

# Kansas Immunization Program Vaccines for Children Policy and Procedure Manual





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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.
IIS Reporting	VFC providers are required to report administered doses to KSWebIZ. Doses should be reported within 24 hours of administration.
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: Dengue* (page 20-21), 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. <i>Borrowing is permitted only in rare, unplanned circumstances</i> .
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 <i>must be notified</i> 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 <i>must be notified</i> 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 Medial 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.
  - O 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)
  - o Post-exposure prophylaxis
  - Disaster relief efforts
  - o Mass vaccination campaigns or exercises for public health preparedness
  - o 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 vaccineeligible) 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:

- 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.
- Only one payer may be billed for the same administration fee.
- 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).
- 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.

- Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.
- Providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.
- When screening patients, providers should select and document the VFC eligibility category requiring the least out-of-pocket expense to the parent.

#### **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.
  - o 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.*
  - o 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 on	<ul> <li>Insured until the fixed dollar limit is met</li> <li>Underinsured after the fixed dollar limit is reached</li> </ul>	
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 on	<ul> <li>Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan</li> <li>Insured if plan is recognized by the state insurance department and covers vaccines</li> <li>Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines</li> </ul>	
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	Yes	AI/AN - However, provider should choose the	
all vaccinations and is (AI/AN)	103	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.	
For Medicaid-eligible children, the	VFC provider	must verify and document Title 19 or Title 21	

For Medicaid-eligible children, the VFC provider must verify and document Title 19 or Title 21 eligibility.

## **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. This requirement applies even in the case of provider retirement or provider location closure.

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
- Electronic digital data logger TXT and PDF reports
- 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
   that occurs within the specified time period after vaccination.
- Adverse events can be reported online at <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>. Examples of the VAERS report can be found in the FORMS AND RESOURCES section of this manual.

#### REPORTING TO KSWebIZ

The Kansas Immunization Information System (IIS) is a web-based registry for tracking immunization for the state of Kansas. The system named KSWebIZ was established in 2005. Kansas law requires administration of vaccines be reported to KSWebIZ:

Statute 65-2886a - Reporting of administration of vaccines by physicians and other authorized individuals. (a) On and after July 1, 2020, physicians and other persons authorized by law in this state to administer vaccines shall report the administration of a vaccine to a person in this state to the state registry maintained for such purpose by the secretary of health and environment in a manner and form as may be required by the secretary, except that if the person vaccinated or, if the person is a minor, the parent or guardian of the minor, objects to the report, the report shall not be made.

VFC providers should report vaccine administration to KSWebIZ within 24 hours of administration, regardless of whether the patient receives VFC or a private vaccine. Timely reporting of data ensures accurate inventory counts, prevents over-immunization and missed opportunities, and prevents data from being entered by other entities (i.e., Medicaid or school nurses) before the administering provider. The chart below provides data elements that are required to be reported.

Patient Demographic Data Elements			
Data Element Definition		Requirement	
Patient Name: First	The patient's first name.	Required	
Patient Name: Middle	The patient's middle name, can be blank if one does not exist.	Required if known	
Patient Name: Last	The patient's last name.	Required	
Patient Date of Birth	The patient's date of birth.	Required	
Patient Gender	The patient gender.	Required	
Patient Address: Street	The state component of the patient's address.	Required	
Patient Address: Street 2	A second street component of the patient's address if needed.	Required if known	
Patient Address: City	The city component of the patient's address.	Required	
Patient Address: County	The county component of the patient's address.	Required	
Patient Address: State	The state component of the patient's address.	Required	
Patient Address: Zip Code	The zip code of the patient's address.	Required	
Patient Telephone Number	The patient's telephone number.	Required if known	
Patient E-mail Address	The patient's e-mail address.	Required if known	
Patient Race	The patient's race, multiple can be added if needed.	Required	
Patient Ethnicity	The ancestry of the patient, can be blank if it does not apply.	Required if known	

Vaccination Event Data Elements			
Data Element	Requirement		
Administration Date	The date the vaccination event occurred.	Required	
Vaccine Type (CVX)	The vaccine type that was administered.	Required	
National Drug Code (NDC)	The vaccine product that was administered: Unit of Sale (UoS) is preferred.	Required	
Manufacturer (MVX)	The manufacturer of the vaccine administered.	Required	
Vaccine lot number	The lot number of the vaccine administered.	Required	
Vaccine expiration date	The expiration date of the vaccine administered.	Required	
Vaccine Administration Site	The body site of vaccine administration.	Required	
Vaccine Route of Administration	The route of vaccine administration.	Required	

# 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://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. 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: https://kdhe.ks.gov/233/ 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.

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  $\pm 1^{\circ}$ 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  $\pm -0.5^{\circ}$ C ( $\pm -1^{\circ}$ 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: <a href="http://ilac.org/ilac-mra-and-signatories/">http://ilac.org/ilac-mra-and-signatories/</a>
- 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 ( $\leq 0.5$  °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 certified 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 daily; first when the clinic opens and again one hour prior to the clinic closing. Current temperatures should be checked and recorded twice daily. Minimum and maximum temperatures should checked twice daily but only need to be recorded at the beginning of the clinic day. If temperatures are found to be out of range during the minimum and maximum temperature review, staff should take immediate action regardless of if the DDL displays an "X". It is also recommended that the current temperature be check 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: https://kdhe.ks.gov/233/ 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.

Paper temperature logs and electronic DDL reports (TXT and PDF) should be kept for a minimum of three years.

#### 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 7<sup>th</sup> day of the month (i.e., Data from January would be uploaded to KSWebIZ by February 7<sup>th</sup>).

Additional details on the KIP-supplied DDLs functions and operation, can be found on the KIP website at: https://kdhe.ks.gov/340/.

# VACCINES OFFERED THROUGH PUBLIC FUNDS

Vaccines that are available through public funding include: Dengue\* (see below), 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.

Dengvaxia is the only dengue vaccine approved by the U.S. Food and Drug Administration and recommended for use by the ACIP. It prevents dengue caused by all four dengue virus serotypes. The vaccine is for use in children and adolescents 9-16 years old who have *laboratory-confirmed previous dengue virus infection* and are living in an area where dengue is endemic (occurs frequently or

continuously). Dengue-endemic areas include the U.S. territories of American Samoa, Puerto Rico, and the U.S. Virgin Islands, and freely associated states, including the Federated States of Micronesia, the Republic of Marshal Islands, and the Republic of Palau. *Do not vaccinate a person without laboratory evidence of previous dengue virus infection.* 

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 1<sup>st</sup> and 7<sup>th</sup> 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.

Provider's 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.
- 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 877-296-0464, 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 prefilled 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
- Inexperienced 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 877-296-0464.

# **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 <a href="http://kdheks.gov/immunize/vaccine">http://kdheks.gov/immunize/vaccine</a> 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 877-296-0464 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.

CDC recommendations and best practices for vaccine handling during a temporary, off-site, or satellite clinic include:

- Do not draw up vaccines before arriving at the clinic site.
- Use manufacturer-filled syringes, if possible, as an alternative to pre-drawing vaccines.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining pre-drawn syringes at the end of the workday.

The number of publicly insured children to be served should be anticipated and appropriate amounts of vaccine should be ordered. Hosting a temporary, off-site, and mass vaccination clinic without appropriate amounts of public and private vaccine does not qualify for borrowing.

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 877-296-0464.

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 <a href="https://kdhe.ks.gov/214/">https://kdhe.ks.gov/214/</a> 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.

# 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

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.

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 safely 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	-			
Instructions: The official VFC registered health ca law who will also be held accountable for compli- enrollment agreement. The individual listed here	ance by the entire or	ganization and its VFC provid		
Last Name, First Name, MI:	Title:		Specialty:	
License No:	Medicaid or NPI No	).:	Employer Identification	on 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?				
Provide Information for second individual as need	led:			
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 Ca	all the Shots' training? Yes	s No	
If yes, please indicate, which trainings were comp		nes for Children (VFC) ne 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				
		or Children (VFC) orage 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: I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the 1. number of children served changes or 2) the status of the facility changes during the calendar year. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccineeligible) 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;

3.

B. State Vaccine-eligible Children

Are enrolled in Medicaid;
 Have no health insurance:

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.

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.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are <u>not</u> eligible to receive VFC-purchased vaccine.

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.
- 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.
- 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.

I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance 8. with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). I will comply with the requirements for vaccine management including: 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 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: 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. 10. 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. I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with 11. VFC program requirements. 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: 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 12. Report required usage data 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. For pharmacies, urgent care, or school located vaccine clinics, I agree to: 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. 13. 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. I agree to replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis. 14. a. Does your facility have insurance to cover this loss of vaccine? 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. The facility will contribute and retrieve immunization information from the Kansas Immunization Registry (KSWebIZ).

16.	I understand this facility or the Kansas agreement, I will properly return any u	_				rminate this				
	ealth care providers participating in the Vacci ed changes or the status of the facility change			nnually or	more frequently if the	number of children				
serve	Date:	s during the calendar year	Provider Identification Numb	per#						
FAC	CILITY INFORMATION									
	ider's Name:				MEDICAID ID#:					
	ity Name:									
Vacc	ine Delivery Address:									
City:	County:		State:		Zip:					
Tele	phone:		Email:							
FAC	CILITY TYPE (select facility type)									
	Private Facilities		Public Fac	cilities						
	Private Hospital	Public Health	n Department Clinic	100	STD/HIV					
	Private Practice (solo/group/HMO)	-	n Department Clinic as agent for		Family Planning					
	Private Practice (solo/groups as agent for FQHC/RHC-deputized)	Public Hospi	tal		Juvenile Detention Ce	enter				
	Community Health Center	FQHC/RHC (	Community/Migrant/Rural)		Correctional Facility					
	Pharmacy	Community	Health Center Tribal/Indian	Drug Treatment Facility						
	Birthing Hospital	Health Servio	ces Clinic Woman Infants		Migrant Health Facilit	у				
	School-Based Clinic	and Children	1		Refugee Health Facilit	Ту				
	Teen Health Center	Other			School-Based					
Clini	Adolescent Only Provider				Teen Health Center					
	Other	_			Adolescent Only					
DDC	OVIDER POPULATION									
Prov grou	ider Population based on patients seen during p. Only count a child <u>once</u> based on the statu y children received VFC vaccine by category, a	s at the last immunization	visit regardless of the number of							
V	FC Vaccine Eligibility Categories	# of	children who received VI	FC Vaco	rine by Age Catego	ory				
v	TC vaccine Eligibility Categories	<1 Year	1-6 Years		7-18 Years	Total				
Enr	olled in Medicaid									
No	Health Insurance									
Am	erican Indian/Alaska Native									
Unc	derinsured in FQHC/RHC or deputized facility <sup>1</sup>									
To	tal VFC:									

Non-VFC Vaccine Eligibility	# of ch	nildren who received nor	ı-VFC Vaccine by Age Ca	ge Category				
Categories	<1 Year	1-6 Years	7-18 Years	Total				
Insured (private pay/health insurance covers vaccines)								
Children's Health Insurance Program (CHIP) <sup>2</sup>								
Total Non-VFC:								
Total Patients (must equal sum of Total VFC + Total Non-VFC)								
<sup>1</sup> Underinsured includes children with health insur that are not covered by insurance. In addition, to receive VFC vaccine, underinsured approved deputized provider. The deputized prov	children must be vaccina	ted through a Federally Qualified	d Health Center (FQHC), Rural F	Health Clinic (RHC) or an				
order to vaccinate these underinsured children. <sup>2</sup> CHIP – Children enrolled in the state Children's H the VFC program. Each state provides specific guid	ealth Insurance Program	(CHIP). These children are consi	dered insured and are not eligi	ble for vaccines through				
TYPE OF DATA LIGED TO DETERMINE		TION						
TYPE OF DATA USED TO DETERMINE F	PROVIDER POPULA	TIUN						
Benchmarking		Doses Administered						
Medicaid Claims Data		Provider Encounter Date						
		Provider Encounter Dat	ia					
IIS		Provider Encounter Dat  Billing System	ra					
П		Flovider Effcounter Dai	ra					
IIS		Flovider Effcounter Dai	ra					
IIS	, I have read and a	Billing System  I Director or authorized to the Vaccines for Common Comm	o sign for Medical Direc Children enrollment req	uirements listed				
Other (must describe):  By signing this form, I certify on behalimmunization providers in this facility above and understand I am accountable.	, I have read and a	Billing System  I Director or authorized to the Vaccines for Common Comm	o sign for Medical Direc Children enrollment req	uirements listed				
Other (must describe):  By signing this form, I certify on behalimmunization providers in this facility above and understand I am accountable requirements.	, I have read and a	Billing System  I Director or authorized to the Vaccines for Coll provider is individually a	o sign for Medical Direc Children enrollment requ accountable) for complia	uirements listed ance with these				



Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)													
1. Patient name: (first)	(last)			scriptions, over-the-			ements, or						
Street address:			herl	bal remedies being t	aken at the time o	f vaccination:							
City: State:	County:												
ZIP code: Phone:	Email:		10. All	lergies to medicatio	ns, food, or other <sub>l</sub>	products:							
2. Date of birth: (mm/dd/yyyy)	<mark>B.</mark> Sex: 🗆 Male 🗆 Fema	ale 🗆 Unknown											
4. Date and time of vaccination: (mm/dd/yyyy)	material Time:	□AM □PM	11. Ot	ther illnesses at the	time of vaccinatio	n and up to one	month prior:						
<b>5.</b> Date and time adverse event started: (mm/dd/yyyy)	Time:	□AM 											
<b>6.</b> Age at vaccination:Years Months 7. Too	lay's date: (mm/dd/yyyy)	<b></b>	12. Chronic or long-standing health conditions:										
8. Pregnant at time of vaccination?:   Yes   (If yes, describe the event, any pregnancy complications, and		ı item 18)											
INFORMATION ABOUT THE PERSON COMPLI	TING THIS FORM	INFORM	/ATION	ABOUT THE FACI	LITY WHERE VAC	CCINE WAS GIV	/EN						
13. Form completed by: (name)		15. Facility/clinic			_	facility: (Check o							
	Detient (				7.	office, urgent ca							
Relation to patient: Healthcare professional/staff Definition Parent/guardian/caregiver	☐ Patient (yourself)	Fax:			☐ Pharmac								
		Street address:		Check if same as item		-							
Street address:					□ Public he	alth clinic							
	_ ZIP code:				Dursing h	nome or senior liv	ing facility						
Phone: Email:		City:			□ School o	r student health	clinic						
14. Best doctor/healthcare Name:		State:	ZIP	code:	D Other:								
about the adverse event:	Ext:	Phone:				1							
WHIC	H VACCINES WERE GIVE	N? WHAT HAPPEN	NED TO	THE PATIENT?									
17. Enter all vaccines given on the date listed in item 4:	(Route is HOW vaccine was give	en, Body site is WHER	E vaccine	was given)	Use Continuation	Page if needed	Dose number						
Vaccine (type and brand name)	Manufacturer		Lot num	Bo	ody site	in series							
18. Describe the adverse event(s), treatment, and outcome	ne(s), if anv: (symptoms, sign	s. time course, etc.)		21. Result or outc	ome of adverse ev	ent(s): (Check all	that apply)						
	(0), u (0)p.to	o, to ooa.oo, oto.,		☐ Doctor or other									
				☐ Emergency room	n/department or u	rgent care							
				☐ Hospitalization	Number of days (	if known)	_						
				City:		State:							
				☐ Prolongation of	existing hospitalizeduring existing hospitalized	zation pitalization)							
	llse (	Continuation Page if	needed	☐ Life threatening			the event)						
19. Medical tests and laboratory results related to the a				☐ Disability or pe		0. 000011110111	0.0.10						
and the second s		•		☐ Patient died – I	ū	ı/dd/yyvv)							
	Use (	Continuation Page if	needed	☐ Congenital and	•								
20. Has the patient recovered from the adverse event(s)		□ Unknown		☐ None of the ab									
	ADDITION	NAL INFORMATIO	N										
22. Any other vaccines received within one month prior		TAE HEI OHMATIO		Use <b>Continua</b>	tion Page if needed	Dose number	Date						
Vaccine (type and brand name)	Manufacturer	Lot number		Route	Body site	in series	Given						
23. Has the patient ever had an adverse event following	any previous vaccine?: (If ye	es, describe adverse e	vent, patio	ent age at vaccination	vaccination dates,	**							
☐ Yes	ntivo 🗆 Anion	□ Diack	or Africa	n American	□ Nativa Uarr	□ No raiian or Other Pa	Unknown						
24. Patient's race: American Indian or Alaska Na (Check all that apply) White	ative 🗆 Asian 🗆 Unknow		JI AIIICA	n American	□ INALIVE HAW	anan or Utilet Pi	acinc islanuer						
25. Patient's ethnicity: ☐ Hispanic or Latino ☐ No	t Hispanic or Latino 🗆	Unknown 26. Ir	nmuniz.	proj. report number:	(Health Dept use on	ly)							
COMPLETE ONL	Y FOR U.S. MILITARY/DE	PARTMENT OF DE	FENSE	(DoD) RELATED RE	PORTS		_						

FORM FDA VAERS 2.0 (09/22)

27. Status at vaccination: □ Active duty □ Reserve □ National Guard □ Beneficiary □ Other:

## **CONTINUATION PAGE** (Use only if you need more space from the front page)

**VAERS** 

17. Enter all vaccines given on the date listed in item 4 (con		1.	Doute		Rody site	Dose number in series	
Vaccine (type and brand name)	Manufacturer	LO	ot number	Route		Body site	111 351153
22. Any other vaccines received within one month prior to the vaccines (two and board name)			David		Dad!	Dose number in series	Date Given
Vaccine (type and brand name) N	lanufacturer	Lot number	Route		Body site	III Series	Giveii
Use the space below to provide any additional information (i	ndicate 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 <a href="www.vaers.hhs.gov/reportable.html">www.vaers.hhs.gov/reportable.html</a> 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,
- By mouth/oral
- Other (specify)

- intradermal, jet injection, and unknown)
- In nose/intranasal

Unknown

For body site, the options include:

• Right arm

• Right thigh

- Nose
- Other (specify)

Left arm

Left thigh

- Mouth
- Unknown

Arm (side unknown)

Thigh (side 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.

# **Routine Vaccine Storage and Handling Plan**

vaccine Coordinators											
Vaccine Coordinators	Name/Title			Т	elephone	Ema	il				
Primary:											
YCTS Training and Date:						·					
Back-up:											
YCTS Training and Date:				•		-					
	VFC	Contact'	s Routine	Roles	and Responsibilit	ies					
Which contact is respons		1	Backup		ls of process:						
Vaccine ordering	-		·								
Receives vaccine shipme	nt										
Inventory Control (separa rotation of stock, invento reporting)											
Temperature monitoring: Refrigerator 2°C to 8°C Freezer -50°C to 15°C Ultra-Cold -80°C to - °60C Documentation 2x day, ex staff initials and min/max	kact time/date and										
Location of vaccine stora breaker:	ge unit's circuit										
Name of Primary thermon	neter:					_Date of C	Calibration:				
Certificate is stored:							ation Due:				
Name of Backup thermom						Date of 0	Calibration:				
Backup thermometer & ca	alibration certificat	e is stored	l:			_Recalibr	ation Due:				
		Vaccine	Emergenc	y Resp	onse Plan						
Name and Address where vaccine will be transported:	Storage uni	t identificat	tion Notes		Contact pers	on	Telephone				
		Va	accine Tra	nsport	Supplies						
Supplies	Location				Contact pers	on	Telephone				
Qualified transport contai	ners										
Conditioned water bottles	5										
Calibrated temperature monitoring devices for transport											

## **Routine Vaccine Storage and Handling Plan**

In case of a power failure or an event that results in out-of-range temperatures in vaccine storage units:

- 1. Secure the door.
- 2. Keep vaccine in the unit.
- 3. Quarantine vaccine and label "Do Not Use."
- 4. Complete the Provider Excursion Worksheet: <a href="https://www.kdhe.ks.gov/233/Vaccine-Storage-Handling">https://www.kdhe.ks.gov/233/Vaccine-Storage-Handling</a>
- 5. Document vaccine antigens, manufacturer and expiration date that were involved.
- 6. Document date and time of the temperature excursion, how long the temps were out-of-range and the highest and lowest (Min/Max) temperatures.
- 7. Notify Regional Consultant or On-Call Consultant 877-296-0464.
- 8. Contact Vaccine Manufacturers to request viability reports per temp excursion details.
- 9. Obtain manufacturer written recommendations on viability of the vaccine.
- 10. Do not leave vaccine in a malfunctioning unit for an extended amount of time. Activate the emergency response and transport vaccine to the designated backup storage unit.
- Vaccine temperatures must be monitored with a certified calibrated thermometer at all times in an appropriate storage unit or qualified shipping container.
- 12. Submit the Provider Temperature Excursion Worksheet to KIP Regional Consultant.
- 13. Request Vaccine return label in KSWeblZ if doses are determined to be non-viable.
- 14. Vaccine deemed "avoidable waste" must be replaced with private stock vaccine by the provider.

Resource Contact List												
Resources	Name Telephone	Email										
Local Health Department:												
KIP Regional Consultant:												
Nurse On-Call:												
Electric Power Company	Priority Site Call-In Number:											
Generator Repair Company	Generator Maintenance Logs:											
Refrigerator Repair Company												
Freezer Repair Company												
Thermometer Manufacturer Company												

Vaccine Storage & 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. Verification documents must be signed and dated. Keep these documents on file for 3 years.

I verify this Vaccine Storage & Handling Worksheet and Emergency Response Plan is current and accurate.

	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<sup>™</sup> 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 +/-1°F (+/-0.5°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.** 



CS249275-I August 2015

# Packing Vaccines for Transport during Emergencies

# **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.





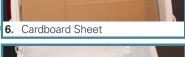
Close lid - Close the lid and attach DDL display and temperature log to the top of the lid.



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, Diluents, and Temperature Monitoring Device Probe

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

thick and must cover cardboard completely).

# NOTE:

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



Styrofoam<sup>TN</sup>



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

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in.



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

# **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)**

<u>VFC I</u>	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:
■ R	ecommended 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  $F \leq 0.5 \, ^{\circ}$ 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: <a href="mailto:IZColdChain@cdc.gov">IZColdChain@cdc.gov</a>

KIP DL Temp	eratu	re Lo	og fo	r Vac	ccines	(Cel	sius)	VI	C PIN	#:		Ref	riger	ator	r Name:Freezer Name:						Month/ Year:								
Day of Month		1		2		3	4		5		6		7		3	9	)	1			1		2		.3		4	1	5
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																													/
<u>≥</u> 11°																													
10°																													
9°																													
8° E	<u> </u>																												<u> </u>
7° <b>[</b>																													<u> </u>
8° 7° 6° 4° 4° 3° 2° 2°																													<u> </u>
→ 5° to																													<u> </u>
4° <b>9</b>																													<del></del>
3° 3°										-																			<del></del>
1°																													
0°																													
≥-12°								-									_											_	
-13°																													
-14°																													
-15°																													
-16°																													
-17°	1																												
-17 -18° -19° <-20°	i																												
-19°																													
<u>&lt;</u> -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 "⚠".
- 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 "⚠".
- 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 877-296-0464, 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:	 	 	

KIP DL Temperature Log for Vaccines (Celsiu							sius)	VI	FC P	PIN#	<sup>!</sup> :	Refrigerator Name:						Freezer Name: _					Month/ Year:											
	Day of			16		17	]	18	1	9	2	20	2	21	2	22	2	23	2	24	2	25	2	26	2	27	2	8	2	29	3	0	3	1
			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
	Exact Ti			<u> </u>				<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>	<del> </del>	<u> </u>				
	Currei Refrigera Max/M	ator in																/												/			/	
R	Previou Refrigera Max/M	ator																																
	<u>≥</u> 11°																																	
	10°																																	
	9°																																	
	8°	emp	•																										<u> </u>					
	7°	<u> </u>				-						-														-			<del>                                     </del>					
	6°	ator																											<u> </u>					
	<b>→</b> 5°	<u>a</u>				-						-	-																<u> </u>					
	4°	9	<b>\</b>			-						-																<u> </u>	ļ					
	3°	Refr				-	1		1			-	1													-			<u> </u>					
	2° 1°																																	
	0°																																	
	<u>&lt;</u> -1°																																	
	<u>≤-1</u> ≥-12°																																	•
	<u>≥</u> -12 -13°																																	
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	-18°	zer																																
	-19°	ree																																
	<-20°	Œ																																
	Currer Freeze Max/M	er Iin																																
	Previou Freeze Max/M	er																																
S	Staff Init	tials																																

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NOTES:	 		
	 	 	·····

# **VFC PROVIDER PROFILE UPDATE FORM**

Provider's Name:			MEDICAID ID#:	
Facility Name:			MEDICAID ID#:	
Vaccine Delivery Address:				
City: County:		State:	Zip:	
Telephone:		Email:		
PROVIDER POPULATION				
Provider Population based on patients seen during group. Only count a child <u>once</u> based on the statu many children received VFC vaccine by category, a	s at the last immunization	visit regardless of the number o		
VEC Various Elimibility Catagonian	# of 0	children who received VI	FC Vaccine by Age Catego	ory
VFC Vaccine Eligibility Categories	<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 <sup>1</sup>				
Total VFC:				
		11	15016	
Non-VFC Vaccine Eligibility  Categories		1-6 Years	-VFC Vaccine by Age Cate 7-18 Years	1
Insured (private pay/health insurance covers	<1 Year	1-6 Years	7-18 Years	Total
vaccines)				
Children's Health Insurance Program (CHIP) <sup>2</sup>				-
Total Non-VFC:				
Total Patients (must equal sum of Total VFC + Total Non-VFC)				
that are not covered by insurance.  In addition, to receive VFC vaccine, underinsured approved deputized provider. The deputized provorder to vaccinate these underinsured children.	vider must have a written a Health Insurance Program (v	greement with an FQHC/RHC at (CHIP). These children are consid	nd the state/local/territorial imm dered insured and are not eligible	nunization program
<sup>2</sup> CHIP – Children enrolled in the state Children's H the VFC program. Each state provides specific gui			d through participating providers	
the VFC program. Each state provides specific gui		ON	d through participating providers	
the VFC program. Each state provides specific gui			d through participating providers	
TYPE OF DATA USED TO DETERMINE P		ON		
TYPE OF DATA USED TO DETERMINE P  Benchmarking		Doses Administered		
TYPE OF DATA USED TO DETERMINE P  Benchmarking  Medicaid Claims Data		Doses Administered Provider Encounter Date		
TYPE OF DATA USED TO DETERMINE P  Benchmarking  Medicaid Claims Data  IIS  Other (must describe):  By signing this form, I certify on behalfimmunization providers in this facility, above and understand I am accountable.	F of myself (Medical , I have read and agr	Doses Administered  Provider Encounter Dat Billing System  Director or authorized to the Vaccines for Cl	o sign for Medical Directo	or) and all
TYPE OF DATA USED TO DETERMINE P  Benchmarking  Medicaid Claims Data  IIS  Other (must describe):  By signing this form, I certify on behalimmunization providers in this facility.	F of myself (Medical , I have read and agr	Doses Administered  Provider Encounter Dat Billing System  Director or authorized to the Vaccines for Cl	o sign for Medical Directo	or) and all

## **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 <a href="mailto-kdhe.vaccine@ks.gov">kdhe.vaccine@ks.gov</a>. 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 BO	DRRO	WING RE	PORT				
BORROWED D	OSE							REPAYMENT	DOSE		
VACCINE BORROWED	LOT # OF BORROWED DOSE	PRIVATE or PUBLIC VACCINE USED	DATE BORROWED	PATIENT IDENTI PT NAME, MEDI RECORD # OR KSWEBIZ # AND	CAL	PATIENT ELIGIBITY	REASON CODE FOR BORROWING (SEE TABLE)	LOT # OF RETURNED DOSE	DATE RETURNED	PATIENT IDENTIFIER: PT NAME, MEDICAL RECORD # OR KSWEBIZ # AND DOB	PATIENT ELIGIBITY
				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		Rea	son for Borr	owing Private	Dose	Code
Private vaco	cine shipment del	ay (vaccine orde	er placed on time/	delay in shipping)	1	Pub	lic vaccine ship	ment delay (or	der placed on t	ime/delay in shipping)	8
Private vaco	cine not useable o	on arrival (vials b	oroken, temperatu	re monitor out of	2	Pub rang		ıseable on arriv	al (vials broken	, temperature monitor out c	of 9
Ran out of p	orivate vaccine b	etween orders (	not due to shipp	ing delays)	3	Rar	out of public va	accine betweer	n orders (not du	ue to shipping delays)	10
Short-dated	private dose wa	s exchanged wi	th publicly funde	ed dose	4	Sho	ort-dated public	dose was exch	anged with priv	vate dose	11
Accidental ι	se of publicly fu	nded dose for a	private child		5	Acc	idental use of a	private dose fo	or a publicly ins	ured/eligible child	12
Replacemer did not cove	t of private dose r vaccine	with publicly fur	nded dose when	insurance plan	6	Oth	er - Describe:				13
Other - De	scribe:				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

53

# **Kansas Immunization Program Vaccine Transfer Form**

Date: Transferring Unit Name/Identifier:					
Transferring Pro	vider:			ı	PIN:
Trunsiering 110					
Receiving Provid	ler:			PIN:	
Regional Immuni	zation Consultan	t Authorizing Transfer: _			
Vaccine	Lot #	Manufacturer	Expiration	Dose Count	Funding Source
			+		
<del> </del>					
Transferring Un	it Temp/Time:_		_ Receiving (	Jnit Temp/Time:	
Hourly Temps	Time:	Temp:	Time·	T	emp:
	Time:	Temp:	Time:		emp:
	Time:	Temp:	Time:		emp:
	Time:	Temp:	Time:	To	emp:
Signing staff attest t	o the above docume	ented temperatures and verif	ied vaccine counts o	lone within the stated	transport date
rransferring Sta	air signature:			Date	:
Receiving Staff	Signature:			Date	·

<sup>\*</sup>Vaccine transfers  $\underline{\text{MUST}}$  be completed in KSWebIZ within current reconciliation period.

#### IF TEMPERATURES ARE OUT OF RANGE, TAKE IMMEDIATE ACTION!

Refrigerator	Freezer	Ultra-Cold
Store between 2°C and 8°C (36°F and 46°F)	Store between -50°C and -15°C (-58°F and +5°F)	Store between -80°C and -60°C (-112°F and -76°F)
(Aim for 5°C or 40°F)	(Aim for -18°C or -1°F or colder)	Thermal shipper storage between -90°C and -60°C (-130°F and -76°F)
Reportable:		(-130 ) and -70 )
□>8°C or higher for 60 minutes or more	Reportable:	Reportable:
□<2°C for any period of time	□>-15°C or higher for 60 minutes or more	□>-60°C for any period of time
□"X" on KIP Data Logger	□<-50°C for any period of time	□<-96°C for any period of time
☐Any out of range temperature (above or	□"X" on KIP Data Logger	
below recommended range) if open multi dose		
vials are present		

Vaccines for Children (VFC) providers must use the Kansas Immunization Program (KIP)-supplied digital data loggers for monitoring temperatures of refrigerator and freezer storage units housing publicly-funded vaccine. VFC providers must receive KIP approval before using another temperature monitoring device.

If a unit is not functioning properly or is not in proper temperature range IMMEDIATELY FOLLOW YOUR <u>VACCINE STORAGE AND HANDLING PLAN WITH</u>

EMERGENCY RESPONSE PLAN. IF NEEDED, TRANSPORT VACCINE TO YOUR PRE-DETERMINED BACKUP EMERGENCY LOCATION.

NON-REPORTABLE TEMPERATURE EXCURSION (TE): 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" waste.

**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 IMMUNIZATION CONSULTANT OR THE CONSULTANT ON-CALL AT 877-296-0464
- CONTINUE TO STORE VACCINES UNDER IN THE RECOMMENDED TEMPERATURE RANGE UNTIL VIABILITY IS DETERMINED. DO NOT DISCARD AFFECTED VACCINE, ASSUMING IT HAS BEEN COMPROMISED.
- CONTACT THE VACCINE MANUFACTURER FOR WRITTEN RECOMMENDATIONS ON THE VACCINE VIABILITY.
- DOWNLOAD AND SUBMIT KIP SUPPLIED DDL REPORTS (.PDF AND .TXT) AND/OR OTHER TEMPERATURE MONITORING DEVICE DOCUMENATION AND SEND TO YOUR IMMUNIZATION CONSULTANT OR CONSULTANT ON-CALL.

PROVIDER NAME:	PIN:	DATE:	
<del></del>	 		Printable TE Form - Revision 1/2023

CLINIC INFORMATION					
Facility Name:		Pin Number:		Date:	
Worksheet Prepared by:		Email:		Phone:	
REPORTING OF TEMPERATUR	E EXCURSION				
KIP staff member TE was repo	rted to:	D	ate and time reporte	ed:	
TE DETAILS					
Date and time discovered:		To	emperature and time	e out or range:	
DDL Device used				Are water bottles present in	unit:
$\square$ KIP supplied Did the DI	DL display an "X" □Yes □No			□Yes	
$\square$ Other, describe: Brand:				□No	
Type:	Ca	libration date:		$\square$ Not recommended by uni	t manufacturer
VACCINE STORAGE UNIT INFO	RMATION				
Brand:					
☐ Refrigerator ☐ Freeze	r □Ultra-cold	□Pharmaceutical □Ho	usehold	□Stand Alone □Combinati	on Unit
Was the temperature adjusted	d prior to this excursion: $\Box$ Yes $\Box$ I	No If yes, describe ter	nperature adjustmer	nts made and/or previous issu	ies with storage
unit:					
SUMMARY: Provide a detailed	d summary of the event. Include ho	w and when the TE was d	iscovered and possik	ole or probably cause.	
ACTIONS TAKEN: Describe act	ions taken. Was vaccine transported	d, if so to where. (If vacci	ne was transported,	how are temperatures being	monitored.)
Contact Vaccine Manufacturers	, report excursion, and request they	fay or email their recomi	mendation		
COVID-19 VACCINE	VACCINES	CASE #	COMMENTS		
Pfizer-BioNTech	□ Pfizer-BioNTech COVID 19 Vaccir		COMMENTS		□Viable
800-438-1985 Option 3	(Specify presentations on-hand in	ie			□ Non-viable
	comments)				
Moderna 866-663-3762	☐ Moderna COVID-19 Vaccine				□Viable
Temperature Excursion Tool	(Specify presentations on-hand in				□Non-viable
	comments)				
Janssen (Johnson & Johnson)	☐ Janssen COVID-19 Vaccine				□Viable
800-565-4008 Option 0					☐Non-viable
Novavax	□Novavax				□Viable
855-239-9174					□Non-viable
PROVIDER N	AME:	<del></del>	PIN:	DATE:	

OTHER VACCINES	VACCINES		CASE #	COMMENTS	
AstraZeneca	□FluMist				□Viable
800-236-9933 Option 1					□Non-viable
Dynavax Technologies (Medical	☐Heplisav-B				□Viable
Information Department)					□Non-viable
844-375-4728					
GlaxoSmithKline (GSK) (Medical	□Bexsero	□Infanrix			□Viable
Information Department)	□Boostrix	☐Kinrix			□Non-viable
877-356-8368	□Engerix-B	□Menveo			
<u>Vaccine Stability Calculator</u>	□Fluarix	☐ Pediarix			İ
	□Flulaval	☐ Priorix			İ
	□Havrix	Rotarix			
	□Hiberix	$\square$ Shingrix			
		□Twinrix			
Merck @ Co, Inc.	□Gardasil	$\square$ Rotateq			□Viable
800-672-6372 Option 2	☐MMR II	$\square$ Vaqta			□Non-viable
Vaccine Stability Calculator	□PedvaxHIB	□Varivax			
	□Pneumovax 23	$\square$ Vaxelis			
	□Proquad	□VAXNEUVANCE			
	☐Recombivax HB	□Zostavax			
Pfizer/Wyeth	☐Prevnar 13	$\square$ Trumemba			□Viable
800-438-1985 Option 3	☐Prevnar 20				□ Non-viable
Vaccine Stability Calculator					
Sanofi Pasteur	□ActHib	□Menactra			□Viable
800-822-2463	□Adacel	☐MenQuadfi			□Non-viable
Vaccine Stability Calculator	□Daptacel	☐ Pentacel			
	□Fluzone	$\square$ Quadracel			
	□IPOL	□Td			
Seqirus	□Afluria	□Fluad			□Viable
855-358-8966 Option 1	□Flucelvax	_			□Non-viable
*For JYNNEOS excursions, plea	se call 877-296-0464				

- Providers experiencing a temperature excursion will be <u>suspended from vaccine administration and ordering</u> until all requested information is submitted and reviewed. Providers will be notified when they may resume vaccinating and ordering. If non-viable vaccines were administered, patients may need to be revaccinated. Your Immunization Consultant will work with your clinic to make this determination.
- Vaccines exposed to out of range temperatures should be labeled with an excursion sticker. Excursion stickers can be ordered from the KIP Order Center.

PROVIDER NAME:	PIN:	DATE:
		Divid T55

- If expiration dates need to be shortened due to excursions, vaccines should be marked with an excursion sticker and the updated expiration date clearly marked on the box. The vaccine should be removed from inventory when the shortened date has been reached.
- 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 FORMS - Submit the following to your Immunization Consultant or Consultant On-Call by email or fax:

- Completed Temperature Excursion Worksheet
- An electronic copy of the .pdf and .txt reports from the KIP provided DDL or other DDL data
- A copy of the manual temperature logs
- A copy of the manufacturers' written recommendations
- A copy of calibration certificate for the temperature monitoring device
- A list of all publicly funded vaccines (public, 317, State) and any COVID-19 vaccine exposed to out of range temperatures. The list should include vaccine brand name/vaccine type, lot numbers, expiration dates, and quantity.

#### VFC IMMUNIZATION CONSULTANT CONTACT INFORMATION

Northwest - Lorraine Baughman (785) 213-4110, Lorraine.Baughman@ks.gov Southwest - Dena Rueb (785) 250-3292, Dena.Rueb@ks.gov

North Central – Melody Couper (785-471-0083), Melody.Couper@ks.gov

South Central – Rachel Sample (785-250-7165), Rachel.Sample@ks.gov

Northeast – Rene' Havner (785) 289-7410, Rene.Havner@ks.gov

Southeast - Jayme Lewis (785) 213-6337, Jayme.Lewis@ks.gov

Consultant On-Call line (877) 296-0464, KDHE.IMMConsultant@ks.gov

VFC Fax (785) 559-4226 (Be sure to indicate who the fax needs to be sent to)

#### ADULT IMMUNIZATION CONSULTANT CONTACT INFORMATION

Tehren Esparza – (785) 471-0091, Tehren.Esparza@ks.gov
Laura Hageman – (785) 471-0095, Laura.Hageman@ks.gov
Gail Pickering – (785) 471-0082, Gail.Pickering@ks.gov
Kayla Burton – (785) 471-0098, Kayla.Burton@ks.gov
Ashley Osborne – (785) 471-0075, Ashley.Osborne@ks.gov
Consultant On-Call line (877) 296-0464, KDHE.IMMConsultant@ks.gov
VFC Fax (785) 559-4226 (Be sure to indicate who the fax needs to be sent to)

PROVIDER NAME:	PIN:	DATE:	