Kentucky Vaccines for Children Program

Provider Manual

July 1, 2021 – June 30, 2022

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Department for Public Health
Division of Epidemiology and Health Planning
Kentucky Immunization Branch
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KENTUCKY CABINET FOR
HEALTH AND FAMILY SERVICES

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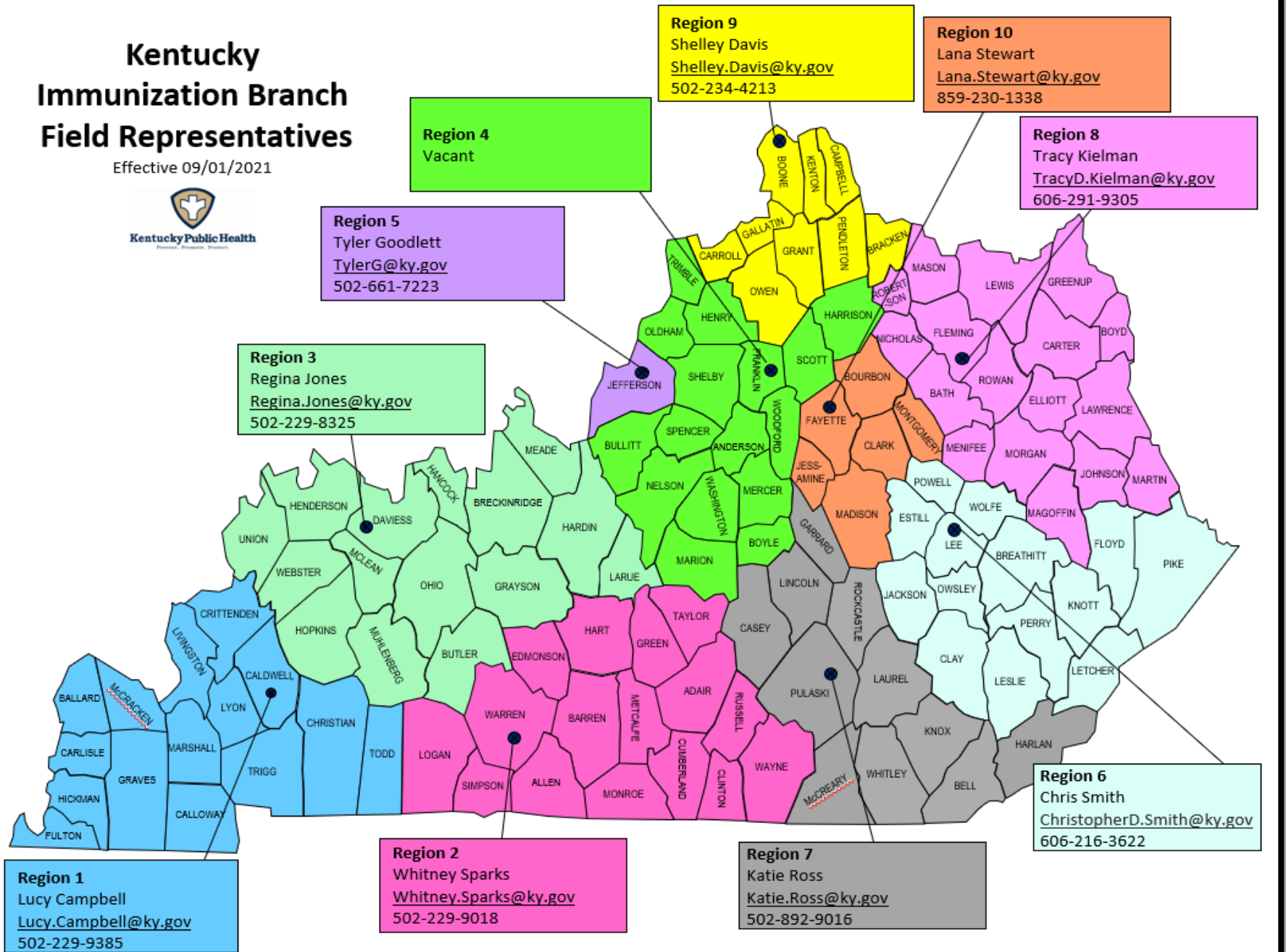KYIR Helpdesk Administrator – Skylar Johnson

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Effective 09/01/2021

Kentucky Public Health
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VFC Program Requirements Summary	
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	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 valid calibration certificate) as a backup, if needed. Providers are responsible for the re-calibration 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 on a monthly basis.
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: DTaP, Hepatitis A and B, HIB, HPV, Influenza, Meningococcal ACWY and B, MMR, Pneumococcal, Polio, Rotavirus, Tdap/Td, and Varicella as single or combination presentations.
Ordering	Proper ordering and inventory management prevents vaccine waste and ensures appropriate stock is available by vaccine type. A VFC Provider must place an order, at a minimum, of once per calendar year in order to remain on the program. In order to place an order, there must be a current balanced reconciliation for each storage unit within the past 13 days.

Receiving	Appropriate trained staff must be available and onsite to receive vaccine shipments. All vaccine orders are delivered in accordance with reported clinic hours of operation.
Inventory Management	Vaccines should be used on the "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. Inventory reconciliations are required monthly (at a minimum) in order to monitor vaccine use, loss, and ordering needs.
Borrowing	Providers are required to maintain inventories of vaccine to administer to both private and public funded children that they serve. Borrowing is permitted only in rare, unplanned circumstances.
Transfers	Transfers of vaccine should be rare and not routinely occur. The Provider must contact and gain approval from their assigned Immunization Field Representative before 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. All expired VFC vaccine 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 vaccine must follow all VFC requirements in addition to enhanced storage and handling practices. All off-site clinics must have approval of assigned Immunization Field Representative.
Temperature Excursions	Once 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 vaccine must be documented in KYIR on monthly reconciliations.
Restitution	The KY Immunization Branch reviews all vaccine loss to determine if it was avoidable or unavoidable. VFC Providers are responsible for repayment of avoidable vaccine loss. The Provider may be required to replace the lost vaccine with 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. The failure to follow the requirements could lead to fraud and abuse of the VFC Program.

Introduction

Vaccines for Children Program

The Vaccines for Children (VFC) program was created as part of the federal Omnibus Budget Reconciliation Act, Section 1928 of the Social Security Act, in August 1993. VFC is a federally funded entitlement program, ensuring 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 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 projects. About ninety percent of these funds are used for vaccine purchase. 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, keeping children in their medical home for comprehensive health care.

The Kentucky Immunization Branch, a part of the Department for Public Health, manages the VFC program at the state and local levels by working closely with providers to help develop and implement systems to assess immunization levels statewide.

ACIP Deliberations and Vaccine Coverage

The Advisory Committee on Immunization Practices (ACIP) is an expert advisory committee whose role is to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Director, Centers for Disease Control and Prevention (CDC), regarding the most appropriate application of antigens and related agents (e.g., vaccines, immune globulins) for effective disease control in the civilian population.

The ACIP meets three times each year. At these meetings, the committee may vote on the inclusion of new vaccines into the VFC program or the modification of existing resolutions. These decisions are codified as VFC resolutions and are considered separate from any other recommendations made by the ACIP.

VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine supply and usage. VFC vaccine must be administered in accordance with ACIP guidelines established through VFC resolutions. Requirements must also be applied in conformity with state-school attendance requirements. Deviation is not permitted.

Administrative Policies

Eligibility Screening

VFC Providers must possess a working knowledge of all VFC eligibility criteria and use those criteria to screen children prior to administering VFC vaccines.

For the purposes of the VFC program, if, on the day of the visit, a child presents with health insurance and coverage for vaccine is not known (i.e. not verified) by the provider, the child must be treated as though they are insured for all vaccines. 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 providers must screen for and document VFC eligibility at each immunization visit. 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 VFC vaccine and that administration fees are billed for as appropriate. Eligibility status must be readily available to staff administering vaccine prior to selecting which vaccine stock to use.

Patient Eligibility

Children through 18 years of age that meet at least one of the following criteria are eligible for VFC vaccine under federal guidelines:

Medicaid- eligible- a child who is eligible or enrolled in the Medicaid program

Uninsured- a child who has no health insurance coverage

American Indian or Alaska Native- as defined by the Indian Health Services Act

Underinsured - A child who has commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (VFC-eligible for non- covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

Underinsured children may only receive VFC vaccine through a Federally Qualified Health Center, Rural Health Clinic, or any local health department in Kentucky.

KCHIP - Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the Federal VFC program; however, KCHIP children can receive vaccines via the VFC Program through an agreement between the Department for Public Health and the Department for Medicaid Services. When a patient presents with a Medicaid card please go to the Medicaid website at:

https://www.kymmis.com/kyhealthnet/provider/eligibility/recipients.aspx to verify if patient is Medicaid or KCHIP eligible. Designation of P7 on this site indicates the child is KCHIP eligible and not Medicaid eligible.

Federally Qualified Health Center (FQHC) – FQHCs are community-based healthcare providers who offer services in underserved areas. These may include Community Health Centers, Migrant Health Centers, and special health facilities such as those for the homeless. FQHCs receive funding from the Human Resources and Services Administration, while "look-alikes" meet the FQHC qualifications, but are not federally funded.

Rural Health Clinic (RHC) – The RHC program was funded for two purposes: 1) to increase access to health care for rural underserved communities, and 2) expand the use of nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) in rural communities. To be eligible for designation as

an RHC, a clinic must be located in a Health Professional Shortage Area, Medically Underserved Area, or a Governor-Designated Shortage Area.

Billing Practices

VFC providers must adhere to proper billing practices for vaccine administration fees and clearly understand that VFC vaccine is provided at no cost to both the VFC provider and eligible children. At no time should billing occur for the cost of VFC vaccine. When administering VFC vaccine, providers should never bill two different "payers" (i.e. patient, Medicaid, insurance) for the same vaccine administration fee amount. For Medicaid-eligible children, Medicaid should be billed for the vaccine administration fee. For all other VFC-eligible populations, the patient may be billed within the state/territory cap established by the Centers for Medicare and Medicaid (CMS), which is $19.93 per vaccine in Kentucky. However, patients cannot be turned away or reported to collections for inability to pay the administration fee.

Effective January 1, 2020, providers who choose to 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.

Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

VFC Eligibility and Insurance Situations		
Child's Insurance Status	VFC Eligible?	VFC Eligibility Category
Enrolled in Medicaid	Yes	Medicaid
Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Yes	- Insured until the fixed dollar limit is met - Underinsured after the fixed dollar limit is reached
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured. Child can only receive vaccines not covered by the plan through VFC program.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare.

Enrolled in a Health Care Sharing Ministry	Depends	- Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan - Insured if plan is recognized by the state insurance department and covers vaccines - Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines
Enrolled in Kentucky's Children's Health Insurance Program (KCHIP)	No but can administer VFC doses for those due to the KY agreement with Medicaid	KCHIP – In Kentucky, there exists an agreement between Public Health and Medicaid allowing KCHIP children to receive vaccines through the KY Immunization Branch. Documentation distinguishing between VFC eligibility and KCHIP eligibility is required for every vaccination visit.
Has no health insurance coverage	Yes	Uninsured

Determining KCHIP Patients from Medicaid Patients

Federal Vaccine for Children (VFC) Eligible:

Medicaid eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program)

Uninsured: A child who has no health insurance coverage

American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (**25 U.S.C.** 1603)

Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC eligible for non-covered vaccines only). **Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC)** or under an approved deputization agreement.

KCHIP Eligible:

Children enrolled in the Kentucky Children's Health Insurance Program (KCHIP). KCHIP provides insurance to children in families with incomes that are above Medicaid eligibility but without access to private insurance. Children with KCHIP insurance are not VFC eligible because they are insured, just as other children with private insurance. In Kentucky, there exists an agreement between Public Health and Medicaid allowing KCHIP children to receive vaccines through the Kentucky Immunization Branch. Documentation distinguishing between VFC and KCHIP is required for eligibility at every vaccination visit. When you are screening the child for VFC eligibility, use the Medicaid website for verification of status: https://home.kymmis.com.

Go to: https://home.kymmis.com put in your user name and password to check eligibility prior to giving services. (Please see screen shots that follow.)
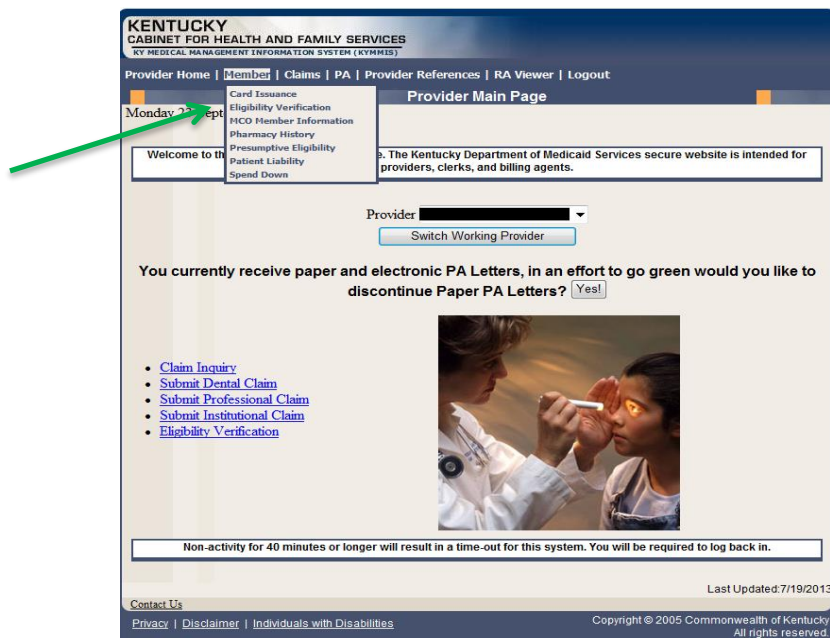
When placing your cursor over a subject, a drop-down box appears with additional topics within that subject. Click on "Eligibility Verification" in the drop-down box.

Service Type is automatically selected as "Health Plan Coverage". Look up type by Member ID or SS# and click Enter.

Enter the "From Date of Service" and "To Date of Service". Click Search.

The next screen shows Program Status. **If it is P7, the patient has KCHIP**.   If it is any other number, the patient has Medicaid.

Special Circumstances

There are some locations and provider types that require additional consideration when offering VFC vaccines:

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 prior to 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 in order to receive administration fee reimbursement from that Medicaid program.

Vaccine Dose Documentation

In accordance with Federal law, all VFC providers must maintain immunization records that include all of the following elements: (1) name of vaccine administered; (2) date vaccine was administered; (3) date VIS was given; (4) publication date of VIS; (5) name of vaccine manufacturer; (6) lot number; (7) name and title of person who administer the vaccine; (8) address of clinic where vaccine was administered.

Additionally, VFC providers are required to distribute the current vaccine information statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Record Retention

VFC providers are required to maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.

Key Clinic Staff

Medical Director: The official registered health care providers who signs the Vaccines for Children Program Agreement. They must be the practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance for the Provider office's responsibilities and conditions outlines 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 a 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 Field Representatives of 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: Responsible for assuming VFC oversight duties in the absence of the primary vaccine coordinator

Vaccine Management Plan

VFC providers must maintain and implement a Vaccine Management Plan for routine and emergency vaccine management. The plan should consist of clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). The plan must contain: the current vaccine coordinator and back-up coordinator; proper storage and handling practices; shipping and receiving procedures; emergency procedures such as equipment malfunctions, power failures, or natural disasters; procedures for vaccine ordering; inventory control (e.g. stock rotation); how to handle vaccine wastage; and staff training/documentation on vaccine management, storage and handling. The plan must be reviewed/updated annually or more frequently if changes occur. A "review date" and signature are required on all plans in order to validate that they are current.

Change in Coordinators

Any change in key clinic staff must be submitted to the KY VFC Program via a Change in Coordinator form within ten business days. It is recommended that changes in key staff be limited to no more than once every 6 months to ensure coordinators are fully trained.

New VFC coordinators must complete the CDC You Call the Shots trainings and a KYIR Inventory training before access to the Inventory Module in KYIR is granted. The Change in Coordinator form can be obtained by contacting the assigned Field Representative.

Failure to notify of a change in coordinator or address change will result in provider suspension.

Provider Education

VFC providers are required to have annual training on the VFC program and storage and handling. New coordinators are also required to complete KYIR inventory module training. All VFC coordinators and back-up coordinators must fulfill this requirement. There are two options to complete VFC provider education:
Completion of the CDC's You Call the Shots modules Vaccines for Children (VFC) and Vaccine Storage and Handling at http://www.cdc.gov/vaccines/ed/youcalltheshots.htm
In-person training conducted by VFC Field Representatives.

The webinar trainings from the CDC "You Call the Shots – VFC" and "You Call the Shots – Storage and Handling" must be completed annually. Certificates of completion must be kept on file and submitted to the KY VFC Program when indicated.
It is recommended that all clinic staff involved with the vaccine delivery process complete the above-mentioned trainings and have a clear understanding of all VFC policies.

Documentation of provider education should be kept on file so that it is easily accessible during a site visit.

Vaccine Accountability Policies

Restitution Policy (January 1, 2017)
Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration. Accountability of vaccine inventory is an essential requirement when receiving vaccines from the Kentucky Immunization Branch (KIB). The KIB Restitution Policy requires any KIB provider deemed negligent by to replace the lost vaccine on a dose-for-dose basis. Receipt of purchase must be submitted to the Vaccine Accountability 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 of 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 KIB before determining that vaccine is spoiled.
- **Lost vaccine:** Any vaccine ordered but not delivered or not delivered in a timely manner by the commercial carrier or delivery service that result in lost and/or spoiled vaccine.

Vaccine that is determined to be expired, spoiled, lost, or otherwise unusable is considered "wasted vaccine." There is a wide range of potential vaccine storage and handling issues that may result in wasted vaccine. The Kentucky Immunization Branch will review each incident of wasted vaccine to determine whether restitution will be required. If restitution is required, the practice will not receive additional VFC vaccine 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 non-viable vaccine that may require restitution. This list is not exhaustive.
- Failure to rotate vaccine stock in order to use vaccine with the shortest expiration date first.
- Failure to notify KIB a minimum of 90 days prior to vaccine expiration date.
- Repeated waste of vaccine due to drawing up or preparing vaccine prior to patient screening.
- Vaccine left out of the refrigerator or freezer resulting in vaccine reaching unacceptable temperatures.
- Freezing vaccine that must be refrigerated.
- Refrigerating vaccine that must be frozen.
- Excessive ordering of vaccine that results in the expiration of vaccine before it can be used.
- Provider staff failing to review and/or appropriately interpret and/or document refrigerator and/or freezer temperatures once 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 KIB when refrigerator or freezer malfunction results in temperature fluctuations.

- Refrigerator or freezer malfunctions or power outages in which provider staff fails to follow their Emergency Vaccine Management Plan and/or fails to contact KIB.
- Planned power outages in which provider staff fails to implement precautions to maintain appropriate storage of vaccine.
- Vaccine received but unaccounted for in stock.
- Transportation of vaccine inappropriately: unnecessary transportation of vaccine, transportation without KIB consent, and/or failure to appropriately maintain cold chain during transportation.
- Failure to use single antigen vaccines or allowing single antigen vaccines to expire in favor of using combination vaccines.
- Failure to notify KIB when provider's office will be closed for non-emergency situations i.e., holidays, trainings, parties, etc. KIB must be notified 30 days in advance of planned closing to prevent 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 practice is deemed not to be at fault. This list is not exhaustive.
- Vaccine is damaged, improperly stored during transit, or not delivered in a timely manner by commercial carrier or delivery service.
- Provider staff moved vaccine to their back-up location as outlined in their Vaccine Management Plan, in anticipation of power outage or due to refrigerator or freezer malfunction and the back-up location experienced 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.
- Partially used multi-dose vials of vaccine.
- A vial of vaccine that is accidentally dropped or broken by provider staff.
- Occasional instances of wasted vaccine due to provider staff error or last-minute patient refusal.
- Expired vaccine the provider staff notified KIB about and redistribution made to another provider.
- Extraordinary situations not listed above which are deemed by KIB to be beyond the provider's control.

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 vaccine from the Kentucky Immunization Branch. The federal Vaccines for Children Program (VFC) is the largest part of the KIB.

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccine at no cost to children who are Medicaid-eligible, uninsured, American Indian/Alaskan Native, or who are underinsured and receiving immunizations at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or a local health department delegated by a FQHC or RHC. The cost and number of vaccines provided by the VFC Program and 317 Programs have increased dramatically over the past few years, thus it is imperative that the KIB have effective and enforceable policies and procedures against fraud and abuse to safeguard this significant investment.

<u>Definitions</u>
- **Authority:** KRS 205.8453(4) directs the Cabinet for Health 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 Branch 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.).

- **Fraud:** An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself/herself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

- **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Examples of Fraud and Abuse:
This list is not is intended to be exhaustive of all acts that may constitute fraud or abuse.
- Providing VFC vaccines to non-VFC eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for the VFC-funded vaccine
- Charging more than the established maximum regional charge for administration of a VFC- funded vaccine to a federal vaccine-eligible child
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen patients for VFC eligibility at every visit
- Failing to maintain VFC records or not complying with other requirements of the VFC Program
- Failing to fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering of VFC doses of vaccine
- Wasting VFC vaccine (e.g., expiring vaccine, ordering too many doses of vaccines, storing or transporting vaccines outside of cold chain procedures, lost or unaccounted for doses, etc.)
- Any activity that will result in an overpayment for costs of the vaccine or administration

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 Immunization Field Representative 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 vaccine. Providers must update these forms as needed, but at least annually for the Provider Profile and bi-annually for the Provider Enrollment, to continue to receive vaccine. 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 management staff review all incoming vaccine orders and reports of doses administered. Vaccine management 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 Enrollment Form, providers may have to reimburse the Immunization Program dose for dose for any vaccines that are unaccounted, spoiled, expired, or are deemed preventable losses. Providers are required to develop corrective action plans and submit proof of replacement vaccine.
- All VFC staff that have interaction 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.
- Immunization Field Representatives inspect for any indications of fraud or abuse during their reviews, and they continue to follow-up on any deficiencies until improvements are made and maintained.
- Immunization Field Representatives conduct additional site visits if providers have vaccine storage and handling problems or other problems 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/ prior to 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 program (IQIP) site visits.

As determined by KIB 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 Section (VAS) Coordinator will implement an Education and Corrective Action Plan and attempt to resolve the situation with KIB 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 Immunization 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 KIB staff, the following information will be collected:
- Medical Provider's name (Medicaid ID if known)
- Address
- Source of allegation
- Date allegation reported to program
- Description of suspected misconduct
- Specific VFC requirements violated value of vaccine involved, if available
- Success of educational intervention
- Disposition (e.g., closed, referred, or entered into 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 KIB 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 Branch 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 KIB 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 Branch staff until the situation is resolved.

Fraud and Abuse Contact

Email: dph.kvp@ky.gov

Telephone number for reporting Fraud and Abuse: (502) 564-4478 on weekdays from 8:00 am – 4:30 pm.

KCHIP Policy for VFC Providers

1. Verify patient eligibility at each immunization visit and record in KYIR.
2. If you do direct data entry into KYIR or your EMR is not live with the Kentucky Health Information Exchange (KHIE) (i.e. patient data with vaccinations do not come over to KYIR automatically from your EMR), update the patient eligibility on the demographics page every time the patient comes in for an immunization.
3. If your EMR is live with KHIE (i.e. patient data with vaccinations does come over to KYIR automatically from your EMR), please ensure that the patient eligibility is coming through into KYIR.

To verify this:

- Take a quick note of a few patient's your office has recently given a vaccination to from your EMR (note the eligibility, name, and date of birth, vaccine)
- Log into KYIR -> Select Patients -> Select Search -> Enter the first few letters of first and last name and date of birth for the patient you wrote down and select Search
- Find your patient in the options in the search results and select "Immunizations" from the drop-down box next to the patient's Name and Date of Birth.

- Once the immunization page loads, find the immunization your clinic administered and documented in your EMR and click "Update" button next to the administered immunization. Make sure the Patient Eligibility is populated and matches what is in your EMR.

If the administration information does not appear in KYIR or does not match, please call the KYIR Helpdesk at 502-564-0038 or email at KYIRHelpdesk@ky.gov and indicate you need help with your EMR messages coming through to KYIR.

Regarding new shipments: VFC and KCHIP doses will still be separated on your packing slip. However, once logged into KYIR to accept the shipment, it all will be received into inventory as VFC in KYIR. Please note that at times there may be special funding situations which would require the KCHIP doses to be listed separately in your Inventory. You can administer your remaining KCHIP vaccine to either VFC or KCHIP patients. Vaccinate both KCHIP and VFC patients with VFC vaccine stock.

317 and State will show as separate on the packing slip and in the KYIR inventory. It is important that these funding sources are not mixed in or combined with your VFC funded inventory.

Borrowing
Routine borrowing from VFC for Private Pay/fully insured patients is not allowed. Borrowing should only be done in extreme cases. In addition, your field representative must approve borrowing in advance. The borrowing report must be completed after approval has been received.

Borrowing Cases
1. If you have insufficient stock to vaccinate the VFC or KCHIP child with VFC vaccine, use private stock. You need to complete a borrowing report for this case. In your EMR/KYIR, please document vaccine administration accurately with correct lot number, funding source, and patient eligibility. Then complete a borrowing report, with the correct borrowing reason code, and send it to your field representative.
2. 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.
3. If you have insufficient stock to vaccinate a private pay/insured child with private vaccine, use what is available to you. You need to complete a borrowing report for this case if VFC vaccine was used. In your EMR/KYIR, please document vaccine administration accurately with correct lot number, funding source, and patient eligibility. Then complete a borrowing report, with the correct borrowing reason code, and send it to your field representative.

   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 approved by the Kentucky Immunization Branch. If accidental borrowing occurs, please follow the procedure detailed above regarding the borrowing report.

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

VFC in Kentucky Immunization Registry (KYIR): Procedures and Processes

- *Patient Eligibility Screening Record*: A paper screening record is only used in VFC clinics when the clinic is not able to enter into an EMR (if applicable) or not able to enter into KYIR. The recommendation is to keep the patient eligibility up to date in KYIR at each visit. Verify patient eligibility at each immunization visit and record in KYIR.
- *Manual data entry into KYIR:* If you do direct data entry into KYIR or your EMR is not live with the Kentucky Health Information Exchange (KHIE) (i.e. patient data with vaccinations do not come over to KYIR automatically from your EMR); update the patient eligibility on the demographics page every time the patient comes in for an immunization. **Direct data entry** is required into KYIR if your clinic does not have an EMR or the EMR is not live with KHIE.
- *Live connection through KHIE:* If your EMR is live with KHIE (i.e. patient data with vaccinations does come over to KYIR automatically from your EMR), please ensure that the patient eligibility is coming through into KYIR.
 *To verify this:*
  - Take a quick note of a few patients your office has recently given a vaccination to from your EMR (note the eligibility, name, and date of birth, vaccine).
  - Log into KYIR -> Select Patients -> Select Search -> Enter the first few letters of first and last name and date of birth for the patient you wrote down and select Search.
  - Find your patient in the options in the search results and select "Immunizations" from the drop-down box next to the patient's Name and Date of Birth.

- o Once the immunization page loads, find the immunization your clinic administered and documented in your EMR and click "Update" button next to the administered immunization. Make sure the Patient Eligibility populates and matches what is in your EMR.
- o If it has not come through or does not match, please call the KYIR Helpdesk at 502-564-0038 or email at KYIRHelpdesk@ky.gov and indicate you need help with your EMR messages coming through to KYIR.

Vaccine *		Manufacturer		
TDAP, ADSORBED		GLAXOSMITHKLINE (FORMERLY SMITHKLINE BEECHAM)		

Lot/Serial	Funding Src	Expiration Date	NDC #
594SR	PRIVATE	07/08/2019	58160-0842-52

Vaccination Date *		Vaccination Time		Patient Eligibility
08/09/2017	42Y 4M 27D	HH:MM AM/PM (HH:MM A/P)		(2) KCHIP <19YRS

Dosage	Body Site	Route	Borrowed	Comment
0.50	LD	INTRAMUSCULAR		

All doses administered need to be entered into KYIR, not only VFC doses.

The purpose is for Immunization Quality Improvement for Providers (IQIP) site visits. IQIP site visits are required by CDC to be conducted with the clinic utilizing coverage assessments in KYIR inclusive of the entire clinic population rather than a subset of patients.

If you want to connect your EMR to KYIR through KHIE contact KHIE to get started by visiting the website, www.khie.ky.gov.

- *Active/Inactive Patient Status:* Providers need to update their patient active/inactive status quarterly to keep the patient roster up to date. Training materials are located in the Reports/Training module of the KYIR. Email the helpdesk if you need help with your account or need additional help.

- *KVP Activity Worksheet***:** VFC providers do not need to keep this once their inventory is tracked in the registry. Hospitals may continue to use it and providers waiting to get their data in KHIE will continue to use it. The provider may also choose to use it as a backup tracking system.

- *Returns and Adjustments in KYIR:* All returns and adjustments are completed in KYIR. Please utilize the quick guides in the reports/training module in KYIR to complete a return or adjustment.

- *3 Month Expiring Soon Notification:* VFC Providers need to notify their Field Representative that they have vaccine expiring in 3 months if they do not anticipate using the entire inventory. KYIR indicates with a red clock next to the vaccine on the Inventory On-Hand page, which vaccines are expiring within the next 3 months.

- *Transfers:* VFC providers first need permission from their assigned Field Representative in order to transfer vaccine to another provider and create the transfer in KYIR. Transferring should be rare and is discouraged due to storage and handling complications when trying to move vaccine.

- *Adult Orders:* VFC providers who also enrolled in the Adult Vaccine Program and approved to order adult vaccines and must place a separate order in KYIR from their VFC pediatric order. When ordering adult vaccines providers must select Adult Intent on the ordering screen in KYIR.

- ***Orders and Returns:*** If there are any upcoming dates or information that could affect the current order or return in submission, the provider should include a note on the Clinic Comments portion of the Order or Return. This would include any future dates when the location would not be available to receive orders and/or any reason why the order would be larger than a normal order (ex. Back-to-school clinic, holiday order, etc.)

The Vaccine Accountability Section (VAS) will communicate with providers regarding their order or return via the VFC Program Comment Box on the Order or Return. Please check your previously submitted order or return to ensure that it has been processed.
In order to view the status of your order or return and view any comment left for you follow the directions below.
Log into KYIR-> Inventory-> Vaccines->Vaccine Orders-> Click the blue Search button -> Find your most recent order-> click View to the right of the order -> Read the 'VFC Program Comments"

- ***"Rejected" Order:*** When an order is rejected, the VAS Representative will leave a note in the VFC Comments section of the order. You will follow the same directions as listed above. After reading the comments, you will be able to make any corrections to the order and leave any additional note in the order. Finally, you will choose Submit to VFC Program again to resubmit your order.

- ***"Rejected" Return:*** When a return is rejected, the VAS Representative will leave a note in the VFC Comments section of the return. There is no option to resubmit an edited return. If you need to resubmit a rejected return with corrections, you will need to create a new return after the rejected return is deleted. Contact the KYIR Helpdesk to delete the rejected return.

- ***Reconciliation:*** VFC Providers are required to reconcile their inventory on a minimum monthly basis. A completed reconciliation for both refrigerator and freezer (if both are applicable) must be completed to open the vaccine-ordering window. This window is open for the clinic to place an order for 13 days from the End Date shown on the most recent reconciliation.

- ***VFC Re-Enrollment/Provider Agreement in KYIR:*** All providers are required to renew their provider agreement in KYIR when notified by the VFC Program.

Log into KYIR-> Clinic Tools-> Enrollments-> Click the Add Enrollment button -> Select the enrollment needed for your facility type
1. Complete each section in order
2. Save Progress upon completion of each section
3. Medical Director must login to KYIR with their own user account in order to review and accept the Primary Agreement
4. Once all sections show a green check mark, the form can be submitted

Log Tag Brand Digital Data Loggers

The KY VFC Program does not require the digital data logger used by Providers to be Log Tag brand. However, if the Provider chooses to use the Log Tag brand they can upload their temperature logs directly into the Kentucky Immunization Registry (KYIR).

The upload process is illustrated in the guide below:

❖ *How to Upload a Log Tag Temperature Log to KYIR*

Stop the Log Tag digital data logger from recording by holding down the Stop/Start/Clear button on the front of the DDL. You will see the work STOPPING flashing on the screen; continue to hold the button down until it stops flashing. The word STOPPED will display on the screen. Take note of which DDL you are working with, either fridge or freezer.

Place the Log Tag into the docking station attached to your computer.

Open the Log Tag Analyzer software if it does not automatically open.

The data will appear on the screen showing the temperature range as well as any excursions.

Save the Log Tag file by clicking on the word File in the menu bar at the top of the screen of the Log Tag Analyzer software. Select the option of Save As…
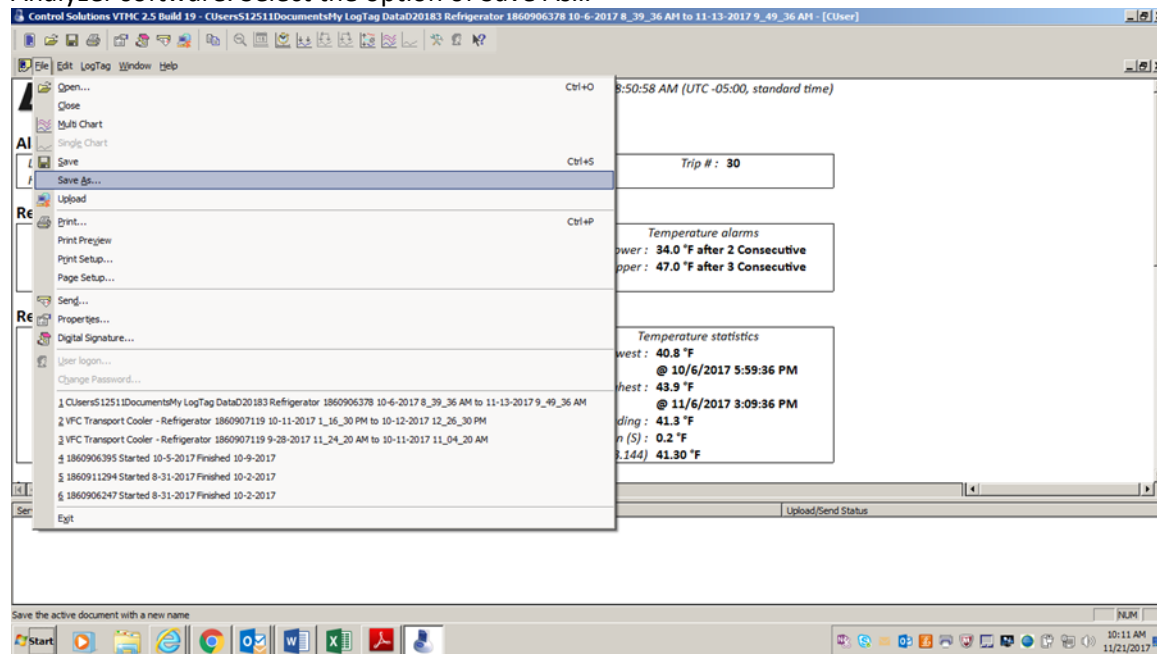

The save window will open. Change the file type to CSV (comma delimited)

You can edit the name of the file to add the word fridge or freezer if desired. Take special care not to remove the 10-digit serial number of the Log Tag from the file name.

If you edit the file name, make sure there is a space before and after the serial number. This number is how the file is matched to the correct data location in KYIR.
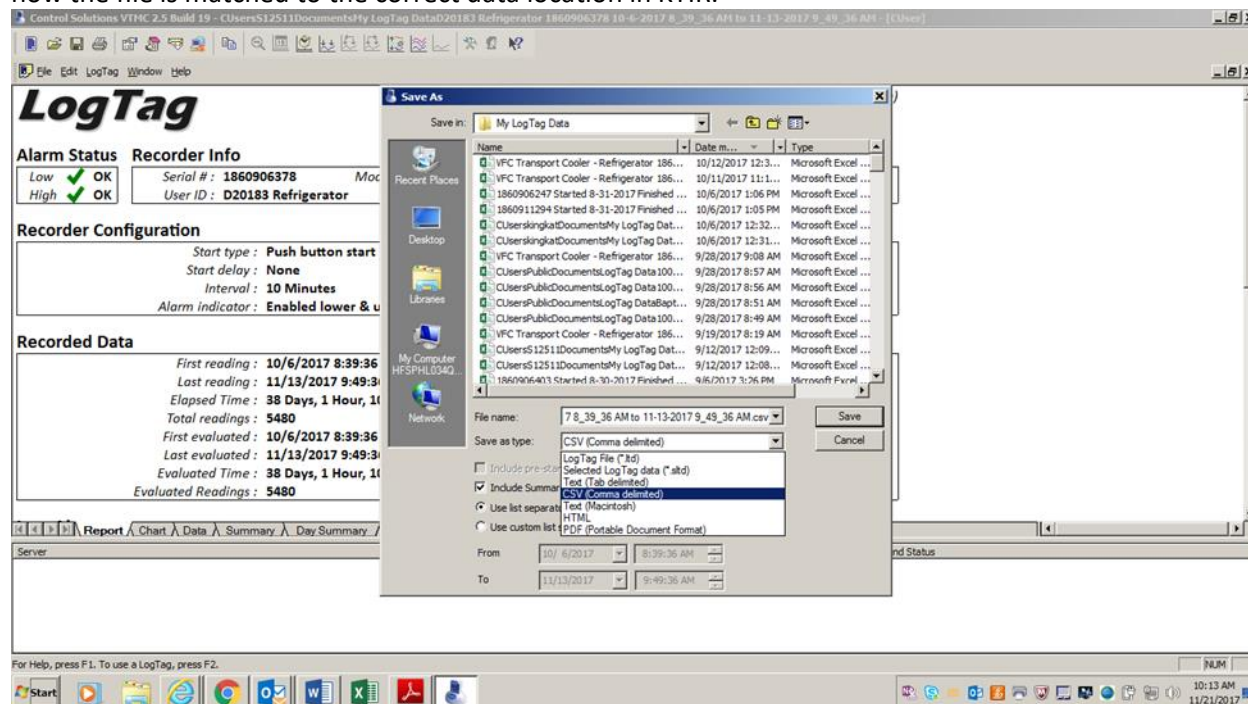
Take note of where the file will be saved on your computer. You will need to find it in order to upload later. It normally saves under Documents in a folder titled My LogTag Data. You can change this to any folder you would like or save it to the Desktop of the computer.
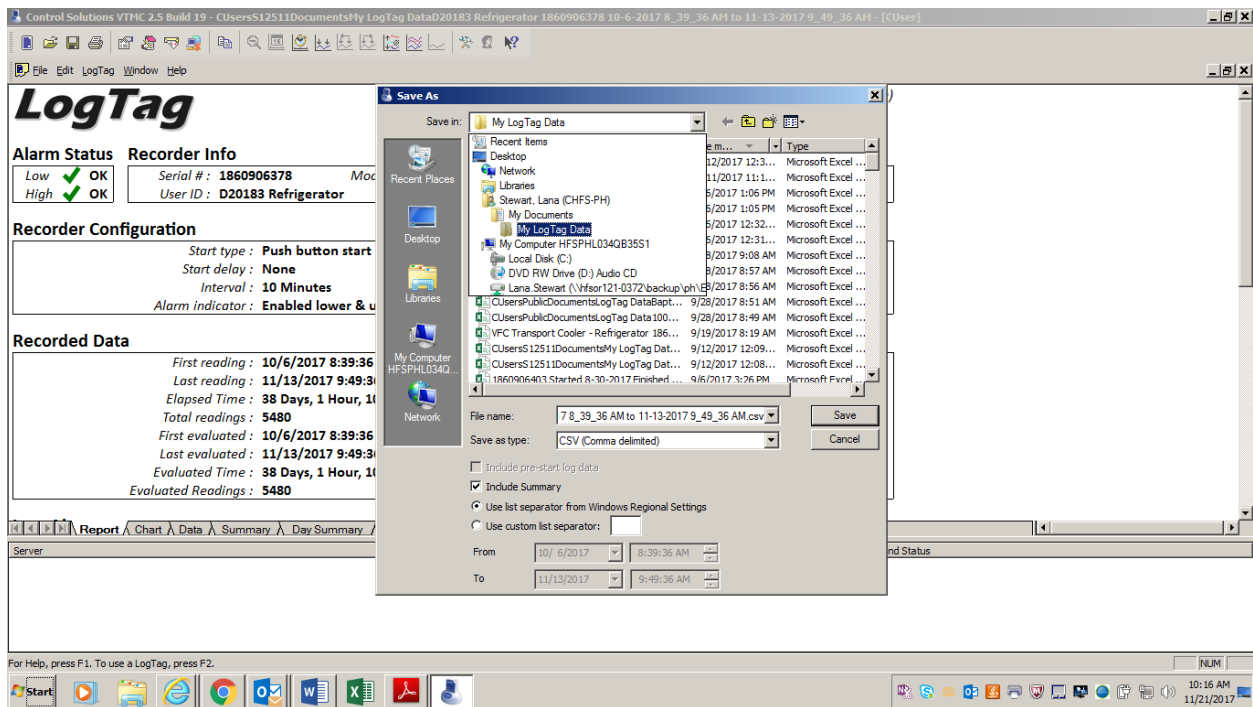
Click on Save.

The screen will show the initial report page again. Print a copy of the Report tab and keep it on file with your other VFC paperwork.

Configuration Settings for Log Tag Thermometers

If your Log Tag does not auto-configure, follow the steps below to prepare it for recording:

Place your LogTag into the cradle to download temperatures or to set up a new LogTag for recording temperatures

Click on Log Tag in the upper menu bar of the Log Tag Analyzer program window and select Configure
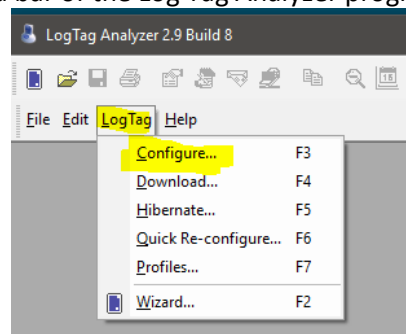
A Log Tag Configure window will open – make sure the settings are correct as shown below
- Refrigerator Alarm Settings
  - Record a reading every 10 minutes
  - Trigger alarm when readings are above/equal to refrigerator setting of 46.5°F
    - After 3 Consecutive readings
  - Trigger alarm when readings are below/equal to refrigerator setting of 35.5°F
    - After 2 Consecutive readings

- Freezer Alarm Settings
  - Record a reading every 10 minutes
  - Trigger alarm when readings are above/equal to freezer setting of 5.5° F
    - After 3 Consecutive readings
  - Trigger alarm when readings are below/equal to freezer setting of -40° F
    - After 3 Consecutive readings

LogTag Configure ✕

Action List

✓ 1. Locate and identify LogTag(s)

▶ 2. Configure LogTag(s) for next use

3. Prepare LogTag(s) for next use

User ID: Freezer

Push button start ▾   **LogTag battery: OK**

☐ Enable pre-start logging

○ Record readings continuously, overwrite oldest when memory full

◉ Record readings so that:

Readings recorded will span at least 110 days

Number of readings to record 15,905   maximum is 15905

Record a reading every 10 Minutes ▾

Begin recording after a delay of 0 Minutes ▾

☑ Trigger alarm when readings above/equal 5.5 °F

☑ After 3 Consecutive ▾ violation readings (30 Minutes)

☑ Audible alarm

☑ Trigger alarm when readings below/equal -40 °F

☑ After 2 Consecutive ▾ violation readings (20 Minutes)

☑ Audible alarm

☐ Configure requires a password

☐ Download requires a password

Advanced Options

< Back   Next >   Close   Help
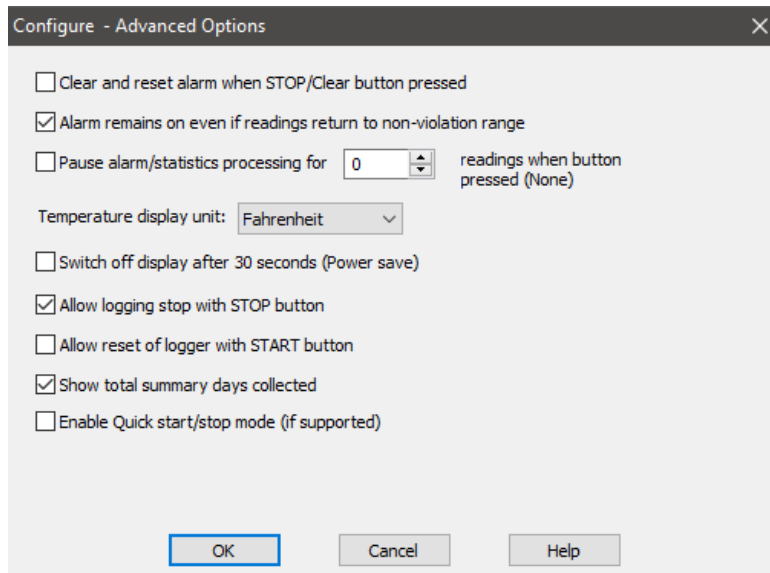
Advanced Options

Click on the Advanced Options button to view more setting options and enable the following options

- Alarm remains on even if readings return to non-violation range
- Temperature display unit: Fahrenheit
- Allow logging stop with Stop button
- Show total summary days collected

Click OK to save

The Log Tag Configure screen will display again. Click on Next to configure.

To Upload a Temp Log file into KYIR
Log into KYIR
Under Clinic Tools, click on Storage Units
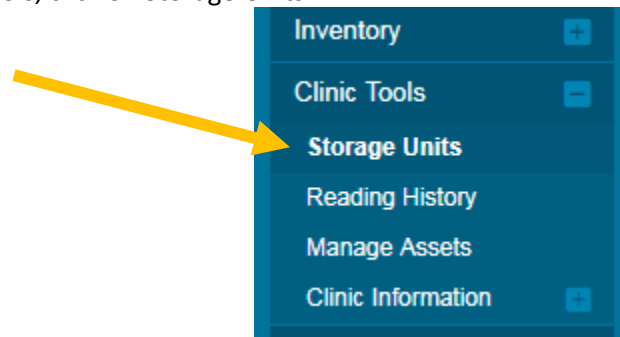
Click on the Log button at the top right of the Storage Unit window and select Log Temp – Upload CTM.
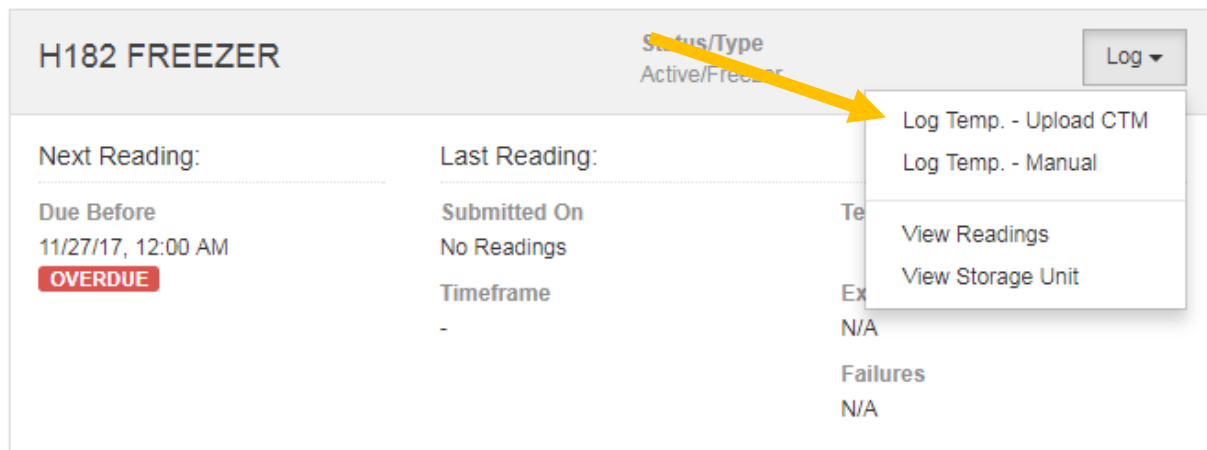
On the next screen, click on the Choose File button and select the correct CSV file from your computer. Select the correct file, click on Open.
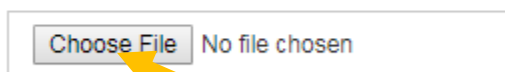
Once the file is selected, click on the blue Upload button at the top right of the screen.

Cancel | Upload

Next Reading
11/27/17, 12:00 AM - OVERDUE

Clinic Notes   Expand   + Add
There are currently no notes entered for this clinic
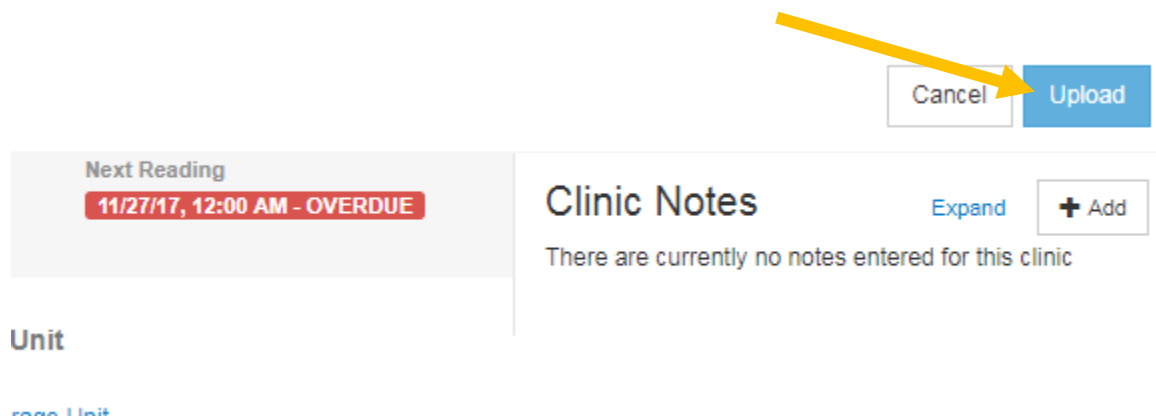
Unit

Repeat the process for any other storage units.

If any of the temperatures on the Temp Log are out of range, a tab to submit a failure report titled Failure will appear on the page. This is in addition to the standard protocol for temperature excursions.

How to Add/Update a Storage Unit or Thermometer in KYIR
To Create/Add a Storage Unit:
Under Clinic Tools, Click on Manage Assets

Clinic Tools
Storage Units
Reading History
Manage Assets
Clinic Information
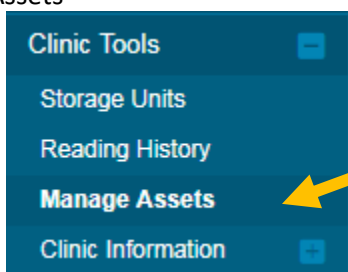
Click on Add Asset blue drop-down box, select Add Storage Unit

Add Asset ▼

Add Storage Unit

Add Thermometer
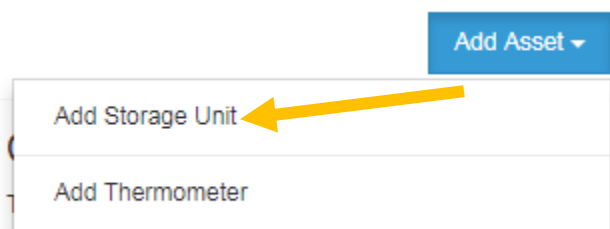
All entry boxes with a red asterisk (*) are required entries.

Add Storage Unit ⓘ

Name *

> ASSET NAME

Date of Purchase

> MM/DD/YYYY   📅

Storage Type *

> ▼

Manufacturer *

> MANUFACTURER

Make *

> MAKE

Model *

> MODEL

Serial Number/ID *

> SERIAL NUMBER/ID

Assigned Thermometer

> ▼

Storage Grade *

> ▼

Comments

> Comments

Name: Name of the asset – include the VFC Pin # and Refrigerator or Freezer and/or any other identifier
Storage Type: Select either Fridge or Freezer
Manufacturer: Type in the name of the manufacturer of the storage unit
Make: Type in the make of the storage unit
Model: Type in the model number of the storage unit
Serial Number/ID: Type in the serial number or ID number of the storage unit
Storage Grade: Select the storage grade of the storage unit. Choices include Commercial, Pharmaceutical, and Standard
Assigned Thermometer: This box will be blank until a thermometer is assigned to the storage unit – this process is completed separately on the Thermometer View info screen.
Comments: Additional comments regarding the addition of the storage unit may be added here.
Once all boxes are filled in, click on the blue Create button at the upper right of the screen.

> Clinics can create a Storage Unit, but its status will show as **Pending** until an Administrator approves it. You will receive a Notification message when approved.

You can view your notification updates in the top blue bar of the KYIR screen. This is visible from all pages of KYIR.

To view your notifications, click on the drop-down arrow beside the bell icon and click on View My Notifications.
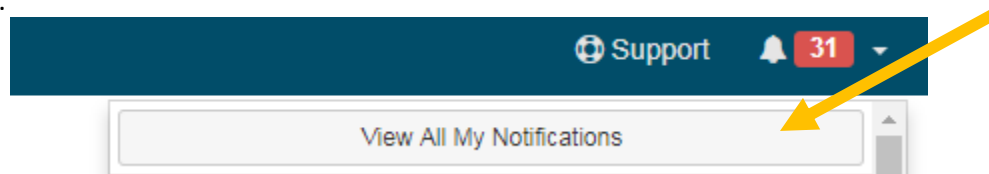
To Create/Add a Thermometer:

Click on the **Add Asset** blue drop-down box, select **Add Thermometer**

All entry boxes with a red asterisk (*) are required entries.

Name: Name of the asset – include the VFC Pin # and Refrigerator or Freezer and/or any other identifier

Thermometer Type: Select from the drop-down box the type of thermometer, Built-In, CTM, or Manual
For all LogTag thermometers, the type is CTM

Manufacturer: Type in the name of the manufacturer of the thermometer
For all LogTag thermometers, the manufacturer is *Control Solutions*

Make: Type in the make of the thermometer

Model: Type in the model number of the thermometer

Serial Number/ID: Type in the serial number or ID number of the thermometer

Calibration Due Every (months): Type in 24 for calibration being due every 2 years

Comments: Additional comments regarding the addition of the thermometer can be added here.

Once all boxes are filled, click on the blue Create button at the upper right of the screen.

To Assign a Thermometer to a Storage Unit:

Once both the Storage Unit and the Thermometer's status has changed to Approved, click on View under the Action Column on the Manage Assets page of the Clinic Tools for the specific Thermometer you wish to assign to a Storage Unit.

Manage Assets

Showing 1 to 6 of 6 entries

Name	Type	Status	Action
H182 - FREEZER THERMOMETER	THERMOMETER	ACTIVE	VIEW
H182 - REFRIGERATOR 1 THERMOMETER	THERMOMETER	ACTIVE	VIEW
H182 - REFRIGERATOR 2 (ADULT) THERMOMETER	THERMOMETER	ACTIVE	VIEW
H182F- FREEZER LAB	STORAGE UNIT	ACTIVE	VIEW

Edit Thermometer ⓘ

Name *
H182 - FREEZER THERMOMETER

Status *
ACTIVE ▾

Date of Purchase
07/12/2017 📅

Thermometer Type *
CTM ▾

Manufacturer *
LOGTAG

Make *
LOGTAG

Model *
TRED30-7

Serial Number/ID *
1060020160

Assigned Storage Unit
▾

Calibration Due Every (months)
24

Comments
Comments

To Submit Calibration Date/Certificate for Thermometer:
From the Edit Thermometer screen click on View of selected Thermometer, click on Calibrate Thermometer on the right-hand side of the screen.

Status *
ACTIVE ▾

Type *

Manufacturer *
LOGTAG

'R

Serial Number/ID *
1060020160

e Every (months)

Thermometer

Edit Thermometer

Calibrate Thermometer

Enter the Calibration Date for the Thermometer.
Submitting a copy of the calibration certificate in KYIR is optional. Clinics must keep a copy of the current calibration certificate on hand for any site visits.

To add a copy of the certificate to KYIR:

Click on Choose File, to select the certificate file from your computer.

Click on the blue Submit button in order to submit your certificate to KYIR.

Please note that uploading a copy of the certificate to KYIR is not a required step.

Temperature Readings in KYIR- Failure Reports and Storage & Handling Incident Reports

After Uploading a Temperature Log, KYIR will analyze the temperatures and determine if there had been any failures. If the temperature readings are good, the upload will result in "0" failures listed in the reading history:

If the temperature readings indicate there has been a failure, the yellow banner alert will appear and a tab for the Failure is created. Click the Failures Tab

Click "File Report" and the Failure report pops up.

Complete the report and document the determination by the manufacturer by selecting the appropriate item in the *Action* drop down box (manufacturer deemed vaccine viable, manufacturer deemed vaccine not viable, manufacturer changed vaccine expiration date, or Defrost Cycle <1 hour and no more than 14° F).

When you have finished the documentation, click submit. Your field representative will receive notification that you have completed the failure report. Also, complete the Storage and Handling Incident Report and send to the assigned field representative or to VaxColdChain@ky.gov

Vaccine Storage and Handling

Storing vaccines improperly reduces vaccine potency, and thus provides inadequate immune responses (inadequate protection against disease) in patients.

Vaccine Cold Chain

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

Cold Chain Flowchart

Vaccine manufacturing → Vaccine distribution → Vaccine arrival at provider facility → Vaccine storage and handling at provider facility → Vaccine administration

Manufacturer responsibility — Manufacturer/distributor responsibility — Provider responsibility
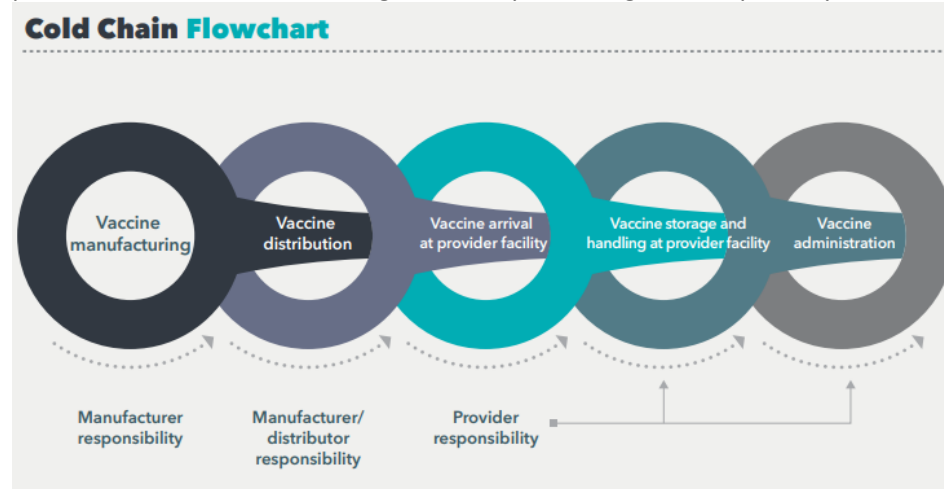
- Excessive hot or cold temperatures damage vaccines. Once vaccine potency is lost, it can never be regained, and the vaccine becomes ineffective at preventing disease. Visual inspection of vaccines is an unreliable method of assuring potency. Inactivated vaccines – even when exposed to freezing temperatures – may not appear frozen, giving no indication of reduced or lost potency.
- 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 fluctuation in temperatures 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.
- 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.
- Never store vaccine in the storage unit doors or in any bins.
- 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.

- 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 stop weekly. Record the date of stock rotation on the daily temperature logs. Expired vaccine should never be stored in the storage units.

Vaccine Management

Successful vaccine management is dependent on five factors:

1. Complete and up-to-date Vaccine Management Plan
2. Properly trained 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 Management Plan

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 vaccines and minimize vaccine loss due to negligence. Vaccine Coordinators (and Backups) are responsible for implementing the plan, and the Provider of Record is ultimately accountable for practice or clinic compliance. Review and update your plan at least once a year. Ensure that all content in each section (including emergency contact information and alternate vaccine storage location) is up to date. Key practice staff must sign and acknowledge the signature log whenever your plan is revised. Providers must assign someone responsible for ensuring their plan is updated and ready to be executed. Keep the plan in a location easily accessible to all staff, ideally near the vaccine storage units.

Staff and Training

Vaccine Coordinators must complete annual training on Storage & Handling. The Kentucky Immunization Branch offers both online and in-person training that fulfills federal education requirements. The Field Representative and the KYIR Helpdesk work together to help provide training and support to providers. Thus, ensuring providers success with the VFC Program.

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 trainings 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 any changes in Vaccine Coordinator staffing. These changes require a signed VFC Change in Coordinator form to be submitted
- All primary and backup VFC Coordinators are required to complete a one-time KYIR Inventory Training in TRAIN. The training must be completed in order to gain access to the Inventory module in KYIR for the clinic. Contact your Immunization Field Rep for more information concerning required training.

The link and information for the TRAIN training and CDC's You Call the Shots are included in the Resources section of this provider manual.

Storage Units

KY VFC Program requires stand-alone refrigerator and freezer units. They must be self-contained units that only refrigerator or freezer and are suitable for vaccine storage.

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.

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

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. Be sure to avoid outlets with built-in circuit switches or a wall switch activates the outlet. An outlet cover can be used to keep from inadvertently unplugging the unit. The outlet AND the circuit breaker in the breaker box must be labels with warning signs such as "Do Not Unplug" and "Do Not Turn Off".

The unit must demonstrate two consecutive days of in-range temperatures prior to being used for vaccine storage. This applies if the unit is new. 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 two consecutive days of in-range temperatures.

For an existing unit being moved due to a change in address, the provider must contact their Field Representative prior to the move to coordinate vaccine transport. The provider must schedule the move of the unit for early in the day. This will allow time for the moved unit to return to in range temperatures before the close of business. All vaccines must be moved to an approved back-up storage location while the unit is being moved or in an approved transport unit. Vaccines can be returned to the primary unit once it has regained in-range temperatures. Vaccines cannot be stored overnight in transport coolers.

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 storage space in the unit.

Back-up storage units must meet the same requirements of the primary units. However, the use of combination units may be allowed for temporary storage. Back-up units shall not be used longer than two weeks.

Refrigerator Specifications

Any storage unit must meet the following requirements:

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. The refrigerator section of a household-grade combo unit is only acceptable and approved storage as a backup storage location for refrigerated vaccines.

Possess a capacity to store all of the practice's vaccines along with sufficient water bottles to stabilize temperatures.

Defrost automatically

Seal tightly and close properly

Be used primarily for vaccine storage
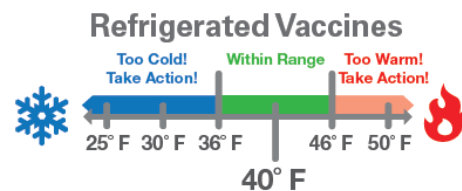
Freezer Specifications

Any freezer storage unit must meet the following requirements:

Maintain consistent temperatures between -58°F and 5°F (-50°C to -15°C)

Be either a stand-alone unit (upright or chest) or pharmaceutical grade combination unit. The freezer section of a household-grade combo unit is not acceptable or approved storage for frozen vaccines.

Possess a capacity to store all of the practice's vaccines along with sufficient frozen water bottles to stabilize temperatures

Defrost automatically

Manual defrost is acceptable if the provider has access to an alternate storage unit for vaccine storage during the defrost process

Seal tightly and close properly

Be used only for vaccine storage
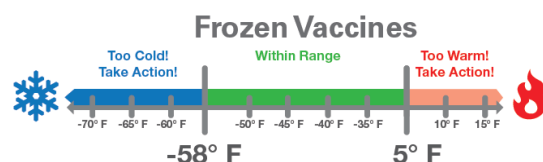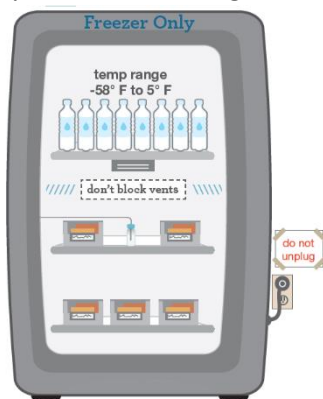
Temperature Monitoring Equipment
VFC Providers are required to have certified calibrated digital data logging thermometers (DDL) in their storage units. Providers need a separate DDL thermometer for each storage unit that holds VFC vaccines. A certified calibrated back-up DDL must be located on site (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 to determine when recalibration is necessary.

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 or 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.

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.

Kentucky VFC Monthly REFRIGERATOR Temperature Log

VFC Pin: _____ Month/Year: _____

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

Day	Time	Min Temp	Max Temp	Staff Initials	Alarm/Action Taken
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
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.

...mperature Log

_____ Month/Year: _____

Take immediate action if temperature is too high (above 5°F)!

Min Temp	Max Temp	Staff Initials	Alarm/Action Taken

25				
26				
27				
28				
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.

Vaccine Storage

The following are considered best practice for organizing and storing vaccines to ensure viability and lessen the risk of administration errors.

- Store each type of vaccine or diluent in its original packaging.
- Store vaccines with similar packaging or names on different shelves. Adult and pediatric versions of the same vaccine should be stored on different shelves and labeled accordingly.
- Diluents packaged with the vaccines should be stored in the refrigerator together. Diluents packaged separately can be stored in the refrigerator or at room temperature, according to manufacturer recommendations. Never store diluent in the freezer.
- Never store vaccines near cooling vents in refrigerator, this can result in freezing the vaccines.
- Store vaccines 2 to 3 inches from unit walls, ceiling, floor, and door. Never store vaccines in the unit door or in drawers as instable temperatures and airflow may expose them to inappropriate conditions.
- If 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 separate from privately purchased vaccines.
- 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.
- Never store food or beverages in the storage units.

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

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:

Temperature Excursion Protocol
1. Consult your Vaccine Management Plan and ensure the primary and/or backup vaccine coordinator is notified.
2. Take an inventory of the effected 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.
6. Complete a Vaccine Storage & Handling Incident Report and send to your Field Representative or email to VaxColdChain@ky.gov
7. 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.

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.

Notify → Document → Contact → Correct

Notify
» Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
» Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document
» Document details of the temperature excursion:
  - Date and time
  - Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
  - Room temperature, if available
  - Name of the person completing the report
  - General description of the event (i.e., what happened)
  - If using a digital data logger (DDL), determine the length of time vaccine may have been affected
  - Inventory of affected vaccines
  - List of items in the unit other than vaccines (including water bottles)
  - Any problems with the storage unit and/or affected vaccines before the event
  - Other relevant information

Contact
» Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
» Be prepared to provide the manufacturer or immunization program with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:	
Merck	1-800-672-6372
Sanofi Pasteur	1-800-822-2463
GlaxoSmithKline	1-888-825-5249
Pfizer	1-800-438-1985
Seqirus	1-855- 358-8966

Correct
» If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
» Check the basics, including:
  - Power supply
  - Unit door(s)
  - Thermostat settings
» If the excursion was the result of a temperature fluctuation, refer to the chapter, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.
» If you believe the storage unit has failed, implement your emergency vaccine SOPs. Never allow vaccines to remain in a nonfunctioning unit.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CS249275-BG

VACCINE STORAGE & HANDLING INCIDENT REPORT

Provider Name:		VFC PIN:	Person Completing Report:

Affected storage unit: ☐ Refrigerator ☐ Freezer	Water bottles in use: ☐ Yes ☐ No	Date & Time of Event:	Duration: hours, minutes

At the time the problem was discovered, what was the storage unit temperature?   Room temperature?

Description of Event:

Corrective Action(s) Taken: State Immunization Program Notified: ☐ Yes ☐ No

Vaccine manufacturers notified: ☐ Yes   ☐ No

Results	Manufacturer Information	Vaccine Status
	Manufacturer: Contact Name: Case ID#:	☐ viable ☐ not viable ☐ viable until new expiration date:
	Manufacturer: Contact Name: Case ID#:	☐ viable ☐ not viable ☐ viable until new expiration date:
	Manufacturer: Contact Name: Case ID#:	☐ viable ☐ not viable ☐ viable until new expiration date:
	Manufacturer: Contact Name: Case ID#:	☐ viable ☐ not viable ☐ viable until new expiration date:
	Manufacturer: Contact Name: Case ID#:	☐ viable ☐ not viable ☐ viable until new expiration date:

Additional Comments:

Vaccine Shipments

- Assure the vaccine cold chain is not interrupted during the receipt of vaccines.
- Deliveries should only be arranged for when the clinic is open and when the vaccine coordinator is on duty.
- All staff must be aware of the importance of maintaining the cold chain and to notify the vaccine coordinator immediately upon vaccine arrival.
- Upon arrival of vaccine shipments, check the contents against the packing slip. Report any discrepancies to either you Field Representative or KYIR Helpdesk upon arrival.
- Store vaccine immediately in appropriate conditions. Log into KYIR and click the link provided on your on-hand screen to accept the shipment into your inventory electronically.

Vaccine Transport

The CDC recommends the transport of vaccine to 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 vaccine 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 for 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. Planned and/or routine transport requires the use of a mobile refrigerator/freezer unit or an approved static temperature-controlled vaccine cooler. Styrofoam coolers and vaccine shipping containers are not approved for transport.
- 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 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.

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 following supplies and packing procedures.
This type of transport is only approved for emergency transport.

Gather Needed Supplies:
- Hard-sided cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range between 35°F and 46°F (2°C and 8°C)
- Conditioned frozen water bottles: place 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 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.

This packout 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 manufacturer determines viability.

Manual Defrost Procedures

The defrost procedures should be following once the ice on the freezer reaches ¼ inch.
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 6° 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 has stabilized and maintains 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 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.

Any questions concerning vaccine storage and handling, temperatures, or vaccine viability can be addressed by contacting your assigned Immunization Field Representative or by emailing
VaxColdChain@ky.gov

Site Visit Expectations

VFC Compliance Site Visit

The goal of the VFC Site Visit is to identify the educational needs of enrolled and active providers in order to support them with meeting program requirements and to ensure that VFC-eligible children receive properly managed vaccine. VFC-related visits will focus on provider compliance with VFC program requirements, including eligibility documentation and proper vaccine storage and handling, and provide an opportunity to perform formal provider training and education.

IQIP Visit

VFC enrolled providers will receive an Immunization Quality Improvement for Providers (IQIP) Visit at the discretion of the Kentucky Immunization Branch. Each VFC provider will receive an IQIP Visit at least once every 4 years. The goal of the IQIP visit is to assess immunization coverage rates of children 24 – 35 months of age and adolescents 13years of age. This visit provides ongoing education
regarding methods to increase immunization coverage levels. Methods include the use of tools within KYIR, making a strong provider recommendation, and scheduling the next immunization appointment before the patient leaves the clinic. Additionally, this visit helps to analyze clinic flow and identify practices that may be affecting immunization rates and delivery of vaccines services to patients.

Storage and Handling Visits

VFC enrolled providers may receive an unannounced or announced storage and handling visit. The goal of this visit is to provide guidance and education, to protect the vaccine, and to ensure that all VFC-eligible children are receiving properly managed vaccines. This visit will be separate from any other VFC or IQIP visit and will be selected based upon a provider's previous history with storage and handling compliance, time elapsed since last visit and geographic distance from providers receiving VFC compliance visits.

Vaccine Management Education Visit

VFC enrolled providers are offered and may request Vaccine Management Education Visits when circumstances warrant, such as a change in coordinators and other issues for which additional vaccine management education would be beneficial.

Resources

Our aim is to provide you with all the tools you need to be successful and grant support in our joint mission of preventing, promoting, and protecting through education and collaboration to eliminate vaccine preventable diseases in Kentucky.

We hope you find the educational resources provided in this manual adequate in your quest to be an Immunization Champion for Kentucky as we move toward our vision of living free of vaccine preventable diseases. If there are additional materials that you feel would benefit other immunization providers in Kentucky, please feel free to contact our office at 502-564-4478.

Thank you for your contribution to our program.

-Kentucky Immunization Branch
https://chfs.ky.gov/agencies/dph/dehp/Pages/immunization.aspx

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

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

Interactive Immunization Scheduler
http://www2a.cdc.gov/nip/kidstuff/newscheduler_le/

Catch-Up Immunization Scheduler
https://www.vacscheduler.org/

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/webiznet_kyir/Login.aspx

KYIR Resources
Training videos and Printable Training Materials are located in the Reports/Training Module of KYIR.

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

Kentucky Health Information Exchange
https://khie.ky.gov/cwkhie/Pages/contactkhie.aspx

Immunization Certificates
Immunization Certificate, Medical Exemption Certificate, Religious Exemption Certificate
http://education.ky.gov/districts/SHS/Pages/Health-Forms.aspx

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

Immunization Practices
Administering Vaccines
http://www.immunize.org/clinic/administering- vaccines.asp

Epidemiology and Prevention of Vaccine- Preventable Diseases
http://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

Epidemiology and Prevention of Vaccine-Preventable Diseases
https://www.cdc.gov/vaccines/ed/webinar-epv/index.html

General Recommendations on Immunizations
http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

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

Vaccine Preventable Diseases
Manual for the Surveillance of Vaccine-Preventable Diseases
http://www.cdc.gov/vaccines/pubs/surv-manual/index.html

Education and Training
CDC Education & Training
https://www.cdc.gov/vaccines/ed/index.html

You Call the Shots
https://www.cdc.gov/vaccines/ed/youcalltheshots.html

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

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

Medical Management of Vaccine Reactions
http://www.immunize.org/catg.d/p3082a.pdf

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 child care 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

Physicians and heads of families to report diseases to local board of health
https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=8772

214.036 Exceptions to testing or immunization requirement
https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=8778

214.020 Cabinet to adopt regulations and take other action to prevent spread of disease
https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=8774

158.297 Meningococcal meningitis disease and vaccine information
https://apps.legislature.ky.gov/law/statutes/chapter.aspx?id=37853

902 KAR 2:020. Disease surveillance
 https://apps.legislature.ky.gov/law/kar/902/002/020.pdf