either a stand-alone unit (upright or chest) or a pharmaceutical-grade combination unit.
  - Possess a capacity to store all the practice's vaccines along with sufficient frozen water bottles for emergency transport use.
  - Manual defrost is acceptable if the provider has access to an alternate storage unit for vaccine storage during the defrost process.
  - Door should seal tightly and close properly.
  - Be used only for vaccine storage.




## Ultra-cold Freezers

Units must maintain temperatures of -76°F to -130°F (-60°C to -90°C).
Ultra-cold freezers are required to have accurate temperature monitoring devices, such as a digital data logger with a probe designed specifically for ultra-cold temperatures. The digital data loggers approved for regular freezer and refrigerator temperatures are not capable of recording temperatures in an ultra-cold freezer.

# Power Supply Protection

Precautions must be taken to protect the storage unit's power supply. The following measures must be used and are reviewed at site visits:

- Post DO NOT UNPLUG stickers at the outlets for all storage units.
- Post DO NOT DISCONNECT stickers at the circuit breakers.
  Plug in only one storage unit per electrical outlet.

# Required Backup Storage Units

All providers must identify a backup storage location for both refrigerator and freezer storage. This information must be included in the Vaccine Management Plan.
If the storage unit fails, the vaccine must be transported to the backup location. Alternative storage locations should be inspected before an emergency to ensure proper vaccine storage conditions can be maintained.

- Vaccines must be transported, stored, and handled appropriately when moved to the backup location.
- Vaccines must always be kept under temperature monitoring with approved digital data-logging thermometers.
- All staff should be aware of the location of the backup unit and the Vaccine Management Plan.

# New, Repaired, or Re-located Storage Units

Any new unit or any unit that has been repaired or relocated requires documentation of stable temperatures and approval by the VFC program before vaccines are stored in it. Units are required to demonstrate 2 continuous days of in-range temperatures before being approved for vaccine storage.

# Temperature Monitoring Equipment

VFC Providers are required to have certified, calibrated digital data logging thermometers (DDL) in their storage units. Providers need a separate DDL thermometer for each storage unit that holds VFC vaccines. A certified, calibrated back-up DDL must be located on site (not in the storage unit) for use in case the primary thermometer is no longer working properly or calibration testing is required.
The calibration certificates shall be on file and easily accessible during a site visit, and used to determine when recalibration is necessary.

It is best practice to choose a desired temperature scale, Fahrenheit or Celsius, record and document all temperatures in the same scale, and set alarms accordingly.

A valid certificate of calibration must include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is within tolerance) per ISO 17025
- Recommended uncertainty of ±1°F (±0.5°C) or less
- The expiration date for a certificate of calibration shall be in accordance with the manufacturer's recommendation (i.e., a 2-year recommended frequency in calibration would mean the certificate expires 2 years from the issue date). If there is no manufacturer recommendation for calibration testing for back-up thermometers that are placed in use, write the "In-Use" date on the certificate. The certificate will expire one year from the in-use date or 2 years from the issue date, whichever occurs first.

## Digital Data Logger (DDL)

An approved digital data logger will have the following features:

- A detachable probe that best reflects vaccine temperatures. It is required to have a bio-safe glycol-encased probe with a digital temperature display that attaches to the outside of the storage unit.
- An alarm for out-of-range temperatures
- A low battery indicator
- Current, minimum, and maximum temperature display
- A recommended uncertainty of ±1°F (±0.5°C) or less
- A logging interval that can be programmed by the user to measure and record temperatures every 10 minutes
- The thermometer probe must be positioned in the center of the unit. The digital temperature display should be attached to the outside of the storage unit. This enables the Provider to monitor the temperature of the unit without opening the unit door.

Download the DDL's data monthly or if there is any temperature excursion. Any temperature failures need to be noted on an Incident Report as part of the Temperature Excursion protocol and followed up with your Field Representative.

## Digital Data Logging Thermometer Alarm Settings

The alarm settings for the DDL should be set for any temperature outside the required temperature range for refrigerated and frozen vaccines.
**Refrigerated vaccines should be kept between 36°F to 46°F (2°C to 8°C).**
**Frozen vaccines should be kept between -58°F to +5°F (-50°C to -15°C).**
**Ultra-cold vaccines should be kept between -130°F to -76°F (-90°C to -60°C)**

Ensure the alarm settings for the thermometers are correct as shown below:

- Record a reading every 10 minutes
- Refrigerator Alarm Settings
  - Upper alarm set for temperatures above 46.1°F (8°C) after 3 consecutive readings
  - Lower alarm set for temperatures below 35.9°F (2°C) after 2 consecutive readings
- Freezer Alarm Settings
  - Upper alarm set for temperatures above +5.1°F (-15°C) after 3 consecutive readings
  - Lower alarm set for temperatures below -58°F (-50°C) after 3 consecutive readings
- Ultra-Cold Alarm Settings
  - Upper alarm set for temperatures above -76°F (-60°C) after 3 consecutive readings

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your Vaccine Management Plan to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

If the temperature alarm goes off repeatedly, do not disconnect the alarm until the cause has been determined and addressed. Perform basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperatures remain out of range, transfer vaccines to the backup unit as noted in your Vaccine Management Plan. A repair technician should check your equipment to determine the need for repair or replacement.

# Temperature Data Upload to KYIR

DDL thermometer data files can be uploaded to the Kentucky Immunization Registry (KYIR). Brands known to have compatible formatting for upload include LogTag from Control Solutions and Fisher Scientific. Other brands may also have compatible formatting.
The KY VFC Program does not require the use of LogTag brand digital data loggers. Any brand is acceptable if it meets all required calibration and recording features.

# Daily Min/Max Temperature Log

Monitoring storage equipment and temperatures are daily responsibilities that ensure the viability of the vaccine supply.
Check and record the minimum and maximum temperatures of each storage unit at the start of each workday. Keep the temperature log sheets on the door of every storage unit.

The temperature log sheets have space for the following entries:

- Minimum temperature of the storage unit in the past 24 hours
- Maximum temperature of the storage unit in the past 24 hours
- Date and time of the recording
- Name of the person who checked and recorded the temperature
- Any actions taken if a temperature excursion occurred

If a reading is missed, leave a blank entry in the log.

KY VFC Providers are required to use the KY VFC Temperature Logs to record the data monthly. Completed logs must remain on-site and may not be falsified. Keep all temperature logs on file for a minimum of three years. They should be easily accessible during a site visit.

# Freezer Defrost

Freezer units with a manual defrost or a frost-free automatic defrost will be approved for vaccine storage. Automatic defrost units are preferred to reduce the need for a defrost plan, which is required of all manual defrost units.
All freezers must be defrosted according to the manufacturer's instructions.

## Manual Defrost Procedures

All freezers with a manual defrost must have a defrost plan included in the Vaccine Management Plan. The defrost procedures should be followed once the ice on the freezer reaches ¼"
Instructions for defrosting manual-defrost vaccine freezers:

**Plan Ahead**

- Ensure the alternate freezer location has enough space to accommodate your inventory
- Set up the backup data logger in the alternate freezer
- Make sure the data logger's alarm settings are set appropriately (alarm above 5° F and below -40° F)
- Have the data logger ready to record temperatures
- Monitor the temperature of the alternate freezer location to confirm it is within the required range.
- Defrosting of the freezer should be started at the beginning of a workday so that the vaccines can be returned to their original unit before closure of the practice.

**Defrost the Freezer**

- Transfer the frozen vaccines to the alternate freezer (including frozen water bottles)
- Make sure the backup data logger is recording, and the temperature is within range
- Download the primary data logger and save/upload the temp file for the primary unit
- Defrost the freezer following the clinic's preferred method identified in the Vaccine Management Plan if different from the steps below:
- Unplug the storage unit
- Open the freezer door
- Place shallow pans, towels, or paper towels to absorb melting ice
- Heat a bowl of water and place it in the freezer to speed up the melting process; reheat the water every 15 minutes if needed.
- Use an ice scraper and remove melting ice to speed up the process; be careful not to puncture freezer walls

**Defrost Completed**

- After the unit has defrosted, clean the interior surfaces with soap and water
- Rinse the soap off and wipe down thoroughly
- Dry interior thoroughly
- Wipe down the door seals
- Plug in the freezer
- Place the primary data logger back in the unit to monitor the unit's return to correct temperature
- Once the temperature stabilizes and maintains a temperature within range, between -40°F and 5°F, return the vaccines from the alternate location to their primary storage unit.

- Remove the primary data logger and store it as the backup data logger
- Bring the data logger that has been with the vaccines in the alternate location to the primary location and keep it in use as the primary data logger.

## Frost-Free Automatic Defrost Guidance

A frost-free automatic defrost freezer unit will experience regular defrost cycles, which cause a brief temperature fluctuation. Any units that experience out-of-range temperature fluctuations require the temperature excursion protocol to be followed to determine the viability of the vaccine. Units with repeated temperature excursions outside the appropriate temperature range should be adjusted to maintain temperature within range. Units that cannot maintain appropriate temperatures without out-of-range fluctuations should be considered for replacement.

# Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. However, if you believe your unit has failed or is failing, do not allow vaccines to remain in the malfunctioning unit. In that situation, all vaccines should be moved to the back-up storage location. Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range.

Any adjustments made to the storage unit thermostat should only be made by either the primary or backup vaccine coordinator. Adjustments should only be made after reviewing previous temperature logs that indicate a trend of too cold or too warm temperatures in the unit. Temperatures within any storage unit will vary slightly and fluctuate with normal use. The change should not be made during a busy workday or when the unit door is frequently opened and closed.

Making a temperature adjustment:

- Refer to the storage unit owner's manual for detailed instructions.
- Make a small adjustment warmer or colder by turning the thermostat slowly to avoid going outside the correct temperature range.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- Recheck the temperature.
- Repeat the steps as needed until the temperature stabilizes at around 40°F for a refrigerator and around 0°F for a freezer.
- Consider placing additional water bottles in the unit to help improve temperature stability.

# Temperature Excursion

If vaccines are exposed to inappropriate storage conditions, the viability of the vaccines may be affected. In the event of a temperature excursion or an alarm of the digital data logger, follow the steps below:

- Consult your Vaccine Management Plan and ensure the primary and/or backup vaccine coordinator is notified.
- Take an inventory of the affected vaccines, place them in a brown paper bag labeled DO NOT USE, or label the outside of the storage unit with DO NOT USE.
- If the primary storage unit is at acceptable temperatures, vaccines may remain in the unit. If the primary unit is still showing temperatures out of range, move the vaccines to the back-up storage location.
- Download the digital data logger information to determine the length of the excursion and the temperatures reached.
- Contact the vaccine manufacturers with the information gathered from the digital data logger. You will need to supply them with the vaccine name, the total amount of time they spent out of range, and the temperatures that were recorded during that time. The manufacturer's stability representative will supply you with a case number and a determination of the vaccine's viability.
- Complete a Vaccine Storage & Handling Incident Report and send to your Field Representative or email to VaxColdChain@ky.gov
    - Inappropriate storage conditions, all mechanical malfunctions, or power outages must be documented on the Incident Report.
- Mark the boxes of vaccines deemed viable by the vaccine manufacturers after an excursion to easily determine if the same inventory is exposed in the event of another excursion.
- Vaccines deemed non-viable and inadvertently administered should not be counted as valid doses and must be repeated.
- Do not create a return or discard non-viable vaccines until your Field Representative or the Storage & Handling Coordinator provides further instructions.

# Power Outages

During a power outage, only open the storage unit door if:

- Power is restored.
- It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative (backup) storage facility.

Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor temperatures via the digital data logging thermometer to determine when additional action should be taken.

- Record room temperature (if possible) and temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- Temperature excursions should be avoided, if possible, by using emergency plans for transport and alternative storage. If temperatures have fallen outside of the recommended range, follow the procedures in the vaccine management plan.
- Even if an excursion has occurred, move your vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures, if possible. Make sure to separate and mark these vaccines “Do Not Use” until a decision can be made about their viability.

# Vaccine Transport

The CDC recommends that the transport of vaccines be a rare occurrence due to the possible risks to the vaccine's viability. In the case of an emergency, you may be required to transport your vaccines to another physical location. KY VFC understands that some providers transport vaccines from a central location to an alternative location, such as a health department, to schools for on-site administration clinics. All personnel involved should receive education on the proper storage and handling (including transport) of vaccines.

The following requirements apply to vaccine transport:

- Contact your Field Representative for approval before transporting vaccines.
- Monitoring temperatures during transport is required using the backup digital data logger.
- Frozen vaccines should never be transported except in an emergency.
- Utilize appropriate storage equipment, including coolers, refrigerators, and digital data loggers.
- Vaccines should only be transported once. Only transport the quantity of vaccine you will administer at the alternative site, so you will not have to transport a second time.
- Limit transport time to 30 minutes or less. If transport requires more time, hourly checks of the temperature are required on a paper temperature log. The total time of transport and storing vaccines off-site should not exceed 8 hours.
- Vaccines cannot be stored overnight in transport coolers.
- Vaccines should be attended at all times during transport. They are never to be placed in the trunk of a vehicle.
- Transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents for reconstitution.
- Do not use dry ice, coolant packs from shipments, or soft-sided food/beverage coolers.

## Transport Method Requirements

Transport packing methods differ between Emergency Transport and Planned Transport, such as for off-site clinics or relocation of inventory. A portable refrigerator/freezer is always the preferred method of transport. Do not use original shipping containers or food/beverage coolers for transporting vaccines. Emergency Transport requires either portable vaccine storage units, qualified containers and pack-outs, or the conditioned water bottle transport system.
Planned Transport requires either a portable refrigerator/freezer or qualified containers and pack-outs (e.g., Cool Cubes). The conditioned water bottle method cannot be used for planned transport.

| Transport Method | Emergency Transport | Planned Transport (Off-site clinic or inventory transfer) |
|---|---|---|
| Portable Vaccine Refrigerator/Freezer (preferred) | **Yes** | **Yes** |
| Qualified Container and Pack-Out | **Yes** | **Yes** |
| Conditioned Water Bottle Transport System | **Yes** | **No** |

- Portable Vaccine Refrigerator/Freezer – A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Example: Engel Portable Fridge-Freezer
- Qualified Container and Pack-Out – A type of container and supplies specifically designed for use when packing vaccines for transport. These are passive containers that do not require a power source and are qualified through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time. For proper use, follow the directions stated in the manufacturer's instructions. Example: Cool Cube transport units
- Conditioned Water Bottle Transport Method – Method outlines according to CDC's Packing for Emergency Transport. This is for emergency transport only. It cannot be used for planned transport, such as off-site clinics or the transfer of inventory.

*The examples provided are for educational purposes only and do not imply endorsement. KY VFC Program does not endorse certain products, brands, manufacturers, etc.*

## Monitoring Vaccines in Transport

- Follow the manufacturer's guidance if using a portable refrigerator/freezer or a qualified container and pack-out designed for vaccine transport (includes specific materials and "conditioning" processes).
- Never freeze diluents, not even during transport.
- Place a calibrated temperature monitoring device – a digital data logging thermometer with a buffered probe) in the container with the vaccines.
- Document the time and temperatures at the start, during, and end of transport – if longer than 1 hour, document hourly.

If any excursion occurs during transport or off-site clinics, follow the Temperature Excursion Protocol. Do not use the vaccine until viability information is obtained from the manufacturers.

**Transporting Opened Multi-dose vials**: A partially used vial cannot be transferred from one provider to another. If necessary, an opened multi-dose vial may be appropriately transported to and from an off-site clinic that's operated by the same provider.

## Transporting Frozen Vaccine

Varicella-containing vaccines are **NOT** recommended for transport (VAR, MMRV). They should only be transported in an emergency.

- A portable freezer is the best practice. All other options may cause a vaccine temperature excursion.
- Use a portable freezer or qualified container and pack-out that maintains temperatures between -58°F to +5°F (-50°C to -15°C).
- Do NOT use dry ice, even for temporary storage or emergency transport.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at the appropriate temperature range (-58°F to +5°F (-50°C to -15°C).
- Ultra-cold transport temperatures need to stay between -130°F to -76°F (-90°C to -60°C). Any stand-alone freezer that maintains these temperatures is acceptable.

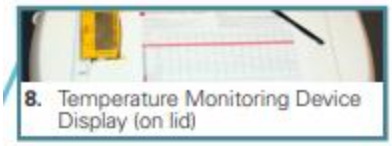
## Packing Vaccines for Emergency Transport

**Refrigerated Vaccines:** It is best practice to transport with a portable refrigerator unit. If a portable unit is not available, a hard-sided insulated cooler may be used during an emergency with the following supplies and packing procedures. This transport option is not for use during vaccine pop-up clinics. It is only for emergency transport to the backup storage location in the event of equipment failure, power outage, or natural disasters.

Gather Needed Supplies for Emergency Transport:

- Hard-sided cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range between 36°F and 46°F (2°C and 8°C)
- Conditioned frozen water bottles: Place a frozen water bottle in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of the bottle. The bottle is properly conditioned if the ice block inside spins freely when the bottle is rotated. Dry the water off the exterior of the bottle.
- Do not reuse vaccine coolant packs from original vaccine shipping containers or dry ice, as they can cause the vaccines to freeze.
- Insulating material – 2 layers of each, and they should all be the same size
- Insulating cushioning material – bubble wrap or Styrofoam at least 1 inch thick.
- Corrugated cardboard – cut to fit the inner dimensions of the cooler
- Digital Data Logger

Pack for Emergency Transport:


8. Temperature Monitoring Device Display (on lid)

**Close lid –** Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

**Conditioned frozen water bottles –** Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

**Insulating material –** Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

**Insulating material –** Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

**Vaccines –** Add remaining vaccines and diluents to cooler, covering DDL probe.
**Temperature monitoring device –** When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
**Vaccines –** Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

**Insulating material –** Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

**Insulating material –** Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

**Conditioned frozen water bottles –** Line bottom of the cooler with a single layer of conditioned water bottles.

**Image 6**: Transport Packout Illustration – available in the Resources section on pages 46-47

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

Arrive at destination:

- Before opening the cooler, record date, time, temperature, and initials on vaccine temperature log. Transfer the boxes of vaccines quickly to the new storage refrigerator.
- If there has been a temperature excursion, follow the appropriate actions and temperature excursion protocol before using vaccines. Label the vaccines “Do Not Use” and store at appropriate temperatures until the manufacturer has determined viability.

## Off-Site Vaccination Clinic Procedures

Follow the steps below when conducting an approved off-site vaccination clinic. These steps include CDC guidelines and best practices for vaccine shipment, transport, storage and handling, preparation, administration, and documentation.

During All Stages:

- Keep vaccines at the correct temperature at all times using proper procedures for vaccine transport, handling, and storage.
- Document temperatures each hour on a paper temperature log.

Pre-Clinic:

- Have the vaccines shipped directly to the site.
- If direct shipment is not possible, vaccines must be transported using correct storage and handling guidelines.
- Train all staff to perform CPR and treat medical emergencies, including anaphylaxis. Ensure that all needed supplies are on site, including the emergency medical kit and infection control supplies.
- Make sure to have enough Vaccine Information Statements (VISs) on hand for all patients.

During the Clinic:

- Check for medical contraindications and allergies before vaccinating. Provide VISs to all patients and guardians.
- Follow manufacturers' instructions and ACIP (Advisory Committee on Immunization Practices guidelines for correct age and intervals.
- Follow manufacturers' instructions for injection dose, site, and route.
- Use only vaccines that are not damaged, not expired, stored at the correct temperatures, and prepared using an aseptic technique.
- Follow safe handling of needles and syringes, including using a new needle and syringe for every injection. Dispose of all sharps in a sharps container.
- Document every vaccination and provide patients with a copy. Record vaccinations in KYIR.

Post-Clinic:

- Keep patient information secure and private.
- A detailed checklist of best practices is available in the Resources section of this guidebook on page 48.

# Resources

See the links below for important immunization information.
The pages following contain copies of VFC required forms and helpful documents.

## Immunization Schedules

Immunization Schedules (Child, Adult, Interactive and Catch-Up Scheduler)
https://www.cdc.gov/vaccines/imz-schedules/index.html

State Regulation Immunization Schedule
https://apps.legislature.ky.gov/law/kar/902/002/060.pdf

Interactive Immunization Quiz
https://www2a.cdc.gov/vaccines/childquiz/

## Kentucky Immunization Registry (KYIR)

KYIR Enrollment Forms
https://chfs.ky.gov/agencies/dph/dehp/idb/Pages/kyir.aspx

Access to KYIR
https://kyir.chfs.ky.gov

KYIR Resources
Training videos and printable guides are in the Reports/Training Module of KYIR.

KYIR Helpdesk
Email: KYIRHelpdesk@ky.gov
Phone: 502-564-0038

## Vaccine Storage and Handling

Storage and Handling Toolkit
https://www.cdc.gov/vaccines/hcp/storage-handling/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

## Immunization Practices

Administering Vaccines
https://www.immunize.org/wp-content/uploads/catg.d/p3085.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)
https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Guide to Contraindications to Vaccinations
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

Vaccine Information Statements
http://www.cdc.gov/vaccines/hcp/vis/index.html

Vaccine Recommendations
http://www.immunize.org/clinic/vaccine-recommendations.asp

## Education and Training

CDC Education & Training
https://www.cdc.gov/immunization-training/hcp/?CDC_AAref_Val=https://www.cdc.gov/vaccines/ed/index.html

You Call the Shots
https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/index.html

TRAIN Learning Network
https://www.train.org/cdctrain/home

## VAERS

Vaccine Adverse Event Reporting System (VAERS)
http://vaers.hhs.gov

Vaccine Adverse Event Reporting System (VAERS) Frequently Asked Questions (FAQs)
https://vaers.hhs.gov/faq.html

FDA MedWatch
https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

## KY Immunization Regulations and Statutes

902 KAR 2:055. Immunization data reporting and exchange
https://apps.legislature.ky.gov/law/kar/902/002/055.pdf

214.015 Reporting of authorized or required immunization
https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=8773

902 KAR 2:060. Immunization schedules for attending day care centers, certified family childcare homes, other licensed facilities which care for children, preschool programs, and public and private primary and secondary schools
https://apps.legislature.ky.gov/law/kar/902/002/060.pdf

# Kentucky Immunization Branch

## Vaccines for Children - Available Vaccines

| Brand Name | Manufacturer | Antigen | NDC on carton | Minimum Order Size/Presentation | CPT Code | CVX Code |
|---|---|---|---|---|---|---|
| Denguvaxia | Sanofi | Dengue | 49281-0605-01 | single dose vial | 90587 | 56 |
| Daptacel | Sanofi | DTaP | 49281-0286-10 | 10 pack/1-dose vials | 90700 | 106 |
| Infanrix | GSK | DTaP | 58160-0810-52 | 10 pack/1-dose syringes | 90700 | 20 |
| Quadracel | Sanofi | DTaP/IPV | 49281-0564-15 | 10 pack/1-dose syringes | 90696 | 130 |
| Kinrix | GSK | DTaP/IPV | 58160-0812-52 | 10 pack/1-dose syringes | 90696 | 130 |
| Pentacel | Sanofi | DTaP/Hib/IPV | 49281-0511-05 | 5 pack/1-dose vials | 90698 | 120 |
| Pediarix | GSK | DTaP/HepB/IPV | 58160-0811-52 | 10 pack/1-dose syringes | 90723 | 110 |
| Vaxelis | Merck | DTaP/IPV/HIB/HepB | 63361-0243-15 | 10 pack/1-dose syringes | 90697 | 146 |
| HyperHEP B | Grifols | HBIG | 13533-0636-03 | 1 pack/1-dose syringe | 90371 | 30 |
| Havrix | GSK | Hep A | 58160-0825-52 | 10 pack/1-dose syringes | 90633 | 83 |
| Vaqta | Merck | Hep A | 00006-4095-02 | 10 pack/1-dose syringes | 90633 | 83 |
| Engerix B | GSK | Hep B | 58160-0820-52 | 10 pack/1-dose syringes | 90744 | 08 |
| Recombivax HB | Merck | Hep B | 00006-4093-02 | 10 pack/1-dose syringes | 90744 | 08 |
| Twinrix | GSK | Hep A/B | 58160-0815-52 | 10 pack/1-dose syringes | 90636 | 104 |
| PedvaxHIB | Merck | Hib | 00006-4897-00 | 10 pack/1-dose vials | 90647 | 49 |
| ActHIB | Sanofi | Hib | 49281-0545-03 | 5 pack/1-dose vials | 90648 | 48 |
| Hiberix | GSK | Hib | 58160-0726-15 | 10 pack/1-dose vials | 90648 | 48 |
| Gardasil 9 | Merck | HPV | 00006-4121-02 | 10 pack/1-dose syringes | 90651 | 165 |
| Seasonal Influenza[1] | Changes each season | Seasonal strains | Various | Various | Various | Various |
| Bexsero | GSK | Men B | 58160-0976-20 | 10 pack/1-dose syringes | 90620 | 163 |
| Trumenba | Pfizer | Men B | 00005-0100-10 | 10 pack/1-dose syringes | 90621 | 162 |
| Menveo (2-vial)[2] | GSK | Men ACWY | 58160-0955-09 | 5 pack/1-dose vials | 90734 | 136 |
| Menveo (1-vial) | GSK | Men ACWY | 58160-0827-30 | 10 pack/1-dose vials | 90734 | 136 |
| Menquadfi | Sanofi | Men ACWY | 49281-0590-10 | 10 pack/1-dose vials | 90619 | 203 |
| Penbraya | Pfizer | MCV4-MenB | 00069-0600-01 | 1 pack/1-dose vial | 90623 | 316 |
| Penbraya | Pfizer | MCV4-MenB | 00069-0600-05 | 5 pack/1-dose vials | 90623 | 316 |
| MMR II | Merck | MMR | 00006-4681-00 | 10 pack/1-dose vials | 90707 | 03 |
| Priorix | GSK | MMR | 58160-0824-15 | 10 pack/1-dose vials | 90707 | 03 |
| ProQuad | Merck | MMR/VZV | 00006-4171-00 | 10 pack/1-dose vials | 90710 | 94 |
| Jynneos | Bavarian Nordic | MPX | 50632-0001-03 | 10 pack/1-dose vials | 90611 | 206 |
| Prevnar 20 | Pfizer | PCV20 | 00005-2000-10 | 10 pack/1-dose syringes | 90677 | 216 |
| Vaxneuvance | Merck | PCV15 | 00006-4329-03 | 10 pack/1-dose syringes | 90671 | 215 |
| Pneumovax 23 | Merck | PPSV23 | 00006-4837-03 | 10 pack/1-dose syringes | 90732 | 33 |
| IPOL | Sanofi | IPV | 49281-0860-10 | 1 pack/10-dose vial | 90713 | 10 |
| Abrysvo | Pfizer | RSV | 00069-0344-01 | 1 pack/1-dose vial | 90678 | 305 |
| Beyfortus 100mg | Sanofi | RSV monoclonal antibody | 49281-0574-15 | 5 pack/1-dose syinges | 90381 | 307 |
| Beyfortus 50mg | Sanofi | RSV monoclonal antibody | 49281-0575-15 | 5 pack/1-dose syringes | 90380 | 306 |
| ~~Enflonsia~~ | ~~Merck~~ | ~~RSV monoclonal antibody~~ | ~~00006-5073-02~~ | ~~10 pack/1-dose syringes~~ | ~~90382~~ | ~~332~~ |
| Rotarix | GSK | RV | 58160-0740-21 | 10 pack/1 oral dose | 90681 | 119 |
| RotaTeq | Merck | RV | 00006-4047-20 | 25 pack/1 oral dose | 90680 | 116 |
| RotaTeq | Merck | RV | 00006-4047-41 | 10 pack/1 oral dose | 90680 | 116 |
| Tenivac | Sanofi | Td | 49281-0215-10 | 10 pack/1-dose vials | 90714 | 113 |
| Tenivac | Sanofi | Td | 49281-0215-15 | 10 pack/1-dose syringes | 90714 | 113 |
| Boostrix | GSK | Tdap | 58160-0842-52 | 10 pack/1-dose syringes | 90715 | 115 |
| Adacel | Sanofi | Tdap | 49281-0400-10 | 10 pack/1-dose vials | 90715 | 115 |
| Adacel | Sanofi | Tdap | 49281-0400-20 | 5 pack/1-dose syringes | 90715 | 115 |
| Varivax | Merck | VZV | 00006-4827-00 | 10 pack/1-dose vials | 90716 | 21 |

[1] Antigens in seasonal influenza vaccines change each year.

[2] Menveo (2-vial) is available in limited quantities for high-risk children aged 2m to 2y. To order, contact your Vaccine Accountability Rep or email DPH.KVP@ky.gov.

## 2025-2026 Influenza Vaccine Products

| Brand Name | Manufacturer | Antigen | NDC | Minimum Order Size/Presentation | CPT Code | CVX Code |
|---|---|---|---|---|---|---|
| FluMist | AstraZeneca | Influenza, live, trivalent, intranasal | 66019-0112-10 | 10 pack/1-dose sprayer | 90660 | 111 |
| Fluarix | GSK | Influzena, split virus, trivalent | 58160-0912-52 | 10 pack/1-dose syringes | 90656 | 140 |
| FluLaval | ID Biomedical | Influenza, split virus, trivalent | 19515-0904-52 | 10 pack/1-dose syringes | 90656 | 140 |
| Fluzone | Sanofi | Influenza, split virus, trivalent | 49281-0425-50 | 10 pack/1-dose syringes | 90656 | 140 |
| Flucelvax | Sequirus | Influenza, MDCK, trivalent | 70461-0655-03 | 10 pack/1-dose syringes | 90661 | 153 |

## ~~2024-2025 COVID-19 Vaccine Products~~

| Brand Name | Manufacturer | Antigen | NDC | Minimum Order Size/Presentation | CPT Code | CVX Code |
|---|---|---|---|---|---|---|
| ~~Moderna 6m-11y~~ | ~~Moderna~~ | ~~COVID-19~~ | ~~80777-0291-80~~ | ~~10 pack/1-dose syringes~~ | ~~91321~~ | ~~311~~ |
| ~~Spikevax 12yr+~~ | ~~Moderna~~ | ~~COVID-19~~ | ~~80777-0110-93~~ | ~~10 pack/1-dose syringes~~ | ~~91322~~ | ~~312~~ |
| ~~Novavax 12y+~~ | ~~Novavax~~ | ~~COVID-19~~ | ~~80631-0107-10~~ | ~~10 pack/1-dose syringes~~ | ~~91304~~ | ~~313~~ |
| ~~Pfizer 6m-4y~~ | ~~Pfizer~~ | ~~COVID-19~~ | ~~59267-4426-02~~ | ~~10 pack/3-dose vials~~ | ~~91318~~ | ~~308~~ |
| ~~Pfizer 5y-11y~~ | ~~Pfizer~~ | ~~COVID-19~~ | ~~59267-4438-02~~ | ~~10 pack/1-dose vials~~ | ~~91319~~ | ~~310~~ |
| ~~Comirnaty 12yr+~~ | ~~Pfizer~~ | ~~COVID-19~~ | ~~00069-2432-10~~ | ~~10 pack/1-dose syringes~~ | ~~91320~~ | ~~309~~ |

**Antigen Abbreviations**

| | | | |
|---|---|---|---|
| DTaP | diptheria, tetanus, acellular pertussis | PCV | pneumococcal conjugate |
| Hep A | hepatitis A | PPSV | pneumococcal polysaccharide |
| Hep B | hepatitis B | RV | rotavirus |
| IPV | polio | Td | tetanus, diptheria |
| Hib | haemophilus influenza type B | Tdap | tetanus, diptheria, acellular pertussis |
| HPV | human papilloma virus | VZV | varicella-zoster virus |
| Men B | meningococcal B | COVID-19 | SARS-CoV-2 |
| Men ACWY | meningococcal A, C, W-135, Y | RSV | respiratory syncytial virus |
| MMR | measles, mumps, rubella | | |

# Vaccine Management Plan

**KEEP THIS MANAGEMENT PLAN POSTED NEAR YOUR VACCINE STORAGE UNITS**

All Vaccines For Children (VFC) Providers and Adult Vaccine Program (AVP) Providers must maintain an updated and current vaccine management plan that includes information for routine and emergency situations.

Plans must be updated and reviewed annually, at a minimum. Management plans must also be updated when program requirements or assigned staff and responsibilities change. Key staff must sign the current plan annually or whenever the plan is updated.

Assigned staff must sign and date the management plan to confirm they understand and agree to the assigned duties.

## Facility/Provider Contact Information

PIN: _____

Facility/Provider Location Name: _____

Address: _____

City: _____ County: _____ Zip: _____

## Key Staff Information

| Staff Role | Name | Phone Number | Email Address |
|---|---|---|---|
| Medical Director/Physician Signing Agreement | | | |
| Primary Vaccine Coordinator | | | |
| Backup Vaccine Coordinator | | | |
| Additional Backup Coordinator | | | |

Vaccine Coordinators are responsible for ensuring that vaccines are handled and stored appropriately, that all necessary documentation is completed, and that all staff are properly trained in the storage and handling of vaccines.

All personnel will complete annual education and training on proper vaccine storage and handling.
All personnel who handle the vaccines will refer to this plan when necessary.

## Required Training

VFC Vaccine Coordinators must complete CDC's You Call the Shots Modules 10 (Storage & Handling) and 16 (Vaccines For Children) for the current year.
The Physician Signing Agreement and any additional staff are recommended to also complete the training.

Primary and Backup Vaccine Coordinators are required to complete the TRAIN courses located at: https://www.train.org/ky/training_plan/4715
Submit certificates for each course completion to the assigned Immunization Field Representative and keep copies available for review during site visits.

| Title | Name | Date Training Completed | | Signature |
|---|---|---|---|---|
| | | S&H Module 10 | VFC Module 16 | |
| Primary Coordinator | | | | |
| Backup Coordinator | | | | |
| Additional Backup Coordinator | | | | |

## Change in Medical Director/Physician Signing Agreement

Changes to the Medical Director must be reported within **2 business days** of the change by informing the assigned Field Rep via email or contacting the Enrollment Team at KYVaxProvider@ky.gov
A change in the Medical Director/Physician Signing Agreement will require the submission of an updated, signed VFC Enrollment Form.

## Change in Vaccine Coordinator

Changes to the assigned staff for the Primary and Backup Coordinator positions must be reported to the KY Immunization Branch within **10 business days** of the changes.
All changes are to be submitted in the Clinic Tools module in the KY Immunization Registry (KYIR).
Changes are limited to once every 90 days unless a result of staff departure.

Either of these changes will result in an update to this Vaccine Management Plan. Submit an updated copy of the Management Plan to the assigned Field Rep and post an updated copy immediately.

## Private Stock

Providers who serve and plan to vaccinate privately insured (non-VFC-eligible or non-Adult Vaccine Program-eligible) populations should stock a separate vaccine supply for the specific vaccines planned to offer to those non-eligible patients.

Providers who do not carry privately purchased stock are not permitted to use VFC or Adult Vaccine program stock on non-eligible patients.

## COVID-19 Vaccine Stock

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, enrolled VFC providers who do not stock COVID-19 vaccines must be aware of accessible locations and be prepared to refer VFC-eligible children accordingly.

Please detail the location's referral plan for VFC-eligible children for COVID-19 vaccinations.

## Vaccine Storage Equipment

- Stand-alone refrigerators where vaccines are stored will be capable of maintaining temperatures between 36°F to 46°F (2°C to 8°C).
- Stand-alone freezers in which vaccines are stored will be capable of maintaining temperatures below 5°F (-15°C).
    a. Select COVID-19 vaccines can be stored in special Ultra-Cold temperature freezers which maintain temperatures of -76°F to -130°F (-60°C to -90°C) based on manufacturer guidelines.
- Approved vaccine storage units will be large enough to provide an adequate capacity to store vaccine supply, including during peak back-to-school and flu season.
- Dorm-style units are never to be used for vaccine storage.
- Maintenance and repair records for all vaccine storage units must be kept on file and available for review upon request.
- Bottles of water will be placed in both storage units to help stabilize temperatures.
- Drawers/deli crispers should be removed from the vaccine storage units.
- Storage units should be located away from walls to allow for air circulation and away from direct sunlight.

| Primary Units | Unit Type | Brand | Model Number | Serial Number |
|---|---|---|---|---|
| Refrigerator | | | | |
| | | | | |
| Freezer | | | | |
| | | | | |

Vaccine storage units must be approved by Immunization Field Representatives prior to storing federal vaccines inside the unit. If purchasing a new storage unit, it's recommended to get prior approval of purchase by contacting the assigned Field Rep.

## Power Supply

- Storage units will not be connected to an outlet with a ground-flow circuit interrupter, or one activated by a wall switch.
- Storage units will be plugged directly into the wall outlet without the use of extension cords or power strips (surge protectors).
- "Do Not Unplug" signs are posted at each outlet, on the front of each storage unit, and at the circuit breakers.

## Vaccine Storage

- Vaccines are to be stored in their original packaging with the lids closed until use.
- Store vaccines in the center of the storage unit with space between the cartons and the sides and back of the unit to allow for airflow around the vaccines.
- Do not store vaccines in the door or drawers inside the unit.
- VFC and private stock must be separated and labeled.
- Rotate stock weekly so that the shortest-dated vaccine is used first. This should be documented on the temperature logs.
- Do not store food or drink in a storage unit where vaccines are stored.

## Inventory Management

- VFC and Adult 317 Vaccine Inventory must be reconciled at least once per month and within thirteen (13) days before placing an order in the Kentucky Immunization Registry (KYIR).
- Expired vaccines must be removed from the storage unit. Expired VFC and Adult/317 vaccines must be returned through a return submitted in KYIR in their original packaging.
- If the vaccine is due to expire within three (3) months and will not be used before expiration, please notify the assigned Immunization Field Rep.
- All orders must be submitted in KYIR and will be approved based on vaccine usage and current inventory on hand.
- Discard reconstituted vaccines not used within the interval allowed on the package insert of the specific vaccine.
- Do not open more than one multi-dose vial of a specific vaccine at a time.
- The Immunization Field Representative must be notified for transfer approval before any vaccine transfer or transport. All inventory transfers must also be documented in KYIR.

## Temperature Monitoring

- Record the minimum and maximum temperatures for the previous 24 hours on the Vaccine Temperature Log daily when the clinic opens.
- Visually check the current temperature of the unit displayed on the digital data logging thermometer when accessing the unit.
- If refrigerator temperatures are not between 36°F to 46°F (2°C to 8°C) or the freezer temperatures rise above 5°F (15°C), determine the cause of the out-of-range temperatures, adjust as needed, and check temperatures again within one-half hour. If the temperature is still not within range, immediately segregate (place in a bag, label “Do Not Use”) and place the vaccine into a proper working storage unit. Follow all steps included in the Temperature Excursion Protocol.
- Use calibrated digital data logging thermometers (DDL) with external detachable probes in glycol that are covered by current and valid certificates of calibration in all units where publicly funded vaccine is stored. The calibration certificates must be readily available for review during site visits.

- Download the DDL data monthly and keep on file for a minimum of three (3) years along with completed Vaccine Temperature Logs. Records must be readily available for review during site visits and upon request for review.
- Always contact the appropriate vaccine manufacturer if there is any question about the storage and handling of any vaccine and inform the Kentucky Immunization Branch.

| Primary DDLs | Brand/Model Number | Calibration Date | Calibration Expiration Date |
|---|---|---|---|
| Refrigerator | | | |
| | | | |
| Freezer | | | |
| | | | |

| Backup DDLs | Brand/Model Number | Calibration Date | Calibration Expiration Date |
|---|---|---|---|
| | | | |
| | | | |

## In Case of a Power Failure or Other Emergency

1. Do not open the refrigerator or freezer during a power outage. Place a "Do Not Open" sign on the storage units. Monitor the temperature until power is restored.
2. Determine the cause of the power failure and estimate the time it will take to restore power.
3. If the outage is prolonged (more than 4 hours) consider moving the vaccines to your backup storage locations.
4. If temperatures in the storage unit are out of recommended ranges, move the vaccine into a proper working storage unit as soon as possible and contact manufacturers for guidance. Follow the manufacturer's recommendations and report the incident to the Kentucky immunization Branch within 72 hours.

If transporting vaccines, a DDL must always remain with the vaccine.

### After Power is Restored

- Verify storage units are functioning properly and temperatures are within range before moving the vaccine back to the primary units.
- Follow the same transport procedures when moving the vaccine back to the primary unit.
- Transported vaccines must have a DDL report to show the temperatures remained in range before being used.
- If any out-of-range temperatures were recorded during the transport process, the temperature excursion protocol must be followed to determine if the vaccine is viable before use.

## Approved Backup or Alternate Storage Locations

| | Alternate Storage Location | Address and City | Point of Contact Name | POC Phone Number |
|---|---|---|---|---|
| **Refrigerator** | | | | |
| **Freezer** | | | | |

Alternate storage locations must have stand-alone vaccine storage units. Any vaccine transferred to the alternate storage location must be monitored with a DDL thermometer at all times.

## Manual Defrost

CDC currently recommends stand-alone refrigerators and stand-alone freezers for vaccine storage. It is also recommended that those units be auto-defrost (self-defrosting) units.

Manual Defrost units must be defrosted once the ice accumulation reaches ¼" thick.

If a Manual Defrost storage unit is used, a temporary storage unit should be available that can maintain temperatures for the vaccines while defrosting the main unit.

Please detail below your location's protocol for defrosting a manual defrost unit. Include how the defrost process will be completed as well as where the vaccines will be located during the process.

# Acknowledgment

Please sign and date this acknowledgment yearly, as well as when any of your location information changes.

All staff signing the acknowledgment agree that they have reviewed, understand, and agree to the assigned duties as vaccine management staff for this location.

---

Medical Director/Physician Signing Agreement: _____

Signature: _____ Date: _____

---

Primary Vaccine Coordinator: _____

Signature: _____ Date: _____

Backup Vaccine Coordinator: _____

Signature: _____ Date: _____

---

# Kentucky Public Vaccine and Eligible Populations – Private Providers (VFC-enrolled Only)

☒ Indicates eligible population at your facility ▩ Indicates ineligible population or unavailable vaccine

| Vaccine Category | Vaccines/Immunizations | Funding Source | Vaccines for Children (VFC) Categories (through 18 years) | | | | Fully Insured[3] |
|---|---|---|---|---|---|---|---|
| | | | Medicaid-Eligible | American Indian/Alaska Native | Uninsured[1] | Underinsured[2] | |
| Pediatric | DTaP<br>IPV<br>HIB<br>Hep A<br>Hep B<br>PCV15, PCV20<br>PPSV23<br>MMR<br>MMRV<br>Rotavirus<br>RSV<br>Varicella<br>Influenza<br>COVID-19 | VFC | X | X | X | Refer to FQHC, RHC, or Local Health Dept | |
| Adolescent | MenACWY<br>MenB<br>Tdap<br>HPV<br>COVID-19 | VFC | X | X | X | Refer to FQHC, RHC, or Local Health Dept | |
| KYIR Eligibility Selection | | | VFC-eligible Medicaid | American Indian/Alaska Native (<19 yrs) | Uninsured (<19 yrs) | Underinsured (<19 yrs) | Fully Insured |

[1] Uninsured: A person who has no public or private health insurance.

[2] Underinsured: A person who has health insurance, but the coverage does not include vaccines, only covers select vaccines, or coverage is capped at a certain amount. They are underinsured for the non-covered vaccines and vaccines received after exceeding the cap.

- VFC-eligible underinsured are only eligible for VFC vaccine at FQHCs, RHCs, and LHDs with a delegation of authority agreement.

[3] Fully Insured: Anyone with insurance that covers the cost of the vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

## Kentucky Public Vaccine and Eligible Populations – Private Provider Locations (Both VFC and AVP-enrolled location)

☒ Indicates eligible population at your facility  ▩ Indicates ineligible population or unavailable vaccine

| Vaccine Category | Vaccines/Immunizations | Funding Source | Vaccines for Children (VFC) Categories (through 18 years) | | | | Adult Vaccine Program (AVP) Categories (19 years +) | | Fully Insured[3] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Medicaid-Eligible | American Indian/Alaska Native | Uninsured[1] | Underinsured[2] | Uninsured[1] | Underinsured[2] | |
| Pediatric | DTaP<br>IPV<br>HIB<br>Hep A<br>Hep B<br>PCV15, PCV20<br>PPSV23<br>MMR<br>MMRV<br>Rotavirus<br>RSV<br>Varicella<br>Influenza<br>COVID-19 | VFC | X | X | X | Refer to FQHC, RHC, or Local Health Dept | | | |
| Adolescent | MenACWY<br>MenB<br>Tdap<br>HPV<br>COVID-19 | VFC | X | X | X | Refer to FQHC, RHC, or Local Health Dept | | | |
| Adult | Hep A<br>Hep B<br>Tdap/Td<br>MMR<br>HPV<br>PCV15, 20<br>PPSV23<br>Influenza<br>COVID-19 | 317 | | | | | X | X | |
| KYIR Eligibility Selection | | | VFC-eligible Medicaid | American Indian/Alaska Native (<19 yrs) | Uninsured (<19 yrs) | Underinsured (<19 yrs) | Uninsured Adult | Underinsured Adult | Fully Insured |

[1] Uninsured: A person who has no public or private health insurance.

[2] Underinsured: A person who has health insurance, but the coverage does not include vaccines, only covers select vaccines, or coverage is capped at a certain amount. They are underinsured for the non-covered vaccines and vaccines received after exceeding the cap.

- VFC-eligible underinsured are only eligible for VFC vaccine at FQHCs, RHCs, and LHDs with a delegation of authority agreement.
- AVP-eligible underinsured are eligible for AVP vaccine at any participating AVP provider.
    - For the COVID-19 Bridge Access Program, Underinsured eligibility also includes a person whose insurance does not provide first-dollar coverage for vaccines or covers only selected vaccines.

[3] Fully Insured: Anyone with insurance that covers the cost of the vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

## Kentucky Public Vaccine and Eligible Populations – FQHC, RHC, & Local Health Depts (Both VFC and AVP-enrolled)

☒ Indicates eligible population at your facility ▩ Indicates ineligible population or unavailable vaccine

| Vaccine Category | Vaccines/Immunizations | Funding Source | Vaccines for Children (VFC) Categories (through 18 years) | | | | Adult Vaccine Program (AVP) Categories (19 years +) | | Fully Insured[3] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Medicaid-Eligible | American Indian/Alaska Native | Uninsured[1] | Underinsured[2] | Uninsured[1] | Underinsured[2] | |
| Pediatric | DTaP<br>IPV<br>HIB<br>Hep A<br>Hep B<br>PCV15, PCV20<br>PPSV23<br>MMR<br>MMRV<br>Rotavirus<br>RSV<br>Varicella<br>Influenza<br>COVID-19 | VFC | X | X | X | X | | | |
| Adolescent | MenACWY<br>MenB<br>Tdap<br>HPV<br>COVID-19 | VFC | X | X | X | X | | | |
| Adult | Hep A<br>Hep B<br>Tdap/Td<br>MMR<br>HPV<br>PCV15, PCV20<br>PPSV23<br>Influenza<br>COVID-19 | 317 | | | | | X | X | |
| KYIR Eligibility Selection | | | Medicaid eligible (<19 yrs) | American Indian/Alaska Native (<19 yrs) | Uninsured (<19 yrs) | Underinsured (<19 yrs) | Un/Underinsured Adult | Un/Underinsured Adult | Insured Not Eligible |

[1] Uninsured: A person who has no public or private health insurance.

[2] Underinsured: A person who has health insurance, but the coverage does not include vaccines, only covers select vaccines, or coverage is capped at a certain amount. They are underinsured for the non-covered vaccines and vaccines received after exceeding the cap.

- VFC-eligible underinsured are only eligible for VFC vaccine at FQHCs, RHCs, and LHDs with a delegation of authority agreement.
- AVP-eligible underinsured are eligible for AVP vaccine at any participating AVP provider.
    - For the COVID-19 Bridge Access Program, Underinsured eligibility also includes a person whose insurance does not provide first-dollar coverage for vaccines or covers only selected vaccines.

[3] Fully Insured: Anyone with insurance that covers the cost of the vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

# Kentucky Public Vaccine and Eligible Populations – Vaccines for Children-enrolled Birthing Hospital locations

**Eligibility screening and documentation is required for all doses administered.**

## Hepatitis B Birth Dose and RSV Monoclonal Antibody Immunizations

Hepatitis B and RSV Monoclonal Antibody immunizations are available through the VFC program for eligible newborns. Eligibility includes Medicaid eligible, American Indian/Alaska Native, or Uninsured.

- Underinsured is only available through FQHCs, RHCs, Local Health Departments, or locations with a delegation of authority agreement.
- VFC-supplied stock is not available for Fully Insured eligibility patients.

Fully insured newborns are not covered through the VFC program and must be administered a privately purchased dose.

- This includes newborns receiving the birth dose of Hepatitis B vaccine before hospital discharge, in which the vaccine is included in a bundled delivery or global delivery package.

☒ Indicates eligible population at your facility ▩ Indicates ineligible population or unavailable vaccine

| Vaccine Category | Vaccines/Immunizations | Funding Source | Vaccines for Children (VFC) Categories (through 18 years) | | | | Fully Insured[3] |
|---|---|---|---|---|---|---|---|
| | | | Medicaid-Eligible | American Indian/Alaska Native | Uninsured[1] | Underinsured[2] | |
| Birth Dose | Hep B | VFC | X | X | X | Refer to FQHC, RHC, or Local Health Dept | |
| Birth Dose | RSV Monoclonal Antibody | VFC | X | X | X | | |
| KYIR Eligibility Selection | | | VFC-eligible Medicaid | American Indian/Alaska Native (<19 yrs) | Uninsured (<19 yrs) | Underinsured (<19 yrs) | Fully Insured |

[1] Uninsured: A person who has no public or private health insurance.

[2] Underinsured: A person who has health insurance, but the coverage does not include vaccines, only covers select vaccines, or coverage is capped at a certain amount. They are underinsured for the non-covered vaccines and vaccines received after exceeding the cap.

- VFC-eligible underinsured are only eligible for VFC vaccine at FQHCs, RHCs, and LHDs with a delegation of authority agreement.

[3] Fully Insured: Anyone with insurance that covers the cost of the vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

### *Eligibility Screening Tool for Hepatitis B vaccines and RSV monoclonal antibody immunizations*

| Mother's Insurance Status | Newborn's Eligibility | VFC Eligible |
|---|---|---|
| Uninsured | Uninsured | Yes |
| Medicaid Coverage | Medicaid-Eligible | Yes |
| Private Insurance | Fully Insured | No |

# Screening and Documenting Eligibility

## Requirements

Eligibility screening results must be:

- Documented for all eligibility categories served, including privately insured (not VFC eligible) and AI/AN.
- Documented at every immunization visit.
- Associated with the patient and the visit date or immunization.
- Documented through a process that informs clinicians what vaccine stock to use.
- Documented in a way that can be tallied to obtain annual Provider Profile numbers.
- Retained for three years.
- Made available to Immunization Program staff on request and during compliance site visits.

## Methods of Documenting Eligibility

Below are typical methods used to document eligibility:

**KYIR (Kentucky Immunization Registry)**

Providers who manually hand-enter administered immunizations into KYIR and deduct doses from their inventory document eligibility as part of this process, and this can serve as eligibility documentation. If data entry is current and accurate, KYIR automatically calculates Provider Profile numbers for annual program re-enrollment.

**Electronic Health Record Systems (EHR)**

Providers who use an EHR that is connected to KYIR through the KY Health Information Exchange (KHIE) can document eligibility in their EHR system. EHRs can be used to document eligibility as long as the information is associated with an immunization or visit date and is not solely in the demographic/personal information fields.

**Facility Name: _____**
**Pin #: _____**

# VACCINE BORROWING REPORT

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. Administer and record the payback dose within 30 days from the borrowing event.**

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
- 317 accidentally used for a VFC- eligible child or non-VFC eligible child

## HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7 Other or 13 Other) 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 VFC dose for a private patient | 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 Private dose for a VFC eligible patient | 12 |
| Other – Describe: | 13 Other |

## WHAT TO DO WITH THIS FORM:

- Submit to your VFC Field Representative
- Completed forms must be retained as a VFC program record and made available to the Kentucky Immunization Program upon request.

**Facility Name: _____**
**Pin #: _____**

**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 & KYIR ID#** | **D** **Patient DOB** (XX/XX/XX) | **E** **Date Dose Administered** (XX/XX/XX) | **F** **Reason Appropriate Vaccine Stock was not Used.** | **G** **Date Dose Returned to Appropriate Stock** (XX/XX/XX) | **H** **Patient DOB** (XX/XX/XX) | **I** **Patient Name & KYIR ID# Receiving Returned Dose (30-day deadline to administer returned dose)** |
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**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:** |
|---|---|---|
| | | |

**Kentucky VFC Monthly FREEZER Temperature Log**

VFC Pin: _____ Month/Year: _____

**Take immediate action if temperature is too high (above -15°C or 5°F)!**

| Day | Time | Min Temp | Max Temp | Staff Initials | Alarm/Action Taken | Weekly Stock Rotation |
|---|---|---|---|---|---|---|
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
| 5 | | | | | | |
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| 31 | | | | | | |

**Record the min/max temperatures daily at the opening of the clinic of the previous 24 hours. If are alarms showing, take immediate action.**
**Rotate stock weekly, moving vaccines expiring first in front of other vaccines to ensure use.**

**Kentucky VFC Monthly REFRIGERATOR Temperature Log**

VFC Pin: _____ Month/Year: _____

**Take immediate action if temperature is too low (below 2°C or 36°F) or too high (above 8°C or 46°F)!**

| Day | Time | Min Temp | Max Temp | Staff Initials | Alarm/Action Taken | Weekly Stock Rotation |
|---|---|---|---|---|---|---|
| 1 | | | | | | |
| 2 | | | | | | |
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| 29 | | | | | | |
| 30 | | | | | | |
| 31 | | | | | | |

**Record the min/max temperatures daily at the opening of the clinic of the previous 24 hours. If are alarms showing, take immediate action.**
**Rotate stock weekly, moving vaccines expiring first in front of other vaccines to ensure use.**

# Temperature Excursion Protocol

If vaccines are exposed to inappropriate storage conditions, the viability of the vaccines may be affected. In the event of a temperature excursion or an alarm of the digital data logger, follow the steps below:

1. Consult your Vaccine Management Plan and ensure the primary and/or backup vaccine coordinator is notified.
2. Take an inventory of the affected vaccines, place them in a brown paper bag labeled "DO NOT USE" or label the outside of the storage unit with “DO NOT USE”.
3. If the primary storage unit is at acceptable temperatures, vaccines may remain in the unit. If the primary unit is still showing temperatures out-of-range, move the vaccines to the back-up storage location.
4. Download the digital data logger information to determine the length of the excursion and the temperatures reached.
5. Contact the vaccine manufacturers with the information gathered from the digital data logger. You will need to supply them with the vaccine name, the total amount of time they spent out of range and the temperatures that were recorded during that time. The manufacturer’s stability representative will supply you with a case number and a determination of the vaccine’s viability. If the manufacturer offers an on-line stability calculator, you may use those, include a printed copy of the results with your completed incident report.

   Merck 1-800-672-6372
   Sanofi Pasteur 1-800-822-2463
   GlaxoSmithKline 1-877-475-6448
   Seqirus 1-855-358-8966
   AstraZeneca 1-877-533-4411
   Dynavax Technologies 1-844-375-4728
   Pfizer 1-800-438-1985 or email cvgovernment@pfizer.com
   Moderna 1-866-MODERNA (1-866-663-3762) or email excursions@modernatx.com
   Janssen 1-800-565-4008 or email jscovidtempexcursions@its.jnj.com
   Bavarian Nordic 1-844-422-8274

6. Complete a Vaccine Storage & Handling Incident Report and send to your Field Representative or email to VaxColdChain@ky.gov

Inappropriate storage conditions and all mechanical malfunctions or power outages must be documented on the Incident Report.

Mark the boxes of vaccines deemed viable by the vaccine manufacturers after an excursion to easily determine if the same inventory is exposed in the event of another excursion.

Vaccines deemed non-viable and inadvertently administered should not be counted as valid doses and appropriate VAERS report should be completed.

Do not create a return or discard non-viable vaccines until your Field Representative or the Storage & Handling Coordinator provides further instructions.

# Vaccine Storage Incident Report

Clinic Name: _____ PIN: _____

Vaccine Coordinator Name: _____ Phone: _____

Email: _____

Send a completed incident report, signed by the provider, to assigned Immunization Field Rep or to VaxColdChain@ky.gov

## Incident Information

Date & Time of Incident: _____

| | | | |
|---|---|---|---|
| Which unit was involved in the excursion? | Refrigerator | | Freezer |
| Select the type of unit | Purpose Built | Pharmaceutical grade | Stand-Alone |
| Are the unit temperatures back within range? | Yes | | No |
| Have the vaccines previously been exposed in a temperature excursion | Yes<br>Date of previous excursion: | | No |
| What were the minimum and maximum temperatures? | Min °F: | | Max °F: |
| How long were the temperatures out of range? | Hours: | | Mins: |
| Were there water bottles in this unit? | Yes | | No |
| Have any of the vaccines been administered after the temperature incident occurred? | Yes | | No |

Incident Cause:

- ☐ Weather related power outage
- ☐ Failure to store properly upon receipt
- ☐ Equipment malfunction
- ☐ Damaged in shipment
- ☐ Failure to respond to out-of-range temperatures
- ☐ Other:_____

## Affected Vaccines

| **Inventory** | | | | **Manufacturer's Instructions** | | |
|---|---|---|---|---|---|---|
| **Vaccine** | Lot Number | Expiration Date | # of doses | Instructions | Case Number | Viable? |
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**Detailed description of the incident**: Please describe when, where, and how the incident occurred.

Written detailed action taken (include time and dates):

_____

_____

_____

_____

_____

_____

**Corrective Action Plan**: What steps are being taken to ensure similar loss does not occur in the future?

_____

_____

_____

_____

_____

_____

Signature of person completing this report: _____ Date: _____

Required Signature of Medical Director: _____Date: _____

# Kentucky Immunization Branch

## Vaccine Transfer Form

**Monitor and record current temperatures on this form every hour during transport.**

**Transferring Location:**

**PIN:_____ Clinic Name: _____**

**Receiving Location:**

**PIN:_____ Clinic Name: _____**

**Instructions:**

- **Check temperatures hourly using a Digital Data Logging Thermometer that complies with KY Immunization Program requirements.**
- **Punctured vials and pre-drawn syringes should not be transported between providers.**
- **All vaccine inventory transfers MUST be completed in KYIR.**
- **Vaccines can only be transported in approved vaccine transport units. Vaccine shipping containers, food coolers, etc. are not approved for vaccine storage or transport.**
- **Check temperatures hourly using a Digital Data Logging Thermometer that complies with KY Immunization Program requirements.**
- **Care should be taken to make sure vaccines are kept covered as many are light sensitive. Vaccines should be wrapped in bubble wrap or other dunnage to prevent vibration and shaking.**

**Refrigerated vaccine safe temperature ranges are 36.0° to 46.0° Fahrenheit (2.0° to 8.0° Celsius).**

**If the temperature goes out of range at any time, do the following:**

1. **Do not use doses exposed to out-of-range temperatures.**
2. **Post a "Do not use" sign.**
3. **Ensure the data logger probe remains in place next to the vaccines and continues recording.**
4. **Store vaccines under proper conditions as soon as possible.**
5. **Contact the manufacturers with the times and temperatures reached to determine vaccine viability. Complete and submit an Incident Report to the KY Immunization program and notify the assigned Field Representative.**

| Starting Location Temperature | Temperature | Staff Initials |
|---|---|---|
| Storage Unit Temperature | °C/°F | |

| Transport Time & Temp | Start of Transport | End of Transport |
|---|---|---|
| Transferring Unit Temperature | °C/°F | °C/°F |
| Time of Transfer | AM/PM | AM/PM |

**Have any of the vaccines been exposed to a prior temperature excursion? ☐ Yes ☐ No**
**If yes, what was the max or min temperature and the total time of exposure?**

_____

## Vaccine Transfer Log

| Time | Staff Initials | Current Temp |
|---|---|---|
| | | |
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**List all vaccines included in the vaccine transfer event below.**
**Keep all records on file for the minimum of three years as required for the VFC and Adult Vaccine programs.**

| Vaccine | Lot Number | Funding Source | Quantity |
|---|---|---|---|
| | | | |
| | | | |
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| | | | |

| Receiving Unit Time & Temp | |
|---|---|
| Storage Unit Temperature | °C/°F |
| Time of Transfer Completion | AM/PM |

| Transferring Staff Signature | Date | Time |
|---|---|---|
| | | AM/PM |
| Receiving Staff Signature | Date | Time |
| | | AM/PM |

**Signing staff attest to the above documented temperatures and verified vaccine counts completed within the stated transport time.**

# Temporary, Mobile, Off-Site, or Satellite Clinics for VFC/AVP Providers

Kentucky Vaccines for Children (VFC) and Adult Vaccine Program (AVP) providers are allowed to include a mobile/off-site immunization clinic in their practice under certain conditions. The mobile/off-site immunization clinic is an extension of the provider's practice and will use the same unique VFC/AVP provider identification number (PIN) assigned to the provider. The mobile/off-site immunization clinic must also comply with all VFC/AVP requirements including eligibility screening and documentation listed in the Provider Agreement and adhere to all general VFC/AVP storage and handling requirements.

## Temporary, Mobile, Off-Site, or Satellite Clinic Requirements:

1. The provider must be enrolled in the VFC or Adult Vaccine program and good standing.
2. Mobile/Off-site Immunization clinics may only be conducted within the state of Kentucky. VFC or AVP-eligible patients are not required to be Kentucky residents to receive vaccinations.
3. Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement.
    - Vaccines are only transferred to the mobile unit/clinic on the day of the clinic.
4. The number of vaccines transported to a temporary, mobile, off-site, or satellite clinic should be based on the anticipated number of VFC or AVP-eligible patients to be served.
5. The provider must complete the **Mobile Immunization Clinic Log** that lists the clinic dates, locations, and the vaccine amounts, by fund type (VFC, Private, etc.), that will be transported to each mobile clinic and/or off-site location.
6. Vaccines must be transported to a temporary site using an approved cold cube or transport unit (ex. Engel portable refrigerator).
    - This includes transporting vaccines to and from the site using appropriate equipment, monitoring temperatures with a Digital Data Logging (DDL) thermometer, and documenting temperatures.
    - Transport should not take longer than 30 minutes.
7. Only staff that know how to transport vaccines should be utilized.
8. Vaccine storage and handling equipment during the mobile/off-site clinic must meet CDC requirements:
    - A portable vaccine refrigerator or qualified container and pack-out. An emergency pack-out cooler is not approved for mobile clinic use.

- VFC-compliant DDL(s) with a probe in buffered material for temperature monitoring at all times during the transport and event.

9. Vaccines must be stored correctly upon arrival at the temporary site to maintain appropriate temperature throughout the clinic day.
10. Temperature data must be reviewed and documented on a temperature log every hour during the clinic using a DDL with a digital display and probe in buffered material.
11. The provider must keep all data logger reports from mobile clinics with all VFC documentation. All documentation must be available upon request.
12. If the vaccines are exposed to out-of-range temperatures, isolate the vaccines in the affected unit, label them DO NOT USE, and keep them in the affected unit. Do not administer any doses exposed to out-of-range temperatures. The affected vaccines must be returned to appropriate temperature storage as soon as possible. At the end of the excursion time, temperature data must be submitted to the manufacturers to determine viability. Follow all guidance in the Temperature Excursion Protocol and submit a completed Incident Report to VaxColdChain@ky.gov
13. At the end of the clinic day, temperature data must be assessed prior to placing the vaccines back into storage units with other VFC/AVP vaccines to prevent the administration of vaccines that may have been compromised.
14. All documentation related to vaccine management must be kept on-site and on file for three (3) years at the provider's office. All documentation must be available upon request.
15. All immunizations administered must be entered into KYIR.

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

- Do not draw up vaccines before arriving at the clinic site. Drawing up doses days or even hours before a clinic is not acceptable.
- Use manufacturer-filled syringes, if possible.
- If pre-drawing must be utilized for clinic workflow, no more than one multi-dose vial (MDV) should be drawn up at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in pre-drawn syringes once they have reached their Beyond Use timeframe. Never return the pre-drawn dose to the vial. Any remaining pre-drawn doses must be discarded at the end of the clinic workday.

# Kentucky Vaccines for Children and Adult Vaccine Program
# Mobile Immunization Clinic Log

**This form is to be used at non-traditional vaccination sites such as temporary, mobile, off-site or satellite clinics.**

**Monitor and record current, MIN, and MAX temperatures on this form every hour.**

**PIN:_____ Clinic Name: _____**

**Instructions:**

**Check temperatures hourly using a Digital Data Logging Thermometer that complies with KY Immunization Program requirements.**

**Refrigerated vaccine safe temperature ranges are 36.0° to 46.0° Fahrenheit (2.0° to 8.0° Celsius).**

**If the temperature goes out of range at any time, do the following:**

1. **Do not use doses exposed to out-of-range temperatures.**
2. **Post "Do not use" sign.**
3. **Alert the on-site supervisor.**
4. **Ensure the data logger probe is still in place next to the vaccines and recording.**
5. **Store vaccines under proper conditions as soon as possible.**
6. **Contact the manufacturers with times and temperatures reached to determine viability of the vaccine. Complete and submit an Incident Report to the KY Immunization program and notify the assigned Field Representative.**

## Hourly Vaccine Temperature Log

| Date | Event Location | Storage Unit |
|---|---|---|
| | | |

| Time | Initials | Current Temp | MIN | MAX |
|---|---|---|---|---|
| | | | | |
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# Kentucky Vaccines for Children and Adult Vaccine Program
# Mobile Immunization Clinic Log

**Location of Mobile Clinic: _____**

**Staff Responsible for Vaccine Transport & Monitoring During Mobile Clinic:**

**_____**

**List all vaccines included in the mobile vaccination event below.**

**Keep all records on file for a minimum of three (3) years as required for the VFC and Adult Vaccine programs. All documentation must be made available upon request.**

| Date | Location | Vaccine | Lot Number | Funding Source | Starting Amount | Ending Amount |
|---|---|---|---|---|---|---|
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# Kentucky Immunization Branch

## Vaccine Storage Units and Data Logger Requirements

### Vaccine Storage Units

**Approved** vaccine storage units must be stand-alone refrigerators and freezers that demonstrate the following:

- Able to maintain stable in-range temperatures.
    A. Refrigerator temperatures between 36°F and 46°F (2°C to 8°C).
    B. Freezer temperatures between -58°F and 5°F (-50°C to -15°C).
- Possess the capacity to store the practice's largest expected vaccine inventory with appropriate separation to maintain airflow and sufficient water bottles to stabilize temperatures of holding the clinic's largest expected inventory with appropriate separation to maintain airflow. (See appropriate storage unit capacity calculations below.)
- Defrost automatically. Manual defrost for freezer units is acceptable if the practice has access to alternate storage units for vaccines during the defrost process.
- Temperatures are monitored by a calibrated, digital data logger[1] that records 24 hours, 7 days a week. (See digital data logger requirements below.)
- One of the CDC-recommended appliance types:
    A. Pharmaceutical-grade[2] – stand-alone[3] or combination[4] unit, or
        - Solid door units are recommended as best practice to protect light-sensitive vaccines.
    B. Household-grade[5] stand-alone unit.

A. B.

The following storage unit types are **prohibited** for vaccine storage at any time:

- Dormitory-style storage units[6], and
- Household-grade combination units – including both refrigerator and freezer sections.
- Household-grade beverage coolers or wine fridges

[1] A digital, continuous monitoring thermometer.
[2] Designed to store pharmaceuticals in a laboratory or pharmacy setting.
[3] An appliance that is either a refrigerator or freezer.
[4] An appliance with both a refrigerator and freezer chamber.
[5] Appliances typically found in homes and sold at retail appliance stores.
[6] A refrigerator with a small freezer inside the refrigerator chamber and only one external door.

# Kentucky Immunization Branch

## Vaccine Storage Units and Data Logger Requirements

### Appropriate Storage Unit Capacity Calculations

Calculate the largest number of doses on hand for the refrigerator and freezer to determine the size of the storage unit needed. Include seasonal flu doses and private stock if all are to be stored in the same unit.

- Multiply the maximum number of doses by 1.25 to account for spacing for appropriate airflow.
- Use this number with the chart below to determine the minimum $ft^3$ needed.

| Refrigerator | | Freezer | |
|---|---|---|---|
| Maximum Doses | Minimum $Ft^3$ Required | Maximum Doses | Minimum $Ft^3$ Required |
| 1001-2000 | 40 | 501-600 | 7-14.8 |
| 900-1000 | 36 | 201-500 | 5-5.6 |
| 801-900 | 21-23 | 0-200 | 3.5-4.9 |
| 701-800 | 17-19.5 | | |
| 401-700 | 11-16.7 | | |
| 100-400 | 4.9-6.1 | | |

### Digital Data Logging Thermometers

Data loggers are digital thermometers capable of continuously monitoring and recording temperatures on a predetermined schedule.
Vaccine providers must have a data logger in each public vaccine storage unit and any transport coolers. A backup calibrated data logger must be kept on hand for use as needed.

An approved digital data logger will have the following features:

- A detachable probe that best reflects vaccine temperatures. It is required to have a bio-safe glycol-encased probe. The probe is to be positioned in the center of the unit away from any vents and walls of the unit.
- A digital temperature display that attaches to the outside of the storage unit that shows the current, minimum, and maximum temperatures.
- An alarm to indicate out-of-range temperature excursions.
- A visible low battery indicator.
- A logging interval that can be programmed by the user to measure and record temperatures at least every 10 minutes.
- Generate reviewable data files upon demand, shared with the vaccine program monthly at a minimum, maintained for 3 years, and shared with program staff upon request.
- Have a current certificate of calibration testing with a valid expiration date.

Data loggers built-in to storage units may be approved if they meet all the requirements listed above.

A valid certificate of calibration must include:

- Model/device name or number and serial number
- Date of calibration – report or issue date
- Confirmation that the instrument passed testing (or is within tolerance) per ISO 17025
- A recommended uncertainty of ±1°F (±0.5°C) or less
- An expiration date in accordance with the manufacturer's recommendation. If there is no manufacturer recommendation for calibration testing, write the "In Use" date on the certificate. The certificate will expire one year from the in-use date or 2 years from the issue date, whichever occurs first.

Sample Compliant Data Loggers:
*List is not exhaustive.*

Control Solutions – VFC Compliant Dataloggers

Onset InTemp – VFC Compliant Dataloggers

Traceable – VFC Compliant Dataloggers

# DIGITAL DATA LOGGING THERMOMETER CHECKLIST

There are many brands available that meet the requirements for digital data logging thermometers (DDLs) needed for the Kentucky Vaccines for Children and Adult Vaccine Programs.
Use this checklist to determine if the chosen digital data logging thermometer meets the program requirements. The device purchased must meet all components listed under **REQUIRED FEATURES**.

Providers need a separate DDL thermometer for each storage unit that holds vaccines. A certified, calibrated back-up DDL must be located on site (not currently in use in the storage unit) for use in case the primary thermometer is no longer working properly or calibration testing is required.

All calibration certificates shall be on file and easily accessible during site visits and to determine when recalibration is necessary.

| REQUIRED FEATURES FOR DDL | |
|---|---|
| ☐ | Accuracy of +/- 1.0°F (+/- 0.5°C) for refrigerator and freezer |
| ☐ | Visual or audible alarm for out-of-range temperatures |
| ☐ | Low battery indicator |
| ☐ | Display with current, minimum, and maximum temperatures that attaches to the outside of the storage unit |
| ☐ | User-programmable logging interval (or reading rate), a minimum of every 10 minutes |
| ☐ | Detachable buffered temperature probe – bio-safe glycol-encased probe |
| ☐ | A valid and current Certificate of Calibration confirming the instrument passed testing per ISO 17025 standards |
| ☐ | Generates summary reports of recorded temperatures that include all readings, minimum and maximum temperatures, total time out of range (if any), and alarm settings |
| **REQUIRED FEATURES FOR CERTIFICATES OF CALIBRATION** | |
| ☐ | Model/device name or number |
| ☐ | Serial number |
| ☐ | Date of calibration (report or issue date) |
| ☐ | Confirmation of passed testing (or instrument is within tolerance) per ISO 17025 standards |
| ☐ | Tolerance testing uncertainty of +/- 1°F (+/- 0.5°C) or less |
| ☐ | Expiration date per the manufacturer's recommendation<br>• If no manufacturer recommendation, write the in-use date on the certificate. It will expire one year from the in-use date or 2 years from the issue date, whichever occurs first. |

| OTHER CONSIDERATIONS |
|---|
| Are calibration services provided by the vendor? |
| Is there training provided on how to set up and use the data logger? |
| Will the device be ready to use out of the box, or will it need additional accessories? |
| Does the device require software installed to set the alarm settings and download temperature reports? |
| Is authorization required to install device software for your practice? |

# Digital Data Logging Thermometer Setup & Use

Use these instructions to configure primary and backup Digital Data Logging (DDL) thermometers. Refer to your device's product or user guide to learn how to use it. Call the vendor's support number for all questions regarding setup and functionality.

## Set Up Your Device

1. Open the box and retrieve its contents.
    - Store the certificate of calibration in the vaccine program binder.
    - Locate the vendor's support number for assistance with setup.
    - Review the manufacturer's operating system requirements and any training video or product guide.
    - Ensure you have all necessary equipment to operate the device (e.g., Wi-Fi, flash drive, smart device, tablet, etc.).
2. Place the buffered probe vertically in the center of the vaccine storage unit and leave there at all times.
    - Slide the probe cable through the hinge side of the door (use the port hole for pharmacy-grade units if available) and close the storage unit door. Be careful not to pinch or bend the probe cable.
    - Place backup DDL buffered probe in the storage unit to ensure it is conditioned and ready to use.
    - Place the probe in a central area directly with the vaccines, but not in the doors, near or against the walls, close to vents, or on the floor of the unit.
3. Set up and prepare your device following any configuration prompts.
    - Install software indicated by the manufacturer based on device make and model.
    - Assign a device name to the DDL
    - Determine how the DDL will communicate temperature alarms (e.g., audible alarms, visual light/icon, or text/email alerts).
    - Configure alarms to alert immediately and continuously when temperatures are out of range.
    - Set readings to be recorded at least every 10 minutes.
    - Configure settings for temperature logging and alarms. Use the limits shown below.
        - Refrigerator:
            - Lower Alarm: 35.9°F (1.9°C) after 2 consecutive readings
            - Upper Alarm: 46.1°F (8.1°C) after 3 consecutive readings
        - Freezer
            - Lower Alarm: -58.1°F (-50.1°C) after 3 consecutive readings
            - Upper Alarm: 5.1°F (-14.9°C) after 3 consecutive readings
4. Place or mount the digital display outside the storage unit so temperatures are visible without opening the storage unit door.
    - Attach the digital display to the probe cable.
5. Ensure the device is set to begin monitoring vaccine temperatures.

## Learn How to Use Your Device

1. Get familiar with the DDL using manufacturer's training materials.
    - Locate the CURRENT, MIN, and MAX readings. Readings might appear on the digital display or be accessed by menu buttons (for example, Review, Start, or Display).

- Ensure all staff can locate all device icons and symbols indicating an alarm has been triggered.

2. Practice retrieving temperature data files (e.g., download, upload, or export depending on device).
   - Locate excursion time/date, MIN/MAX readings, and total time above or below alarm limits.
   - Locate the summary report that includes MIN/MAX readings, alarm settings, and total time out of range (if any) since device reset.
3. Save the temperature data file to your computer or cloud account.
   - Note where data files will be saved on your computer. Print the summary report to keep in the Vaccine Program binder.
4. Resume temperature recording after data downloads.
   - After download, ensure device memory has been cleared, settings are correct, and the device has restarted recording after reconnection to the probe cord.
5. Update your Vaccine Management Plan with the primary and backup DDL device information.
   - The Vaccine Management Plan must include information on device maintenance and calibration schedules.

## Daily Temperature Monitoring

1. Record MIN and MAX temperatures for the previous 24-hour period on the monthly temperature log at the start of each workday.
   - If any temperatures are out of range, take action immediately.
2. Remind all staff to check the DDL device for in-range temperatures and any potential alarm notifications whenever accessing the vaccine storage units.