

# Kentucky Immunization Program Provider Manual 2017



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## 2017 Provider Manual Table of Contents

- I. Introduction
  - a. Vaccines for Children Program
  - b. Patient Eligibility
  - c. ACIP Deliberations and Vaccine Coverage
- II. Administrative Policies
  - a. Restitution Policy
  - b. Situations Requiring Restitution
  - c. Situations That Do Not Require Restitution
  - d. Procedure for Restitution
  - e. Fraud and Abuse Policy
  - f. Preventing Fraud and Abuse
  - g. Detecting, Investigating, Reporting and Resolving Fraud and Abuse
- III. Vaccine Accountability (Ordering)
  - a. VFC in Kentucky Immunization Registry: Procedures and Processes
- IV. Storage and Handling
  - a. The Cold Chain
  - b. Optimal Storage and Handling
  - c. Provider Education
  - d. Storage Units
  - e. Temperature Monitoring
  - f. Inappropriate Conditions
  - g. Vaccine Shipments
  - h. Vaccine Transport
  - i. Vaccine Management Plan
- V. Site Visit Expectations
  - a. VFC Compliance
  - b. AFIX
  - c. Unannounced
  - d. Vaccine Management Education
- VI. Resources
  - a. Immunization Schedules
  - b. Kentucky Immunization Registry
  - c. Immunization Certificates
  - d. Vaccine Management
  - e. Immunization Practices
  - f. Vaccine Preventable Diseases
  - g. Education and Training
  - h. VAERS
  - i. Kentucky Immunization Regulations and Statutes

# Introduction

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## *Vaccines for Children Program*

The Vaccines for Children (VFC) program was created by the Omnibus Budget Reconciliation Act (OBRA), on August 10, 1993. Since its inception, it has become a critical element of the President's Childhood Immunization Initiative.

Funds for the VFC program are annually transferred from the Centers for Disease Control and Prevention (CDC) and awarded to immunization projects. About ninety percent of these funds are used for vaccine purchase. The remaining funds are used for program operational activities such as provider recruitment and enrollment, evaluation, vaccine ordering and accountability. The VFC program, which operationally began October 1, 1994, represents an unprecedented national approach to improving vaccination services nationwide by providing vaccine to VFC-eligible children through enrolled public and private health care providers.

The VFC program:

- Provides public purchased vaccine, for eligible children, at no charge to public and private providers in all states;
- automatically covers vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), established by resolution and approved by the CDC;
- saves parents and enrolled providers out-of-pocket expenses for vaccine purchases;
- provides cost savings to states by bulk purchase vaccine contracts at lower prices while reducing state-to-state variations in contract prices;
- eliminates or reduces vaccine cost as a barrier to the vaccination of eligible children;
- reduces the practice of referring children from the private sector to the public sector for vaccination, keeping children in their medical home for comprehensive health care.

The VFC program allows private providers in all States to receive publicly purchased vaccine. By eliminating cost as a barrier to vaccinating children, and providing opportunities for vaccinations at as many health provider locations as possible, the VFC program supports improving and sustaining coverage levels among eligible children. The goal is to ensure that no VFC-eligible child contracts a vaccine preventable disease because of a parent's inability to pay for the vaccine or its administration.

CDC's National Immunization Program (NIP) is responsible for policy development and the provision of technical assistance to projects for VFC program operations. State health department immunization programs manage the VFC program at the State and local levels.

## *Patient Eligibility*

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

- **Medicaid enrolled**- a child who is eligible or enrolled in the Medicaid program
- **Uninsured**- a child who has no health insurance coverage
- **American Indian or Alaska Native**- as defined by the Indian Health Services Act
- **Underinsured** - A child who has commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

It is a federal requirement that underinsured children receive VFC vaccine only through a Federally Qualified Health Center or Rural Health Clinic. In the state of Kentucky underinsured children can also go to any local health department.

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines, 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 had not been met. Insured patients with a deductible are not eligible for VFC vaccines.

- **KCHIP** - Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the Federal VFC program but in Kentucky because Public Health and Medicaid have an agreement, KCHIP children can receive publicly purchased vaccines through KIP. See section 1(b) on page 7 of the Kentucky Immunization Program Provider Agreement for more information on KCHIP. When a patient presents with a Medicaid card please go to the Medicaid website at: <https://www.kymmis.com/kyhealthnet/provider/eligibility/recipients.aspx> to verify if patient is Medicaid or KCHIP eligible. Designation of P7 on this site indicates the child is KCHIP eligible and not Medicaid eligible.
- **Federally Qualified Health Centers** – FQHCs include community and migrant health centers, special health facilities such as those for the homeless that receive grants under the Public Health Service (PHS) Act, and “look-alikes” which meet the qualifications, but do not actually receive grant funds.
- **Rural Health Clinics** – The RHC program was funded for two purposes: 1) to increase access to health care for rural underserved communities, and 2) expand the use of nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) in rural communities. To be eligible for certification as an RHC, a clinic must be located in a Health Professional Shortage Area, Medically Underserved Area, or a Governor-Designated Shortage Area.

## *ACIP Deliberations and Vaccine Coverage*

The Advisory Committee on Immunization Practices (ACIP) is an expert advisory committee whose role is to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Director, Centers for Disease Control and Prevention (CDC), regarding the most appropriate

application of antigens and related agents (e.g., vaccines, immune globulins) for effective disease control in the civilian population.

The ACIP meets three times each year. At these meetings the committee may vote on the inclusion of new vaccines into the VFC program or the modification of existing resolutions. These decisions are codified as VFC resolutions and are considered separate from any other recommendations made by the ACIP. In most cases, a VFC resolution takes effect after a CDC contract for the purchase of a vaccine is established.

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

# Administrative Policies

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## *Restitution Policy (January 1, 2017)*

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

### **Definitions**

**Expired vaccine:** Any vaccine with an expiration date that has passed.

**Spoiled vaccine:** Any vaccine that is stored or transported outside of the limits of the approved cold chain procedures or any vaccine that has been pre-drawn and not used within acceptable time frames. Always consult with KIP before determining that vaccine is spoiled.

**Lost vaccine:** Any vaccine ordered but not delivered or not delivered in a timely manner by the commercial carrier or delivery service that result in lost and/or spoiled vaccine.

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

## *Situations Requiring Restitution*

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

- Failure to rotate vaccine stock in order to use vaccine with the shortest expiration date first
- Failure to notify KIP a minimum of 90 days prior to vaccine expiration date
- Repeated waste of vaccine due to drawing up or preparing vaccine prior to patient screening
- Vaccine left out of the refrigerator or freezer resulting in vaccine reaching unacceptable temperatures
- Freezing vaccine that must be refrigerated

- Refrigerating vaccine that must be frozen
- Excessive ordering of vaccine that results in the expiration of vaccine before it can be used
- Provider staff failing to review, appropriately interpret and/or document refrigerator and/or freezer temperatures twice daily
- Vaccine that is considered spoiled due to temperature monitoring problems/errors
- Unplugged refrigerator/freezer unit or electrical breaker switched off for extended periods of time
- Failure to contact KIP 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 KIP
- Planned power outages in which provider staff fails to implement precautions to maintain appropriate storage of vaccine
- Vaccine received but unaccounted for in stock
- Transportation of vaccine inappropriately: unnecessary transportation of vaccine, transportation without KIP 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 KIP when provider's office will be closed for non-emergency situations i.e., holidays, trainings, parties, etc. KIP must be notified 3 weeks in advance of planned closing to prevent delivery of vaccines during this time
- Substantial vaccine wastage resulting from repeated or unresolved incidents from the list below of "Situations That Do Not Require Restitution"

### *Situations That Do Not Require Restitution*

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

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

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

The following information outlines the policy and procedures to prevent, detect, investigate, and resolve suspected fraud and abuse allegations for medical providers receiving vaccine from the Kentucky Immunization Program. The federal Vaccines for Children Program (VFC) is the largest part of the KIP.

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

### **Definitions**

**Authority:** KRS 205.8453(4) directs the Cabinet for Health Services to institute other measures necessary or useful in controlling fraud and abuse. The Kentucky Department for Public Health is responsible for monitoring the utilization of services in the Kentucky Immunization 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.).

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

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

### **Examples of Fraud and Abuse:**

This list is not intended to be exhaustive of all acts that may constitute fraud or abuse.

- Providing VFC vaccines to non-VFC eligible children;
- Selling or otherwise misdirecting VFC vaccine;
- Billing a patient or third party for the VFC-funded vaccine;

- Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a federal vaccine-eligible child;
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay the administration fee;
- Failing to implement provider enrollment requirements of the VFC program;
- Failing to screen patients for VFC eligibility at every visit;
- Failing to maintain VFC records or not complying with other requirements of the VFC Program;
- Failing to fully account for VFC vaccine;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering of VFC doses of vaccine ;
- Wasting VFC vaccine (e.g., expiring vaccine, ordering too many doses of vaccines, storing or transporting vaccines outside of cold chain procedures, lost or unaccounted for doses, etc.)
- Any activity that will result in an overpayment for costs of the vaccine or administration.

### *Preventing Fraud and Abuse*

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

- Upon enrollment into the VFC Program, new immunization providers will receive an educational training session from the Immunization Field Staff to explain the VFC Program in detail. Providers will be educated about the purpose, eligibility requirements, and VFC program requirements.
- All providers who participate in the VFC Program are required to submit a completed Provider Profile and signed Provider Enrollment form before they can receive vaccine. Providers must update these forms as needed, but at least annually, to continue to receive vaccine. The Provider Enrollment form outlines the requirements with which providers must comply to participate in the VFC Program. By signing the Provider Enrollment form, providers certify that they will comply with the VFC Program requirements.
- All incoming vaccine orders and reports of doses administered are reviewed by the vaccine management staff. Any inconsistencies on these reports (e.g., ordering more vaccine than is usually ordered, reports of wasted/expired vaccine) are addressed quickly by vaccine management staff, and adjustments are made as appropriate.
- Per the Enrollment Form signed yearly providers may have to reimburse the Immunization Program dose for dose for any vaccines that cannot be accounted for, spoiled, expired or are deemed preventable losses. Providers are required to develop corrective action plans and submit proof of replacement vaccine.
- All VFC staff that have interaction with VFC-enrolled providers are thoroughly trained to prevent, identify, and resolve issues and instances of programmatic fraud and abuse and non-compliance in a provider's office/clinic as part of their job responsibilities.

- Immunization Field Staff inspect for any indications of fraud or abuse during their reviews, and they continue to follow-up on any deficiencies until improvements are made and maintained.
- Immunization Field Staff conducts additional site visits if providers have vaccine storage and handling problems or other problems and follow-up with the providers until improvements are made and maintained.
- Storage and handling training for primary and backup coordinators, which could include in-person training and/or CDC Modules, is required annually.
- As a quality assurance measure, VFC staff will review the *List of Excluded Individuals and Entities* list located at <http://exclusions.oig.hhs.gov/> prior to allowing new VFC providers on the program and yearly when updated enrollment forms are received. The list is used to identify parties excluded from participation in federal health care programs. Any VFC enrolled provider that newly appears on the exclusion list will be immediately suspended from the VFC Program and any VFC vaccine in inventory will be retrieved by VFC staff.

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

Instances of potential fraud and abuse are most often reported as complaints or referrals from outside sources regarding a provider who has inappropriately used vaccines or billed Medicaid or private insurers for the cost of VFC vaccines. Instances of potential fraud and abuse might also be detected during review of providers' vaccine orders or during Assessment, Feedback, Incentives, eXchange program AFIX/VFC site visits.

As determined by KIP staff, if an instance of fraud and abuse is determined to result from an excusable lack of knowledge or misunderstanding of the VFC Program requirements, the Vaccine Accountability Section (VAS) Coordinator will implement an Education and Corrective Action Plan and attempt to resolve the situation through the use of KIP staff. This determination will be made on a case-by-case basis depending on such factors as the 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, and the willingness of the provider's staff to participate in the educational referrals and post-education follow-ups. In addition, a visit by the Immunization Field Staff to the provider's office and follow-up will be provided until the situation improves.

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

- Medical Provider's name (Medicaid ID if known)
- Address
- Source of allegation
- Date allegation reported to program
- Description of suspected misconduct
- Specific VFC requirements violated

- Value of vaccine involved, if available
- Success of educational intervention
- Disposition (e.g., closed, referred, or entered into education process) of case and date of disposition.

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

If a VFC Provider's actions are determined to constitute fraud or abuse, the provider may be required to reimburse vaccine or other costs, terminated from the VFC Program and have his/her name added to the KIP excluded provider list, and/or may be referred for criminal prosecution. If a VFC provider's actions are determined to not 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](mailto:dph.kvp@ky.gov)
- Telephone number for reporting Fraud and Abuse: (502) 564-4478, business days from 8:00 am – 4:30 pm.

# Vaccine Accountability (Ordering)

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## *VFC in Kentucky Immunization Registry: Procedures and Processes*

- **Patient Eligibility Screening Record:** VFC clinic uses only when no EMR or not on KYIR yet. Once on KYIR, patient eligibility will be recorded in KYIR.
- **Returns and Adjustment Form:** VFC providers no longer need to do the R&A form. All returns and adjustments are completed in KYIR. Create a return in KYIR by going to Inventory → Vaccines → Vaccine Returns → Add New Vaccine Return.
- **3 Month Expiring Soon Notification:** VFC Providers need to notify VAS that they have vaccine expiring in 3 months if they do not anticipate using the entire inventory. KYIR will let providers know which vaccines are expiring soon.
- **Transfers:** VFC providers first need permission from VAS to transfer vaccine to another provider and then it is conducted in KYIR. Transferring is still discouraged due to storage and handling complications when trying to move vaccine.
- **Adult Inventory:** VFC providers approved for adult intent (mainly LHDs) must submit Adult Inventory Quarterly Reports by the 5th of the following months: January, April, July and October. If the adult inventory is in the registry, you do not need to fax in a report.
- **Adult Orders:** VFC providers approved for adult intent must place a separate order via KYIR from their VFC order when requesting adult vaccine.
- **KVP Activity Worksheet:** VFC providers do not need to keep this once their inventory is being tracked in the registry. Hospitals may continue to use it and providers waiting to get their data in KHIE will continue to use it. The provider may also choose to use it as a backup tracking system.
- **VFC Program Comment Box on Orders and Returns:** VAS will communicate with providers regarding their order or return via the VFC Program Comment Box. Please check your previously submitted order or return to ensure that it has been processed.

In order to view the status of your order or return and view any comment a KY Vaccine Accountability Rep left you follow the directions below.

Log into KYIR-> Inventory-> Vaccines->Vaccine Orders-> Click the blue Search button -> Find your most recent order-> click view to the right of the order -> Read the 'VFC Program Comments'

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

- **“Rejected” Return Function:** When a return is rejected, VAS will leave a note in the VFC Comments section of the return. You will follow the same directions as listed above. However, after a return is rejected you will need to delete the entire return. There is no option to resubmit an edited return. If you need to resubmit a rejected return with corrections, you will need to create a new return after deleting the rejected one.
- **Reconciliation:** VFC Providers need to reconcile their inventory on a monthly basis.
- **Borrowing:** This procedure must be approved by the Vaccine Accountability Section.  
Day to day replacement or borrowing is not allowed.  
This practice applies when insurance claims are filed by the provider and the claim is denied due to a lapse in coverage.  
This practice does not apply to patient with insurance that covers vaccines, but requires a copayment, co-insurance, or high deductible.  
Please contact your VAS Rep to request approval.  
Fax/email completed Vaccine Borrowing Report to the Kentucky Immunization Program at 502-696-4923 or email to [DPH.KVP@KY.Gov](mailto:DPH.KVP@KY.Gov) attention VAS Rep.  
Document the borrowed/need to pay back vaccine in KYIR.

# Vaccine Storage and Handling

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

## *The Cold Chain*

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

### **Manufacturer → Distributor → Provider's Office → Administration to the Patient**

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.

## *Optimal Storage and Handling*

Providers are required to separate VFC stock and private stock.

Refrigerated vaccines must be kept between 36° and 46°F (2° and 8°C). You should aim for 40°F (4.4°C), which allows some fluctuation in temperatures without going out of range. Be careful not to keep refrigerator temperatures too cold.

Frozen vaccines must be kept at 5° to -58°F (-15° to -50°C). Aim for temperatures below 0°F (-17.7°C) to allow for defrost cycles.

Some vaccines are light-sensitive. Therefore, vaccines must be kept in their original box packaging with the lid of the box kept intact and reclosed each time a vial is removed. 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 vaccines. Never store vaccine in storage unit doors or in vegetable bins.

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 their vaccines.

Never store food or beverages in the vaccine storage unit.

**Always check to make sure the storage unit door is closed.** Some providers may opt to use door latches to ensure that the door is completely closed.

Providers are required to review expiration dates of vaccine and rotate VFC stock weekly. Record on the temperature logs the dates you assessed vaccine expiration and rotated your vaccine stock. Expired vaccine should never be stored in vaccine storage units.

### *Provider Education*

VFC providers are required to have annual training on VFC basics and storage and handling. All VFC coordinators and back-up coordinators must fulfill this requirement. There are two options to complete VFC provider education:

- (1) Completion of the CDC's You Call the Shots modules *Vaccines for Children (VFC)* and *Vaccine Storage and Handling* at <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>
- (2) In-person training on vaccine storage and handling.

New vaccine coordinators must contact their designated KIP Field Representative for additional training information. Documentation of provider education must be filed so that it is easily accessible during a site visit.

### *Storage Units*

KIP requires stand-alone refrigerator and freezer units (self-contained units that only refrigerate or freeze and are suitable for vaccine storage). Units vary in size, from compact, under-the-counter style to large, stand-alone, pharmaceutical-grade storage units. Combination units will be approved only if they are pharmaceutical-grade and have documentation of being such.

The storage unit should be large enough to hold your largest vaccine inventory. Keep in mind your inventory during flu season or back to school clinics and prior to holidays when vaccine shipments are halted.

Place the storage unit(s) in a well-ventilated room with good air circulation around the unit. The unit should be plugged directly into the wall outlet without use of extension cords. Also be sure to avoid outlets with built-in circuit switches or that are activated by a wall switch. You may wish to use an outlet cover to keep from inadvertently unplugging the storage 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 storage unit must demonstrate one full week of acceptable temperatures prior to using for vaccine storage. This applies if the storage unit is new or if the provider office has a change of address. Your designated KIP Field Representative will determine whether your storage unit is satisfactory for vaccine storage. To make this determination, provide your KIP Field Representative with a copy of the purchase order for the storage unit and one full week of temperature logs.

Water bottles in the refrigerator and freezer are recommended to help maintain appropriate temperatures inside the storage unit, especially in instances of power outages. The doors and top and bottom shelves are ideal locations for water bottles.

Back-up storage units must meet the same requirements; however, the use of combination units may be allowed for temporary storage. Back-up storage units should be utilized no longer than two weeks.

### *Temperature Monitoring*

VFC providers are required to have certified calibrated digital data logging thermometers in their storage units. The Kentucky Immunization Program requires that the thermometers have an external biosafe glycol-encased probe. Having consistently accurate thermometers is a fundamental requirement to the safety of your vaccine. The certificate of calibration should be filed so that it is easily accessible during a site visit and to determine when recalibration is necessary.

To be considered valid, the 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 in tolerance)
- Recommended uncertainty of  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ) or less.

The expiration date for a certificate of calibration shall be in accordance with the manufacturer's recommendation (i.e. a 2-year recommended frequency in calibration would mean the certificate expires 2 years from the issue date). If there is no manufacturer recommendation for calibration testing or for back-up thermometers that are placed in use, write the "In-Use" date on the certificate. The certificate will expire one year from the in-use date or 2 years from the issue date, whichever occurs first.

The thermometer should be placed close to vaccines in the center of the unit.

In addition to the primary certified calibrated thermometer in the storage unit, you must also have a certified calibrated back-up thermometer 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.

Keep temperature log sheets on the door of every storage unit. Document the minimum and maximum temperatures daily. Minimum and maximum temperatures are the lowest and highest temperatures actually reached in the storage unit within a 24-hour period. Assess and record the unit's current temperature at least twice daily— upon arrival to the clinic in the morning and prior to leaving in the evening. This helps narrow the window for excessive temperatures. If a reading is missed, leave the log space empty rather than guessing what the temperature may have been. The time, date, and initials of the person documenting the temperatures must also be included on the temperature log. VFC providers are required to use the Kentucky Immunization Program's Temperature Logs and Storage and Handling Incident Report. Download data loggers monthly or if there is an excursion and send to your VAS representative.

Keep temperature logs and incident reports for a minimum of three years. They should be easily accessible during a site visit.

## *Inappropriate Conditions*

If you are unsure of vaccine potency due to exposure to inappropriate storage conditions (including, but not limited to, out-of-range minimum or maximum temperatures and twice-daily temperature checks), take an inventory of affected vaccines, put them into a paper bag or other appropriate container marked “Do Not Use” and then return them to appropriate storage conditions. The state immunization program and the respective vaccine manufacturers must then be contacted and informed of the problem so that further guidance can be given.

Immediately call the Kentucky Immunization Program and applicable vaccine manufacturers.

Inappropriate storage conditions and all mechanical malfunctions or power outages must be documented on the Storage and Handling Incident Report. Such information helps identify the length of time the vaccines were exposed to out of range temperatures, which is necessary information for determining viability of the vaccine. Providers are required to send a copy of the incident report and downloaded data to the Kentucky Immunization Program.

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.

Mishandled doses that were inadvertently administered should not be counted as valid doses and must be repeated.

## *Vaccine Shipments*

Assure the vaccine cold chain is not interrupted during the receipt of vaccines. Deliveries should only be arranged for when the clinic is open and when the vaccine coordinator is on duty. All staff must be aware of the importance of maintaining the cold chain and to immediately notify the vaccine coordinator of vaccine arrival. Upon arrival of vaccine shipments, store vaccine immediately in appropriate conditions.

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

## *Vaccine Transport*

The CDC recommends the transport of vaccine to be a rare occurrence due to the possible risks to the vaccine’s viability. The KIP understands that some providers transport vaccine from a central shipping location to an alternative location, such as a health department to school sites. In doing so, the following requirements apply:

- Personnel transporting vaccine should receive education on the proper storage and handling (including transport) of vaccines.
- Utilize appropriate storage equipment, including coolers, refrigerators, and thermometers.

- Vaccine 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 back to the shipping site.
- Limit transport time to 30 minutes or less. If transport requires more time, hourly checks of the temperature must be documented on a temperature log.
- If vaccine will be kept at the site over weekends, breaks, etc., a certified calibrated digital data logger must be used.

### *Vaccine Management Plan*

Providers are required to develop a detailed written Vaccine Management Plan that is updated annually. This plan shall include all aspects of routine vaccine management, from ordering and managing inventory to monitoring storage conditions. In addition, providers must include detailed written emergency plans in the event of refrigerator and/or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate storage conditions.

Include signature, name, and title of the person(s) who prepared the plans. Ensure that all staff members who administer or handle vaccines in any way are familiar with these plans. Keep plans near storage unit(s) and make sure staff members know where to find them.

The following should be included in the Vaccine Management Plan:

- Up-to-date contact information Primary and alternate (back-up) vaccine coordinators
- Descriptions of the roles and responsibilities of the primary and alternate (back-up) vaccine coordinators
- Policy on education and training for facility staff
- Summaries of the storage requirements for each type of vaccine and diluent in your inventory
- Protocols for vaccine storage unit temperature monitoring
- Protocols for vaccine storage equipment maintenance
- Protocols for the correct placement of vaccines within storage units
- Protocols for responding to vaccine storage and handling problems
- Protocols for vaccine/diluent inventory management
- Protocols for receiving and unpacking vaccine/diluent deliveries
- Protocols for transporting vaccines/diluents to off-site/satellite facility(ies)
- Protocols for handling vaccines/diluents prior to administration
- Manufacturers of vaccines in your inventory
- Refrigerator and freezer maintenance and repair companies
- Vaccine storage unit alarm company (if applicable)
- Sources for packing materials, calibrated temperature monitoring devices, and portable refrigerator/freezer units or qualified containers
- Protocols for proper disposal of vaccines, diluents, and supplies.

# Site Visit Expectations

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## *VFC Compliance Site Visit*

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

## *AFIX Visit*

VFC enrolled providers will receive an AFIX Visit at the discretion of the Kentucky Immunization Program. The goal of the AFIX visit is to assess immunization coverage rates of children 24 – 35 months of age and adolescents 13 – 14 years of age. This visit provides ongoing education regarding methods to increase immunization coverage levels. Methods include the use of reminder/recall systems as well as immunizing children during sick visits and well-child visits. Additionally, this visit helps to identify protocols/practices that may be affecting immunization rates and delivery of vaccines services to patients.

## *Unannounced Site Visit*

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

## *Vaccine Management Education Visit*

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

# Resources

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

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

Thank you for your contribution to our program.

-Kentucky Immunization Program

<http://chfs.ky.gov/KIP>

## *Immunization Schedules*

Immunization Schedules (Child, Adult, Interactive and Catch-Up Scheduler)

<http://www.cdc.gov/vaccines/schedules/index.html>

State Regulation Immunization Schedule

[www.lrc.ky.gov/kar/902/002/060.htm](http://www.lrc.ky.gov/kar/902/002/060.htm)

Interactive Immunization Scheduler

[http://www2a.cdc.gov/nip/kidstuff/newscheduler\\_le/](http://www2a.cdc.gov/nip/kidstuff/newscheduler_le/)

Catch-Up Immunization Scheduler

<https://www.vacscheduler.org/>

## *Kentucky Immunization Registry*

Enrollment Forms, Training Videos, and Printable Training Materials

<http://www.chfs.ky.gov/dph/epi/kir.htm>

## *Immunization Certificates*

Immunization Certificate, Medical Exemption Certificate, Religious Exemption Certificate

<http://education.ky.gov/districts/SHS/Pages/Health-Forms.aspx>

## *Vaccine Management*

Kentucky Immunization Program Specific Guidelines

<http://chfs.ky.gov/dph/epi/Health+Care+Professionals.htm>

Storage and Handling Toolkit

<http://www.cdc.gov/vaccines/recs/storage/toolkit/>

## *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

[www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm](http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm)

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>

<http://www.cdc.gov/mmwr/PDF/wk/mm6029.pdf>

Vaccine Recommendations

<http://www.immunize.org/clinic/vaccine-recommendations.asp>

## *Vaccine Preventable Diseases*

Vaccine Preventable Disease List

[www.cdc.gov/vaccines/vpd-vac/vpd-list.htm](http://www.cdc.gov/vaccines/vpd-vac/vpd-list.htm)

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>

## *VAERS*

Vaccine Adverse Event Reporting System (VAERS)

<http://vaers.hhs.gov/>

Frequently Asked Questions

<http://vaers.hhs.gov/about/faqs>

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

<http://www.lrc.ky.gov/kar/902/002/055.htm>

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

<http://www.lrc.ky.gov/kar/902/002/060.htm>

Reporting of Immunization Results

<http://www.lrc.ky.gov/KRS/158-00/037.PDF>

Physicians and heads of families to report diseases to local board of health

<http://www.lrc.ky.gov/KRS/214-00/010.PDF>

Exceptions to testing or immunization requirement

<http://www.lrc.ky.gov/KRS/214-00/036.PDF>

Cabinet to adopt regulations and take other action to prevent spread of disease

<http://www.lrc.ky.gov/KRS/214-00/020.PDF>

Meningococcal meningitis disease and vaccine information

<http://www.lrc.ky.gov/KRS/158-00/297.PDF>

902 KAR 2:020. Disease surveillance

<http://www.lrc.ky.gov/kar/902/002/020.htm>