Kentucky VFC Program

Provider Manual

Updated July 2023

Cabinet for Health and Family Services
Department for Public Health
Division of Epidemiology and Health Planning
Kentucky Immunization Branch
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Table of Contents

Vaccine Storage & Handling

- Storage Unit Requirements
- Temperature Monitoring Requirements
- Temperature Excursion Reporting
- Manual Storage Unit Defrost Procedures
- Adjusting Storage Unit Temperatures

Vaccine Transport

- Emergency Transport
- Transport for Off-Site Events

Digital Data Logging Thermometer Uploads in KYIR

- Configuration
- Assigning to Storage Unit

Resources

Introduction

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 that ensures all children have access to life-saving vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP). This is accomplished by providing vaccines at no cost to VFC-eligible children through public and private providers enrolled in the program. The VFC Program is regulated by the Centers for Disease Control and Prevention (CDC) and the National Immunization Program (NIP).

Funds for the VFC program are annually transferred from the Centers for Disease Control and Prevention (CDC) and awarded to immunization projects. About ninety percent of these funds are used for vaccine purchases. The remaining funds are used for program operational activities such as provider recruitment and enrollment, evaluation, vaccine ordering, and accountability.

The VFC program:

Provides vaccines free of charge to eligible children.

Covers all vaccines recommended by the ACIP.

Reduces vaccine cost as a barrier to the vaccination of eligible children.

Reduces the practice of referring children for vaccination and keeping children in their medical homes for comprehensive health care.

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

VFC Program Benefits

Provides cost-savings to states and territories through the bulk purchase of vaccines at lower prices using CDC's contracts and eliminates state-to-state differences in price.

Reduces referrals of children from private providers to local health departments for vaccination.

Saves VFC-enrolled providers out-of-pocket expenses for vaccines.

Eliminates or reduces vaccine costs as a barrier to immunizing eligible children.

Provider Manual

This provider manual contains best practices, recommendations, and requirements of the Kentucky VFC Program.

Providers enrolling in the VFC program agree to all conditions contained in the Provider Agreement and this manual.

The most current version will be posted on the Immunization Program webpage. When revisions are made, providers will be notified through an all-provider email with the revised section(s) and the revised version will be posted on the webpage.

It is the provider's responsibility to keep the most up-to-date version by discarding outdated sections and replacing them with current versions.

Acronyms

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

Immunization Program Contact Information

VFC Enrollment	
Contact for enrollment questions, to report a facility change, or update the Primary and Backup VFC Contacts.	Email: KYVaxProvider@ky.gov
Vaccine Ordering & Accountability Section	
Contact for vaccine ordering, inventory, reconciliation, returns, and supply issues.	Email: DPH.KVP@ky.gov
Vaccine Storage & Handling	
Contact for VFC vaccine storage and handling issues, temperature excursions	Email: VaxColdChain@ky.gov
KYIR Helpdesk	
Contact for general KYIR assistance, user accounts, password resets, and facility enrollment.	Email: KYIRHelpdesk@ky.gov Phone: 502-564-0038 Available Monday – Friday 8:00 am – 4:00 pm EST

Kentucky Immunization Program

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

KYIR Helpdesk

The KYIR Helpdesk is an important resource for VFC providers.
All VFC providers are assigned a unique Personal Identification Number (PIN) which should be referenced when contacting the Helpdesk.
Hours of Operation: Monday – Thursday 8:00 am to 4:00 pm eastern and Friday 8:00 am to 12:00 pm eastern.
Telephone: 502-564-0038
Email: KYIRHelpdesk@ky.gov

Immunization Regional Field Representative

The Regional Field Representatives act as the primary liaison between the VFC program and prospective or enrolled providers. They provide a variety of support services for VFC providers: approve sites for enrollment, conduct site visits, provide on-site training, and provide answers for all things VFC.

Kentucky Immunization Branch Field Representatives

Effective 07/05/2023

Kentucky Public Health
Prevent. Promote. Protect.

Region 1
Lucy Campbell
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502-229-9385

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Lauren Wallace
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502-229-6995

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Region 9
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Shelley.Davis@ky.gov
502-234-4213

Region 10
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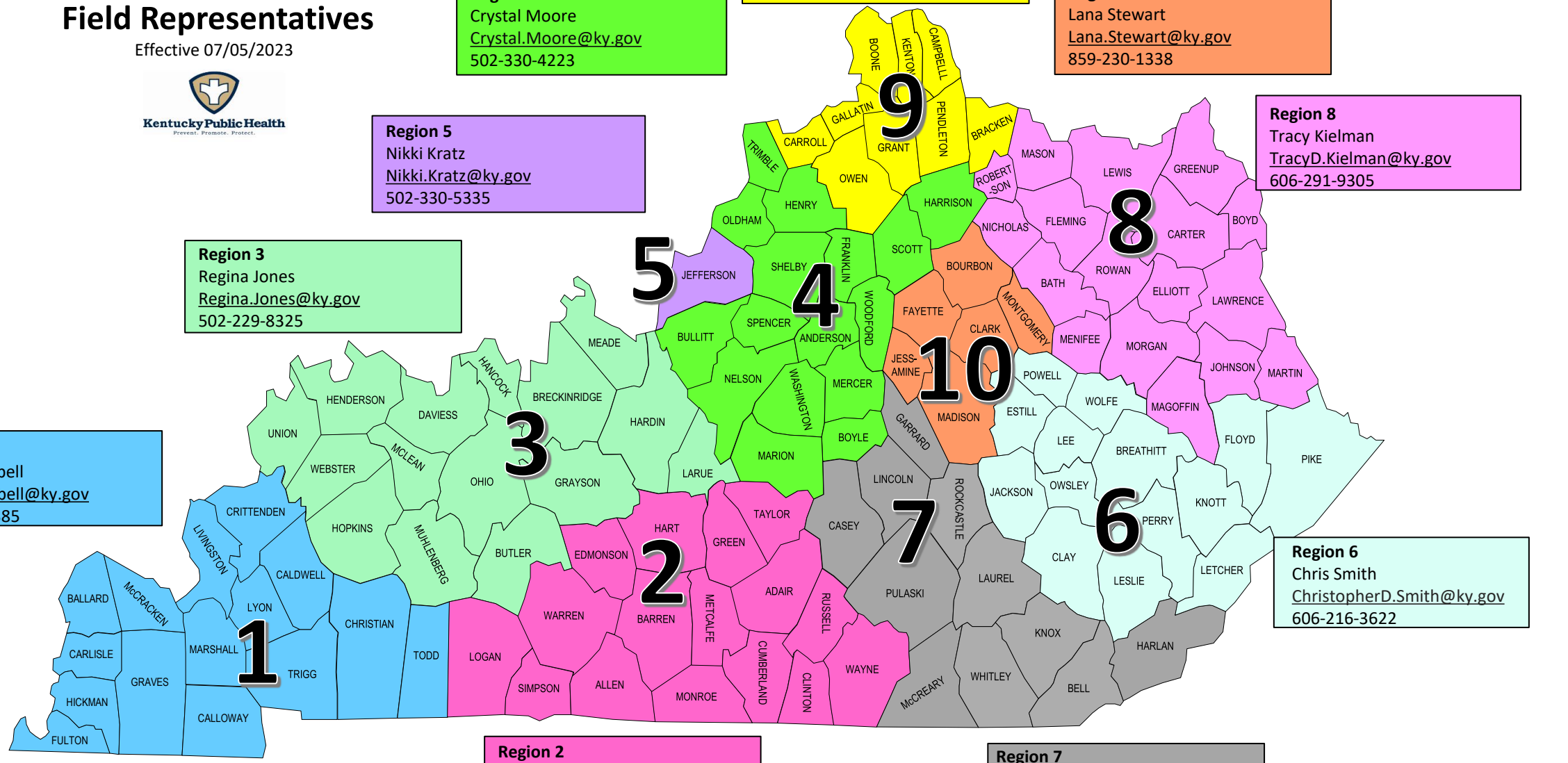


VFC Program Requirements Summary	
Staff	Key Clinic Staff includes a Medical Director, Primary Vaccine Coordinator, and a Backup Vaccine Coordinator. Required training must be completed prior to enrollment as well as annually. Any changes in key clinic staff must be submitted to the VFC Program within 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 a 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 all ACIP-recommended vaccines in both 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, once per calendar year to remain on the program. To place an order, there must be a currently balanced reconciliation for each storage unit within the past 13 days.
Receiving	Appropriately trained staff must be available and 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 vaccines to administer to both private and public-funded children that they serve. Borrowing is permitted only in rare, unplanned circumstances.
Transfers	Transfers of vaccines should be rare and not routinely occur. The Provider must contact and gain approval from their assigned Immunization Field Representative before the transfer is to take place. Only transfers that are within 1 hour will be approved. Immunization Field Representatives will handle transports greater than 1 hour.
Expiration Dates and Returns	VFC Providers must monitor vaccine expiration dates and notify their assigned Immunization Field Representative within 3 months of vaccine expiration. The short-dated vaccine may be transferred to another VFC Provider with Field Representative approval. All expired VFC vaccines must be returned to the manufacturer through a return submitted in KYIR. Exceptions include opened multi-dose vials, which must be adjusted out of VFC inventory in KYIR.
Mass Clinics	Providers who conduct off-site and/or mass vaccination clinics with publicly funded vaccines must follow all VFC requirements in addition to enhanced storage and handling practices. All off-site clinics must have the approval of the assigned Immunization Field Representative.
Temperature Excursions	Once a vaccine has been exposed to temperatures outside the recommended temperature range, Providers must follow the temperature excursion protocol which includes completing/submitting an incident report to the assigned Field Representative after contacting the manufacturers to determine vaccine viability.
Wasted Vaccines	VFC Providers must maintain vaccine inventory to minimize the risk of vaccine loss. All wasted or discarded vaccines must be documented in KYIR on monthly reconciliations.
Restitution	The KY Immunization Program reviews all vaccine loss to determine if it was avoidable or unavoidable. VFC Providers are responsible for the repayment of avoidable vaccine loss. The Provider may be required to replace the lost vaccine with a privately purchased vaccine on a "dose for dose" basis.
Fraud and Abuse	All VFC Providers must agree to operate based on requirements to avoid fraud and abuse. Failure to follow the requirements could lead to fraud and abuse of the VFC Program.

VFC Program Policies

The VFC program was created to increase access to healthcare and allow children to remain in their medical homes for immunizations.

Program Enrollment

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

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

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

- Pediatricians
- Family practitioners
- General practitioners
- Local health departments
- Specialty care providers can include (but are not limited to):
- OB/GYNs
- Specialty provider practices
- School-located vaccination clinics *
- Pharmacists *
- Urgent Care Centers *

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

Specialty Providers

Specialty providers who serve a unique client base and offer only specific pediatric vaccines are eligible for the VFC program. Unless otherwise noted below, specialty providers must follow all requirements of the VFC program.

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

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

- **Birthing Hospitals**
  Hepatitis B vaccination is recommended for all infants soon after birth and before hospital discharge. The Immunization Program funds a universal hepatitis B birth dose vaccine program for all infants born in the state. Because this program is partially funded through the VFC Program, Kentucky birthing hospitals must be enrolled in the VFC Program and fulfill all program requirements to receive publicly supplied vaccines.
  All newborns in Kentucky qualify for the vaccine. <u>However, enrolled birthing hospitals must track birth dose recipients by VFC eligibility in KYIR or their EHR that's connected to KYIR.</u>
- **Pharmacies**
  Kentucky pharmacies are allowed to provide vaccines to children aged 3 through 18 years of age. Pharmacies can enroll in the VFC Program in order to serve Medicaid and other VFC-eligible children.
  - <u>Pharmacies must agree to vaccinate all "walk-in" VFC-eligible children and not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.</u>
  - Pharmacies must report all doses administered and eligibility to the Kentucky Immunization Registry.
  - Pharmacies must adhere to state law when administering immunizations.

VFC Provider Agreement

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

Enrollment – New Providers

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

New provider enrollment involves the following steps:

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

VFC enrollment can be completed in two to four weeks although the sequence and timing of enrollment activities may vary depending on your location and availability of Immunization Program staff.

Final approval into the VFC program is dependent upon the on-site Enrollment Site Visit. After successfully passing the Enrollment Site Visit, the practice will be able to place their first VFC vaccine order in KYIR.

Training Requirements for Primary and Backup Vaccine Coordinators:

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

Required documents for Enrollment:

- Completed VFC Provider Agreement with the signature of Medical Director.
  Provider Agreement must include a completed Provider Population Profile. The KY Immunization Program uses the numbers of VFC and non-VFC-eligible children in the practice to evaluate the appropriateness of VFC vaccine orders. Provider Profile numbers are required to be reviewed and updated at least annually.
    - To determine the patient population, a provider may use patient records and/or vaccine administration data submitted to KYIR. It is essential to be accurate when submitting patient population; this information determines the number of vaccines each provider will need in the coming year.

- Completed Vaccine Management Plan
- CDC You Call the Shots training certificates of completion for modules 10 & 16 for the Primary and Backup vaccine coordinators.
- Two consecutive days of digital data logging (DDL) thermometer readings for each vaccine storage unit for review and approval.
- Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit the current Notice of Award from the US Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA).

Once all required enrollment documentation has been approved, the Regional Field Representative will schedule an Enrollment Site Visit. Final approval into the VFC program is dependent on passing this visit. After successfully passing the Enrollment Site Visit, the provider will be able to place its first VFC vaccine order in KYIR.
Newly enrolled practices will be authorized to order only one box of each vaccine on their initial order. This is to ensure that all shipping information is correct, and doses are delivered correctly. Subsequent orders are limited based on the use of available vaccines and provider population profile submitted to the program.

Re-enrollment – Current Providers

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

Provider Population Profile

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

Key Clinic Staff

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

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

VFC Provider Education Requirements

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

- Designate fully trained on-site primary and backup Vaccine Coordinators.
- Ensure that the Vaccine Coordinators comply with VFC educational requirements such as annual training and make sure they demonstrate competency in their assigned roles.
- Train staff, including any new employees, on temperature monitoring, including the use of digital data loggers and corrective actions for out-of-range temperatures.
- Make sure that staff authorized to accept packages are trained to immediately notify the Vaccine Coordinator when vaccines are delivered.
- Immediately report to the VFC program via the Regional Field Representative of any changes in Vaccine Coordinator staffing. These changes required a signed VFC Change in Coordinator form to be submitted.

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

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

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

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

Vaccine Management Plan

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

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

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

Providers can compose their own plan or use the fillable version supplied by the KY Immunization program.
A sample Vaccine Management Plan is provided in the reference section at the end of this manual.

Provider Identification Number (PIN)

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

Change Notification Requirement

Current providers must notify the Immunization Program immediately if:

- Their contact information, vaccine management personnel, or vaccine shipment instructions change.
- The medical director (or equivalent) who signed the Provider Agreement changes.
- The number of immunization patients at their facility changes significantly.
- The facility type changes.
- They add or acquire new VFC vaccine storage units and/or data logger thermometers.
- Their facility status changes (e.g. closure, moving, or merging with another facility).
- Changes to address must be reported at least 10 business days before moving the VFC vaccine to the new location.
    - Once vaccine storage units are moved to a new location, two days of in-range temperatures will need to be submitted for review and approval prior to the vaccine being placed in these units.

VFC Documentation Retention

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

- Enrollment documentation
- VFC patient screening and eligibility documentation
- Billing records
- Medical records of immunizations
- Vaccine ordering records

- Vaccine purchase and accountability records (such as Borrowing forms and invoices for replacement of borrowed vaccines)

Private Stock

Enrolled VFC providers are required to maintain a private vaccine inventory that is sufficient to serve their non-VFC-eligible patient population, as reported on the Provider Profile portion of the VFC Provider Agreement.

The CDC generally considers a "sufficient" supply to be a four-week inventory, based on the size of the practice's stated non-VFC patient population.

Termination

VFC providers may terminate the Provider Agreement at any time.

A provider location that is closing or withdrawing from the VFC program must provide at least 10 business days written notice to allow time for VFC vaccine to be relocated by the Regional Field Rep.

The Immunization Program may terminate the Provider Agreement due to:

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

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

Program Initiated Termination Policy

When responding to non-compliance issues, the KY Immunization Program considers the seriousness of the issue, whether it is repetitive, intentional, negligent, an error due to lack of knowledge, or whether extenuating circumstances are involved. We reserve the right to escalate non-compliance issues that are repetitive, serious, or substantial instances of fraud and abuse.

Typical Non-compliance Follow-Up: The KY Immunization Program uses the online CDC program PEAR (Provider Education, Assessment, and Reporting) to report and track VFC compliance. PEAR prescribes corrective actions for one-time, non-serious incidences of non-compliance. PEAR prescribes two types of corrective actions:

- On-site Actions can be completed at the time of the visit with no additional follow-up.
- Follow-Up Actions require the provider to correct the non-compliance issue and then perform additional tasks by a deadline in the future. Some follow-up actions may require a return visit from the Regional Field Rep.

Escalated Follow-Up: Providers enter escalated follow-up if their non-compliance issue is repetitive (i.e. same issue occurred within the past two site visits), serious, or if a prescribed follow-up action is not completed within a given time frame. Escalated follow-up puts the provider on probation and involves agreed-upon, written corrective actions with firm deadlines and increased Immunization Program oversight. Failure to complete an escalated follow-up plan results in termination from the VFC program.
Termination: Termination is the removal of a provider due to uncorrected, non-compliance issues; substantiated instances of fraud or abuse; or a permanent condition such as being included on the "List of Excluded Individuals and Entities" from the Office of Inspector General.
Terminated providers must return any unused public vaccine as directed by the Immunization Program. Once all vaccine has been accounted for, the Immunization Program issues a memo to the provider finalizing the termination.
A terminated provider may be allowed to re-enroll if they complete the enrollment process, including an enrollment site visit, and demonstrate full VFC program compliance.

Billing

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

- ### Vaccine
  Providers cannot charge patients, Medicaid, or private insurance for the VFC-supplied vaccine. At no time should billing occur for the cost of VFC vaccine.
- ### Administration Fee
  - Providers agree to accept the administration fee set by the state Medicaid agency for Medicaid patients.
  - Providers can charge non-Medicaid VFC-eligible patients an administration fee up to $19.93 per vaccine (not per antigen in combination vaccines).
  - VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.
  - Unpaid administration fees cannot be sent to collections, and providers cannot refuse to vaccinate an eligible child whose parent or guardian has unpaid vaccine administration fees.
  - Providers who bill for the vaccine administration fee of a non-Medicaid VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.
  - Providers should never bill two different "payers" (i.e., patient, Medicaid, insurance) for the same vaccine administration fee amount.

Patient Eligibility

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

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

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

Screening and documentation must include the date of the visit and the child's specific eligibility category. VFC provides must use screening results to ensure that only VFC-eligible children receive the VFC vaccines and that administration fees are billed appropriately. Eligibility status must be readily available to staff administering vaccines prior to selecting which vaccine stock to use.
Children who have insurance that covers vaccines are not VFC-eligible even if the patient has a high deductible or copays. Additionally, children with insurance seeking vaccination services either from an out-of-network provider or outside the geographic coverage area of their policy are considered fully insured and are therefore not eligible to receive VFC vaccines.

VFC Eligibility Categories

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

- Medicaid-eligible: For the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably. Children covered by private insurance who have Medicaid as a secondary insurer are eligible for the VFC vaccine (see table below).
    - Note: A child is VFC-eligible in Kentucky if they are insured by Medicaid in any state.
- Uninsured: A child who has no health insurance coverage. Self-reported status is accepted.
    - A child covered by a Health Care Sharing Ministries is considered "uninsured" in Kentucky. These plans are nonprofit alternatives to purchasing health insurance and are not recognized as insurance by the Kentucky Department of Insurance.
- American Indian or Alaska Native (AI/AN): As defined by the Indian Health Care Improvement Act (25 U.S.C 1603).
- Underinsured:
    - A child who has health insurance, but coverage does not include any vaccines.
    - A child who has health insurance, but coverage does not include all ACIP recommended vaccines. (Underinsured for non-covered vaccines).
    - A child who has health insurance but there is a fixed dollar limit or cap for vaccines (Underinsured after the limit or cap is reached).
    - Note: Underinsured children are only eligible to receive the VFC vaccine at Federally Qualified Health Centers [1](FQHC), Rural Health Clinics[2] (RHC), or Local Health Departments (LHD). If providers cannot verify vaccine insurance coverage, underinsured children are considered insured and not VFC eligible.

FQHCs, RHCs, or LHDs that serve underinsured children are REQUIRED to verify a child's underinsurance status.

For patients eligible under more than one category, providers should select the category that requires the least out-of-pocket expense to the parent or guardian.
Fully insured children are ineligible for VFC vaccines. Children whose health insurance covers vaccinations as a benefit are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

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

Documenting Eligibility Screening

Eligibility screening results must be:

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

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

Special Eligibility Circumstances

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

Medicaid as Secondary Insurance

Any insured or underinsured child who has Medicaid as secondary insurance is eligible for the VFC program but is not required to participate. There are two options for billing. Children with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Billing options when Medicaid is the secondary insurance:

Use private vaccine and bill the primary insurer for the vaccine and the administration fee. If the claim is denied, bill Medicaid for the administration fee and repay the private dose with a VFC dose. Document the repayment as required and described in this manual under Borrowing.

Use VFC vaccine and bill the primary insurer for the administration fee. If the claim is denied, bill Medicaid for the administration fee.

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 to receive administration fee reimbursement from that Medicaid program.

Incarcerated Juveniles

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

Dual Eligibility – American Indian/Alaska Native

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

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

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

VFC Site Visits

A compliance site visit is when a Regional Field Representative visits your clinics and assesses the implementation of the VFC program at your location. Compliance visits consist of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves the administration of a questionnaire, evaluating compliance with requirements, and providing education. The visit includes a formal review of vaccine management practices, as well as a review of patient records and other documentation to ensure appropriate vaccine eligibility screening and administration documentation is occurring.
All VFC providers receive a compliance site visit within 12 months of enrollment and at least every 24 months after that.

Site Visit Preparation

Approximately one month prior to your visit, the Field Representative will contact you by telephone or email to schedule the visit.

During the Site Visit

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

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

Approximately one hour of the site visit is a conversation with the vaccine coordinator. The Field Representative will ask questions pertaining to the VFC program and provides a list of public vaccines shipped to your facility over the last year. They will also inspect your vaccine storage units.
At the end of the visit, the Field Representative will provide verbal feedback on their findings and a follow-up plan detailing any corrective actions.

There are 2 types of corrective actions:

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

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

Site Visit Follow-Up

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

Other Types of Visits from the Immunization Program

- Unannounced Storage and Handling Visits – Throughout the year, the Immunization program perform unannounced visits that focus on vaccine storage and handling. Any active VFC provider may receive an unannounced visit. They take approximately 30 minutes and include an inspection of the vaccine storage units.
- Educational Visits – Educational visits are those where the main purpose is education and not assessing compliance. Providers may request an education visit from the Immunization program at any time (subject to staff availability). Education can also be conducted by telephone or webinar.
- Enrollment Visits – Enrollment visits occur during the enrollment process for newly enrolling or re-enrolling providers. The purpose of this visit is to provide education on the VFC program requirements and verify that the facility has the appropriate resources to implement program requirements.
- IQIP Visits – Immunization Quality Improvement for Providers visits are covered in their own section in this provider manual.

Advisory Committee on Immunization Practices (ACIP)

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

VFC Resolutions

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

Please note the following about VFC resolutions:

VFC Resolutions may not be identical to published ACIP recommendations.

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

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

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

ACIP Recommendations

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

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

National Childhood Vaccine Injury Act

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

Vaccine Information Statements (VIS)

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

Vaccine Adverse Event Reporting System (VAERS)

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

Reportable Events – Required

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

Reportable Events – Voluntary

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

Vaccine Charting Requirements

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

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

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

VFC providers are required to record in KYIR, every vaccine administered to all patients 0 through 18 years of age, regardless of VFC status, within 24 hours of the administration date.

Vaccine Ordering and Accountability

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

Reconciling Inventory

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

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

Ordering Vaccines

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

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

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

Inform the VAS Staff of special circumstances such as off-site clinics and campaigns where you need more vaccine than your usage history allows by placing a note in the “Clinic Comments” section of the order request.
Inform the VAS Staff of any upcoming clinic closures within the next 30 days by placing a note in the “Clinic Comments” section of the order request.
Inform the Immunization Program if your shipping address or delivery times change immediately.

Receiving Vaccine Shipments

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

Follow the steps below when receiving vaccines:

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

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

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

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

Accepting Shipments in KYIR

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

- Click on the link to initiate the receipt of the shipment.
- Each vaccine is separate from the list of shipped vaccines. Verify that the quantity shipped is in fact the quantity you received. Click Receive.
- If you have already manually entered the doses into your inventory in KYIR, click on Dismiss so that you do not double your inventory erroneously.
- Enter the date and time when you received the shipment. This date should be accurate so that your inventory count stays correct.
- Select the Inventory location where the vaccine is going to be stored.
- Verify that the Lot Number, Expiration Date, and Number of Doses are correct. Click Create.
- KYIR will check the NDC and lot numbers you already have in your inventory and try to match your shipment to what you already have.
- Check the Match Confidence Percentage. If and only if the vaccines are an exact match (100% match) then click "Add To This Inventory Line Item"; if it shows anything less than 100% click on the blue "Proceed With Create" at the top of the page.

Seasonal Influenza Vaccine Orders

The Immunization Program pre-books seasonal influenza vaccine months in advance and distributes doses during the season as they become available.
The Immunization Program opens an Influenza Pre-book order form early each calendar year. It lists the vaccine offerings for the coming season and instructions for submitting the form.
The influenza vaccine pre-book must contain your order for the coming flu season and be returned by the submission deadline in order to reserve your vaccines for the season.
As influenza doses become available at the warehouse, we ship allocations to enrolled providers. Shipments typically begin the first of September and last through December until all orders are fulfilled. You may not receive your entire pre-book request at once.
After pre-book orders are fulfilled, we often have extra doses available on a first come, first serve basis.
Seasonal influenza vaccine expires June 30th of each year. DO NOT discard expired vaccines. It must be returned to McKesson following the procedure for all expired VFC vaccines.
Contact the Vaccine Accountability and Ordering Section with questions about influenza vaccine orders. (Email: DPH.KVP@ky.gov).

Inventory Management

Organizing and Rotating Stock

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

Short-dated Vaccine

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

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

Expired Vaccines

Expired vaccine is nonviable and should never be administered to patients. Providers must check expiration dates weekly and immediately remove expired vaccines from storage units.
All VFC vaccine that has expired must be reported in KYIR so that they may be returned to the supplier.
The return process must be completed in KYIR. A prepaid return shipping label will be emailed to the primary vaccine coordinator's email on file.
Expired vaccines must be returned within 6 months of the expiration date.

Adjustments of Wasted Vaccine

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

Restitution Policy (January 1, 2017)

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

Definitions

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

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

Situations Requiring Restitution

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

- Failure to rotate vaccine stock in order to use the vaccine with the shortest expiration date first.
- Failure to notify KIB a minimum of 90 days prior to the 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 vaccines that results in the expiration of the vaccine before it can be used.
- Provider staff failing to review and/or appropriately interpret and/or document refrigerator and/or freezer temperatures 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 the vaccine.
- Vaccine physically received but unaccounted for in KYIR inventory reporting.

- Transportation of vaccine inappropriately; unnecessary transportation of vaccine, transportation with 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 the 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 the planned closing to prevent the delivery of vaccines during this time.
- Substantial vaccine wastage resulting from repeated or unresolved incidents from the list below of "Situations That Do Not Require Restitution."

Situations That Do Not Require Restitution

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

- Vaccine is damaged, improperly stored during transit, or not delivered in a timely manner by a commercial carrier or delivery service.
- Provider staff moved vaccines to their backup location as outlined in their Vaccine Management Plan, in anticipation of a power outage or due to refrigerator or freezer malfunction, and the backup location experienced 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 vaccines 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.

Procedures for Vaccine Restitution

The Immunization Program considers each situation when determining whether vaccine must be replaced. The factors considered includes but are not limited to: provider communications, program staff observations, temperature data and temperature logs, incident reports, inventory records including wastage and expired doses, eligibility screening documents and borrowing reports.

If restitution is required, the Immunization program will notify the provider in writing including the vaccine, number of doses, monetary value, and the reason replacement is requested.

Providers must reimburse public vaccine dose-for-dose with vaccine from private stock. Monetary payment directly to the Immunization Program is not allowed. Providers must enter and manage the replacement doses in KYIR within 90 days of notification of restitution. Providers will be required to provide copies of purchase invoices of private stock used to replace doses.

Vaccine Borrowing

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

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

Borrowing Cases

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

Note: If you receive 317 funded vaccines, per federal guidelines, 317 funds are only to be used for the uninsured or underinsured or during an outbreak that has been approved by the Kentucky Immunization Program. If accidental borrowing occurs, please follow the procedure detailed above regarding the borrowing report.

Record the borrowed and payback 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. Payback is dose-for-dose and is not interchangeable among vaccine types.
Completed reports must be retained as a VFC program record and made available to the Kentucky Immunization Program upon request.

Fraud and Abuse

By submitting a signed Provider Agreement and accepting shipment of VFC vaccine, you agree to abide by the statutory requirements of the VFC program. These requirements are federal law and as the administrator of the VFC program in Kentucky, the Immunization Program is charged with enforcement. Federal fraud and abuse laws apply to the VFC program. Good stewardship of federal entitlement program taxpayer funding is a top priority. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC program.

The Kentucky Immunization Program refers to Centers for Medicare and Medicaid Services (CMS) any instances of fraud or abuse that appear intentional and results in financial benefits to the provider.

Fraud and Abuse Policy (December 7, 2012)

The following information outlines the policy and procedures to prevent, detect, investigate, and resolve suspected fraud and abuse allegations for medical providers receiving vaccine from the Kentucky Immunization Program. The federal Vaccines for Children (VFC) program is the largest part of the KIB. The Vaccines for Children program is a federally funded program that provides vaccine at no cost to children who are Medicaid-eligible, uninsured, American Indian/Alaska Native, or who are underinsured and receiving immunizations at a Federally Qualified Health Center (FQHC), Rural Health Center (RHC), or a local health department delegated by a FQHC or RHC. The cost and number of vaccines provided by the VFC program, and Adult/317 programs have increased dramatically over the past few years, thus it is imperative that the KIB has effective and enforceable policies and procedures against fraud and abuse to safeguard this significant investment.

Authority: KRS 205.8453(4) directs the Cabinet for Health and Family Services to institute other measures necessary or useful in controlling fraud and abuse. The Kentucky Department for Public Health is responsible for monitoring the utilization of services in the Kentucky Immunization Program and refers any concerns of fraud, abuse, and/or waste to the Office of Inspector General (OIG) as the designated Single State Agency for the Kentucky Medicaid Program. Referrals outlining the potential fraud, abuse, or waste will be forwarded to the OIG, Division of Audits & Investigations, Medicaid Preliminary Investigations (MPI) Branch. The MPI Branch will review complaints of potential fraud, abuse, and/or waste. The MPI Branch is responsible for referring any situations in which they have determined that fraud, abuse, and/or waste may have occurred to an outside agency for further investigation and prosecution (i.e., the Kentucky Office of the Attorney General, Department of Insurance, U.S. Department of Health & Human Services, U.S. Office of the Attorney General, etc.).

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

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

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

Fraud and Abuse Examples

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

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

Preventing Fraud and Abuse

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

- Upon enrollment into the VFC program, new immunization providers will receive an educational training session from the Regional Field Rep to explain the VFC program in detail. Providers will be educated about the purpose, eligibility requirements, and VFC program requirements.
- All providers who participate in the VFC program are required to submit a completed Provider Profile and signed Provider Enrollment form before they can receive the vaccine. Providers must update these forms as needed, annually for the Provider Profile and bi-annually for the Provider Enrollment, to continue to receive vaccines. The Provider Enrollment form outlines the requirements with which providers must comply to participate in the VFC program. By signing the Provider Enrollment form, providers certify that they will comply with the VFC program requirements.
- The Vaccine Accountability and Ordering staff reviews all incoming vaccine orders and reports of doses administered. VAS staff address any inconsistencies on these reports (e.g. ordering more vaccine than is usually ordered, reports of wasted/expired vaccine) quickly, and adjustments are made as appropriate.
- Per the Provider Enrollment form, the provider may have to reimburse the Immunization Program dose for dose for any vaccines that are unaccounted, spoiled, expired, or deemed preventable losses. Providers are required to develop corrective action plans and submit proof of replacement.
- All VFC staff 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.
- Regional Field Representatives conduct additional site visits if providers have vaccine storage and handling problems or other issues and follow up with the providers until improvements are made and maintained.
- Storage and handling training for primary and backup coordinators, which could include in-person training and/or CDC modules is required annually.

- As a quality assurance measure, VFC staff will review the List of Excluded Individuals and Entities list located at http://exclusions.oig.hhs.gov/ 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 (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 and Ordering 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 Regional Field Representative to the provider's office and follow up will be required until the situation improves.

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

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

A suspected instance of fraud or abuse that is determined to be intentional or is not able to be resolved by 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 Program staff will gather and provide any additional information requested by Medicaid/CDC.

If a VFC Provider's actions are determined to constitute fraud or abuse, the provider may be required to reimburse vaccine or other costs, terminated from the VFC program, and have his/her name added to

the 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 Program staff until the situation is resolved.

Fraud and Abuse Contact

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

Vaccine Storage & Handling

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

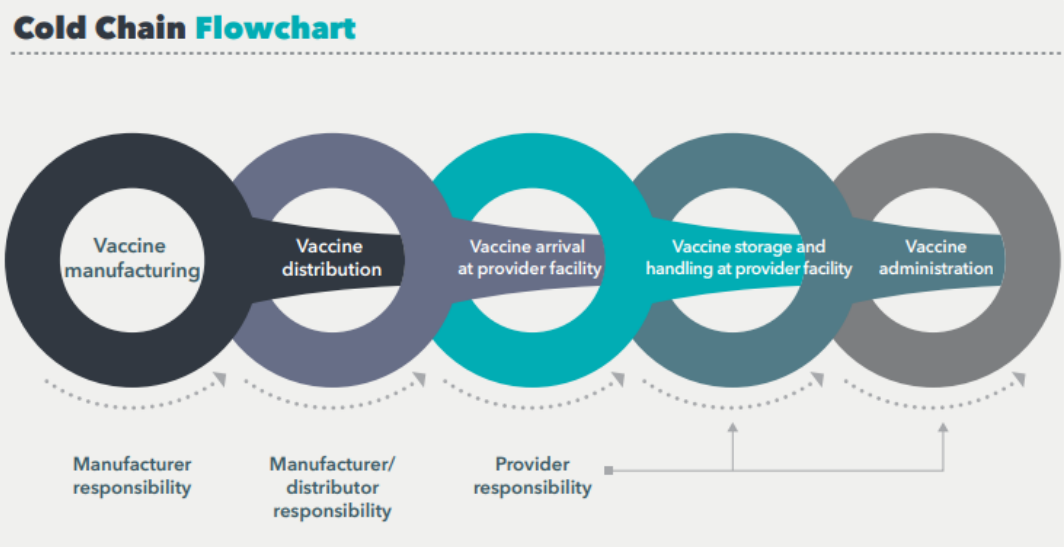
Both VFC Program requirements and Best Practices are provided in this section to assist providers in ensuring viable vaccines are administered to their patients.

Successful vaccine management is dependent on five factors:

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

Vaccine Cold Chain

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



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

- ✓ 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.

Storage Units

The Kentucky VFC program requires stand-alone refrigerator and freezer units. They must be self-contained units that operate only as a refrigerator or freezer and are suitable for vaccine storage. 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 times of high inventory such as during flu season, back-to-school, and prior to holidays when vaccine 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. Also, be sure to avoid outlets with built-in circuit switches or those activated by a wall switch. 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 labeled with warning signs such as "Do Not Unplug" and "Do Not Turn Off".

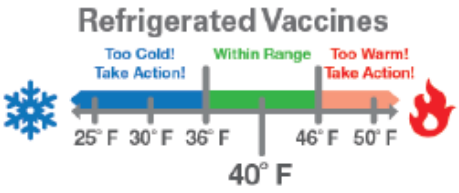
The unit must demonstrate two consecutive days of in-range temperatures prior to being used for vaccine storage. This applies if the unit is new or if the provider has a change in address. The designated Field Representative will approve the storage unit if it is satisfactory for vaccine storage. Providers will need to supply the Field Representative with a copy of the purchase order for the unit and a temperature log of 2 consecutive days of in-range temperatures.

Thermal ballast, such as water bottles, in the refrigerator and freezer is recommended as best practice to help maintain appropriate temperatures inside the storage unit. The doors and top and bottom shelves are ideal locations for water bottles. Thermal ballast may occupy up to 25% of the storage space in the unit.

Back-up storage units must meet the same requirements as 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.

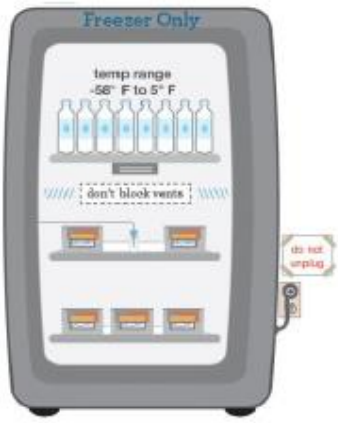
Refrigerator Specifications

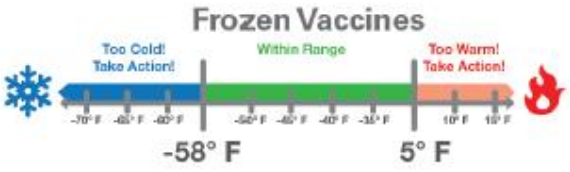
- Any storage unit must meet the following requirements to be approved:
- Maintain consistent temperatures between 36°F and 46°F (2°C to 8°C).
- Be a stand-alone unit at a commercial or pharmaceutical grade.
- Possess the capacity to store all the practice's vaccines along with sufficient water bottles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



Freezer Specifications

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





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 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.

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. The VFC Program has VFC stickers to denote VFC vaccines upon request.
- 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.

Vaccine Order Deliveries

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

Follow the steps below when receiving vaccine shipments:

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

Reporting Procedures:

Out of range temperature indicators inside the shipment:

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

Damaged package or missing doses:

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

Provider Location change reporting:

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

Temperature Excursion

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

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

Manual Defrost Procedures

The defrost procedures should be following once the ice on the freezer reaches ¼"
Instructions for defrosting manual-defrost vaccine freezers:

Plan Ahead

- Ensure the alternate freezer location has enough space to accommodate your inventory
- Set up the backup data logger in the alternate freezer
- Make sure the data logger's alarm settings are set appropriately (alarm above 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 stabilizes 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.

Adjusting Storage Unit Temperatures

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

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

Making a temperature adjustment:

- Refer to the storage unit owner's manual for detailed instructions.
- Make a small adjustment warmer or colder by turning the thermostat slowly to avoid going outside the correct temperature range.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.

- Recheck the temperature.
- Repeat the steps as needed until the temperature stabilizes at around 40°F for a refrigerator and around 0°F for a freezer.
- Consider placing additional water bottles in the unit to help improve temperature stability.

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.
- Vaccines should only be transported once. Only transport the quantity of vaccine you will administer at the alternative site so you will not have to transport a second time.
- Limit transport time to 30 minutes or less. If transport requires more time, hourly checks of the temperature are required on a paper temperature log. The total time of transport and storing vaccines off-site should not exceed 8 hours.
- Vaccines cannot be stored overnight in transport coolers.
- Vaccines should be attended at all times during transport. They are never to be placed in the trunk of a vehicle.
- Transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents for reconstitution.

Packing Vaccines for Transport

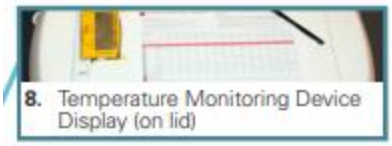
Refrigerated Vaccines: It is best practice to transport with a portable refrigerator unit. If a portable unit is not available, a hard-sided insulated cooler may be used during an emergency with following supplies and packing procedures.

<u>Gather Needed Supplies for Emergency Transport:</u>

- 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 Emergency Transport:


8. Temperature Monitoring Device Display (on lid)

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


7. Conditioned Water Bottles

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


6. Cardboard Sheet

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


5. Bubble wrap, packing foam, or Styrofoam™

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


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

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


3. Bubble wrap, packing foam, or Styrofoam™

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


2. Cardboard Sheet

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


1. Conditioned Water Bottles

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

Image 6: Transport Packout Illustration – available in Resources section on page 46-47

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

Arrive at destination:

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

Off-Site Vaccination Clinic Procedures

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

During All Stages:

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

Pre-Clinic:

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

During the Clinic:

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

Post-Clinic:

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

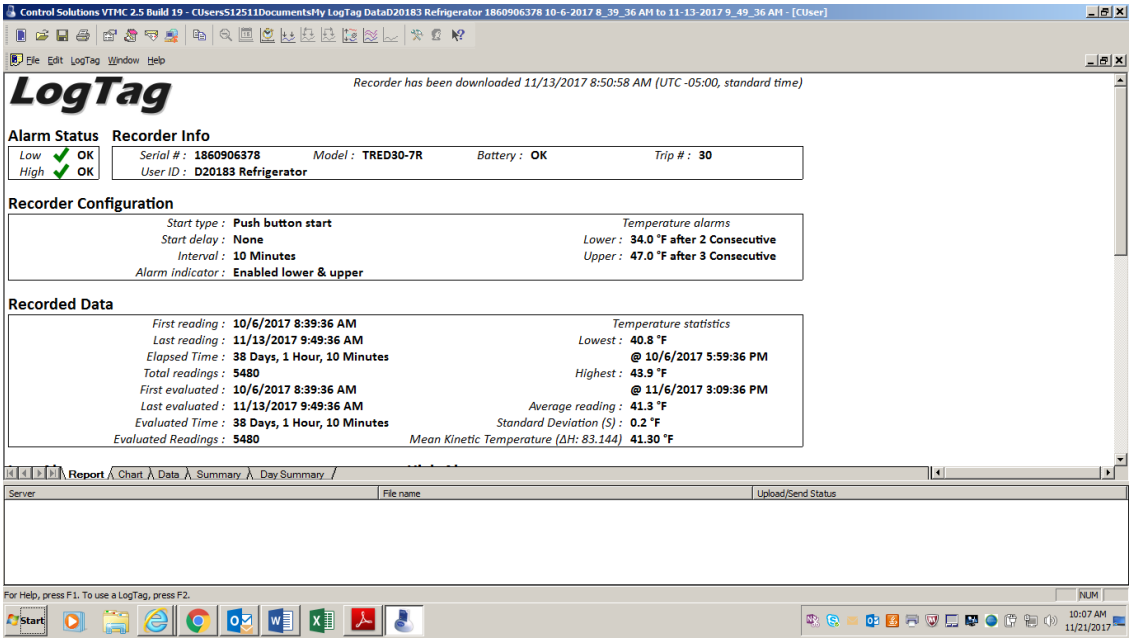
Log Tag Brand Digital Data Loggers

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).

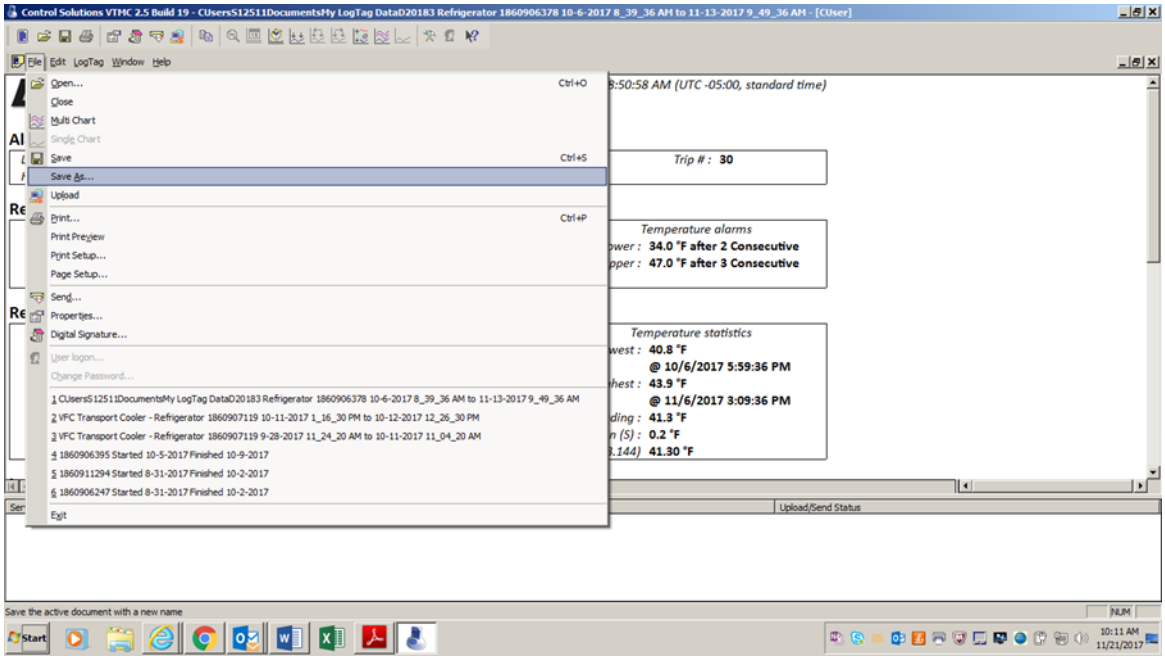
The upload process is illustrated in the protocol below:

How to Upload a Log Tag Temperature Log to KYIR

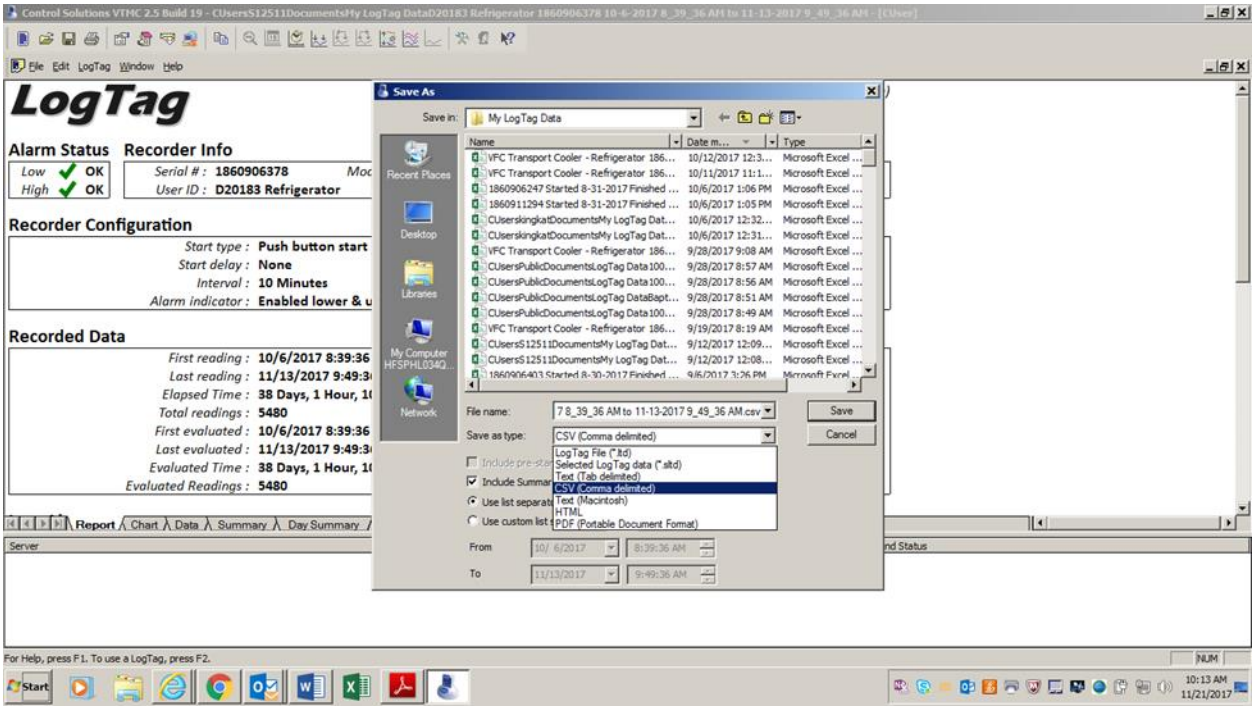
- Stop the Log Tag digital data logger from recording by holding down the Stop/Start/Clear button on the front of the DDL. You will see the work STOPPING flashing on the screen; continue to hold the button down until it stops flashing. The word STOPPED will display on the screen. Take note of which DDL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



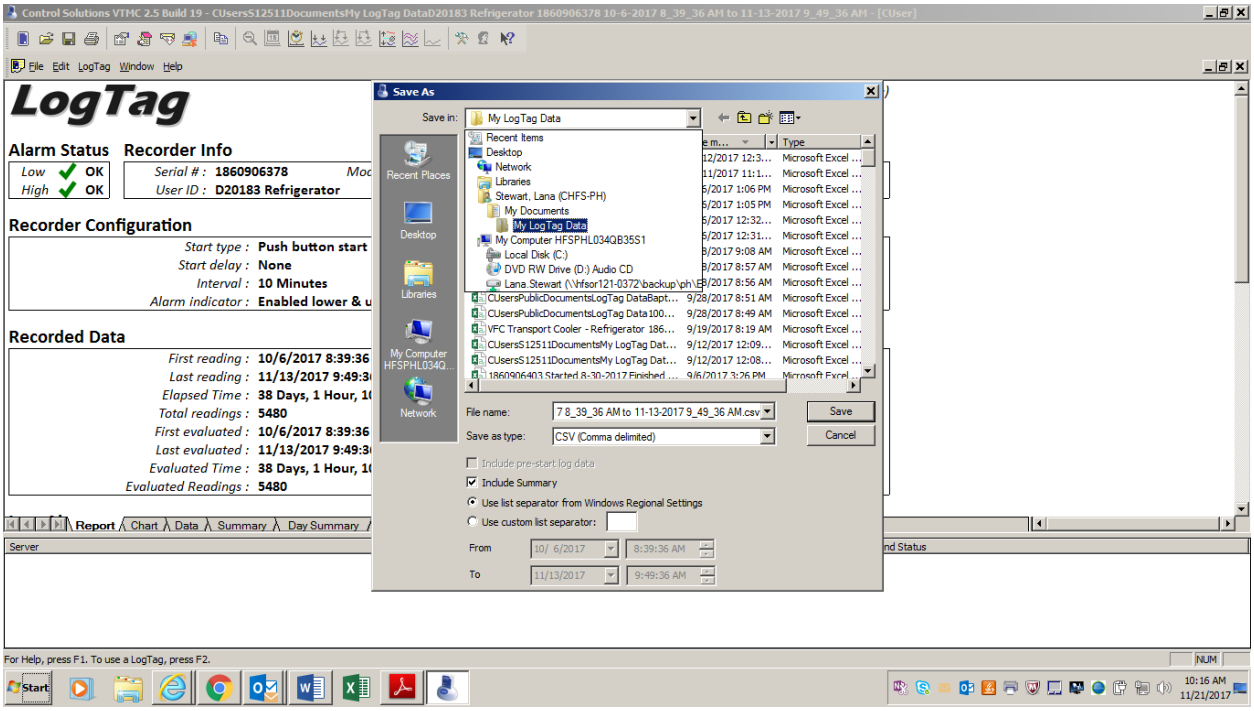
- Save the Log Tag file by clicking on the word File in the menu bar at the top of the screen of the Log Tag Analyzer software. Select the option of Save As…



- 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 to not 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**.

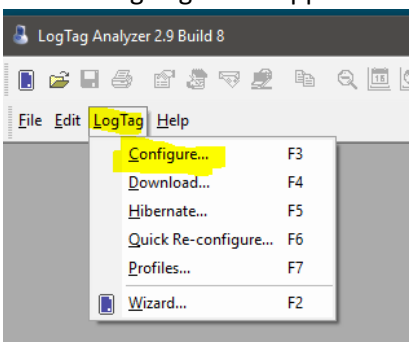
The screen will show the initial report page again. Print a copy of the Report tab and keep it on file with your other VFC paperwork.

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**

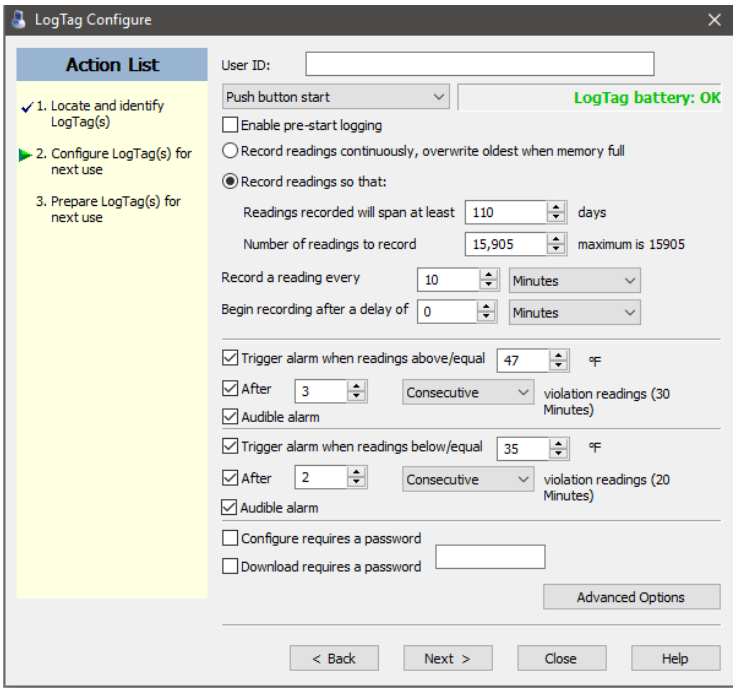


A Log Tag Configure window will open – make sure the settings are correct as shown below

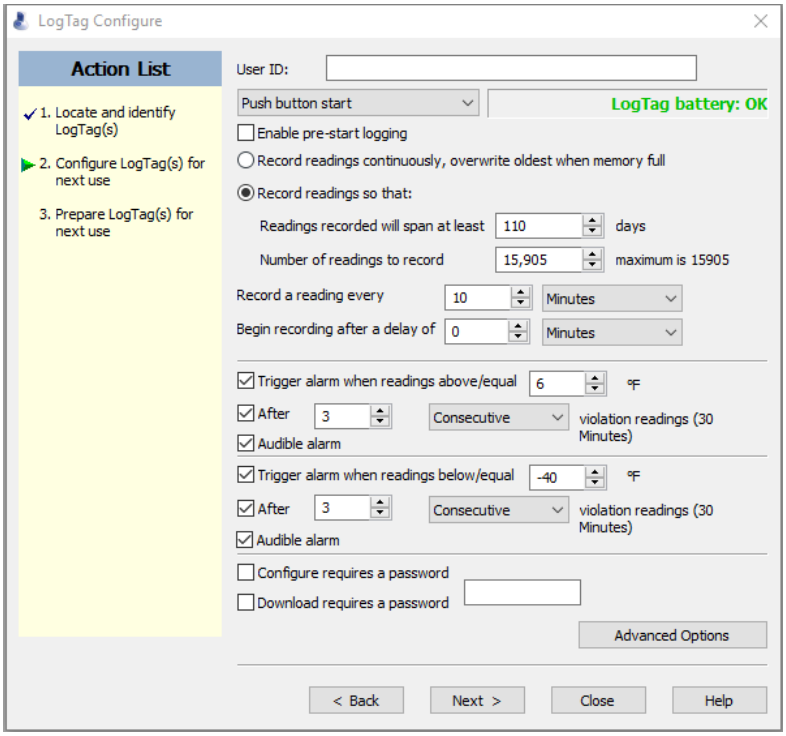
- Record a reading every 10 minutes
- Trigger alarm when readings are above/equal
  - Refrigerator setting of 47 F

- After 3 Consecutive readings

- Freezer setting of 6 F
  - After 3 Consecutive readings



- Trigger alarm when readings are below/equal
  - Refrigerator setting of 35 F
    - After 2 Consecutive readings
  - Freezer setting of -40 F
    - After 3 Consecutive readings

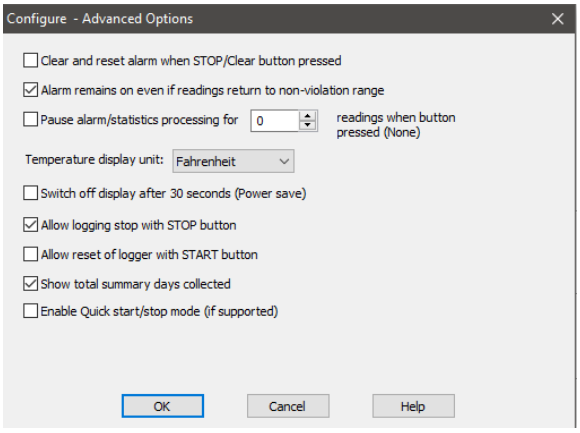


Advanced Options

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

- Check the box for the alarm to remain on after an alarm
- Temperature display unit: Fahrenheit
- Allow logging stop with Stop button
- Show total summary days collected

Click OK to save

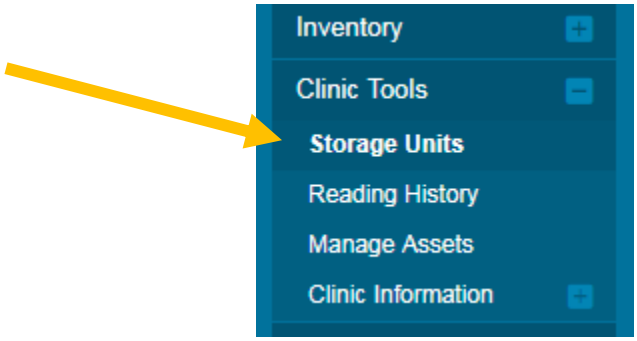


The Log Tag Configure screen will display again. Click on Next to configure.

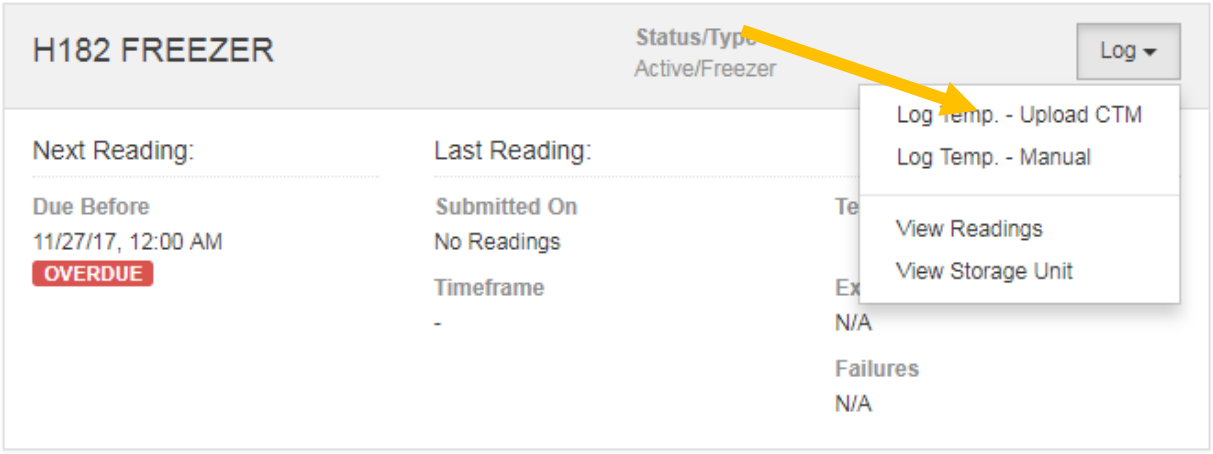
To Upload a Temp Log file into KYIR

Log into KYIR

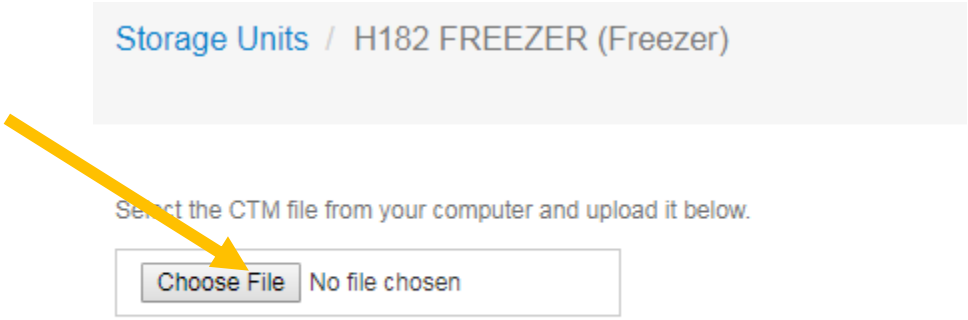
Under Clinic Tools, click on Storage Units



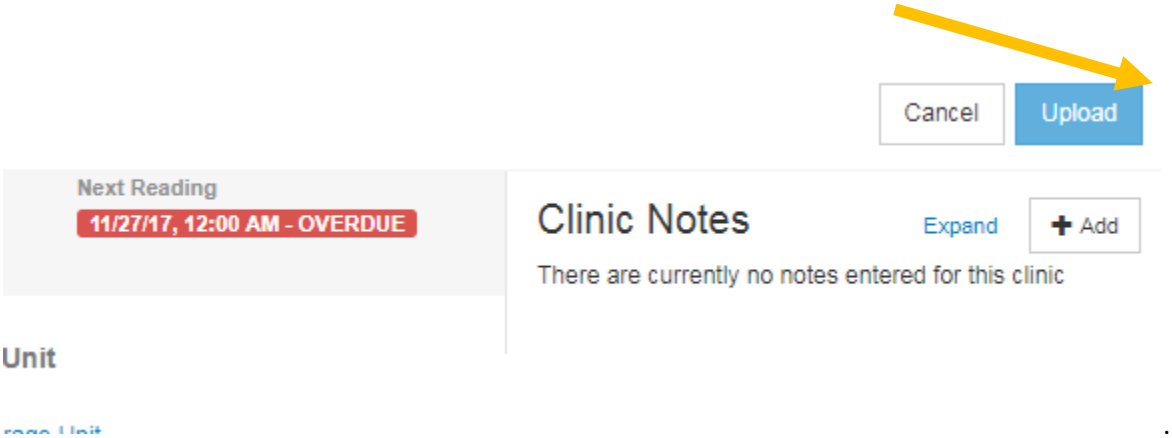
Click on the Log button at the top right of the Storage Unit window and select Log Temp – Upload CTM.



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.



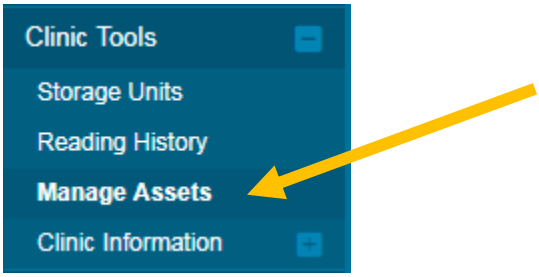
Repeat the process for any other storage units.

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.

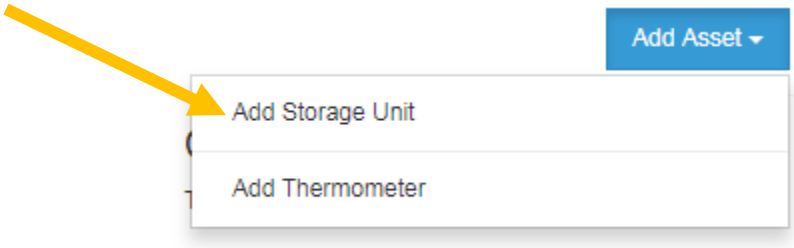
How to Add/Update a Storage Unit or Thermometer in KYIR

To Create/Add a Storage Unit:

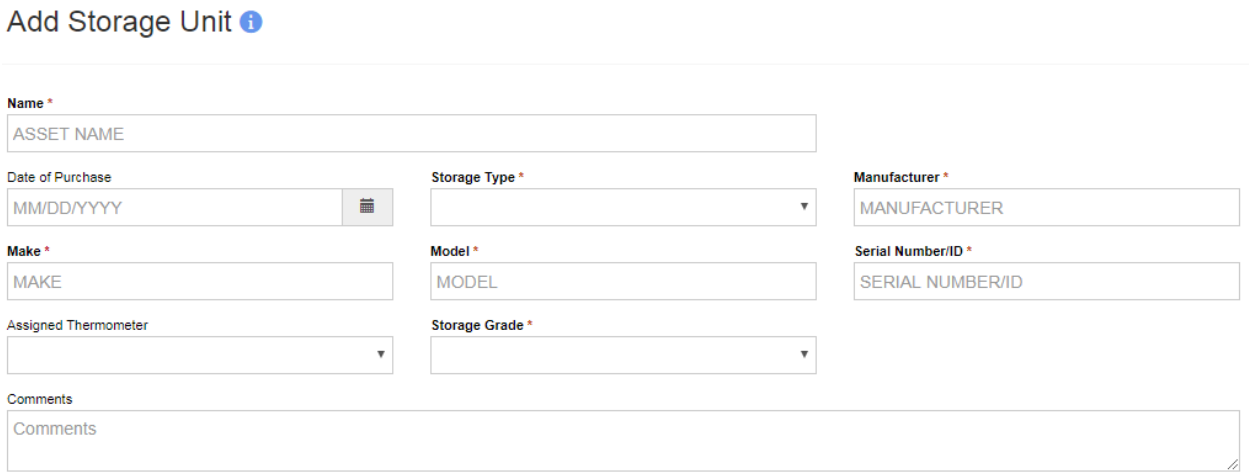
Under Clinic Tools, Click on Manage Assets



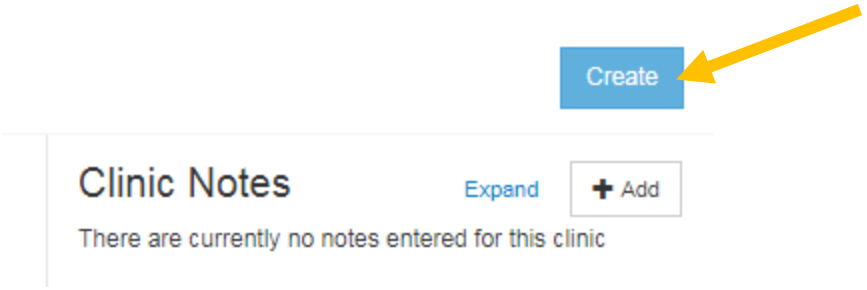
Click on Add Asset blue drop-down box, select Add Storage Unit



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

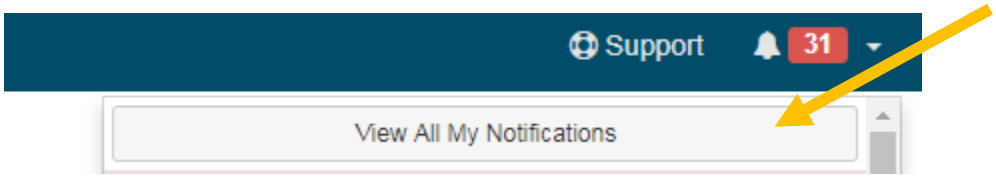


Name: Name of the asset – include the VFC Pin # and Refrigerator or Freezer and/or any other identifier
Storage Type: Select either Fridge or Freezer
Manufacturer: Type in the name of the manufacturer of the storage unit
Make: Type in the make of the storage unit
Model: Type in the model number of the 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.



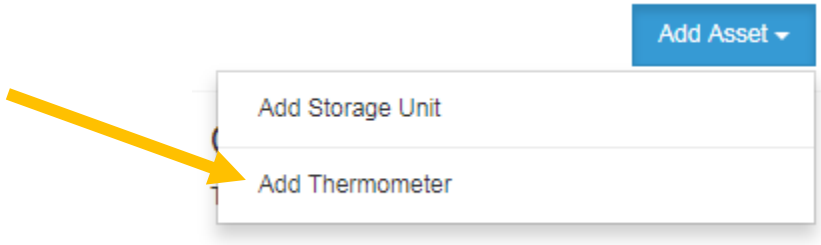
Clinics can create a Storage Unit, but its status will show as **Pending** until it is **Approved** by an Administrator. You will receive a Notification message when approved.

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.

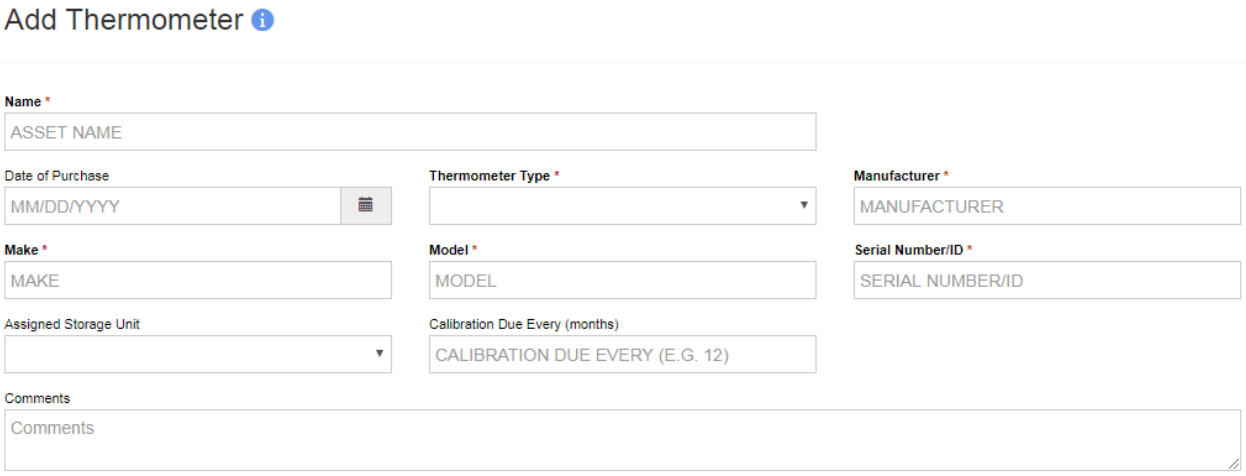


To Create/Add a Thermometer:

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

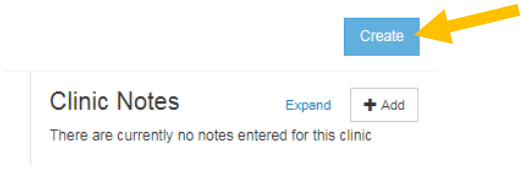


All entry boxes with a red asterisk (*) are required entries.



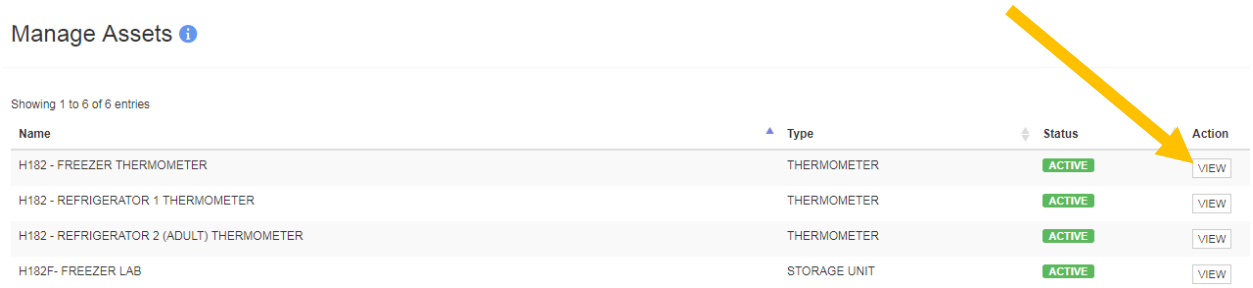
Name: Name of the asset – include the VFC Pin # and Refrigerator or Freezer and/or any other identifier
Thermometer Type: Select from the drop-down box the type of thermometer, Built-In, CTM, or Manual
For all LogTag thermometers, the type is CTM
Manufacturer: Type in the name of the manufacturer of 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.

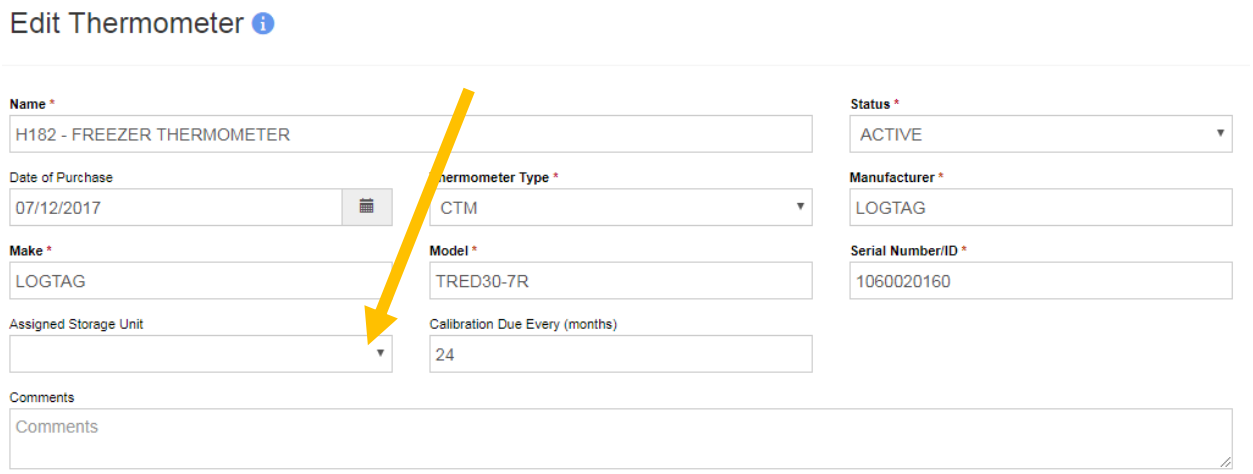


To Assign a Thermometer to a Storage Unit:

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.

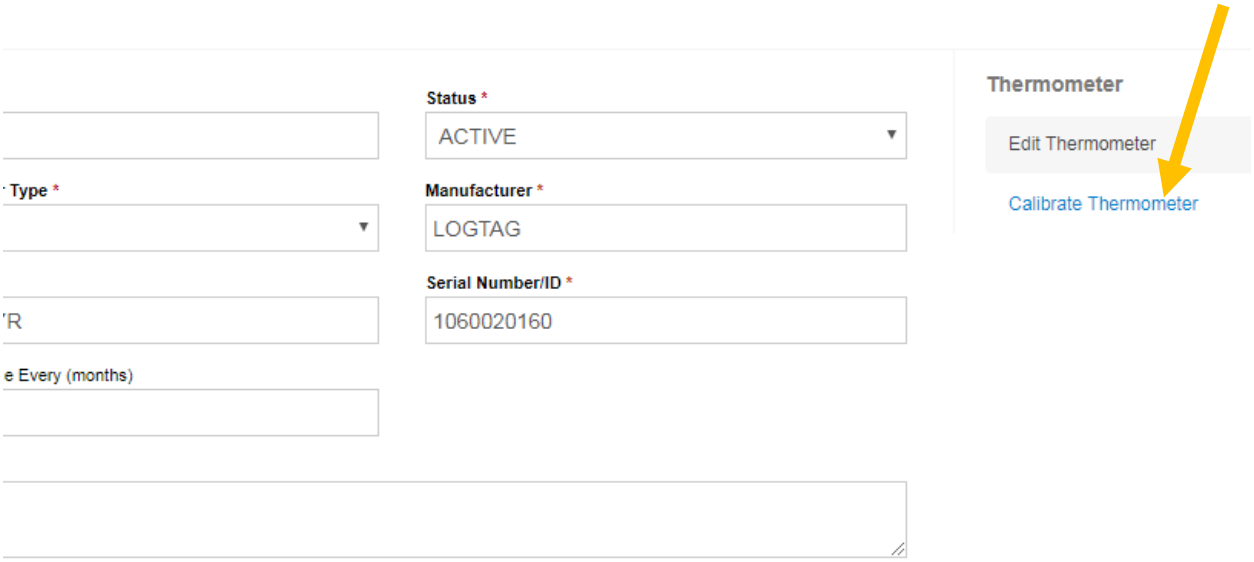


On the Edit Thermometer screen, click on the Assigned Storage Unit drop-down box and select the correct Storage Unit for the Thermometer.



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.



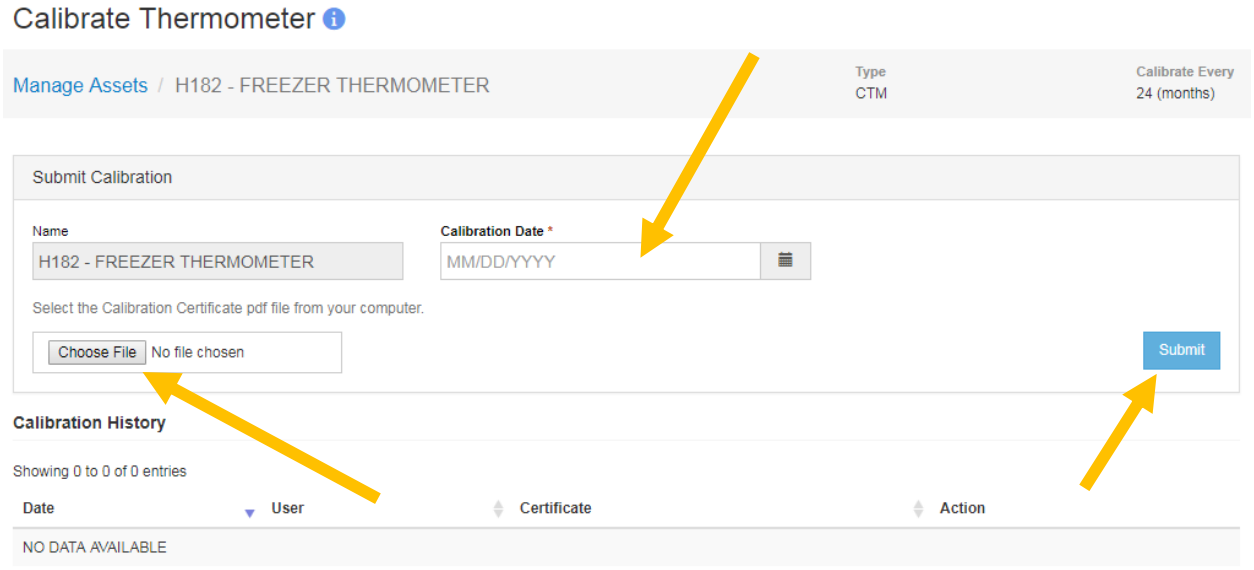
Enter the Calibration Date for the Thermometer.

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:

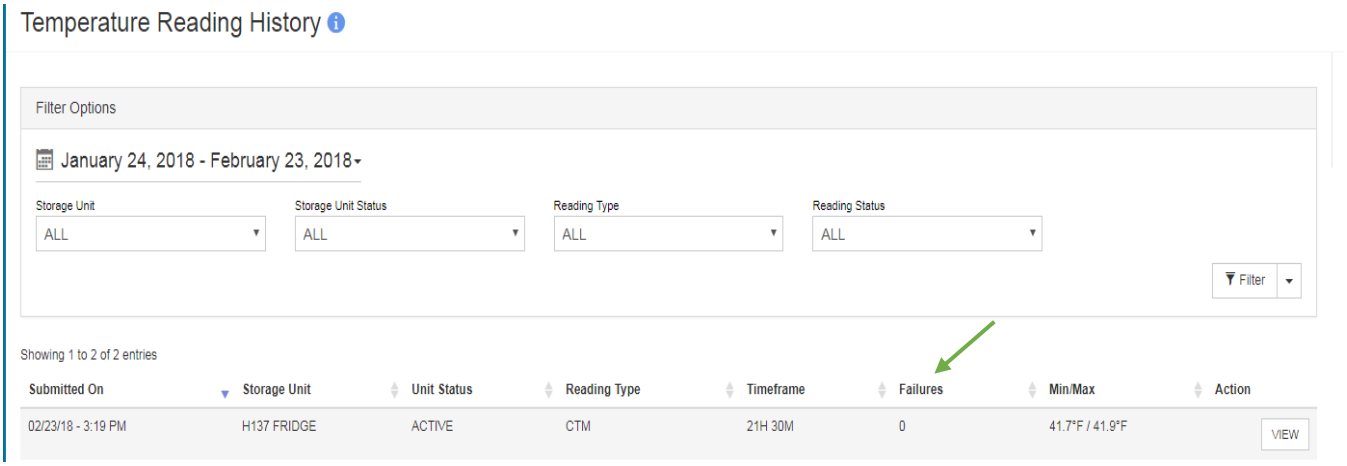
Click on Choose File, to select the certificate file from your computer.

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

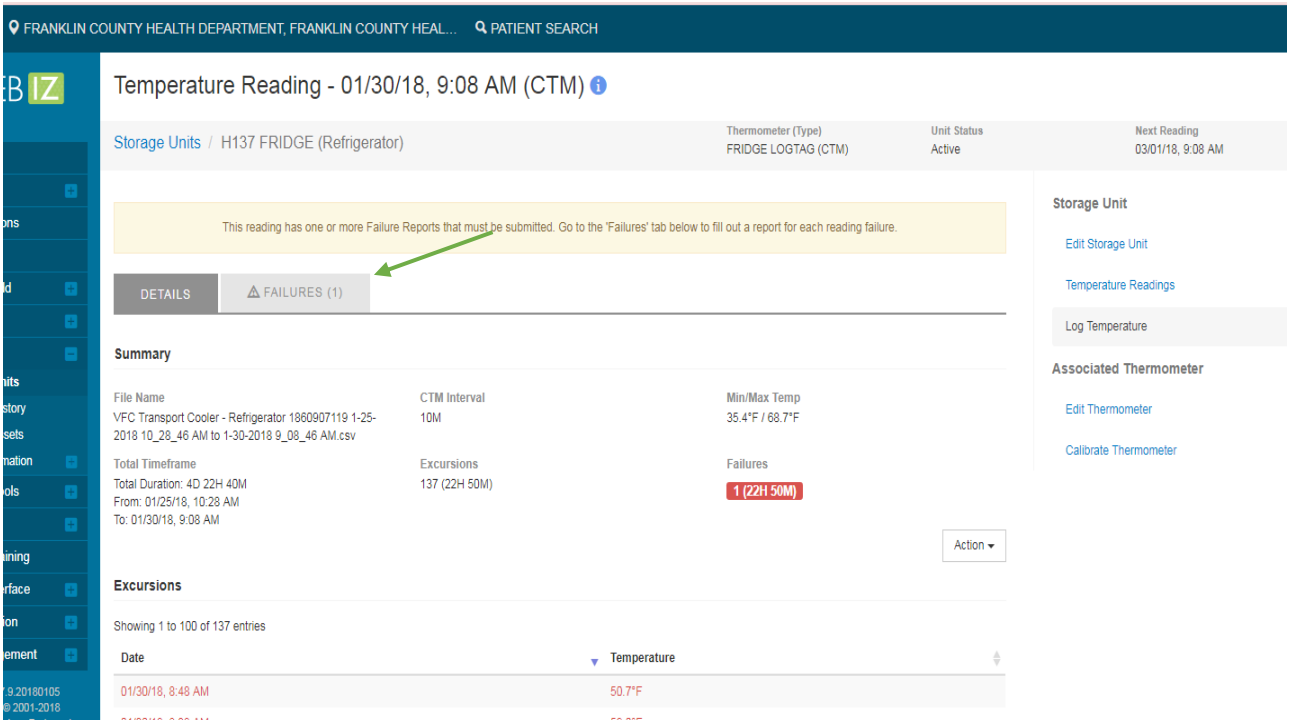


Failure Reports in KYIR

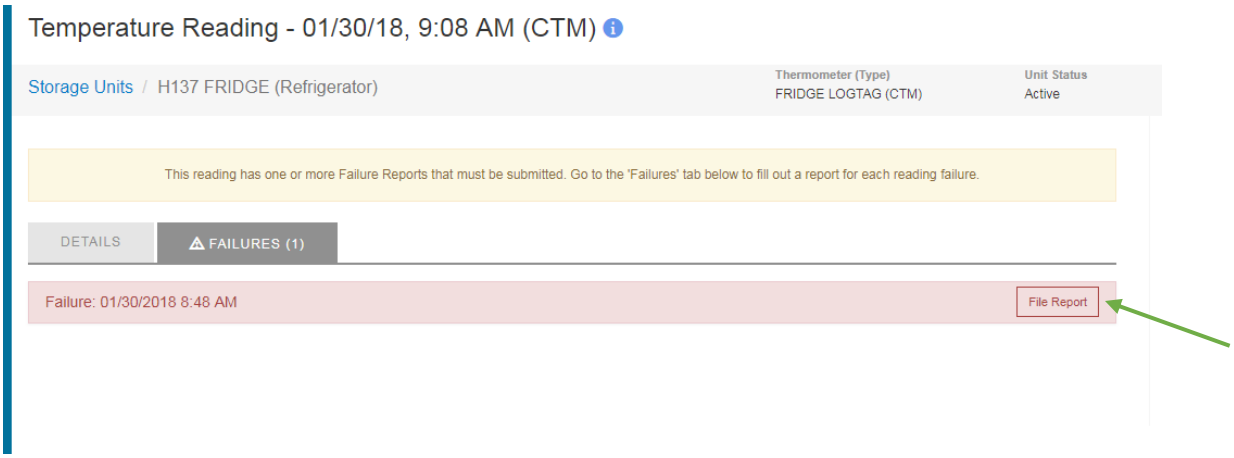
After Uploading a Temperature Log, KYIR will analyze the temperatures and determine if there had been any failures. If the temperature readings are good, the upload will result in 0 failures listed in the reading history:



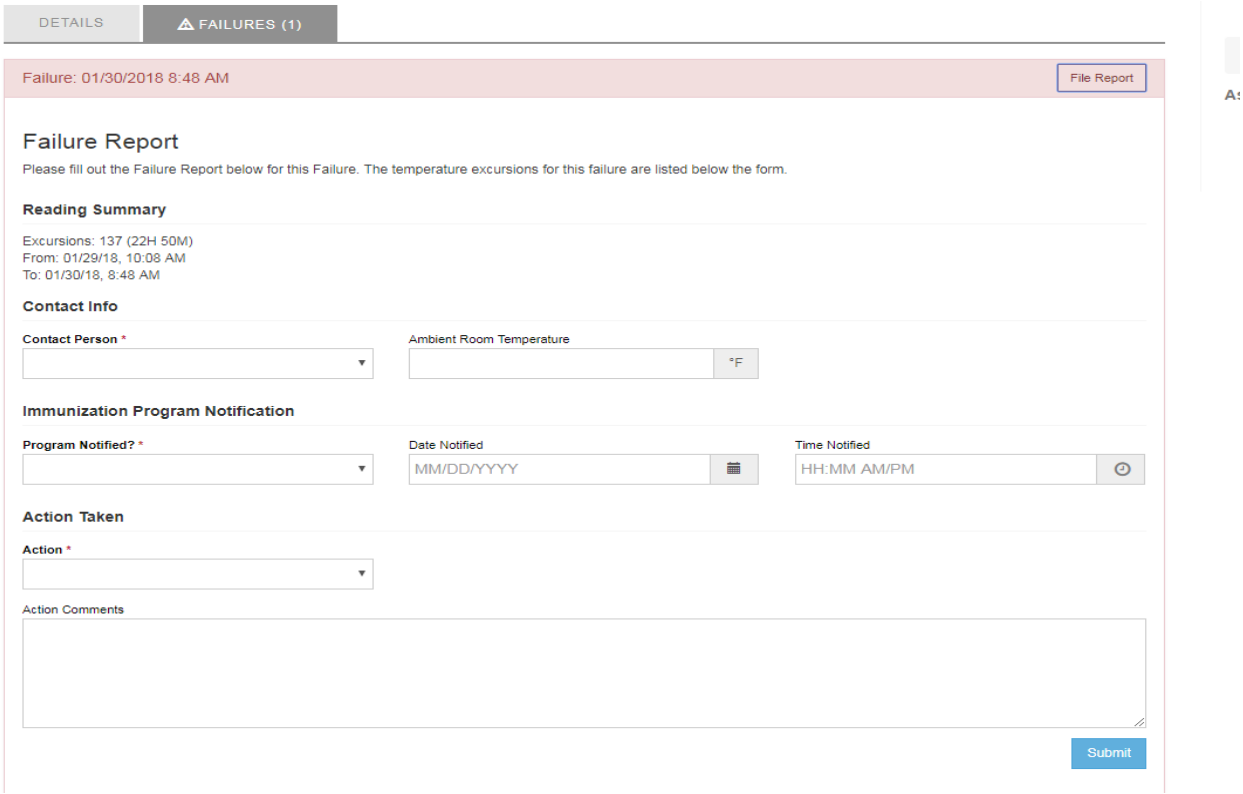
If the temperature readings indicate there has been a failure, the yellow banner alert will appear and a tab for the Failure is created. Click the Failures Tab



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 degrees 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 the assigned field representative or the KYIR Helpdesk.

Resources

The following pages contain copies of required forms and helpful documents to assist you in performing the storage and handling duties for your clinic.

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

Vaccine Management Plan

KEEP THIS MANAGEMENT PLAN POSTED NEAR YOUR VACCINE STORAGE UNITS

All Vaccines For Children (VFC) Providers, Adult/317 Vaccine Providers, and COVID-19 Vaccine Providers are required to maintain an updated and current vaccine management plan that includes information for both routine and emergency situations.

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

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

Facility/Provider Contact Information

PIN: _____

Facility/Provider Location Name: _____

Address: _____

City: _____ County: _____ Zip: _____

Key Staff Information

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

Vaccine Coordinators are responsible for ensuring that vaccines are handled and stored appropriately, that all necessary documentation is completed and that all staff are properly trained in the storage and handling of vaccines.
All personnel will complete annual education and training on proper vaccine storage and handling.
All personnel who handle the vaccines will refer to this plan when necessary.

Required Training

VFC Vaccine Coordinators must complete CDC's You Call the Shots Modules 10 (Storage & Handling) and 16 (Vaccines For Children) for the current year.
The Physician Signing Agreement and any additional staff are recommended to also complete the trainings.
If receiving COVID-19 vaccines, the Vaccine Coordinators must complete CDC's COVID-19 Vaccine Training modules. All staff who routinely handle or administer COVID-19 vaccine are recommended to participate in these trainings.

Primary and Backup Vaccine Coordinators are required to complete the TRAIN courses located at:
VFC: https://www.train.org/ky/training_plan/4715
COVID-19: https://www.train.org/ky/training_plan/4832
Submit certificates for each course completion to https://redcap.link/KYIRTrainingCompletion

Title	Name	Date Training Completed			Signature
		S&H Module 10	VFC Module 16	COVID-19 Modules	
VFC					
Primary Coordinator					
Backup Coordinator					
COVID-19					
Primary Coordinator					
Backup Coordinator					

Change in Medical Director/Physician Signing Agreement

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

Change in Vaccine Coordinator

Changes to the assigned staff for the Primary and Backup Coordinator positions must be reported to the KY Immunization Branch with **10 business days** of the changes.
A completed Change in Coordinator form must be submitted to the assigned Field Rep or to the Enrollment Team at KYVaxProvider@ky.gov Changes are limited to once every 90 days unless a result of staff departure.

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

Vaccine Storage Equipment

- Stand-alone refrigerators where vaccines are stored will be capable of maintaining temperatures between 36°F to 46°F (2°C to 8°C).
    a. The only exception is COVID-19 vaccine can be stored in a household combination unit using only the refrigerator section. The freezer section of a household combination unit is not approved for vaccine storage.
- Stand-alone freezers in which vaccines are stored will be capable of maintaining temperatures below 5°F (-15°C).
    a. COVID-19 vaccines can be stored in special Ultra-Cold temperature freezers which maintain temperatures of -76°F to -130°F (-60°C to -90°C) based on manufacturer guidelines.
- Approved vaccine storage units will be large enough to provide an adequate capacity to store vaccine supply, including during peak back-to-school and flu season.
- Dorm-style units are never to be used for vaccine storage.
- Maintenance and repair records for all vaccine storage units must be kept on file and available for review upon request.
- Bottles of water will be placed in both storage units to help stabilize temperatures.
- Drawers/deli crispers should be removed from the vaccine storage units.
- Storage units should be located away from walls to allow for air circulation and away from direct sunlight.

Primary Units	Unit Type	Brand	Model Number	Serial Number
Refrigerator				
Freezer				

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

Power Supply

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

Vaccine Storage

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

Inventory Management

- VFC and Adult 317 Vaccine Inventory must be reconciled at least once per month and within thirteen (13) days prior to placing an order in the Kentucky immunization Registry (KYIR).
- COVID-19 Vaccine Inventory must be reconciled weekly in KYIR.
- Expired vaccines must be removed from the storage unit. Expired VFC and Adult/317 vaccines must be returned through a return submitted in KYIR in their original packaging.
- If vaccine is due to expire within three (3) months and will not be used prior to expiration, please notify the assigned Immunization Field Rep.
- All orders must be submitted in KYIR and will be approved based on vaccine usage and current inventory on-hand.
- Discard reconstituted vaccines not used within the interval allowed on the package insert of the specific vaccine.
- Do not open more than one multi-dose vial of a specific vaccine at a time.
- Immunization Field Rep must be notified for transfer approval prior to any vaccine transfer or transport. All inventory transfers must also be documented in KYIR.

Temperature Monitoring

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

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

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

Backup DDLs	Brand/Model Number	Calibration Date	Calibration Expiration Date

In Case of a Power Failure or Other Emergency

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

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

After Power is Restored

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

Approved Backup or Alternate Storage Locations

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

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

Manual Defrost

CDC currently recommends stand-alone refrigerators and stand-alone freezers for vaccine storage. It is also recommended that those units be auto defrost (self-defrosting) units.
Manual Defrost units must be defrosted once the ice accumulation reaches ¼" thick.
If a Manual Defrost storage unit is used, a temporary storage unit should be available that can maintain temperatures for the vaccines while defrosting the main unit.
Please detail below your location's protocol for defrosting a Manual-Defrost unit. Include how the defrost process will be completed as well as where the vaccines will be located during the process.

Acknowledgment

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

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

Medical Director/Physician Signing Agreement: _____

Signature: _____ Date: _____

VFC

Primary Vaccine Coordinator: _____

Signature: _____ Date: _____

Backup Vaccine Coordinator: _____

Signature: _____ Date: _____

COVID-19

Primary Vaccine Coordinator: _____

Signature: _____ Date: _____

Backup Vaccine Coordinator: _____

Signature: _____ Date: _____

Facility Name:
Pin #:

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible. Obtain permission to borrow from your vaccine ordering representative. Administer and record the payback dose within 90 days from the borrowing event.**

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

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child
- 317 accidentally used for a VFC- eligible child or non-VFC eligible child

HOW TO COMPLETE THIS FORM:

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

Reason for Vaccine Borrowing and Replacement Coding Legend

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

Reason for Borrowing Private Dose	Code
VFC vaccine shipment delay (order placed on time/delay in shipping)	8
VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated VFC dose was exchanged with private dose	11
Accidental use of a Private dose for a VFC eligible patient	12
Other – Describe:	13 Other

WHAT TO DO WITH THIS FORM:

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

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

VACCINE BORROWING REPORT TABLE							
A **Vaccine Type Borrowed**	**B** **Stock Used** (VFC or Private)	**C** **Patient Name**	**D** **Patient DOB** (XX/XX/XXXX)	**E** **Date Dose Administered** (XX/XX/XXXX)	**F** **Reason Appropriate Vaccine Stock was not Used** (Use legend code on page 1 to mark one reason for each dose borrowed)	**G** **Date Dose Returned to Appropriate Stock** (XX/XX/XXXX)	**H** **Patient Name Receiving Returned Dose (90 day deadline to administer returned dose)**

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

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

Temperature Excursion Protocol

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

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

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

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

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

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

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

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

Vaccine Storage Incident Report

Clinic Name: _____ PIN: _____

Vaccine Coordinator Name: _____ Phone: _____

Email: _____

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

Incident Information

Date & Time of Incident: _____

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

Incident Cause:

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

Affected Vaccines

Inventory				**Manufacturer's Instructions**		
Vaccine	Lot Number	Expiration Date	# of doses	Instructions	Case Number	Viable?

Detailed description of the incident: Please describe when, where, and how the incident occurred.

Written detailed action taken (include time and dates):

_____

_____

_____

_____

_____

_____

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

_____

_____

_____

_____

_____

_____

Signature of person completing this report: _____ Date: _____

Required Signature of Medical Director: _____Date: _____

Kentucky 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)!

Vaccines for Children

Day	Time	Min Temp	Max Temp	Staff Initials	Alarm/Action Taken	Weekly Stock Rotation
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.

Kentucky VFC Monthly FREEZER Temperature Log

VFC Pin: _____ Month/Year: _____

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

Day	Time	Min Temp	Max Temp	Staff Initials	Alarm/Action Taken	Weekly Stock Rotation
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
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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.

Kentucky VFC Monthly REFRIGERATOR Temperature Log

VFC Pin: _____ Month/Year: _____

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

Vaccines for Children

Day	Time	Min Temp	Max Temp	Staff Initials	Alarm/Action Taken	Weekly Stock Rotation
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
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29						
30						
31						

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

Kentucky VFC Monthly FREEZER Temperature Log

VFC Pin: _____ Month/Year: _____

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

Day	Time	Min Temp	Max Temp	Staff Initials	Alarm/Action Taken	Weekly Stock Rotation
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
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31						

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

CHECKLIST of Best Practices FOR Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. These CDC guidelines and best practices are essential for patient safety and vaccine effectiveness. This checklist should be used in any non-traditional vaccination clinic settings, such as workplaces, community centers, schools, makeshift clinics in remote areas, and medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, walk-through, curbside, and drive-through clinics, and vaccination clinics held during pandemic preparedness exercises. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held**. To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

This document also contains sections, marked in red, that outline best practices for vaccination during the COVID-19 pandemic. For continued up-to-date guidance, please visit www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. This person will be responsible for completing the steps below and will be referred to as "you" in these instructions.
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: STOP. If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic. Follow your organization's protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed you can move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, whether patients' personal information was protected appropriately, or other responses that you have marked as "NO" in rows that do not have the STOP.
5. This checklist should be used in conjunction with CDC's *Vaccine Storage and Handling Toolkit*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer's package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures** (i.e., between 2–8° Celsius or 36–46° Fahrenheit).
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). (*If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.*)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts) and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor: _____

Name of facility where clinic was held: _____

Address where clinic was held (street, city, state): _____

Time and date of vaccination clinic shift (the portion you oversaw): _____ (Time (AM/PM)) _____ (Date (MM/DD/YYYY))

Time and date when form was completed: _____ (Time (AM/PM)) _____ (Date (MM/DD/YYYY))

Signature of clinic coordinator/supervisor: _____

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

This document was created by the Influenza Work Group of the National Adult and Influenza Immunization Summit.
Version 9 (Updated August 18, 2020)

BEFORE THE CLINIC (Please complete each item before the clinic starts.)

VACCINE SHIPMENT

YES	NO	N.A.	
☐	☐		Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (*Direct shipment is preferred for cold chain integrity.*)

VACCINE TRANSPORT (IF IT WAS NOT POSSIBLE TO SHIP VACCINES DIRECTLY TO THE FACILITY/CLINIC SITE)

YES	NO	N.A.	
☐	☐ STOP	☐	**Vaccines were transported using a portable vaccine refrigerator or qualified container and packout designed to transport vaccines** within the temperature range recommended by the manufacturers (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. *See CDC's* Vaccine Storage and Handling Toolkit *for information on qualified containers and packouts*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP	☐	The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (*Your qualified container and packout should include packing instructions. If not, contact the company for instructions on proper packing procedures.*)
☐	☐	☐	The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).
☐	☐ STOP	☐	A digital data logger with a buffered probe and a current and valid Certificate of Calibration Testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.
☐	☐	☐	The amount of vaccine transported was limited to the amount needed for the workday.

VACCINE STORAGE AND HANDLING (UPON ARRIVAL AT FACILITY/CLINIC)

YES	NO	N.A.	
☐	☐ STOP	☐	If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
☐	☐ STOP	☐	If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion (i.e., out-of-range temperature) during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). *Note: CCMs are for one-time use and should be thrown away after being checked.*
☐	☐ STOP		Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain the manufacturer-recommended temperature range). *Follow the guidance for unpacking and storing vaccines specified in CDC's* Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP		Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (*i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*).
☐	☐		Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.
☐	☐ STOP		Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.

CLINIC PREPARATION AND SUPPLIES

YES	NO	N.A.	
☐	☐		A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.
☐	☐ STOP		An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.
☐	☐ STOP		All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in an emergency, and know the location of epinephrine and are trained in its indications and use.
☐	☐		There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
☐	☐		Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles and syringes and a sharps container are provided.
☐	☐		Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
☐	☐	☐	If using a standing order protocol, the protocol is current and available at the clinic/facility site.
☐	☐		A process for screening for contraindications and precautions is in place.
☐	☐ STOP		A sufficient number of vaccine information statements (VISs or Emergency Use Authorization [EUA]) forms, if required) for each vaccine being offered is available at the clinic/facility site.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐		A designated clean area for vaccine preparation has been identified and set up prior to the clinic.
☐	☐		A qualified individual has been designated to oversee infection control at the clinic.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
☐	☐		Sufficient supply of PPE for staff is available, including face masks, gloves, and, if appropriate, eye shields.
☐	☐		Sufficient supply of face coverings is available for visitors and patients who may not have one.
☐	☐		Sufficient hand sanitizer is available so that staff and patients can repeatedly practice hand hygiene.
☐	☐		Cleaning supplies are available so workspaces can be cleaned regularly (note the amount needed may be more than normally required). (See EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2 the virus that causes COVID-19.)
☐	☐		Additional controls, such as counters and plastic shields, are in place to minimize contact where patients and staff interact (e.g., registration or screening areas).
☐	☐		Signs, barriers, and floor markers to instruct patients to remain 6 feet apart from other patients and clinic staff have been set up before the clinic.
☐	☐		Sufficient supply of thermometers to check patient temperatures prior to entering the vaccination clinic and COVID symptom checklists.

DURING THE CLINIC (Please complete each item while the clinic is occurring and review at the end of your shift.)

VACCINE STORAGE AND HANDLING (AT FACILITY/CLINIC)

YES	NO	N.A.	
☐	☐ STOP		Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (*i.e., a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain correct temperatures when opened and closed during the clinic*).
☐	☐ STOP		Vaccine temperature is being monitored during the clinic using a digital data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. *Follow the monitoring guidance specified in CDC's* Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP	☐	If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (*i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*). *If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.*
☐	☐ STOP	☐	If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified packout with a temperature monitoring device (with a probe in a thermal buffer) placed as close as possible to the vaccines, and temperatures are being read and recorded at least once an hour. The container is being kept closed as much as possible.
☐	☐		Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.

VACCINE PREPARATION

YES	NO	N.A.	
☐	☐ STOP		Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered. *(Note: If you are using multidose vials, be sure to review beyond use dates, along with expiration dates.)*
☐	☐		Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items.
☐	☐ STOP	☐	If using reconstituted vaccines, they are being prepared according to the manufacturer's guidelines.
☐	☐	☐	Vaccines are being prepared at the time of administration.
☐	☐	☐	If vaccines are predrawn from a multidose vial, **only the contents of 1 multidose vial are being drawn up at one time by each staff member administering vaccines (the maximum number of doses per vial is described in the package insert).**
☐	☐	☐	If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine.
☐	☐ STOP		Once drawn up, vaccines are being kept in the recommended temperature range. (*Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.*)

VACCINE ADMINISTRATION

YES	NO	N.A.	
☐	☐ STOP		Vaccine information statements (VISs or Emergency Use Authorization [EUA] forms, if required) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
☐	☐ STOP		All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐	■	Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled. www.cdc.gov/handhygiene/providers/index.html
☐	☐	☐	If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between patients.
☐	☐	■	Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer's package insert, if applicable) before administering vaccine.
☐	☐ STOP	■	Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
☐	☐	■	Each staff member is administering only the vaccines they have prepared.
☐	☐	☐	If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
☐	☐ STOP	■	Vaccines are being administered using aseptic technique.
☐	☐ STOP	■	Staff is administering vaccine to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient's name and date of birth are verified prior to vaccination).
☐	☐ STOP	■	Staff is administering vaccines using the correct route per manufacturer instructions.
☐	☐ STOP	■	Staff is administering the correct dosage (volume) of vaccine.
☐	☐ STOP	■	Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
☐	☐ STOP	☐	For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval. *Follow the recommended guidelines in Table 3-1 of the* General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#t-01.
☐	☐ STOP	☐	If vaccine administration errors are observed, corrective action is being taken immediately.
☐	☐	☐	Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
☐	☐	■	Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events. **This is especially critical at drive-through or curbside clinics where drivers are being vaccinated.**

ADMINISTRATION OF INJECTABLE VACCINES *(In this section, N.A. is ONLY an option if the clinic is EXCLUSIVELY using non-injectable vaccines, such as live, attenuated influenza vaccine.)*

YES	NO	N.A.	
☐	☐ STOP	☐	**A new needle and new syringe are being used for each injection. (Needles and syringes should never be used to administer vaccine to more than one person.)**
☐	☐ STOP	☐	Single-dose vials or manufacturer-filled syringes are being used for only one patient.
☐	☐ STOP	☐	Vaccines are being administered following safe injection practices.
☐	☐	☐	For walk-through clinics, seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.
☐	☐ STOP	☐	Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥3 years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged 1–2 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤12 months. For subcutaneous route: thigh for infants aged <12 months; upper outer triceps of arm for children aged ≥1 year and adults [can be used for infants if necessary].)
☐	☐	☐	Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
YES	**NO**	**N.A.**	
☐	☐ STOP	☐	Multidose vials are being used only for the number of doses approved by the manufacturer.
☐	☐ STOP	☐	Vaccines are never being transferred from one syringe to another.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐ STOP	☐	Used needles and syringes are being immediately placed in a sharps container following administration. (Needles are NOT being recapped.)

VACCINE DOCUMENTATION

YES	NO	N.A.	
☐	☐		Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine type, lot number, manufacturer; patient receipt of vaccine information statement (VISs or Emergency Use Authorization [EUA] form), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.
☐	☐	☐	Your state's immunization information system (IIS) was used to document vaccinations administered. (*CDC recommends using your state's IIS to document vaccinations.*)
☐	☐		Patients are receiving documentation for their personal records and to share with their medical providers.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
☐	☐		All staff and patients have their temperature checked before entering the clinic and are answering the COVID screening questions before entering the clinic.
☐	☐		All patients are wearing a face covering. Face masks should not be placed on children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
☐	☐		All staff is wearing recommended personal protective equipment (PPE), including face masks, gloves (optional for subcutaneous and intramuscular injections, required for intranasal and oral vaccinations), and eye protection (based on level of community transmission). See www.cdc.gov/vaccines/pandemic-guidance/index.html for current guidance.
☐	☐		Social distancing guidance is being followed, including signs, banners, and floor markers to instruct staff and patients where to stand, shields as appropriate when the 6-foot minimum distance cannot be observed, and one-way traffic flow.
			All areas are being wiped down and cleaned more frequently than normal cleaning that takes place during vaccine preparation and administration and between patients.

AFTER THE CLINIC (Please complete each item after the clinic is over.)

POST-CLINIC ACTIONS

YES	NO	N.A.	
☐	☐	☐	Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer-recommended temperature (i.e., *between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*), follow your organization's protocols and/or contact your state or local health department for guidance.
☐	☐	☐	Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. *An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines or returned to the supplier for credit.*
☐	☐ STOP	☐	**Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer-recommended temperature range at the end of the clinic day and was not stored in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.** (This includes vaccine transported for a multi-day clinic to a remote location where adequate storage at the site is not available.)
☐	☐	☐	Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization).
☐	☐	☐	Any vaccine administration errors were reported to all appropriate entities.
☐	☐		All biohazardous material was disposed of properly.

POST-CLINIC DOCUMENTATION

YES	NO	N.A.	
☐	☐	☐	Vaccinations were recorded in the jurisdiction's immunization information system (IIS) where available.
☐	☐	☐	If not submitted to an IIS, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.
☐	☐	☐	Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): vaers.hhs.gov/index.
☐	☐ STOP		All patient medical information was placed in a secured storage location for privacy protection.
☐	☐		The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).

N.A. means Not Applicable.

This checklist was adapted from materials created by the California Department of Public Health, the Centers for Disease Control and Prevention, and the Immunization Action Coalition.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

ADDITIONAL INFORMATION AND RESOURCES

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

COVID-19 information can be found at:

- www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

» CDC's guidelines and resources for vaccine storage, handling, administration, and safety:

- Vaccine storage and handling: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- Vaccine administration:
  - www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
  - www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
  - www.cdc.gov/vaccines/hcp/admin/resource-library.html
- Injection safety: www.cdc.gov/injectionsafety/providers.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/
- Videos on preparing and administering vaccines. www.cdc.gov/vaccines/hcp/admin/resource-library.html (includes videos on intramuscular injections and administration of live, attenuated influenza vaccine)

» The Immunization Action Coalition has a skills checklist for staff administering vaccines: www.immunize.org/catg.d/p7010.pdf.

» The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:

- Screening tools: http://www.immunize.org/handouts/screening-vaccines.asp
- Vaccination after-care:
  - Children: www.immunize.org/catg.d/p4015.pdf
  - Adults: www.aimtoolkit.org/docs/vax.pdf

» The Immunization Action Coalition has information on the medical management of vaccine reactions:

- Children and adolescents: www.immunize.org/catg.d/p3082a.pdf
- Adults: www.immunize.org/catg.d/p3082.pdf

» Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: www.immunize.org/packageinserts/pi_influenza.asp

This checklist is a valuable resource for use in temporary mass vaccination clinics and other vaccination exercises, such as those conducted at vaccine points of dispensing (PODs) or vaccination and dispensing clinics (VDCs) as part of public health emergency preparedness (PHEP) program activities.

Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.

States have laws on documentation of vaccinations, use of immunization information systems (IISs), and types of health care providers who can administer vaccines.