



Kansas Immunization Program Vaccines for Children Policy and Procedure Manual



Version 2

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SUMMARY OF VFC PROGRAM REQUIREMENTS

Staff Requirements	Key Clinic Staff: Medical Director, Primary Vaccine Coordinator, Backup Vaccine Coordinator, and Non-Physician Contact. There is required training for key clinic staff prior to enrollment and at annual recertification. Any changes in key clinic staff must be communicated to the Kansas Immunization Program within 10 business days.
Provider Enrollment, Reenrollment, Recertification	Provider demographics, population profile, and key clinic staff contacts must be updated in KSWebIZ via the VFC Program Provider Agreement and the VFC Program Provider Profile.
Guidance for Specific Vaccine Types	Through the Kansas Immunization Program vaccines are available at no cost to children who might not otherwise be vaccinated because of inability to pay. Children who are eligible for public vaccines are entitled to receive vaccines recommended by the Advisory Committee on Immunization Practices.
Eligibility	VFC providers must possess a working knowledge of ALL vaccine funding sources and use the eligibility criteria to determine the appropriate funding source for children prior to administering vaccines.
Billing	VFC providers must adhere to proper billing practices for vaccine administration fees.
Documentation	Immunization records must be maintained in accordance with federal law.
Vaccine Management Plans	VFC providers must develop and maintain current, written standard operating procedures for routine and emergency response vaccine management.
Digital Data Loggers and Backup Thermometers	A digital data logger with a current and valid certificate of calibration is the only acceptable method of monitoring temperatures in accordance with VFC requirements. The Kansas Immunization Program-supplied digital data loggers are required as the primary thermometer for each storage unit that holds public vaccines. Providers must also provide at minimum, a digital thermometer with a certificate of calibration to be used as a back-up, if needed.
Temperature Documentation	Correct refrigerator temperature range is 2°C through 8°C and correct freezer temperature range is -50°C through -15°C. Temperatures outside of this range could affect the viability of the vaccine. VFC providers should have standard operating procedures for temperature monitoring to ensure vaccine viability.
Vaccine Offered Through Public Funds	Vaccines that are available through public funding include: DTaP, Hepatitis A and B, HIB, HPV, Influenza, Meningococcal ACWY and B, MMR, Pneumococcal, Polio, Rotavirus, Tdap/Td and Varicella as single or combination presentations.
Vaccine Ordering	Vaccine management practices must include proper ordering and inventory management to prevent vaccine waste and ensure appropriate stock is available by funding type.
Receiving Vaccines	Providers must be available and onsite with appropriate staff to receive vaccine shipments. Vaccines are delivered in accordance with reported clinic hours of operation.
Vaccine Inventory	All vaccine should be maintained at the appropriate temperature to ensure vaccine viability. Correct refrigerator temperature range is 2°C through 8°C. Correct freezer temperature range is -50°C through -15°C.

Vaccine Borrowing	VFC providers are required to maintain adequate inventories of vaccine to administer to both privately-insured and publicly-insured children that they serve. Borrowing is permitted only in rare, unplanned circumstances.
Vaccine Redistribution	VFC providers may have vaccine stock that is close to expiring. If practical and the cold chain can be maintained, short-dated vaccine can be transferred between VFC providers to avoid vaccine wastage. The Regional Immunization Consultant assigned for the area must be notified prior to transfer of vaccine. The Kansas Immunization Program maintains a list of publicly funded vaccines available for redistribution.
Vaccine Transfers	Transfers of vaccine should not routinely occur. The Regional Immunization Consultant assigned to the area must be notified prior to transportation of vaccine if the transport time is one hour or more. The Regional Immunization Consultant will handle transports greater than one hour.
Off-Site and Mass Vaccination Clinics	VFC Providers that will be conducting off-site and/or mass vaccination clinics with publicly funded vaccine must follow all VFC requirements, in addition to enhanced storage and handling practices.
Temperature Excursions	If there is evidence vaccine has been exposed to temperatures outside the recommended temperature range, providers must follow the instructions found on the Provider Temperature Excursion Worksheet found in the Forms and Resources section of this manual.
Expired, Spoiled, and Wasted Vaccine	VFC providers must have vaccine management plans and equipment in place to maintain appropriate temperatures for publicly funded vaccines and to minimize the risk of vaccine loss.
Vaccine Loss	All vaccine loss will be carefully reviewed and categorized as avoidable or unavoidable by the Kansas Immunization Program. All VFC providers are responsible for repayment of avoidable vaccine loss.
Vaccine Repayment	Kansas Immunization Program is responsible for determining when a provider has had an avoidable waste of vaccine. If the loss is determined to be an avoidable waste, the VFC provider may be required to replace the wasted vaccine with privately purchased vaccine on a “dose for dose” basis.
Fraud and Abuse	VFC providers must agree to operate in a manner intended to avoid fraud and abuse. When providers enroll in the VFC program, they agree to follow the requirements of the program. Failure to follow the requirements could lead to fraud and abuse of the VFC program.
What’s Happening Wednesday and Special Alerts	What’s Happening Wednesday and Special Alerts are the primary source of communication with VFC providers on matters related to being part of the VFC program. It is expected that these documents will be reviewed upon release from the Kansas Immunization Program.
Forms and Resources	See Table of Contents for complete list of forms and resources.

STAFF REQUIREMENTS

KEY CLINIC STAFF

- **Medical Director:** The official registered health care provider signing the Vaccines for Children (VFC) Program Provider Agreement. The Medical Director must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance for the organization/clinic and its VFC providers with the responsible conditions outlined in the provider enrollment agreement.
- **Primary Vaccine Coordinator:** Responsible for providing oversight for all vaccine management within the clinic, including:
 - Developing and maintaining the Vaccine Management Plan
 - Monitoring storage and handling and vaccine administration practices in the clinic
 - Overseeing vaccine ordering and notifying the Kansas Immunization Program (KIP) if vaccines will expire before they are administered
 - Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire
 - Participating in, and documenting completion of, annual training on VFC requirements
 - Storing all required documentation for three years, or longer, if required by state statutes or rules
- **Backup Vaccine Coordinator:** Will assume VFC oversight responsibilities in the absence of the primary vaccine coordinator.
- **Non-Physician Contact:** Will assume VFC oversight and responsibilities in the absence of the primary and backup vaccine coordinator.

The Vaccine Coordinator, Backup Vaccine Coordinator, and Non-Physician Contact must be fully trained on routine and emergency standard operating procedures for vaccine ordering, storage, handling, transport, and inventory management.

The required training, *“You Call the Shots - VFC Requirements”* and *“You Call the Shots - Storage and Handling”* learning modules must be completed annually. Certificates of completion must be submitted to the KIP when indicated.

At a minimum, the Primary, Backup, and Non-Physician Contact must undergo required training prior to enrollment and annual recertification. It is recommended that the Medical Director or equivalent who signed the provider agreement and other clinic staff that are involved with implementing vaccine management plans also complete the training.

It is also recommended that all clinic staff involved with the vaccine delivery process complete the above training and have a clear understanding of all VFC policies and procedures.

Any changes in key clinic staff must be communicated to the KIP, within 10 business days, following the instructions in KSWebIZ under Reports>Documents>VFC Change of Information

Instructions.

PROVIDER ENROLLMENT, REENROLLMENT, RECERTIFICATION

PROVIDER ENROLLMENT AND REENROLLMENT

- Providers wanting to enroll or reenroll in the VFC program must meet eligibility criteria to include:
 - Provider signing the VFC Program Provider Agreement, located in the FORMS AND RESOURCES section of this manual, has the authority to sign on behalf of the entire organization/clinic and agrees to all program requirements, including participation in site visits and educational opportunities.
 - Provider signing the VFC Program Provider Agreement has a valid license to administer vaccines in Kansas.
 - Provider and provider staff are not included on the Office of Inspector General (OIG) List of Excluded Providers (LEIE).
 - Provider has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring.
 - Provider clinic is open at least four consecutive hours on a day, other than a Monday, to receive VFC vaccines.

- All new or recertifying VFC providers must receive a VFC enrollment site visit. Through this visit, education on VFC requirements, proper vaccine management, and review of the vaccine management plan will be provided. This visit must be completed before the provider can receive public vaccines (VFC and CHIP).

PROVIDER RECERTIFICATION

- Annually, VFC providers will:
 - Submit a complete, accurate, and signed VFC Program Provider Agreement, which includes the VFC Provider Profile.
 - Complete annual training requirements of the VFC program and submit training certificates to Kdhe.ImmunizationRegistry@ks.gov or fax to 785-559-4227.

ADDITIONAL REQUIREMENTS

The electronic signature of the Medical Director or equivalent must be completed to authorize the VFC Program Provider Agreement.

Email addresses of the Medical Director (or designee), primary and backup contacts must be provided to the KIP to assist with program communication.

If a facility has multiple providers operating under one Medical Director (or equivalent), the facility must maintain a current list of providers ordering vaccines in addition to the provider of record who authorizes the VFC Program Provider Agreement.

If the VFC Program Provider Agreement is terminated, the provider will return any unused federal vaccine as directed by the KIP but no later than 30 days from termination or unenrollment.

GUIDANCE FOR SPECIFIC VACCINE TYPES

PUBLIC VACCINE (VFC AND CHIP)

Public vaccine is available through the VFC program. The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. The Centers for Disease Control and Prevention (CDC) buys vaccines at a discount and distributes them to the KIP, who in turn distributes them at no charge to VFC providers. Children who are eligible for public vaccines are entitled to receive vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). Public vaccines are available for the following eligibility groups.

- American Indian/Native-American or Alaska Native (AI/AN): AI/AN children are always eligible to receive VFC vaccine. However, if they have private insurance, Medicaid (T19), or CHIP (Title 21), it may be more cost effective for them to receive immunizations through those programs rather than through the VFC program as there would be no cost to the parent/guardian for the administration fee.
- Medicaid-eligible: A child who is eligible for KanCare, the state Medicaid program. Health services are purchased through either a managed care model or a fee-for-service model. The KanCare program is the State of Kansas' managed care program. KanCare is provided to all Medicaid and CHIP consumers. Kansas has contracted with three health plans, or managed care organizations (MCOs), to coordinate health care for nearly all beneficiaries.
 - Medicaid (Title 19): A federal-state program that provides health and long-term care services to low income families. As a condition of state participation, each state must agree to cover certain populations and provide certain services. KanCare can be billed for the vaccine administration fee of each vaccine, but not for the antigen. Kansas Medical Assistance Program (KMAP) eligibility documentation is required to be kept on file for a minimum of 3 years after the administration of a vaccine.
 - Child Health Insurance Plan - CHIP (Title 21): Health care coverage for low income children living in families with incomes that exceed Medicaid limits. Unlike Medicaid, CHIP is not open-ended; states are awarded yearly allotments. Kansas provides low cost health insurance coverage to children who are under the age of 19, do not qualify for Medicaid, have family incomes under 232 percent of the federal poverty level, and are not eligible for state employee health insurance and are not covered by private health

insurance. Medicaid, including KanCare can be billed for the vaccine administration fee of each vaccine, but not for the antigen. KMAP eligibility documentation is required to be kept on file for a minimum of 3 years after the administration of a vaccine.

- Border states- The vaccinating provider must be a Medicaid-enrolled provider for the state where the child resides to receive reimbursement for the administration fee from the neighboring state's Medicaid program. If the provider is not enrolled with the border state's Medicaid program, the child is still VFC-eligible, but the administration fee is the responsibility of the parent/guardian. The child may not be turned away for inability to pay the administration fee. The parent/guardian may be billed after the visit but, any portion of an unpaid bill cannot be turned into collections. The provider can also choose to waive the administration fee.
- Uninsured: The child has no health coverage (KanCare or private insurance) and, therefore, is considered VFC-eligible. An administration fee may be charged to the parent/guardian for each vaccination. The uninsured child may not be turned away for inability to pay the administration fee. The parent/guardian may be billed after the visit but, any portion of an unpaid bill cannot be turned into collections. Incarcerated juveniles without insurance are also considered uninsured.
- Underinsured: A child that has insurance, but the insurance:
 - Does not cover vaccines, either because of age or specific antigen. Only the specific vaccines that are not covered would be eligible for coverage as underinsured.
 - Has non-covered ACIP-recommended vaccines. Only the specific vaccines that are not covered would be eligible for coverage as underinsured.
 - Has a cap on the coverage. The provider must have documentation that the insurance company was contacted, and the insurance cap has been reached. The documentation is required to be kept on file for a minimum of 3 years after the administration of a vaccine.

Underinsured children can only be vaccinated with public vaccine at a Federally Qualified Health Center (FQHC), Rural Health Center (RHC), or a deputized local health department (LHD).

317 VACCINE

Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Section 317-purchased vaccine has been directed towards meeting the needs of priority populations. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels. Immunizations with 317-vaccine can be provided to:

- Newborns receiving the birth dose of hepatitis B prior to hospital discharge that are covered under bundled delivery or global delivery package (no routine services can be individually billed) that does not include hepatitis B vaccine
- Fully insured infants of hepatitis B-infected women and the household or sexual contacts of hepatitis B-infected individuals

- Uninsured or underinsured adults
- Fully insured individuals seeking vaccines during public health response activities including:
 - Outbreak response (regardless of insurance status)
 - Post-exposure prophylaxis
 - Disaster relief efforts
 - Mass vaccination campaigns or exercises for public health preparedness
 - Individuals in correctional facilities and jails

STATE VACCINE

State vaccine is available on occasion for special projects and campaigns. The KIP will let providers know when this vaccine is available and the eligibility guidelines surrounding vaccine use.

PRIVATE VACCINE

Vaccine that is purchased by the provider to use for individuals that have health insurance that covers the cost of vaccinations. Children who have insurance that covers all ACIP-recommended vaccines are not VFC-eligible, even if the patient has a high deductible or copay. 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 vaccine. For the purposes of the VFC Program, if on the day of the visit, a child presents with health insurance and coverage for vaccines is not known (i.e. not verified) by the provider, the child **must** be treated as though they are insured for all vaccines.

The KIP does not provide oversight on the use of or storage and handling procedures associated with private vaccine.

ELIGIBILITY

ELIGIBILITY SCREENING

VFC providers should screen for and document the VFC eligibility (i.e., federal or state vaccine-eligible) status of patients at each immunization encounter.

Federally purchased public (VFC and CHIP) vaccine should be administered only to children who are 18 years of age or younger who meet one or more of the following categories:

- Are an American Indian/Native-American or Alaska Native;
- Are enrolled in Medicaid;
- Have no health insurance;
- Are underinsured: A child who has health insurance, but the coverage does not include vaccines; or a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or a deputized local health department.

Occasionally, children may be VFC-eligible for more than one eligibility category. Providers should select and document the VFC eligibility category that will require the least amount of out-of-pocket expense to the parent/guardian for the child to receive needed immunizations.

State purchased vaccine, including 317 funded vaccines, should be administered to children who are 18 years of age or younger who are not eligible to receive federally purchased VFC vaccines.

Children whose health insurance covers the cost of vaccinations are **not eligible** for public (VFC and CHIP) vaccine. This applies even when a claim for the cost for the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

DOCUMENTATION REQUIREMENTS

Documentation of funding source eligibility status is required:

- Prior to each immunization visit
- To be created and kept on file for a minimum of three years after the date of the vaccination
- To be available for staff that are administering vaccines so that appropriate vaccine stock can be administered

LOCATION OF SERVICES

- School-Based and Mass Vaccination Clinics: Children must be screened, and their eligibility documented prior to administering public (VFC and CHIP) vaccine.
- Bordering State: If a VFC-eligible child receives their healthcare in a bordering state instead of their state of residency, the provider must be a Medicaid-enrolled provider for the state where the Medicaid VFC-eligible child resides to receive reimbursement for the administration fee from the neighboring state's Medicaid program.
- Sexually-Transmitted Disease (STD) Clinics, Family Planning Clinics:
 - If a minor under 19 years of age is seen in an STD or Family Planning Clinic, does not know their insurance status or because of the confidential circumstances of seeking services does not have access to insurance coverage, they can be considered uninsured for the purposes of the VFC program.
 - Provision of public (VFC and CHIP) vaccine to unaccompanied minors without insurance status in STD and Family Planning Clinics is a provider's choice and must follow the state's medical consent laws as they relate to minors.
- Juvenile Detention Facilities: Juveniles under 19 years of age who are incarcerated in detention facilities that have lost access to health insurance due to incarceration are considered uninsured and VFC-eligible.

BILLING

BILLING PRACTICES

VFC providers must adhere to proper billing practices for vaccine administration fees, which include the following elements:

- Vaccine administration fees charged for non-Medicaid, VFC-eligible children must not exceed \$20.26 per dose (Centers for Medicare and Medicaid Services (CMS) Kansas fee cap).
- Only one payer may be billed for the same administration fee.
- Billing should never occur for the cost of publicly funded vaccine. Publicly funded vaccine is provided at no cost to the provider and eligible child.
- Established patients that are VFC-eligible cannot be denied vaccination or be reported to collections based on the parent or guardian's inability to pay the vaccine administration fee. The “Established Patient” rule does not apply to pharmacies, urgent care clinics, or school-based clinics.

INSURED EXCEPTIONS

➤ American Indian/Native-American or Alaska Native (AI/AN) with insurance that covers immunizations:

- Because the VFC is an entitlement program, participation is not mandatory.
- If the child has private insurance (plans created or purchased after March 23, 2010 when the Patient Protection and Affordable Care Act (ACA) was signed into law) or is enrolled in the Medicaid or CHIP programs, it results in less out of pocket expenses if the child receives immunizations through those programs than through the VFC program because there would be no cost for vaccine administration.

➤ Insured and Medicaid as secondary insurance:

- If the child has private health insurance covering vaccines and Medicaid as secondary insurance, the child is considered VFC-eligible because they have Medicaid.
- Parents are not required to participate in the VFC program so there are two options for billing and the provider must choose the option that is most cost-effective for the family. The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

- Billing Option 1: The VFC provider can administer public (VFC and CHIP) vaccines and bill Medicaid for the administration fee. ***Considerations: This is the easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee; there is no out-of-pocket costs to the parent for the vaccine or the administration fee.***
- Billing Option 2: The VFC provider can administer private vaccines and bill the primary insurance for the cost of the vaccine and the administration fee. ***Considerations: The VFC provider may be reimbursed a higher dollar amount if private vaccine is administered and both the vaccine and administration fee are billed to the primary insurer.***

1. If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee.
 2. If the child has a high-deductible private insurance plan requiring the parent/guardian to pay out-of-pocket for vaccines until the deductible has been reached, the child should be considered VFC-eligible and the administration fee billed to Medicaid until the deductible is reached.
- High-Deductible Plan and Medicaid as secondary insurance with the parent required to pay out of pocket for the vaccines until the deductible is met: The child **is** VFC-eligible, VFC vaccine should be used and the administration fee billed as Medicaid until the deductible is met.
 - Underinsured: Children have health insurance but the insurance:
 - Doesn't cover any ACIP-recommended vaccines
 - Doesn't cover all ACIP-recommended vaccines; only selected vaccines are covered. The child is VFC-eligible for non-covered vaccines only
 - Does cover ACIP-recommended vaccines, but has a fixed dollar limit or cap for vaccines; once the fixed dollar is reached, the child is considered underinsured

VFC providers should verify coverage of ACIP-recommended vaccines from the health insurance plan. If verification of vaccine coverage cannot be made, then the child would be considered insured and not be eligible to receive public (VFC and CHIP) vaccines.

- Health Care Sharing Ministry: Non-profit alternative to purchasing health insurance from private, for-profit insurers. Generally, Health Care Sharing Ministries are organizations whose members share a common belief system and collectively "share" the cost of their members' medical care.
 - If the plan is not recognized as insurance by the state insurance department then the child is VFC-eligible.
 - If the plan is recognized as insurance by the state insurance department and covers the cost of vaccines then the child is considered insured.
 - If the plan is recognized as insurance by the state insurance department and does not cover all the ACIP-recommended vaccines then the child is considered underinsured and can receive non-covered public vaccines through a FQHC, RHC, or deputized LHD.

Quick View of Public (VFC or CHIP) Eligibility and Insurance Situations		
Insurance Status of Child.	Eligible for Publicly Funded Vaccine	Public (VFC or CHIP) Eligibility Category.
Enrolled in Medicaid	Yes	Medicaid
Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured - This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Depends	<ul style="list-style-type: none"> • 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	Partial	Underinsured - Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured - With implementation of ACA, this situation should be rare.
Enrolled in a Health Care Sharing Ministry	Depends	<ul style="list-style-type: none"> • Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan • Insured if plan is recognized by the state insurance department and covers vaccines • Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines
Enrolled in a separate Children's Health Insurance Program (CHIP)	Yes	The state CHIP program is responsible for vaccine payment for its members.
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is (AI/AN)	Yes	AI/AN - However, 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 - Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.
<i>For Medicaid-eligible children, the VFC provider must verify and document Title 19 or Title 21 eligibility.</i>		

DOCUMENTATION

VFC RECORDS

All VFC documents must be kept on file for a minimum of 3 years from the date of vaccination and available for review.

VFC documents include, but are not limited to:

- VFC screening and eligibility documentation for each immunization encounter
- Billing records
- Medical records that verify receipt of vaccine
- Vaccine ordering records and packing slips
- Vaccine purchase records
- Temperature logs
- Digital data logger files
- Annual enrollment agreements
- Provider profiles
- Other accountability records

COMPLIANCE WITH THE NATIONAL CHILDHOOD VACCINE INJURY ACT (NCVIA)

Provide Vaccine Information Statements (VIS):

- The current VIS must be distributed each time a vaccine is administered
- Record information for each VIS provided; date provided and publication date

Maintain vaccine administration records, including documentation of:

- Name of vaccine provided
- Date vaccine was administered
- Name of vaccine manufacturer, vaccine lot number and expiration date
- Name and title of person who administered the vaccine
- Address of the clinic where the vaccine was administered and where medical record will be maintained
- Date VIS provided and publication date of VIS

Report serious health problems following vaccination to the Vaccine Adverse Event Reporting System (VAERS)

- Any adverse event listed by the vaccine manufacturer as contraindication to further doses of the vaccine or any adverse event listed in the [https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified time period after vaccination.
- Adverse events can be reported online at <https://vaers.hhs.gov/reportevent.html>. Examples of the VAERS report can be found in the FORMS AND RESOURCES section of this manual.

VACCINE MANAGEMENT PLANS

The management of publicly purchased vaccine is one of the most important responsibilities for VFC providers. Proper vaccine storage and handling procedures and sound vaccine management practices will minimize vaccine loss and waste, and the potential need to revaccinate that could result from administering compromised vaccine. Vaccine loss is costly and much of the time, it is preventable. The CDC Vaccine Storage and Handling Toolkit outlines guidance and best practices for vaccine storage and handling. All VFC providers must keep the most current version of the CDC Storage and Handling Toolkit available.

The toolkit can be found at: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>.

There are many reasons for vaccine loss, including: heat and/or light exposure, inappropriate freezing, broken vials and syringes, poor reconstitution practices, possible contamination, missing inventory, etc. The most significant cause of vaccine loss is attributed to poor vaccine management. Maintaining the vaccine potency is a shared responsibility of manufacturers and clinic staff that handle the vaccine until the dose is administered.

VFC providers must develop, maintain, and implement vaccine management plans with clearly written, detailed, and up-to-date standard operating procedures for routine and emergency vaccine management. The vaccine management plan must include:

- Names and contact information for primary and backup clinic coordinators
- Provider staff roles and responsibilities
- Documented training related to vaccine management
- Proper storage and handling practices, including how to handle a temperature excursion
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster

EMERGENCY RESPONSE PLANS

VFC providers must also develop emergency response plans to assure vaccine viability in the case of natural disasters, power outages, or other emergencies. Such emergency plans might include the use of a backup generator. If used, generators should be tested quarterly and serviced annually or based on manufacturer's instructions.

Emergency response may also include plans for transporting vaccines to another location for storage. VFC providers should maintain supplies needed for emergency transport of public vaccine. Emergency response facilities must have vaccine storage units that will maintain proper temperatures and can be monitored with calibrated digital data loggers (DDLs). Alternate vaccine storage units must be an appropriate size to accommodate additional vaccine inventories without overcrowding. Staff at the emergency response facility must have a clear understanding of proper vaccine management while the vaccine is being stored in their facility.

It is the responsibility of the VFC provider to ensure that temperature excursions are avoided regardless of where vaccines are stored.

Vaccine management and emergency response plans should be easily accessible and kept near the vaccine storage units.

Each provider's vaccine management and emergency response plans must be updated annually (sooner if there are changes to the plan), including authorized signature and date. The KIP Regional Consultants will review VFC provider policies and procedures as a component of VFC compliance site visit and/or unannounced visits.

The KIP is available to provide education and guidance to providers for proper vaccine management. A template for Provider Vaccine Storage and Handling Plan/Emergency Response Plan can be found at: <http://www.kdheks.gov/immunize/storage.htm> or in the FORMS AND RESOURCES section of this manual. In addition, directions for packing vaccines for transport during emergencies is also located in the FORMS AND RESOURCES section of this manual.

VACCINE STORAGE UNITS

VFC providers must utilize storage equipment that consistently and properly maintains recommended temperatures:

- Refrigerated vaccines must be stored between 2°C and 8°C (36°F and 46°F)
- Frozen vaccine must be stored between -50°C and -15°C (-58°F and +5°F)

Vaccine storage units must be of adequate size to store the largest inventory at the busiest point in the year without crowding (i.e., flu season or back to school).

The CDC also recommends that units be large enough to store water bottles in the refrigerator and freezer to stabilize temperatures. This recommendation does not apply to pharmaceutical units if the manufacturer indicates that water bottles negatively impact the functionality of the unit.

Vaccine storage units in order of preference, based on historical ability to maintain temperature to ensure vaccine viability:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units
- Stand-alone refrigerator and freezer units; sizes can vary and include compact, under-the-counter style to large, stand-alone, pharmaceutical-grade storage units

In the event the units above are unavailable, then combination household refrigerator/freezer units can be used, using only the refrigerator compartment to store vaccines; a separate stand-alone freezer should be used to store frozen vaccines.

Dormitory or bar-style units are **prohibited**.

Regardless of the type of unit used, it must demonstrate that proper vaccine storage temperatures will be maintained.

There are several manufacturers of vaccine storage units. The Vaccine Storage Equipment Needs document provides information from the American Academy of Pediatrics on vaccine storage units. This document can be found at: <http://www.kdheks.gov/immunize/storage.htm>.

The KIP does not endorse or recommend any specific product or manufacturer. Each provider is responsible for the terms and conditions of any purchase made.

POWER SOURCE

A “Do Not Unplug” warning sign must be placed next to the electrical outlets for each vaccine storage unit and on the electrical breaker that services these outlets. Tamper proof plugs are also recommended.

Large healthcare systems and hospitals may meet this requirement without signage, if it is demonstrated that there is a comprehensive policy and standard operating procedures to prevent vaccine storage units from being physically disconnected from the power source.

DIGITAL DATA LOGGERS AND BACKUP THERMOMETERS

DIGITAL DATA LOGGERS

Digital data loggers (DDLs) must monitor the temperature of public vaccines during routine storage, time in transport, and off-site storage. **VFC providers must use the KIP-supplied DDLs as the primary thermometer for each storage unit that holds public vaccines.** DDLs must be placed in the center of the unit with vaccines surrounding it. DDLs should not be placed in unit doors, near or against walls, or close to the floor, ceiling, or vents.

To meet VFC program requirements, the KIP-supplied DDLs have:

- A buffered temperature probe
- An active temperature display that can be easily read from the outside of the storage unit
- The ability to continuously monitor and record temperatures
- The ability to download temperature readings

The KIP-supplied DDLs also meet the additional CDC recommended features for DDLs that are used to monitor public vaccine:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature display
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes

All KIP-supplied DDLs have a current and valid certificate of calibration, which is the only acceptable method of monitoring temperatures in accordance with VFC program requirements.

The Certificates of Calibration testing **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)

Optional testing element:

- Uncertainty of +/- 0.5°C (+/-1° F) or less as recommended by CDC

If it is unclear as to whether the Certificate of Calibration Testing or Report of Calibration is issued by an appropriate entity, look for one or more of the following items documented regarding the calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. ILAC/MRA signatories may be found at: <http://ilac.org/ilac-mra-and-signatories/>
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

A Certificate of Calibration Test (Report of Calibration) form can be found in the FORMS AND RESOURCES section of this manual.

BACKUP THERMOMETER

VFC providers must also have a backup digital thermometer that is readily available and has a certificate of calibration testing meeting the requirements listed above. It is recommended that the calibration dates for the backup thermometer are different than the primary thermometer to stagger the need for replacement on the same date. The backup thermometer is needed in the event the KIP-supplied DDL malfunctions or is no longer working. **VFC providers should contact their Regional Immunization Consultant or the Consultant On-Call immediately if the KIP-supplied DDL malfunctions or stops working.** A replacement unit will be shipped immediately upon notification.

TEMPERATURE DOCUMENTATION

VFC providers must have established protocols for reviewing and recording temperature readings. All VFC providers are required to maintain paper temperature logs and electronic files from the KIP-supplied DDLs. **Paper temperature logs and electronic files from the DDL downloads must be kept on file for a minimum of 3 years and be available upon request.**

TEMPERATURE LOGS

Temperatures must be manually checked and recorded on the KIP temperature log. Minimum and maximum temperatures must be recorded at the start of each clinic day and the current temperature

should be recorded twice daily; when the clinic opens and one hour prior to the clinic closing. It is also recommended that the current temperature is checked prior to accessing and administering vaccines.

Documentation should include actual temperature readings, time and date of readings, the name (or initials) of the person who checked and recorded the readings, and any actions taken if a temperature excursion occurred. Temperature logs can be found at:

http://www.kdheks.gov/immunize/datalogger_information.htm or in the FORMS AND RESOURCES section of this manual.

In the event a facility is closed, no more than 3 days may pass without manually checking and recording the temperature.

It is not necessary to submit paper temperature logs monthly unless specifically requested by the KIP.

DIGITAL DATA LOGGERS

The KIP-supplied DDLs continuously monitor temperatures of vaccine storage units and alert clinic providers when the storage unit temperatures are out of range.

The DDL takes temperature readings every minute and records them every five minutes. The DDL will hold 56 days of readings.

VFC providers should download DDL files (.pdf and .txt) monthly and maintain an electronic copy per the KIP guidelines **in addition** to the monthly upload into KSWebIZ.

Data from the DDLs should be uploaded to KSWebIZ no later than the 7th day of the month (i.e., Data from January would be uploaded to KSWebIZ by February 7th).

Additional details on the KIP-supplied DDLs functions and operation, can be found on the KIP website at: http://www.kdheks.gov/immunize/datalogger_information.htm

VACCINES OFFERED THROUGH PUBLIC FUNDS

Vaccines that are available through public funding include: DTaP, Hepatitis A and B, HIB, HPV, Influenza, Meningococcal, MMR, Pneumococcal, Polio, Rotavirus, Tdap/Td and Varicella as single or combination presentations.

Combination vaccines should be offered when possible rather than a single antigen. Combination vaccines reduce the number of injections required to prevent some diseases, improve timely vaccination coverage, reduce the cost of vaccine administration, and reduce the number of health-care visits.

All recommended vaccines must be offered according to the ACIP schedules, recommended dosage, and contraindications unless:

- In the VFC provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child
- The parent/guardian of the child has secured an appropriate exemption in accordance with Kansas Statutes.

VACCINE ORDERING

The KIP works to ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business, and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted publicly funded vaccines. The management of publicly purchased vaccine is one of the most important responsibilities for VFC providers. Vaccine management practices must include proper ordering and inventory management to prevent vaccine waste and ensure appropriate stock is available by funding type.

Prior to submitting vaccine orders, providers must perform an analysis of the number of children served in the past 12 months by age, funding source, presentation, and number of doses used. If any changes are identified in the patient population then a Provider Profile Update Form should be submitted to the Regional Immunization Consultant. The Provider Profile Update Form can be found in the FORMS AND RESOURCES section of this manual.

Providers should place a vaccine order while they still have a four-week supply of vaccine available to account for possible delays.

Check your order! Be sure you ordered the correct vaccine and number of doses! Providers who order the wrong vaccine are responsible for administering those vaccines before the expiration date.

Vaccine orders must be submitted between the 1st and 7th day of the month, after doing a physical count of vaccine and diluent inventory.

The following conditions must be met prior to placing a vaccine order:

- Reconciliation reports must be closed within the past 7 days. Prior to closing reconciliation reports, ensure that pending vaccine shipments are accepted into the on-hand inventory, doses administered are verified, and returns are complete within the reporting period.
- Data from the KIP-supplied DDLs should be uploaded into KSWebIZ and approved by the KIP in the past 7 days.
- Vaccine orders must be consistent with the Provider Profile on file.

Orders should arrive 1 to 2 weeks from the date of the order.

Providers ordering > 500 doses in the previous 6 months may place an additional order 10 days after the first order of the month, if needed. Providers should place smaller, more frequent orders, to minimize vaccine loss in the event of an incident during shipping or with the vaccine storage unit.

Vaccine loss due to expiration is frequently a consequence of over-ordering and/or poor inventory management.

Providers must have an adequate storage unit size to accommodate vaccine orders during the busiest time of the year (i.e., back to school and flu season).

RECEIVING VACCINES

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccine in optimal conditions. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain. Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless. All VFC vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.

Providers must be available and onsite with appropriate staff to receive vaccine shipments. The clinic should be open at least four consecutive hours on a day, other than a Monday, to receive VFC vaccines.

Vaccines are delivered in accordance with reported clinic hours of operation in KSWebIZ. Clinic hours must be updated during the provider enrollment process in KSWebIZ. Providers may request a change in hours of operation by following the instructions in KSWebIZ under Reports>Documents> VFC Change of Information Instruction.

All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain. Receiving staff should be trained to immediately notify the VFC primary or back-up coordinator when deliveries arrive so that vaccines are checked in and stored quickly.

Upon receipt of a vaccine shipment, providers must immediately unpack vaccines and diluents, store them at recommended temperatures, and document appropriately.

VFC providers should:

- Examine the shipping container and vaccine vials for signs of physical damage
- Compare the contents of the container to the packing list to ensure accurate shipment
- Make sure lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluents; diluents for varicella-containing vaccines are stored in a separate compartment in the lid of the shipping container and are stored separately in the refrigerator
- Check vaccine and diluent expiration dates to ensure none are expired or soon to expire
- Check the cold chain monitor for any indication of temperature excursion during transit; cold chain monitors are stored in a separate compartment of the shipping container and may not be included when vaccines are shipped directly from the manufacturer; cold chain monitors should be thrown away after being checked
- Determine the amount of time vaccines were in transit and compare it against the packing list in the container, which shows acceptable transit time (frozen vaccines only)

Contact the KIP Vaccine Coordinator immediately at 785-296-1948, if the following issues are identified with the vaccine delivery:

- Vaccine were compromised or there was a problem with the temperature monitors
- Vaccines were received that were not ordered

- Vaccines were ordered but not received
- Vaccines are short-dated (less than 6 months until the expiration date). Only in special circumstances are short-dated vaccines shipped. Good faith efforts to use short-dated vaccines will not be billed if wasted, unless the waste is due to gross negligence.

VACCINE INVENTORY

All vaccine should be maintained at the appropriate temperature to ensure vaccine viability. Vaccines remain in optimal condition when they are kept in a temperature-controlled environment, which is maintained from the manufacturing plant through distribution to the provider clinic and through vaccine administration. Too much exposure to heat, cold, or light at any step could result in loss of vaccine potency. Each time vaccines are exposed to improper conditions, potency is reduced further. If the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.

- Correct refrigerator temperature range is 2°C through 8°C
- Correct freezer temperature range is -50°C through -15°C

VACCINE AND DILUENT PLACEMENT

Following best practices, vaccines and diluents received at the VFC provider clinic, should be:

- Stored in original manufacturer packaging with lids closed until ready for administration; never store loose vials or manufacturer-filled syringes outside of their packaging
- Placed in a central location in the unit, 2-3 inches away from walls, ceiling, floor, and door
- Placed in units that have water bottles (labeled “DO NOT DRINK”) stored against the walls, in the back, on the floor, and in the door racks throughout refrigerator and freezer units; this does not apply if the manufacturer indicates that the water bottles negatively impact the functionality of the unit
- Arranged in rows, allowing space between rows to promote air circulation and consistent temperature
- Labeled and placed on different shelves if there is similar packaging or names; adult and pediatric formulations should also be placed on different shelves to minimize the risk of administration errors
- Placed with the earliest expiration dates in front of those with later expiration dates; check and rotate every week and when a new shipment arrives
- Removed if expired. Bag and label all expired vaccine: “DO NOT USE” and return to the CDC centralized distributor; a return request can be obtained from the KIP and must be submitted to return expired vaccines, except for open multi-dose vials (MDVs); open MDVs cannot be returned, and should be appropriately disposed of in accordance with facility policy

Vaccine should **not** be:

- Placed in the storage unit too tightly; this can restrict air circulation and impact vaccine viability
- Stored in the door, deli/fruit/vegetable bins, on the floor of a unit, or under/near a cooling vent
- Placed in units with food and/or drinks

Vaccine inventories must be clearly differentiated as Public (VFC and CHIP), 317, State, or Private for reporting and placement in the storage unit.

- Direct data entry users in KSWebIZ must verify the funding source in the demographic screen prior to documenting an administered dose of vaccine.
- Electronic Medical Records (EMR) reporting must verify the funding source and track doses administered either electronically or on paper form.

VACCINE HANDLING AND PREPARATION

Vaccines should be prepared immediately prior to administration.

Vaccines should be prepared in a designated, clean medication area, away from any possible contamination.

Vaccine expiration dates should always be checked prior to preparing for administration.

Lyophilized vaccine should be reconstituted with the diluent that came with the vaccine and nothing else.

A single-dose vial contains one dose and should only be used for one patient.

A separate, sterile needle and syringe should be used for each injection.

Discard any pre-drawn doses no later than the end of the workday or per the manufacturer instructions.

During mass vaccination clinics, vaccines should not be pre-drawn. Instead use of manufacture pre-filled syringes is recommended.

VACCINE BORROWING

VFC providers are required to maintain adequate inventories of vaccine to administer to both privately-insured and publicly-insured children that they serve. VFC vaccine should never be used as a continuous or routine source of replacement for private vaccine. **Borrowing is permitted only in rare, unplanned circumstances.**

Borrowing is only allowed in the following situations:

- VFC seasonal influenza vaccine is not yet available; providers may use private-stock seasonal influenza vaccine to vaccinate publicly-insured children and replace it when VFC vaccine arrives; this one-directional borrowing is unique to seasonal influenza vaccine only
- Lack of vaccine due to delayed or spoiled shipments
- Vaccine will expire soon and will be lost if not used; to be used only by providers with small, privately-insured populations. In this instance, providers can administer short-dated, private vaccine to a publicly-insured child and replace it with longer-dated, VFC dose
- New staff calculated ordering interval incorrectly, causing a lack of either private or public vaccine; this may occur only prior to proper vaccine ordering training

Borrowing doses from public funding stock **must not** prevent a publicly-insured child from receiving needed vaccine.

During scheduled mass immunization clinics, the vaccine needs must be anticipated, and an adequate amount of vaccine should be in the vaccine inventory prior to holding the clinic. Borrowing is not allowed.

A Vaccine Borrowing Report must be completed for all vaccine borrowed, whether it is VFC vaccine administered to a privately-insured child or private vaccine administered to a publicly-insured child. The borrowing event is complete when the borrowed dose is replaced through administration. The Vaccine Borrowing Report can be found in the FORMS AND RESOURCES section of this manual.

All Vaccine Borrowing Reports must be maintained for at least three years after the dose was borrowed. In addition, VFC providers should also maintain copies of invoices showing the purchase of private vaccine used to replace borrowed public vaccine. The reports and invoices must be made available during site visits or upon request the KIP.

Vaccine Borrowing Reports should be submitted to the KIP at the end of each month. Reports can be faxed to 785-559-4226 or emailed to kdhe.vaccine@ks.gov.

Corrective actions will be taken when excessive or inappropriate borrowing activities are noted. The KIP is required to follow up with providers with multiple borrowing instances.

For questions regarding borrowing, contact your Regional Immunization Consultant or the Consultant On-Call at 785-296-5592.

VACCINE REDISTRIBUTION

On occasion, VFC providers may find they have vaccine stock that is close to expiring. If practical and the cold chain can be maintained, short-dated vaccine can be transferred between VFC providers to avoid vaccine wastage. The KIP maintains a list of publicly funded vaccines available for redistribution. The list can be found on the KIP website at http://www.kdheks.gov/immunize/vaccine_redistribution.htm.

VFC providers may place short-dated vaccine on the Vaccine Redistribution list if:

- The vaccine has a minimum of 90 days and a maximum of 365 days before the expiration date
- The vaccine is in a full box or unopened multi-dose vial

VFC providers with short-dated publicly funded vaccine are responsible for any doses which expire on the Vaccine Redistribution list that have not been accepted for transfer by another VFC provider.

VFC providers interested in receiving the short-dated vaccine should contact the VFC provider listed on the Vaccine Redistribution list. The Vaccine Redistribution list contains information for the primary clinic contact, including a phone number and email address.

VFC providers accepting vaccine from the Vaccine Redistribution list are responsible for using the doses once they are transferred. VFC providers should only accept doses they can administer before the expiration date.

The Regional Immunization Consultant or Consultant On-Call **must** be notified prior to transferring any vaccine.

The transferring and receiving VFC providers should document the vaccine on their monthly reconciliation reports as transferred vaccines.

Once the vaccine is transferred, the transferring VFC provider should contact the KIP Vaccine Coordinator at 785-296-1948 so that the Vaccine Redistribution list can be updated.

Frozen, publicly funded vaccines will not be posted on the Vaccine Redistribution list. Frozen vaccines are very intolerant of out of range temperatures so VFC providers should contact their Regional Immunization Consultant or On-Call Consultant for assistance.

VACCINE TRANSFERS

Transfers of vaccine should not routinely occur. The Regional Immunization Consultant assigned to the area **must** be notified prior to transportation of vaccine if the transport time is one hour or more. The Regional Immunization Consultant will handle transports greater than one hour.

If the following conditions are met, vaccines can be transferred:

- Approval is received from the KIP; transfer will take place under guidance of the KIP
- A process is in place to ensure vaccine viability during the transfer, following the guidance outlined in the CDC Vaccine Storage and Handling Toolkit
- The vaccine will be transferred in a qualified container with a certified calibrated thermometer
- Vaccine temperatures are monitored and documented throughout the transfer using the Vaccine Transfer Form

The Vaccine Transfer Form can be found in the FORMS AND RESOURCES section of this manual. Vaccine Transfer Forms should be maintained for at least three years after the transfer and be available during site visits or upon request by the KIP.

OFF-SITE AND MASS VACCINATION CLINICS

VFC Providers that will be conducting off-site and/or mass vaccination clinics with public vaccine, must follow all VFC requirements in addition to enhanced storage and handling practices. Consultation with the Regional Immunization Consultant prior to the clinic will ensure that VFC requirements for such clinics are understood and followed by VFC providers.

The number of publicly-insured children to be served should be anticipated and appropriate amounts of vaccine should be ordered.

Vaccines must be transported according to the guidelines outlined in VACCINE TRANSFERS. The Regional Immunization Consultant should be notified prior to any transfer of vaccine, appropriate equipment should be available and used, and temperatures should be monitored and logged on the Vaccine Transfer Form hourly while in transit.

Vaccines must be stored correctly throughout the clinic to maintain appropriate temperatures. Temperatures should be monitored and documented hourly on the Vaccine Transfer form or on the paper temperature logs provided by the KIP.

After completion of the clinic, the temperatures of the vaccine during transit and the clinic must be evaluated to ensure vaccine temperatures were maintained within acceptable temperature ranges. If temperatures were maintained appropriately, vaccine may be returned to regular storage units.

If there were any instances of temperatures falling out of range, the vaccines should be labeled, “DO NOT USE,” and the temperature excursion process should be completed so that a determination on vaccine viability can be made.

TEMPERATURE EXCURSIONS

If a cold chain failure is suspected, or there is evidence vaccine has been exposed to temperatures outside the recommended temperature range, providers must follow the instructions found on the Provider Temperature Excursion Worksheet found in the FORMS AND RESOURCES section of this manual.

Mark vaccines DO NOT USE, and leave vaccines refrigerated or frozen until the vaccine manufacturers and the KIP have been notified.

Providers must report the incident by phone to the Regional Immunization Consultant or Consultant On-Call immediately at 785-296-5592.

Temperatures of the storage unit will need to return to acceptable ranges within a couple of hours or the vaccines will need to be moved to the backup storage unit/location as outlined in the Provider Vaccine Storage and Handling Plan/Emergency Response Plan.

The vaccine manufacturers must be contacted, and their written recommendations sent by fax or email to the Regional Immunization Consultant or Consultant On-Call. Information to report to vaccine manufacturers includes: vaccine antigens, length of time vaccines were exposed to temperatures out of recommended range, and the exact temperatures to which the vaccines were exposed.

Not all vaccines are non-viable if the temperature excursion and time factors are minimal, so vaccine manufacturer recommendations are essential in determining whether the vaccine can be used or if it needs to be discarded.

VFC providers should maintain and track temperature excursions and exposure time for each vaccine deemed viable to ensure appropriate vaccine manufacturer recommendations are received. If **vaccine is deemed viable after a temperature excursion**, the vaccine can be used but should be marked with excursion stickers to easily identify their history.

- Excursion stickers are available from the KIP Online Order Center, located at <http://www.kdheks.gov/immunize/index.html> under the VFC Provider Info tab.
- Blue excursion stickers indicate the vaccine was exposed to adversely low temperatures; red excursion stickers indicate the vaccine was exposed to adversely high temperatures
- Place and date appropriate colored stickers on each vaccine affected by the temperature excursion; add excursion stickers for any subsequent temperature excursions
- Viable vaccines that have been affected by a temperature excursion should be used first because they usually will have a shortened expiration date

The completed Provider Temperature Excursion Worksheet and supporting documentation must be submitted to the Regional Consultant or Consultant On-Call for review before approval to resume vaccinating with public vaccine will be made. If the temperature excursion resulted in vaccine loss, a determination will also be made by the KIP as to whether the vaccine loss was avoidable or unavoidable.

EXPIRED, SPOILED, AND WASTED VACCINE

VFC providers must have vaccine management plans and equipment in place to maintain the cold chain for publicly funded vaccines and to minimize the risk of vaccine loss. The KIP works with VFC providers to assist with updating vaccine storage units and developing strong vaccine management policies and procedures.

The KIP is required to identify and report poor vaccine management, program fraud, or abuse. It is the goal of the KIP to educate and assist providers in identifying mechanisms to prevent wasted vaccine and improve the overall vaccine management process. These steps increase program and provider accountability for the valuable vaccine resources available in Kansas.

EXPIRED OR SPOILED VACCINE

Expired or Spoiled Vaccine: Non-viable vaccine in its original container (vial or syringe) that **should be returned** to McKesson. This includes expired vaccine or vaccine that has been spoiled because of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure
- Recall

WASTED VACCINE

Wasted Vaccine: Non-viable vaccine that **cannot be returned** to McKesson. This includes:

- Vaccine drawn into the syringe but not administered
- Vaccine in open multi-dose vials but not all doses administered
- Compromised vial, broken vial, or lost vial

LOST OR UNACCOUNTED VACCINE

Lost or Unaccounted Vaccine: Lost or unaccounted for vaccines in which the physical vaccine or syringe is missing.

All vaccine loss will be carefully reviewed and categorized as avoidable or unavoidable by the KIP. VFC providers are responsible for repayment of avoidable publicly funded vaccine loss. See VACCINE LOSS for further detail.

RETURN OF VACCINE

All expired, spoiled, or wasted vaccines should be removed from the storage units and labeled “DO NOT USE.” Expired and spoiled vaccine should be returned to McKesson; wasted vaccine cannot be returned.

Expired vaccine must be returned to McKesson after the expiration date. Vaccine **cannot** be returned before the expiration date. Report the expired vaccine within 72 hours in KSWebIZ.

Instructions on how to return vaccines can be found at the following link:

http://www.kdheks.gov/immunize/download/Requesting_a_Vaccine_Return_in_KSWebIZ.pdf

VACCINE LOSS

Whenever there is a loss of publicly funded vaccine, the KIP will review details surrounding the incident and decide whether the loss was avoidable or unavoidable.

AVOIDABLE WASTE: Waste that occurs under the control of the provider and is preventable.

Avoidable waste includes, but is not limited to:

- Failure to notify the KIP immediately of a temperature excursion
- Refrigerator/freezer door left open
- Vaccine left out of the storage unit for an extended amount of time
- Vaccine placed in wrong storage unit (i.e., refrigerated vaccine placed in the freezer)
- Failure to take corrective action on temperature excursion or indications that the storage unit may be having difficulty maintaining appropriate temperatures (i.e., temperature is running high)
- Failure to fully complete the Temperature Excursion Worksheet in a timely manner
- Over-ordering (i.e., stockpiling vaccine)
- Ordering vaccine that is inconsistent with the Provider Profile

- Failure to notify the KIP 3 months in advance of vaccine expiration date when provider will be unable to use all the doses on hand
- Failure to properly transport vaccines
- Vaccines with longer expiration dates administered prior to vaccines with shorter expiration dates
- Failure to determine client eligibility prior to administering vaccination
- Patterns of vaccine drawn up in a syringe but not used

UNAVOIDABLE WASTE: Waste that occurs due to an act of nature and could not have been avoided (i.e., tornados, floods) provided that the VFC provider followed their Storage & Handling/Emergency Response Plan and took reasonable action to prevent the waste of vaccine.

For instances of **avoidable vaccine loss**, VFC providers will be responsible to repay the vaccine loss on a dose-per-dose basis as described in Vaccine Repayment.

VACCINE REPAYMENT

The KIP is responsible for determining when a VFC provider has had an **avoidable loss of vaccine**. If the loss is determined to be avoidable, the VFC provider may be required to replace the lost vaccine with privately purchased vaccine on a dose-for-dose basis.

Vaccine loss repayment will be dependent on:

- Size of the loss
- Number of past wastage incidences by a specific clinic/organization
- Provider’s response to the temperature excursion
- Provider’s response to education and corrective action plan

Replaced doses must be used only for VFC-eligible children using the same proportions of the original funding sources of the lost doses. If the provider is unable to use the replacement doses, the KIP may determine it is necessary to transfer the doses to another VFC provider for use. VFC providers who accept redistributed vaccine will not be billed for waste so long as the receiving provider has made a good faith effort to use all the vaccines prior to their expiration date (this applies to vaccine repayment only).

VFC providers must submit a paid invoice for the privately purchased vaccine reflecting the dose-for-dose replacement to the KIP within 90 days of the vaccine loss.

VFC providers must use the “Public Wastage Replacement” funding category in KSWebIZ for the privately purchased vaccine to be used to vaccinate VFC and CHIP children.

VFC providers will not be able to order the specific public (VFC and CHIP) vaccine they are required to replace, until documentation has been provided showing all wasted vaccine has been replaced dose-for-dose.

VFC providers will be required to specifically identify internal mechanisms to avoid future wastage and to submit these policies to the KIP.

VFC providers with ongoing avoidable wasted vaccine may be placed **on vaccine hold or may be unenrolled** from the VFC program should the patterns of wastage continue.

Non-viable vaccine must be reported and submitted in KSWebIZ within 72 hours as outlined in RETURN OF VACCINE.

FRAUD AND ABUSE

The KIP works to ensure that vaccine management practices of VFC providers are consistent with sound immunization, fiscal, business, and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted publicly funded vaccines. The management of publicly purchased vaccine is one of the most important responsibilities for VFC providers. Vaccine management practices must include proper ordering and inventory management to prevent vaccine waste and ensure appropriate stock is available by funding type.

VFC Providers must agree to operate in a manner intended to avoid fraud and abuse. When providers enroll in the VFC program, they agree to follow the requirements of the program. Failure to follow the requirements could lead to fraud and abuse of the VFC program.

- Fraud - Intentional deception or misrepresentation made by a person with the knowledge that 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 laws.
- Abuse – Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program. The VFC program is a part of each state’s Medicaid program.

Some examples of fraud and abuse include, but are not limited to:

- Failing to comply with any part of the VFC Program Provider Agreement
- Providing publicly funded vaccine to privately-insured children
- Selling or otherwise misdirecting publicly funded vaccine
- Charging more than the established maximum regional fee for administration of publicly funded vaccine
- Over-ordering publicly funded vaccine
- Excessive waste of publicly funded vaccine
- Denying publicly-insured children publicly 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 publicly funded vaccine
- Failing to properly store and handle publicly funded vaccine

Regional Immunization Consultants will work with VFC providers to ensure they understand the requirements of the program.

WHAT'S HAPPENING WEDNESDAY AND SPECIAL ALERTS

What's Happening Wednesday and Special Alerts are the primary source of communication with VFC providers on matters related to the VFC program. It is expected that all VFC providers are reviewing these documents as they come out and are sharing the information with others in the practice as appropriate.

FORMS AND RESOURCES

- **Vaccines for Children Program Provider Agreement (includes Provider Profile)**
- **VAERS Report**
- **Vaccine Storage and Handling Plan with Emergency Response Plan**
- **Packing Vaccines for Transport During Emergencies**
- **Certificate of Calibration Testing (Report of Calibration)**
- **Temperature Log (Days 1-15)**
- **Temperature Log (Days 16-31)**
- **Provider Profile Update**
- **Borrowing Form**
- **Transfer Form**
- **Temperature Excursion Worksheet**
- **Immunization Resources**

KANSAS IMMUNIZATION PROGRAM

VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

FACILITY INFORMATION			
Facility Name:	VFC PIN #:		
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address			
City:	County:	State:	Zip:

MEDICAL DIRECTOR OR EQUIVALENT		
<p>Instructions: The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.</p>		
Last Name, First Name, MI:	Title:	Specialty:
License No:	Medicaid or NPI No.:	Employer Identification No:
Has the Medical Director or Equivalent completed CDC's annual 'You Call the Shots' training? Yes No		
If yes, please indicate, which trainings were completed?		
<i>Provide Information for second individual as needed:</i>		
Last Name, First Name, MI: ,	Title:	Specialty:
License No:	Medicaid or NPI No.:	Employer Identification No:

VFC VACCINE COORDINATOR	
Primary Vaccine Coordinator Name:	
Telephone:	Email:
Has the Primary Vaccine Coordinator completed CDC's annual 'You Call the Shots' training? Yes No	
If yes, please indicate, which trainings were completed?	Vaccines for Children (VFC) Vaccine Storage and Handling
Backup Vaccine Coordinator Name:	
Telephone:	Email:
Has the Backup Vaccine Coordinator completed CDC's annual 'You Call the Shots' training? Yes No	
If yes, please indicate, which trainings were completed?	Vaccines for Children (VFC) Vaccine Storage and Handling

PROVIDERS PRACTICING AT THIS FACILITY (additional spaces for providers at end of form)

Instructions: List below all licensed health care providers (MD, DO, NP and PA) at your facility who have prescribing authority.

Provider Name	Title	License No.	Medicaid or NPI No.	EIN (optional)

PROVIDERS PRACTICING AT THIS FACILITY (additional spaces for providers at end of form)

To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or practice administrator or equivalent:

1. I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:
 - A. Federally Vaccine-eligible Children (VFC eligible)
 1. Are an American Indian or Alaska Native;
 2. Are enrolled in Medicaid;
 3. Have no health insurance;
 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.
 - B. State Vaccine-eligible Children
 1. In addition, to the extent that my state designates additional categories of children as “state vaccine-eligible”, I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are not eligible to receive VFC-purchased vaccine.
3. For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
 - a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
 - b. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4. I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6. I will not charge a vaccine administration fee to non-Medicaid federal and state vaccine-eligible children that exceeds the administration fee cap of \$20.26 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
7. I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	<p>I will comply with the requirements for vaccine management including:</p> <ul style="list-style-type: none"> a. Ordering vaccine and maintaining appropriate vaccine inventories; b. Not storing vaccine in dormitory-style units at any time; c. Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet the Kansas Immunization Program storage and handling recommendations and requirements; d. Returning all spoiled/expired public vaccines to CDC’s centralized vaccine distributor within six months of spoilage/expiration
10.	<p>I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with 'fraud' and 'abuse' as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:</p> <p>Fraud: is 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.</p> <p>Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</p>
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	<p>For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Kansas Immunization Program to serve underinsured VFC-eligible children, I agree to:</p> <ul style="list-style-type: none"> a. Include “underinsured” as a VFC eligibility category during the screening for VFC eligibility at every visit; b. Vaccinate “walk-in” VFC-eligible underinsured children; and c. Report required usage data <p>Note: “Walk-in” in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to underinsured patients as well.</p>
13.	<p>For pharmacies, urgent care, or school located vaccine clinics, I agree to:</p> <ul style="list-style-type: none"> a. Vaccinate all “walk-in” VFC-eligible children and b. Will not refuse to vaccinate VFC-eligible children based on a parent’s inability to pay the administration fee. <p>Note: “Walk-in” refers to any VFC eligible child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve VFC patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to VFC patients as well.</p>
14.	<p>I agree to replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a <u>dose-for-dose</u> basis.</p> <ul style="list-style-type: none"> a. Does your facility have insurance to cover this loss of vaccine? Yes No b. The facility understands that, with or without insurance to cover vaccine, they have full financial responsibility for the replacement of non-viable vaccine due to provider negligence.
15.	The facility will contribute and retrieve immunization information from the Kansas Immunization Registry (KSWebIZ).

16. I understand this facility or the Kansas Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Kansas Immunization Program.

All health care providers participating in the Vaccines for Children (VFC) program must complete this form annually or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

Date:	Provider Identification Number#
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FACILITY INFORMATION

Provider's Name:		MEDICAID ID#:	
Facility Name:			
Vaccine Delivery Address:			
City:	County:	State:	Zip:
Telephone:		Email:	

FACILITY TYPE (select facility type)

Private Facilities	Public Facilities	
<input type="checkbox"/> Private Hospital	<input type="checkbox"/> Public Health Department Clinic	<input type="checkbox"/> STD/HIV
<input type="checkbox"/> Private Practice (solo/group/HMO)	<input type="checkbox"/> Public Health Department Clinic as agent for FQHC/RHC-deputized	<input type="checkbox"/> Family Planning
<input type="checkbox"/> Private Practice (solo/groups as agent for FQHC/RHC-deputized)	<input type="checkbox"/> Public Hospital Public Hospital	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> Community Health Center	<input type="checkbox"/> FQHC/RHC (Community/Migrant/Rural)	<input type="checkbox"/> Correctional Facility
<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Community Health Center Tribal/Indian	<input type="checkbox"/> Drug Treatment Facility
<input type="checkbox"/> Birthing Hospital	<input type="checkbox"/> Health Services Clinic Woman Infants and Children	<input type="checkbox"/> Migrant Health Facility
<input type="checkbox"/> School-Based Clinic	<input type="checkbox"/> Other _____	<input type="checkbox"/> Refugee Health Facility
<input type="checkbox"/> Teen Health Center		<input type="checkbox"/> School-Based Clinic
<input type="checkbox"/> Adolescent Only Provider		<input type="checkbox"/> Teen Health Center
<input type="checkbox"/> Other _____		<input type="checkbox"/> Adolescent Only

PROVIDER POPULATION

Provider Population based on patients seen during the previous 12 months. Report the number of children who received vaccinations at your facility by age group. Only count a child once based on the status at the last immunization visit regardless of the number of visits made. The following table documents how many children received VFC vaccine by category, and how many received non-VFC vaccine.

VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or deputized facility ¹				
Total VFC:				

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

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

In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate these underinsured children.

²CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION

<input type="checkbox"/> Benchmarking	<input type="checkbox"/> Doses Administered
<input type="checkbox"/> Medicaid Claims Data	<input type="checkbox"/> Provider Encounter Data
<input type="checkbox"/> IIS	<input type="checkbox"/> Billing System
<input type="checkbox"/> Other (must describe):	

By signing this form, I certify on behalf of myself (Medical Director or authorized to sign for Medical Director) and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.

Facility Name:	VFC PIN #:
Signature <input type="checkbox"/> I agree to the above terms and conditions as set forth by the Kansas Immunization Program.	Date:

Signed electronically by:



INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

<p>1. Patient name: (first) _____ (last) _____ Street address: _____ City: _____ State: _____ County: _____ ZIP code: _____ Phone: _____ Email: _____</p>	<p>9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: _____</p>
<p>2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown</p>	<p>10. Allergies to medications, food, or other products: _____</p>
<p>4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM</p>	<p>11. Other illnesses at the time of vaccination and up to one month prior: _____</p>
<p>5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM</p>	<p>12. Chronic or long-standing health conditions: _____</p>
<p>6. Age at vaccination: _____ Years _____ Months 7. Today's date: (mm/dd/yyyy) _____ </p>	
<p>8. Pregnant at time of vaccination?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)</p>	

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

<p>13. Form completed by: (name) _____ Relation to patient: <input type="checkbox"/> Healthcare professional/staff <input type="checkbox"/> Patient (yourself) <input type="checkbox"/> Parent/guardian/caregiver <input type="checkbox"/> Other: _____ Street address: _____ <input type="checkbox"/> Check if same as item 1 City: _____ State: _____ ZIP code: _____ Phone: _____ Email: _____</p>	<p>15. Facility/clinic name: _____ Fax: _____ Street address: _____ <input type="checkbox"/> Check if same as item 13 City: _____ State: _____ ZIP code: _____ Phone: _____</p>	<p>16. Type of facility: (Check one) <input type="checkbox"/> Doctor's office, urgent care, or hospital <input type="checkbox"/> Pharmacy or store <input type="checkbox"/> Workplace clinic <input type="checkbox"/> Public health clinic <input type="checkbox"/> Nursing home or senior living facility <input type="checkbox"/> School or student health clinic <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown</p>
<p>14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: _____ Ext: _____</p>		

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

<p>17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed</p>						
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	
<p>18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) Use Continuation Page if needed</p>					<p>21. Result or outcome of adverse event(s): (Check all that apply) <input type="checkbox"/> Doctor or other healthcare professional office/clinic visit <input type="checkbox"/> Emergency room/department or urgent care <input type="checkbox"/> Hospitalization: Number of days (if known) _____ Hospital name: _____ City: _____ State: _____ <input type="checkbox"/> Prolongation of existing hospitalization (vaccine received during existing hospitalization) <input type="checkbox"/> Life threatening illness (immediate risk of death from the event) <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Patient died – Date of death: (mm/dd/yyyy) _____ <input type="checkbox"/> Congenital anomaly or birth defect <input type="checkbox"/> None of the above</p>	
<p>19. Medical tests and laboratory results related to the adverse event(s): (include dates) Use Continuation Page if needed</p>						
<p>20. Has the patient recovered from the adverse event(s)?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>						

ADDITIONAL INFORMATION

<p>22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed</p>						
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
<p>23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>						
<p>24. Patient's race: <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Other: _____</p>						
<p>25. Patient's ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown</p>			<p>26. Immuniz. proj. report number: (Health Dept use only) _____</p>			

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

<p>27. Status at vaccination: <input type="checkbox"/> Active duty <input type="checkbox"/> Reserve <input type="checkbox"/> National Guard <input type="checkbox"/> Beneficiary <input type="checkbox"/> Other: _____</p>	<p>28. Vaccinated at Military/DoD site: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
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17. Enter all vaccines given on the date listed in item 4 (continued):					Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		

Use the space below to provide any additional information (indicate item number):

COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
 - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
 - By mouth/oral
 - Other (specify)
 - In nose/intranasal
 - Unknown

For body site, the options include:

- Right arm
- Left arm
- Arm (side unknown)
- Right thigh
- Left thigh
- Thigh (side unknown)
- Nose
- Mouth
- Other (specify)
- Unknown

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."

- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Vaccine Storage and Handling Plan with Emergency Response Plan

Vaccine Coordinators			
Vaccine Coordinators	Name/Title	Telephone	Email
Primary			
Back-up			
VFC Contact's Routine Roles and Responsibilities			
Which contact is responsible for each duty	Primary	Backup	Details of process
Vaccine ordering			
Receives vaccine shipment			
Inventory Control (e.g. stock rotation, funding source label, dose count, wastage response)			
Monitoring temperatures: Refrigerator: 2°C through 8°C, Freezer: -50°C through -15°C. Document minimum/maximum temperatures daily, current temperatures 2 times per day. Document time of day and initials of person reading temperatures			
Location of vaccine storage unit's circuit breaker			
Name of Primary Thermometer _____ Recalibration Date _____ Certificate is Stored _____			
Name of Primary Thermometer _____ Recalibration Date _____ Certificate is Stored _____			
Clinic has multiple thermometers. Certificates of calibration can be found in the following location: _____			
Name of Backup Thermometer _____ Recalibration Date _____ Certificate is Stored _____			
Where Backup Thermometer is Stored _____			

Vaccine Emergency Response Plan			
Name and Address of location where vaccine will be transported to:	Storage unit identification Notes	Contact person	Telephone
Transport Supplies			
Supplies	Location	Contact person	Telephone
Qualified transport containers			
Conditioned water bottles			
Calibrated temperature monitoring devices for transport			

Vaccine Storage and Handling Plan with Emergency Response Plan

In case of a power failure or an event that results in vaccine being stored outside of recommended temperature ranges:

1. Secure the door and keep vaccine in the unit.
2. Quarantine vaccine and label "Do Not Use."
3. Notify the Regional Immunization Consultant or Consultant On-Call at 785-296-5592.
4. Complete the Provider Temperature Excursion Worksheet, which is located in the KIP Vaccine Policy and Procedure Manual.
 - Document vaccine antigens, manufacturer and expiration date that were involved.
 - Document date and time of the temperature excursion, how long the temperatures were out of range and the extreme temperature reading (highest and lowest reading).
 - Contact Vaccine Manufacturers to report the temperature excursion and obtain manufacturer written guidance attesting the integrity of the vaccine. See Temperature Excursion Worksheet for guidance.
 - Submit the completed Provider Temperature Excursion Worksheet and required supporting documentation to the Regional Immunization Consultant.
5. Do not leave vaccine in a malfunctioning unit for an extended amount of time. Activate the Emergency Response Plan and transport vaccine to the designated backup storage unit, if appropriate.
6. Vaccine temperatures must be monitored with a certified, calibrated thermometer at all times in an appropriate storage unit or qualified shipping container.
7. If there is vaccine loss, the vaccine should be reported in KSWebIZ within 72 hours and a Vaccine Return Label should be obtained. Follow instructions from the KSWebIZ manual.
8. Vaccine loss due to avoidable waste are required to be replaced by the provider with private vaccine on a dose-for-dose basis. The Regional Immunization Consultant will provide guidance to providers, as appropriate.

Resource Contact List

Resource Contact List			
Resources	Name	Telephone	Email
Local Health Department			
Regional Immunization Consultant			
Electric Power Company			
Generator Repair Company			
Refrigerator Repair Company			
Freezer Repair Company			
KIP-Supplied DDL Manufacturer Company	Berlinger, Inc. Jim Lawrence	508-366-0084	Jim.lawrence@berlinger.com
Backup Thermometer Manufacturer Company			

Vaccine Storage and Handling Policies and Procedures must be reviewed annually or when changes have been made to the plan. Additional instructions may accompany this document to support staff regarding details of the Emergency Response Plan. All documents within the plan must be signed and dated by the Medical Director and/or the Primary Vaccine Coordinator. Keep these documents on file for at least 3 years past the effective date.

I verify that the above Vaccine Storage and Handling Worksheet with the Emergency Response Plan have been reviewed for accuracy. Post on the front of the vaccine storage unit.

Signature _____ Date _____

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

1 Gather the Supplies



Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



- **Temperature monitoring device** – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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

Distributed by

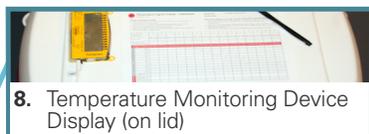
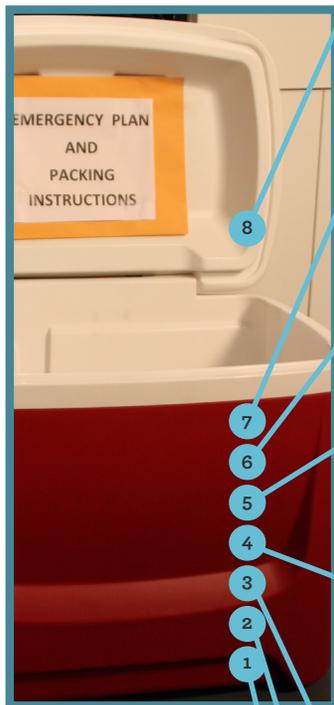
Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



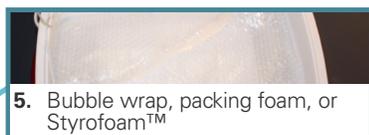
8. Temperature Monitoring Device Display (on lid)



7. Conditioned Water Bottles



6. Cardboard Sheet



5. Bubble wrap, packing foam, or Styrofoam™



4. Vaccines, Diluents, and Temperature Monitoring Device Probe



3. Bubble wrap, packing foam, or Styrofoam™



2. Cardboard Sheet



1. Conditioned Water Bottles

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

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

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

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

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.

Insulating cushioning 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).

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

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

NOTE:

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

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.

Certificate of Calibration Testing (Report of Calibration)

VFC Required Elements:

- Model/Device Name or Number**
- Serial Number**
- Date of Calibration (Report or Issue Date)**
- Instrument Passed testing (Instrument In Tolerance)**

VFC Optional Element:

- Recommended uncertainty = +/- 0.5°C

Additional information:

If you are looking for ways to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, you can check to see if the Certificate indicates one or more of the following items below about calibration testing:

- *Conforms to ISO 17025*
- *Was performed by an ILAC/MRA Signatory body accredited Laboratory*
List of the ILAC/MRA signatories may be found at: <http://ilac.org/ilac-mra-and-signatories/>
- *Is traceable to the standards maintained by NIST*
- *Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better*
- *Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.*

Note: The CDC recommends that certifications be issued for the entire monitoring unit (detachable probe, data logger, etc.) and not individual certificates for each component.

If you have questions or concerns about particular certificates, please send them to: IZColdChain@cdc.gov

*****IMMEDIATE ACTION SHOULD BE TAKEN IF TEMPERATURES ARE IN THE SHADED AREAS*****

KIP DL Temperature Log for Vaccines (Celsius) VFC PIN #: _____ Refrigerator Name: _____ Freezer Name: _____ Month/ Year: _____

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Current Refrigerator Max/Min	/																													
Previous day Refrigerator Max/Min	/																													
≥11°	Refrigerator Temp																													
10°																														
9°																														
8°																														
7°																														
6°																														
5°																														
4°																														
3°																														
2°																														
1°	Freezer Temp																													
0°																														
≤-1°																														
≥-12°																														
-13°																														
-14°																														
-15°																														
-16°																														
-17°																														
-18°																														
-19°																														
≤-20°																														
Current Freezer Max/Min	/																													
Previous day Freezer Max/Min	/																													
Staff Initials																														



Instructions for Manual Temperature Monitoring and Recording Using the Fridge Tag® 2L Data Loggers

When the clinic opens:

1. For each storage unit, view the data logger for any alarms as indicated by an “X” or “ \triangle ”.
2. Record the temperature displayed on the data logger in the “AM” space provided. ***Do not write X in place of the actual temperature.***
3. Press the “Read” button to view the maximum temperature since midnight and record this information.
4. Press the “Read” button a second time to view the minimum temperature since midnight and record this information.
5. Press the “Read” button a third time to view the maximum temperature for the previous day and record this information.
6. Press the “Read” button a fourth time to view the minimum temperature for the previous day and record this information.
7. Repeat the steps above for any additional days the clinic was closed (i.e. weekends and Holidays). ***No more than 3 consecutive days are allowed without recorded daily and maximum/minimum temperatures.*** Record this information on the temperature log for each additional day being monitored.
8. Record the exact time the data logger information was reviewed (in military time as indicated on the data logger).
9. Record the initials of the person completing the manual temperature reading.

At least 1 hour prior to clinic closure:

1. For each storage unit, view the data logger for any alarms as indicated by an “X” or “ \triangle ”.
2. Press the “Read” button twice to review the maximum and minimum temperatures (does not need to be documented) and then press “Set.” This action will time stamp your data logger report.
3. Record the temperature displayed on the data logger into the “PM” space provided. ***Do not write X in place of the actual temperature.***
4. Record the exact time the data logger information was reviewed (in military time as indicated on the data logger).
5. Record the initials of the person completing the manual temperature reading.

Action should be taken any time a data logger displays a temperature out of the recommended range of 2°C to 8°C for refrigerator units and -50°C to -15°C for freezer units. Out of range temperature readings may be found while reviewing the twice daily manual temperature readings or while reviewing the minimum/maximum temperatures. Assess for reasons the unit would be out of range (i.e., frequent opening and closing of door, door ajar, placing or counting inventory) and take appropriate and immediate action. Anytime a storage unit goes out of temperature range, quarantine the vaccine, label the vaccine “Do Not Use,” contact your Regional Immunization Consultant or the Consultant On-Call at 785-296-5592, and follow the instructions found on the temperature excursion worksheet which can be located in the KIP Vaccines for Children Policy and Procedure Manual.

NOTES: _____

*****IMMEDIATE ACTION SHOULD BE TAKEN IF TEMPERATURES ARE IN THE SHADED AREAS*****

KIP DL Temperature Log for Vaccines (Celsius) VFC PIN #: _____ Refrigerator Name: _____ Freezer Name: _____ Month/ Year: _____

Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Current Refrigerator Max/Min	/																															
Previous Refrigerator Max/Min	/																															
Refrigerator Temp	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="display: flex; align-items: center; width: 100%;"> → <div style="border: 1px solid black; padding: 2px;">5°</div> </div> </div>																															
Freezer Temp																																
Current Freezer Max/Min	/																															
Previous Freezer Max/Min	/																															
Staff Initials																																

*****IMMEDIATE ACTION SHOULD BE TAKEN IF TEMPERATURES ARE IN THE SHADED AREAS*****

Instructions for Manual Temperature Monitoring and Recording Using the Fridge Tag® 2L Data Loggers

When the clinic opens:

1. For each storage unit, view the data logger for any alarms as indicated by an “X” or “ Δ ”.
2. Record the temperature displayed on the data logger in the “AM” space provided. *Do not write X in place of the actual temperature.*
3. Press the “Read” button to view the maximum temperature since midnight and record this information.
4. Press the “Read” button a second time to view the minimum temperature since midnight and record this information.
5. Press the “Read” button a third time to view the maximum temperature for the previous day and record this information.
6. Press the “Read” button a fourth time to view the minimum temperature for the previous day and record this information.
7. Repeat the steps above for any additional days the clinic was closed (i.e. weekends and Holidays). *No more than 3 consecutive days are allowed without recorded daily and maximum/minimum temperatures.* Record this information on the temperature log for each additional day being monitored.
8. Record the exact time the data logger information was reviewed (in military time as indicated on the data logger).
9. Record the initials of the person completing the manual temperature reading.

At least 1 hour prior to clinic closure:

1. For each storage unit, view the data logger for any alarms as indicated by an “X” or “ Δ ”.
2. Press the “Read” button twice to review the maximum and minimum temperatures (does not need to be documented) and then press “Set.” This action will time stamp your data logger report.
3. Record the temperature displayed on the data logger into the “PM” space provided. *Do not write X in place of the actual temperature.*
4. Record the exact time the data logger information was reviewed (in military time as indicated on the data logger).
5. Record the initials of the person completing the manual temperature reading.

Action should be taken any time a data logger displays a temperature out of the recommended range of 2°C to 8°C for refrigerator units and -50°C to -15°C for freezer units. Out of range temperature readings may be found while reviewing the twice daily manual temperature readings or while reviewing the minimum/maximum temperatures. Assess for reasons the unit would be out of range (i.e., frequent opening and closing of door, door ajar, placing or counting inventory) and take appropriate and immediate action. Anytime a storage unit goes out of temperature range, quarantine the vaccine, label the vaccine “Do Not Use,” contact your Regional Immunization Consultant or the Consultant On-Call at 785-296-5592, and follow the instructions found on the temperature excursion worksheet which can be located in the KIP Vaccines for Children Policy and Procedure Manual.

NOTES: _____

VFC PROVIDER PROFILE UPDATE FORM

FACILITY INFORMATION

Provider's Name:		MEDICAID ID#:	
Facility Name:			
Vaccine Delivery Address:			
City:	County:	State:	Zip:
Telephone:		Email:	

PROVIDER POPULATION

Provider Population based on patients seen during the previous 12 months. Report the number of children who received vaccinations at your facility by age group. Only count a child once based on the status at the last immunization visit regardless of the number of visits made. The following table documents how many children received VFC vaccine by category, and how many received non-VFC vaccine.

VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or deputized facility ¹				
Total VFC:				

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

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

In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate these underinsured children.

²CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION

<input type="checkbox"/> Benchmarking	<input type="checkbox"/> Doses Administered
<input type="checkbox"/> Medicaid Claims Data	<input type="checkbox"/> Provider Encounter Data
<input type="checkbox"/> IIS	<input type="checkbox"/> Billing System
<input type="checkbox"/> Other (must describe):	

By signing this form, I certify on behalf of myself (Medical Director or authorized to sign for Medical Director) and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.

Facility Name:	VFC PIN #:
----------------	------------

Signature	Date:
<input type="checkbox"/> I agree to the above terms and conditions as set forth by the Kansas Immunization Program.	

Signed electronically by:

VACCINE BORROWING REPORT

Vaccines for Children (VFC) Providers are expected to manage and maintain an adequate inventory of vaccine for both private and publicly insured/eligible children. **Planned to borrow of publicly funded vaccine, including the use of publicly funded vaccine as a replacement system for a provider's private vaccine inventory, is not permissible.**

VFC Providers must ensure borrowing publicly funded vaccine will not prevent a publicly insured child from receiving a needed vaccination. Infrequent exchanges between public and private vaccine can occur only when: there is a lack of vaccine due to delayed or spoiled shipments; vaccine will expire soon and will be lost if not used (to be used only by providers with small, privately insured populations), or new staff calculated ordering interval incorrectly, causing a lack of either private or public vaccine (this may occur only prior to proper vaccine ordering training).

COMPLETE THIS FORM WHEN:

- A dose of publicly funded vaccine is administered to a privately-insured child.
- A dose of privately funded vaccine is administered to a publicly-insured/eligible child.

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed on a separate row on the Vaccine Borrowing Report.
- All columns must be completed for each dose borrowed and replaced through administration of vaccine.
- Provider must sign and date at the bottom of each page of the report.
- Submit the completed Vaccine Borrowing Report to the Kansas Immunization Program (KIP) at the end of each month. Fax to 785-559-4226 or email to kdhe.vaccine@ks.gov. For questions regarding borrowing, contact your Regional Immunization Consultant.
- Keep the Vaccine Borrowing Report on file in the clinic a minimum of 3 years after the borrowing event. VFC providers should also maintain copies of invoices showing the purchase of private vaccine used to replace borrowed public vaccine. The reports and invoices must be made available during site visits or upon request the KIP.

VACCINE BORROWING REPORT

BORROWED DOSE							REPAYMENT DOSE			
VACCINE BORROWED	LOT # OF BORROWED DOSE	PRIVATE or PUBLIC VACCINE USED	DATE BORROWED	PATIENT IDENTIFIER: PT NAME, MEDICAL RECORD # OR KSWEBIZ # AND DOB	PATIENT ELIGIBILITY	REASON CODE FOR BORROWING (SEE TABLE)	LOT # OF RETURNED DOSE	DATE RETURNED	PATIENT IDENTIFIER: PT NAME, MEDICAL RECORD # OR KSWEBIZ # AND DOB	PATIENT ELIGIBILITY
				ID					ID	
				DOB					DOB	
				ID					ID	
				DOB					DOB	
				ID					ID	
				DOB					DOB	
				ID					ID	
				DOB					DOB	
				ID					ID	
				DOB					DOB	

Reason for Borrowing Public Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	Public vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	Public vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of public vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with publicly funded dose	4	Short-dated public dose was exchanged with private dose	11
Accidental use of publicly funded dose for a private child	5	Accidental use of a private dose for a publicly insured/eligible child	12
Replacement of private dose with publicly funded dose when insurance plan did not cover vaccine	6	Other – Describe:	13
Other – Describe:	7		

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

FACILITY NAME	PIN
PRINTED NAME	SIGNATURE
	DATE

Temperature Excursion Worksheet

IF TEMPERATURES ARE OUT OF RANGE TAKE IMMEDIATE ACTION!

REPORTABLE TEMPERATURES

REFRIGERATOR – IDEAL TEMPERATURE 2°C THROUGH 8°C (AIM FOR 4°C TO 5°C)

Reportable:

- >8°C or higher for 60 minutes or more
- <2°C for any period of time
- "X" on KIP Data Logger

FREEZER – IDEAL TEMPERATURE -50°C THROUGH -15°C (AIM FOR -18°C OR LESS)

Reportable:

- >-15°C or higher for 60 minutes or more
- <-50°C for any period of time
- "X" on KIP Data Logger

The Kansas Immunization Program (KIP) will only consider a documented temperature valid if it is recorded from the KIP-supplied digital data logger (DDL). If using a backup thermometer, it must have a current certificate of calibration to be considered valid. **If a unit is not functioning properly or is not in proper temperature range IMMEDIATELY FOLLOW YOUR VACCINE STORAGE AND HANDLING PLAN WITH EMERGENCY RESPONSE PLAN. IF NEEDED, TRANSPORT VACCINE TO YOUR PRE-DETERMINED BACKUP EMERGENCY LOCATION.**

NON-REPORTABLE TEMPERATURE EXCURSION: If temperatures are out of range but have not yet reached the reportable range, temperature adjustments need to be made. Begin to stabilize temperatures. Secure unit doors and check the power source. If needed, make a slight adjustment to the thermostat. Continue to monitor temperatures every 30 minutes until stable. If the excursion occurs at the end of clinic day, DO NOT leave vaccine in the unit. Move your vaccine to another unit that is monitored according to VFC requirements or to your backup emergency location. ***Adjusting temperatures prior to the close of a clinic day and leaving vaccines in a unit with temperature out of range could lead to an "avoidable" vaccine loss.***

REPORTABLE TEMPERATURE EXCURSION: If the storage unit is now working properly and is in the appropriate temperature range then take the following actions.

- QUARANTINE THE AFFECTED VACCINE AND MARK "DO NOT USE." DO NOT USE UNTIL APPROVED BY THE KIP
- CONTACT YOUR REGIONAL IMMUNIZATION CONSULTANT OR THE CONSULTANT ON-CALL AT 785-296-5592
- CONTINUE TO STORE VACCINE UNDER THE CORRECT TEMPERATURE UNTIL VIABILITY IS DETERMINED. DO NOT DISCARD AFFECTED VACCINE, ASSUMING IT HAS BEEN COMPROMISED.
- CONTACT THE VACCINE MANUFACTURERS FOR WRITTEN RECOMMENDATIONS ON THE VACCINE VIABILITY
- DOWNLOAD DATA FROM DATA LOGGER (.PDF AND .TXT FILES), OBTAIN MANUAL TEMPERATURE LOGS, AND VACCINE MANUFACTURER RECOMMENDATIONS AND COMPLETE THE TEMPERATURE EXCURSION WORKSHEET.
- SEND ALL INFORMATION TO THE REGIONAL IMMUNIZATION CONSULTANT

REGIONAL IMMUNIZATION CONSULTANT CONTACT INFORMATION

Northwest - Lorraine Baughman (785) 213-4110 lorraine.baughman@ks.gov

Southwest - Dena Rueb (785) 250-3292 dena.rueb@ks.gov

South Central – Susan Smith (785) 250-7165 susan.smith@ks.gov

Central and East - Jayme Lewis (785) 213-6337 jayme.lewis@ks.gov

Kansas City – Becky (785) 213-2972 becky.prall@ks.gov

Northeast - Jackie Strecker (785) 207-1916 jackie.strecker@ks.gov

Consultant On-Call line (785) 296-5592

VFC Program Fax (785) 559-4226 (Be sure to indicate who should receive the fax)

Temperature Excursion Worksheet

CLINIC INFORMATION		VFC		Date:	
Clinic Name:		Pin:			
Worksheet prepared by:					
Email:			Phone:		
KIP REPORTING: Date, time, and KIP staff person the excursion was first reported to:					
Date:	Time:	KIP staff name:			
Date discovered:			Time Discovered:		
Temperature:					
KIP-Supplied	Yes	No	Did DDL display an "X" alarm or out of range temperature:	Yes	No
DDL:					
Was back up thermometer used:		Yes	No	Brand:	
Calibration date on backup thermometer:					
STORAGE UNIT					
Type of vaccine storage unit:		Refrigerator/Freezer	Pharmaceutical/Household	Stand Alone/Combo	
Brand:					
Was temperature adjusted prior to this excursion:			Yes	No	Water Bottles: Present / Added
Describe previous temperature adjustments made to the storage unit and/or any previous issues:					
SUMMARY: Provide a detailed summary of the event (when and how it was discovered, possible or probable cause, any temperature adjustments made to the unit, etc.)					
ACTIONS TAKEN: Describe corrective actions taken (was vaccine transported? If so to where? Who is monitoring temperatures? How are the temperatures being monitored? Data logger? Backup thermometer? Other?)					

Temperature Excursion Worksheet

Contact Vaccine Manufacturers, report excursion and request they fax or email their recommendations.

Manufacturer	Vaccines	Vaccines	Case #	Comments
GlaxoSmithKline (GSK) 877-356-8368 Vaccine.service-center@gsk.com	<input type="checkbox"/> Bexsero <input type="checkbox"/> Boostrix <input type="checkbox"/> Cervarix <input type="checkbox"/> Engerix-B <input type="checkbox"/> Fluarix <input type="checkbox"/> Flulaval <input type="checkbox"/> Havrix <input type="checkbox"/> Hiberix	<input type="checkbox"/> Infanrix <input type="checkbox"/> Kinrix <input type="checkbox"/> Menhibrix <input type="checkbox"/> Menveo <input type="checkbox"/> Pediarix <input type="checkbox"/> Rotarix <input type="checkbox"/> Twinrix		
Merck @ Co, Inc. 877-829-6372	<input type="checkbox"/> Gardasil <input type="checkbox"/> MMR II <input type="checkbox"/> PedvaxHIB <input type="checkbox"/> Pneumovax 23 <input type="checkbox"/> Proquad	<input type="checkbox"/> Recombivax HB <input type="checkbox"/> Rotateq <input type="checkbox"/> Vaqta <input type="checkbox"/> Varivax <input type="checkbox"/> Zostavax		
Pfizer/Wyeth 800-438-1985	<input type="checkbox"/> Prevnar 13	<input type="checkbox"/> Trumemba		
Sanofi Pasteur 800-822-2463	<input type="checkbox"/> ActHib <input type="checkbox"/> Adacel <input type="checkbox"/> Daptacel <input type="checkbox"/> DT <input type="checkbox"/> Fluzone	<input type="checkbox"/> IPOL <input type="checkbox"/> Menactra <input type="checkbox"/> Pentacel <input type="checkbox"/> Quadracel <input type="checkbox"/> Td		

- **Providers that have a temperature excursion are placed on-hold from vaccine administration and ordering until all requested information is submitted and reviewed. Providers will be notified when they may begin vaccinating and ordering again. If non-viable vaccines were administered, children may need to be revaccinated. The Regional Immunization Consultant will work with the clinic to make this determination.**
- **If expiration dates need to be shortened due to excursions, excursion stickers needed to be ordered from the KIP Online Order Center and placed on the affected vaccines to easily identify vaccines involved in the excursion.**
- **If the excursion is deemed avoidable, providers will be required to replace the publicly-funded non-viable vaccine dose-for-dose with the same vaccine that is privately purchased as outlined in the VFC Program Provider Enrollment Agreement.**

Submit the following to your Regional Immunization Consultant or Consultant On-Call by email or fax:

- Completed Temperature Excursion Worksheet
- A copy of downloaded data from the DDL (.pdf and .txt files)
- A copy of the manual temperature logs
- A copy of the manufacturer's written recommendations
- A copy of back up thermometer calibration certificate (if used)
- A print out of current KSWebZ inventory (direct entry user) or (aggregate user) a copy of vaccines, lot numbers, expiration dates, quantity and funding source of all vaccines (public, 317, State) exposed to out of range temperatures

PROVIDER NAME _____ VFC PIN _____ DATE _____

Immunization Resources

CENTERS FOR DISEASE CONTROL AND PREVENTION

<p>CDC Pink Book The CDC "Pink Book" offers information on vaccine administration, dosing schedules, Brand specific information, as well as information on specific diseases https://www.cdc.gov/vaccines/pubs/pinkbook/index.html</p>	<p>Immunization Schedules Current immunization schedules including children, adolescents and adults as well as the catch-up schedule https://www.cdc.gov/vaccines/schedules/hcp/</p>
<p>CDC Pink Book Webinar Series The CDC Pink Book Webinar Series provides 15 webinars, reviewing each chapter in the CDC Pink Book (CEU credit is available for each webinar) https://www.cdc.gov/vaccines/ed/webinar-epv/index.html</p>	<p>CDC Keys to Storing and Handling your Vaccine Supply A CDC video demonstrating key storage and handling elements and inventory management https://www2.cdc.gov/vaccines/ed/shvideo/</p>
<p>CDC Vaccine Storage and Handling Toolkit Best practice guidance for storage and handling, transport, and emergency management as well as many other topics https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/</p>	<p>CDC Vaccine Administration Recommendations Information on vaccine administration, dosing, route, site, diluents and managing reactions. https://www.cdc.gov/vaccines/hcp/admin/recs-guidelines.html</p>
<p>CDC HPV resources https://www.cdc.gov/hpv/hcp/index.html</p>	<p>CDC Influenza resources https://www.cdc.gov/flu/professionals/vaccination/index.htm</p>

IMMUNIZE KANSAS COALITION

HPV Vaccine Toolkit, Meningococcal Vaccine Toolkit, and Tdap Vaccine Toolkit

Immunize Kansas Coalition Toolkits offer resources for HCP, including videos and printable materials. Printable materials also available for parents.
<https://www.immunizekansascoalition.org/hpv-resources.asp>
<https://www.immunizekansascoalition.org/meningitis-toolkit.asp>
<https://www.immunizekansascoalition.org/tdap-toolkit.asp>

IMMUNIZATION ACTION COALITION

<p>IAC Ask The Experts Ask The Experts offers answers to questions from vaccines, to vaccine schedules and contraindications. It also offers answers regarding vaccine errors and catch up schedules. http://www.immunize.org/askexperts/</p>	<p>IAC Handouts for Patients and Staff Printed materials for staff training as well as materials for patient education. These resources include schedules, storage and handling, and parent handouts http://www.immunize.org/handouts/ http://www.immunize.org/handouts/administering-vaccines.asp</p>
<p>IAC Talking about Vaccines Answers to vaccine questions including Thimerosal, Autism, Vaccine safety http://www.immunize.org/talking-about-vaccines/</p>	<p>IAC Standing Orders for Administering Vaccines http://www.immunize.org/standing-orders/</p>
<p>Current Vaccine Information Statements (VIS) http://www.immunize.org/vis/ https://www.cdc.gov/vaccines/hcp/vis/current-vis.html Spanish http://www.immunize.org/vis/vis_spanish.asp Language Index http://www.immunize.org/vis/</p>	<p>Kansas Immunization Program Order Center for educational materials and incentives https://kdhe.myprintdesk.net/DSF/SmartStore.aspx#!/Storefront Vaccines for Children (VFC) Program http://www.kdheks.gov/immunize/vfc_program.html</p>