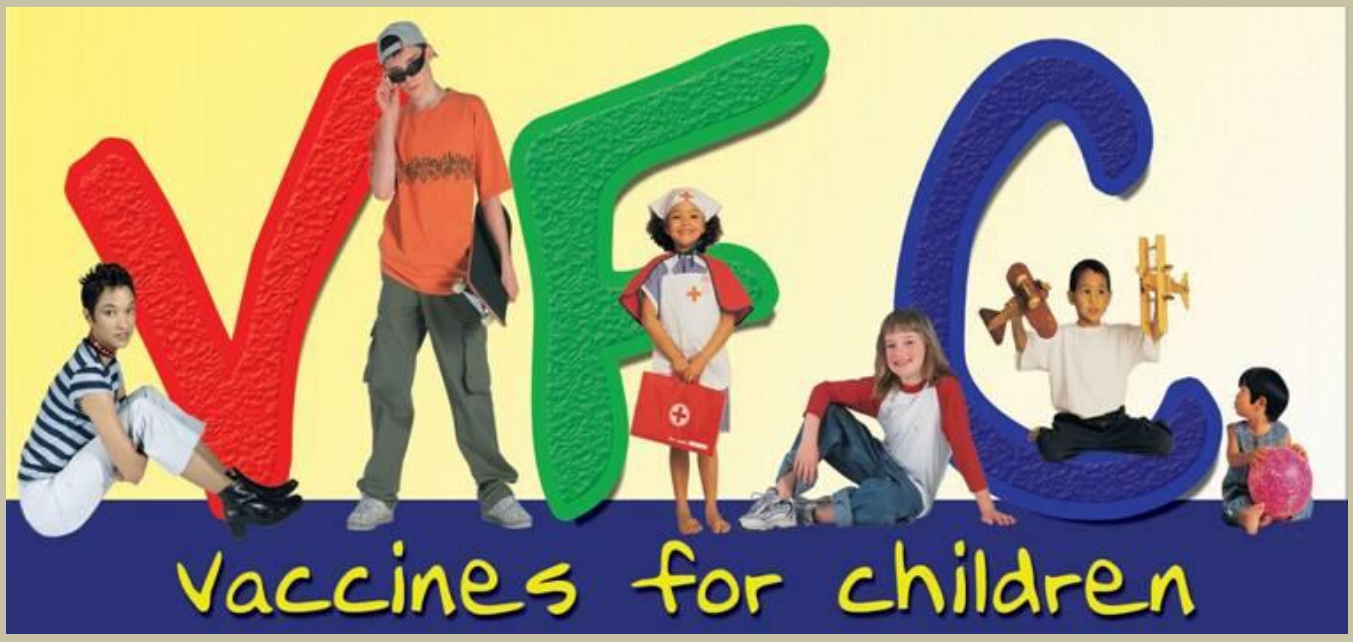
Montana Department of Public Health and Human Services

Immunization Program



Provider Handbook/ Vaccine Management Plan

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MONTANA DPHHS
Healthy People. Healthy Communities.
Department of Public Health & Human Services

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VFC Provider Handbook

INTRODUCTION

Vaccines for Children (VFC) is a federally funded entitlement program that provides vaccines at no cost to children who might not be vaccinated because of inability to pay. It was created through federal law (42 USC § 1396) and is administered by the Centers for Disease Control and Prevention (CDC) as a component of each state's Medicaid plan. Children through 18 years of age who meet eligibility requirements can receive VFC vaccine. Since its inception in 1994, the VFC Program has improved vaccine availability, increased immunization coverage, and reduced disparities in access to health care.

VFC in Montana

The Montana Immunization Program implements the VFC Program within the state. We manage the budget, order vaccines, enroll and educate providers, and ensure compliance through periodic site visits. Our two main goals are to make sure VFC vaccine is at your clinic when you need it and that you are complying with the program's federally mandated requirements.

Funding

Montana's publicly supplied vaccines are funded through three main sources: VFC, Section 317 of the US Public Health Service Act (317), and State appropriations. As a Medicaid entitlement program, the VFC budget adjusts annually to cover all recommended childhood vaccines for Montana's VFC-eligible children. Vaccine programs funded from other sources vary year to year in response to changing budgets and public health concerns. Contact the Immunization Program for information on our currently funded public vaccine programs (444-5580 hhsiz@mt.gov).

imMTrax – Ordering and Managing Publicly Funded Vaccine

Requirement

Montana VFC providers must order and manage publicly supplied vaccine through the State's web-based Immunization Information System, imMTrax. To gain access to imMTrax, provider facilities must complete and submit an imMTrax Memorandum of Agreement. Each person needing access to imMTrax must submit a System Access Request Form, imMTrax User Memorandum of Agreement, and any additional requirements specific to the imMTrax user role requested.

When setting up your account in imMTrax, you must decide whether your facility will be an integrated or aggregate provider. See definitions below:

Integrated providers manually enter patient immunization records directly into imMTrax. Patient VFC eligibility status is documented during this process and doses administered are automatically decremented from inventory.

Aggregate providers track doses administered and VFC eligibility status outside of imMTrax (see Section 4 for tracking methods). Once per month during inventory reconciliation, aggregate providers enter doses administered by lot number and age cohort. Patient immunization records may be entered through an electronic data feed or manually entered as historical records.

This handbook does not provide in-depth imMTrax training. For imMTrax help, contact imMTrax Training and Support at 444-2969 (hhsiz@mt.gov).

Document Retention Requirements

VFC-Related Documents

VFC providers must retain all VFC-related documents and electronic information for three years. This includes VFC screening and eligibility records, temperature logs, data logger (digital thermometer) data, borrowing forms, billing records, medical records that verify receipt of vaccine, and vaccine purchase and accountability records.

Requirement

Immunization Records

Montana law requires hospitals to retain immunization records for at least 10 years (ARM 37.106.402) and health care facilities other than hospitals to retain immunization records for at least 6 years (ARM 37.106.314).

Medicaid Billing Records

Montana law requires health care facilities to retain Medicaid (Healthy Montana Kids Plus) billing records for at least 6 years and 3 months from the date of service (ARM 37.85.414).

This Document

This handbook is divided into two main parts**:** the ***VFC Provider Handbook*** (Sections 1–10) and the ***Vaccine Management Plan*** (Sections 11–17). It contains immunization best practices, recommendations, and requirements of the Montana VFC Program. Requirements are underlined and marked with red arrows:

The Montana Immunization Program provides a paper copy of this document to all enrolled providers and posts the most current version on our website. When revisions are made, the Montana Immunization Program notifies providers through an all-provider memo, provides a copy of the revised section(s), and posts the revised section(s) to our website. It is your responsibility to keep your handbook up to date by discarding outdated sections and replacing them with current versions. This document is designed for duplex (2-sided) printing.

Requirement

PROVIDER ENROLLMENT

Who can enroll?

The VFC Program was created to increase access to health care and allow children to remain in their medical home for immunizations.

Requirement

Any Montana health care provider serving children 0 through 18 years of age who meet the following criteria can enroll in the VFC Program:

- Provider agrees to all program requirements, including participation in site visits and education requirements, and providing all ACIP-recommend vaccines for the populations they serve (See Provider Agreement below).
- The health care professional signing the Provider Agreement is the medical director or equivalent in a group practice, has a valid license to administer vaccines in Montana, and the authority to ensure that the facility and all providers listed on the agreement adhere to the requirements of the program.
- Provider has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring capacity as described in Sections 11–17.
- Provider and provider staff are not included on the Office of Inspector General List of Excluded Individuals and Entities (LEIE).
- Provider is on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

VFC providers can be both public and private facilities and those not registered as Medicaid providers. Pharmacists can enroll, but are limited to influenza immunizations for children 12 through 18 years of age.

VFC Provider Agreement

Requirement

All VFC providers must submit a Provider Agreement annually. New providers do so during the enrollment process. Current providers complete a new Provider Agreement when they submit a new Site Contract during annual re-enrollment (See Re-Enrollment–Current Providers below).

You can find a copy of the current Montana VFC Provider Agreement on our website under the “VFC” link.

Re-Enrollment – Current Providers

Requirement

Each year, all current VFC providers must re-enroll in the program by completing a Site Contract in imMTrax. The Immunization Program notifies providers when the re-enrollment period begins and provides instructions for completing the process. Completed Site Contracts are sent electronically to the Immunization Program for approval. Once annual enrollment begins, providers are prohibited from ordering vaccine until their Site Contract is approved.

When completing your Site Contract, you must provide and/or update the following information:

- **Evidence of having completed the Provider Education Requirement** – Vaccine Manager and Alternate Manager must complete the annual Provider Education Requirement (see Section 19 for more details).

Required information for Site Contract in imMTrax:

- **Facility Information** – Facility name, shipping address, and contact information. Review and update, if necessary.
- **Facility Type** – Select the most appropriate type.
- **Vaccines Offered –** With the exception of "Specialty Providers" (see Section 18), VFC providers must offer all ACIP-recommended vaccines for the populations they serve.
- **Provider Population** – Annual immunization patient numbers for your facility by age group and VFC eligibility status. The source of the numbers differs depending on whether you are an integrated or aggregate provider (see page 8 for definitions):
  - **Integrated Providers** – If data entry is up to date and client VFC eligibility status has been accurately designated throughout the year, then provider population numbers will automatically populate the table based on the immunizations entered into imMTrax over the past year. Please review for accuracy.
  - **Aggregate Providers** – Pre-populated numbers are from the previous year's Site Contract. Enter updated information using your eligibility screening documentation from the past year (See Section 4 – Documenting Eligibility Screening).
- **Type of Data Used to Determine the Provider Population** – Select all that apply
- **Vaccine Delivery Times** – Facilities must be open with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day. Enter times in military format (24-hour clock).
- **Medical Director or Equivalent** – Name, specialty, license number, Medicaid or NPI number, and employee identification number.
- **VFC Vaccine Coordinator (Manager) and Alternate Information –** Name, contact information, and status of annual training completion.
- **List of Providers** – Name, title, license number, and date of birth.
- **Provider Agreement** – This portion of the contract lists the federal statutory requirements of the VFC Program as defined in 42 USC § 1396 and must be signed by the medical director or equivalent at your facility. By electronically signing this document and accepting shipment of VFC vaccine, your facility agrees to abide by the requirements of the VFC Program.

Enrollment – New Providers

Health care providers wishing to enroll in the VFC Program can begin by contacting the VFC Coordinator at the Montana Immunization Program either by telephone (444-0277) or email (hhsiz@mt.gov). The VFC Coordinator will briefly describe the program, learn about your facility, and determine whether the VFC Program is a good fit for your clinic.

New provider enrollment involves the following steps:

Requirement

- **VFC Enrollment Packet** – A VFC enrollment packet is mailed to you prior to enrolling and contains information and forms pertaining to the VFC Program. Please review this

material before your enrollment visit.

- **Submission of VFC Site Contract, imMTrax Memorandum of Agreement (MOA), and System Access Requests** – The VFC Site Contract outlines the requirements of the VFC Program and captures required enrollment information. After your initial enrollment (on paper), you must re-enroll each year by updating your Site Contract electronically in imMTrax. The imMTrax MOA (one per facility) and System Access Requests (one per person requesting imMTrax access) are required to set up your imMTrax account.
- **Data Logger Issuance and Installation** – The Immunization Program provides digital data loggers (thermometers) for all public vaccine storage units plus one backup. They must be installed according to Immunization Program guidance in the *Data Logger Instruction Manual*.
- **Enrollment Visit** – During an enrollment visit, a Montana Immunization Program staff member explains the VFC Program, inspects your vaccine storage equipment, delivers State-supplied thermometers, and answers questions. Enrollment visits are conducted in person.
- **Issuance of VFC PIN and imMTrax Access Information** – Once your VFC paperwork is processed and you have received an enrollment visit, you will be issued a VFC PIN number and imMTrax login information. New provider training is available through the imMTrax Training and Support (444-2969).
- **Fulfillment of Education Requirement** – New VFC providers must designate a primary VFC Vaccine Manager and an alternate. Vaccine Managers and Alternate Vaccine Managers must complete an education requirement prior to placing their first vaccine order. See Section 19 for more details.
- **Storage Unit Approval** – New VFC providers must submit one week of data logger (digital thermometer data) and corresponding paper temperature logs for all VFC vaccine storage units and cannot receive VFC vaccine until the Immunization Program approves the storage units (See Section 13).

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

Change Notification Requirement

<u>Current providers must notify the Immunization Program any time during the year if</u>:

Requirement

- Their contact information, vaccine management personnel, or vaccine shipping instructions change
- The medical director (or equivalent) who signed the Provider Agreement changes
- Their providers or clinicians listed in imMTrax change
- The number of immunization patients at the facility changes significantly
- The facility type changes
- They add or decommission a VFC vaccine storage unit.

Termination

Termination is the permanent removal of a provider from the program due to uncorrected, non-compliance issues, substantiated instances fraud or abuse, or a permanent condition such as being listed on the “List of Excluded Individuals and Entities” (see Section 9 – Non-Compliance, Fraud, and Abuse for more information).

BILLING

There are two costs associated with vaccine— the cost of the vaccine and the administration fee.

The billing requirements of the VFC Program are statutorily defined as follows:

Requirement

Vaccine

- Providers may not charge patients, Medicaid, or private insurance for VFC vaccine.

Administration Fee

- The maximum regional charge set for the Montana VFC vaccine administration fee is $21.32 per vaccine (not per antigen in combination vaccines).
- Patients must never be charged more than the VFC administration fee cap.
- Private insurance may be billed VFC vaccine administration fees at the private rate.
- VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

Please refer to the tables in Section 4 – VFC Eligibility – Special Eligibility Circumstance for billing information under various VFC eligibility scenarios.

See “Borrowing” in Section 16, for options for adjusting inventory to correct for improperly billed vaccine.

VFC ELIGIBILITY

Requirement

VFC providers are required to screen ALL patients for VFC eligibility at every immunization visit, document the screening results at every immunization visit, and retain the documentation for three years. Neglecting to screen for and document eligibility or knowingly administering VFC vaccine to unqualified patients may be grounds for termination from the VFC Program and may be investigated as fraud and abuse.

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

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

Determining VFC Eligibility Status

Basic Eligibility Criteria

Children through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:

- **Medicaid eligible:** A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program.)
- **Uninsured:** A child who has no health insurance coverage
- **American Indian or Alaska Native (AI/AN):** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- **Underinsured*:** A child who has commercial (private) health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only); or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

*Underinsured children are eligible to receive VFC vaccine only through Federally Qualified Health Centers[1] (FQHC) or Rural Health Clinics[2] (RHC).

FQHC and RHC facilities are marked with an asterisk (*) in the second column of our List of VFC Providers.

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

Fully Insured Children

Fully insured children are not eligible for the VFC Program. The VFC Program defines fully insured as having insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

Table 1 summarizes VFC eligibility determinations based on various insurance scenarios.

Table 1 Summary of VFC Eligibility and Insurance Status (From: *2014 VFC Operations Guide*, page 31. CDC January 2014)

VFC eligibility scenario: Child is insured and…	Insurance Status	Is child VFC eligible?
Has not yet met plan's deductible	Insured	No
Plan covers all ACIP recommended vaccines but excludes certain products/ combination vaccines	Insured	No
Plan covers only a portion of the vaccine cost and does not *have Medicaid as secondary insurance*	Insured	No
Has insurance, but plan limits coverage to a specific number of provider visits annually.	Underinsured (once the limited number of allowable visits are reached during the year)	Yes, once the limited number of visits have been reached AND only administered by a FQHC, RHC or approved deputized provider
Seeking contraceptive or sexually-transmitted disease (STD) services at school-based clinic or facility whose main services are primary or acute care and wants to be immunized but does not want to access insurance	Insured	No
Seeking contraceptive or STD services at family planning clinic or STD clinic and wants to be immunized but does not want to access insurance or doesn't know status.	Uninsured	Yes
Has Medicaid as secondary insurance	Medicaid eligible	Yes
Plan covers only a portion of the vaccine cost and *has Medicaid as secondary insurance*	Medicaid eligible	Yes
Has not yet met plan's deductible and *has Medicaid as secondary insurance*	Medicaid eligible	Yes
Has exceeded plan's annually allowed number of provider visits	Underinsured Only through FQHC/RHC	Yes
Cannot access health insurance due to being incarcerated	Uninsured	Yes
Children enrolled in separate Children's Health Insurance Program – Healthy Montana Kids (HMK)	Insured	No
Children enrolled in Medicaid-expansion Children's Health Insurance programs – Healthy Montana Kids Plus (HMK Plus)	Medicaid eligible	Yes

Documenting Eligibility Screening

Requirements

Requirement

Eligibility screening results must be:

- Documented for all eligibility categories you serve, including privately insured (not VFC eligible)
- Documented at every immunization visit
- Associated with the patient and the visit date or immunization
- Documented through a process that informs clinicians what vaccine stock to use
- Documented in a way that can be tallied to obtain annual Provider Population Numbers
- Retained for three years
- Made available to Montana Immunization Program staff on request and during compliance site visits.

Methods of Documenting Eligibility Screening

Below are typical methods used to document eligibility. This list is not exhaustive, and any method or combination of methods that meet the criteria above is acceptable.

imMTrax

Integrated providers can use imMTrax to document eligibility. If data entry is current and accurate, imMTrax will automatically calculate Provider Population Numbers for annual re-enrollment. If you do not manage your private vaccine in imMTrax, you must document eligibility screening for privately insured patients outside of imMTrax. Aggregate providers cannot use imMTrax to document eligibility.

Paper Eligibility Logs

The Immunization Program maintains paper eligibility logs that capture all required information and can be used to tally Provider Population Numbers for annual re-enrollment and estimate order quantities. If you use these forms as the only method of documenting eligibility, you must list all pediatric patients including those who are privately insured. Contact the Immunization Program if you need a log sheet. They are no longer available on our website. Be sure to use the form appropriate to your facility type.

Electronic Health Record

Most electronic health records can capture VFC eligibility information. EHRs can be used to document eligibility as long as the information is associated with an immunization or visit date and is not solely in the demographic/personal information fields. You also must be able to extract Provider Population Numbers from the system for all VFC eligibility categories you serve.

Face-Sheets or Patient Check-In Questionnaires

Patient-completed face sheets or questionnaires can be used to document eligibility as long as they are completed for each immunization visit (dated), saved or archived for three years, and able to be tallied to determine Provider Population Numbers for annual re-enrollment.

Provider Population Numbers – Immunization Patient Numbers for Re-enrollment

Each year during VFC program re-enrollment, you must estimate for the coming year your total number of immunization patients by age and VFC eligibility category including privately insured patients (See Section 2 – - Re-enrollment–Current Providers). This information is your "Provider Population" and must be obtained from actual immunization data from the previous year. Providers must document eligibility screening throughout the year so that the information can be used to estimate your provider population.

Special Eligibility Circumstances

Requirement

This section covers special VFC eligibility situations that may be encountered. In general, when selecting between eligibility options:

1) Select the eligibility category that confers the least out-of-pocket expenses to the child's parent or guardian.
2) Select the eligibility category that is least likely to change.

Healthy Montana Kids

Nationally, the Children's Health Insurance Program (CHIP) enables states to expand health insurance coverage for uninsured children. In Montana, CHIP is called Healthy Montana Kids. Healthy Montana Kids *Plus* is the State Medicaid program. For VFC eligibility purposes:

- Healthy Montana Kids children are considered insured.
- Healthy Montana Kids Plus children are Medicaid eligible.

VFC eligibility under these two programs is summarized in the table below.

Table 2 VFC Eligibility for Healthy Montana Kids and Healthy Montana Kids Plus

Population	VFC Provider Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee[1]
Healthy Montana Kids	Any	Insured	Ineligible	Private	Healthy MT Kids	Healthy MT Kids
Healthy Montana Kids Plus	Any	Medicaid	Medicaid	VFC	No charge	Medicaid

[1] VFC vaccine administration fees billed to patients cannot exceed $21.32 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

Medicaid as Secondary Insurance

Any insured or underinsured child who has Medicaid as secondary insurance is eligible for the VFC Program (Table 3).

Insured children with Medicaid as secondary are not required to participate in the VFC Program. The decision to participate should be based on what is most cost-effective for the patient.

At private facilities, underinsured children with Medicaid as secondary should be designated "Medicaid" for VFC eligibility so they qualify for VFC vaccine. If marked as "underinsured," they can only receive VFC vaccine at designated FQHC/RHC facilities.

Table 3 VFC Eligibility for Children with Medicaid as Secondary Insurance

Population	Facility Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee[1]
Medicaid as Secondary	Any	Insured/ Medicaid Secondary	Insured	Private	Insurer	Insurer[2]
			Medicaid	VFC	No charge	Medicaid
Medicaid as Secondary	FQHC/RHC	Underinsured/ Medicaid Secondary	Underinsured	VFC	No charge	Patient
			Medicaid	VFC	No charge	Medicaid
Medicaid as Secondary	Private	Underinsured/ Medicaid Secondary	Medicaid	VFC	No charge	Medicaid

[1] VFC vaccine administration fees billed to patients cannot exceed $21.32 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

[2] Private insurance can be billed administration fees at the private rate. Medicaid can be billed for the balance of unpaid administration fees up to $21.32. If the primary insurer denies payment for the vaccine, VFC stock can be used to replace the private stock used (See Borrowing in Section 16).

Family Planning Clinics

Unaccompanied minors through 18 years of age who present at family planning clinics for contraceptive services or sexually transmitted disease (STD) treatment are considered uninsured and VFC-eligible if they do not want to access their insurance due to the confidential nature of their visit. This special eligibility status is restricted to family planning clinics. Family planning clinics must track VFC vaccine given to patients in this eligibility category using the form found on our website under the "VFC" link. Clinics are responsible for providing care in conformance with Montana's medical consent laws as they pertain to minors.

Incarcerated Juveniles

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

Dual Eligibility – American Indians/Alaskan Natives

American Indians and Alaskan Natives (AI/AN) can be eligible for the VFC Program under more than one category. Please use the following table to determine VFC eligibility status, vaccine stock, and vaccine billing for AI/AN populations seen at providers *other than* Indian Health Service (IHS), tribal, and urban Indian clinics (Table 4).

Table 4 VFC Eligibility for American Indian and Alaskan Native Populations at Facilities Other than Indian Health Service, Tribal, and Urban Indian Clinics

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

[1] VFC vaccine administration fees billed to patients cannot exceed $21.32 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

[2] Insured AI/AN children are not required to participate in the VFC Program. The decision whether to participate should be based on what is most cost effective for the patient. However, we encourage providers to use private stock on fully insured patients.

[3] Private insurance can be billed administration fees at the private rate. If the primary insurer denies payment for the vaccine, VFC stock can be used to replace the private stock used (See Borrowing in Section 16). Patients may be balance billed un-reimbursed VFC vaccine administration fees up to $21.32.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory panel that recommends routine immunization practices for children and adults in the US.

The major functions of the ACIP are to:

- Develop technical recommendations on vaccine use and immunization practices
- Harmonize immunization schedules with those of other advisory groups such as the American Academy of Pediatrics and the American Academy of Family Physicians
- Approve vaccines for use in the VFC Program.

After approval, ACIP recommendations are published in *Morbidity and Mortality Weekly Report* (MMWR), a scientific periodical prepared by the CDC and become the standard of practice for administering the applicable vaccines.

VFC Resolutions

Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC Program by passing a VFC Resolution. VFC Resolutions determine what vaccines are available through the VFC Program, including dosage, schedule, and contraindications. VFC Resolutions are the rules that providers must follow when administering vaccines under the VFC Program.

The CDC publishes current VFC Resolutions on their VFC Resolution webpage.

Please note the following about VFC resolutions:

- VFC resolutions may not be identical to published ACIP recommendations.
- An ACIP recommendation does not apply to the VFC Program until the VFC resolution is approved.
- For newly recommended vaccines, a VFC resolution must be approved before the CDC can negotiate a purchase contract with the manufacturer. Therefore, there may be a delay between when the resolution is approved and when the vaccine is available.

The Montana Immunization Program monitors ACIP recommendations and VFC resolutions and ensures that the Montana VFC Program reflects current guidance. We notify our VFC providers when new and amended ACIP recommendations and VFC resolutions become available.

ACIP Recommendations

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

Requirement

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

National Childhood Vaccine Injury Act Requirements

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Health care professionals who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC Program.

Vaccine Information Statements (VIS)

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. You must provide a current vaccine-specific VIS to your patient or your patient's legal guardian at each vaccination visit.

Requirement

VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on their VIS webpage.

Whether managed as electronic or paper documents, in a paper folder or through your EHR—you must provide *current* VISs to your patients. We recommend storing all VISs in one location and designating one person responsible for updating them. The CDC VIS webpage (link provided above) offers a "Get email updates" function that notifies you by email when VISs are changed. Another option is to download VISs directly from the CDC website as needed. That way, they are always up to date.

Vaccine Adverse Event Reporting System (VAERS)

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

Reportable Events – Required

The NCVIA requires health care providers to report to VAERS:

Requirement

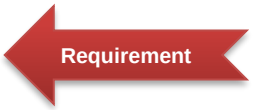
- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

Reportable Events – Voluntary

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

Vaccine Charting Requirements

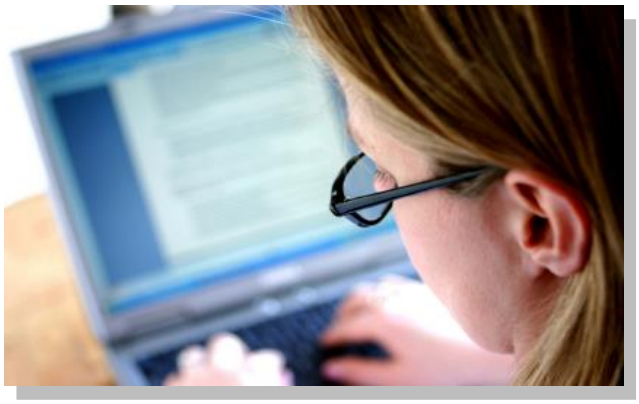


The NCVIA requires that vaccination records be included in a patient's permanent medical record and that they include the following information:

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

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

VFC COMPLIANCE SITE VISITS



Overview

The CDC requires the Immunization Program to periodically visit VFC providers to assess compliance with program requirements. These visits are called VFC compliance site visits or simply "site visits."

The goal of the Montana Immunization Program is to ensure provider compliance through effective communication, and a site visit should be considered more of an educational opportunity than an audit. Most program compliance issues are addressed through education. Only cases of repeated and intentional non-compliance progress to escalated follow-up action or termination. Please refer to Section 9 for details on how non-compliance, fraud, and abuse are handled in the Montana VFC Program.

Self-Assessment

We encourage you to continuously assess your VFC compliance, especially prior to a site visit, by using the checklist in Section 8 – VFC Program Requirements. This list details the main requirements of the VFC Program and references sections of this handbook for more information.

Site Visit Process

Requirement

VFC providers in Montana can expect a site visit from the Montana Immunization Program **at least every other year**, typically in the spring, summer, or early fall.

VFC site visits may be combined with other assessment functions of the Montana Immunization Program such as AFIX visits, where facility immunization rates are determined. Only VFC compliance site visit procedures are outlined in this handbook.

Site Visit Preparation

1. Approximately one month prior to your visit, a Montana Immunization Program staff member will contact you by telephone or email to schedule the visit.
2. After the visit is scheduled, you will receive a letter confirming the date and detailing items needed before and during the visit. An Immunization Program staff member may contact you by telephone to obtain more information about your clinic prior to the visit.

During the Site Visit

3. Site visits can take from 1 to 4 hours depending on the size of your clinic, whether other assessment activities are performed, and the compliance issues that arise.
4. Please make the following available during the visit:
    a. The Vaccine Manager and any key staff involved in the VFC Program

b. Three months of temperature logs and Data Logger data from your vaccine storage units
c. Your completed and annually reviewed *Vaccine Management Plan* (Section 12 of this Handbook)
d. VFC eligibility screening documentation for the last six months
e. Borrowing reports (if applicable)
f. Your paper stock or electronic source of VISs
g. The circuit breaker for your vaccine storage units or your facility power loss prevention policy
h. Any VFC-related documentation requested during the visit.

5. Approximately one hour of the site visit is a one-on-one conversation with your vaccine manager. Immunization Program staff ask questions pertaining to the VFC practices at your facility and provide a list of public vaccines shipped to your facility over the last year. They also inspect your vaccine storage units.

6. After the one-on-one with the vaccine manager, the Immunization Program staff may work independently as they review documents, take notes, fill-out forms, and enter data into the computer.

7. At the end of the visit, you receive verbal feedback on your compliance and a follow-up plan detailing any corrective actions. There are two types of corrective actions: on-site actions that can be performed during the visit and follow-up actions that require you to correct an issue and submit documentation by a deadline in the future. Repeated or serious non-compliance may result in escalated follow-up. Please see Section 9 Non-compliance, Fraud, and Abuse for details.

8. Before ending the compliance site visit, a provider representative (preferably the Vaccine Manager or Provider) and the site visit reviewer must sign an acknowledgement of receipt of the follow-up plan attesting that everyone understands any non-compliance issues and the actions necessary to address them.

Requireme

Site Visit Follow-Up

9. In order to remain in good standing with the VFC Program, you must carry out follow-up actions by the deadline. Immunization Program staff will be in contact by telephone, email, or fax or may return to your facility for a follow-up visit.

Requireme

10. Six months to a year after your visit, you will receive an Interim Site Visit Communication reiterating program requirements and recommendations.

Other Visits from the Montana Immunization Program

- **Unannounced Storage and Handling Visits** – The CDC requires the Immunization Program to perform unannounced "spot check" visits throughout the year. Any active VFC Provider could receive an unannounced visit, which takes approximately 30 minutes and focuses on vaccine storage and handling, including an inspection of your VFC vaccine storage units.

Requireme

- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance. Providers may request an educational visit from the Montana Immunization Program at any time (subject to staff availability). They can also be conducted by telephone or webex.
- **Enrollment Visits** – Enrollment visits occur during the enrollment process, See Section 2 – Provider Enrollment for more information on VFC Program enrollment.

VFC REQUIREMENT CHECKLIST

Requirement

Table 5 VFC Requirement Checklist by Frequency

X	VFC Requirement by Frequency	More Information
Once (upon enrollment or as needed)		
	Submit Site Contract, imMTrax MOA, and imMTrax System Access Requests.	Sections 2
	Receive VFC PIN # and imMTrax login credentials.	Sections 2,15
	Set up vaccine storage units and thermometers. Submit one week of temperature data for approval through online Vaccine Incident Report. Login to imMTrax and set up cold storage units.	Sections 13,14
	Post “DO NOT DISCONNECT” signs on outlets and circuit breakers or establish electrical loss prevention policy.	Section 13
	Complete (or update) and review *Vaccine Management Plan* with staff. Document the update/review in Section 12. Copy and post completed Section12 on vaccine storage units.	Sections 11,12
	Fulfill Vaccine Manager and Alternate Manager education requirements.	Section 19
Every Vaccination Visit		
	Screen for VFC eligibility and document using a compliant method.	Section 4
	Distribute current Vaccine Information Statement to patient (VIS).	Section 6
	Chart required vaccination information.	Section 6
Twice Daily		
	Log temperatures and Data Logger LED status for each storage unit on state-supplied paper temperature log.	Sections 13,14
Monthly (by the 15th of every month)		
	Download, review, and save Data Logger (thermometer) data for the previous month.	Section 14
	Enter monthly cold chain certification in imMTrax and submit to the State.	Section 15
	Reconcile inventory in imMTrax for the previous month.	Section 15
	Order vaccine in imMTrax (must have reconciled within 14 days to order).	Section 15
Yearly		
	Review *Vaccine Management Plan* with staff and update/re-post Section 12, if necessary.	Sections 11-17
	Re-enroll by submitting a new Site Contract in imMTrax (per State instructions).	Section 2
	Fulfill annual Vaccine Manager and Alternate Manager education requirement.	Section 19
Every Other Year		
	Host a compliance site visit from the Montana Immunization Program.	Section 7
As Needed		
	Report all storage unit temperature excursions using the online Vaccine Incident Report	Section 13
	Document all issues with vaccine storage units on your Trouble-shooting Log (pg. 3 of temp logs)	
	Submit VAERS incidents.	Section 6
	Document borrowing and repayment on VFC Vaccine Borrowing Report.	Section 16
	Update and re-post Section 12 of the *Vaccine Management Plan* if information changes.	Sections 11, 12
	Retain VFC documents for three years (e.g., eligibility screening logs, temperature logs).	Sections 1,4,14
	Submit temperature data for new or repaired storage units prior to using appliance or if requested by the Immunization Program for quality control purposes.	Sections 13,14

NON-COMPLIANCE, FRAUD, AND ABUSE

Requirement

By submitting a Site Contract in imMTrax and accepting shipment of VFC vaccine, you agree to abide by the statutory requirements of the VFC program. These requirements are federal law, and as the administrator of the VFC Program in Montana, the Immunization Program is charged with enforcement.

Non-compliance, fraud, and abuse is typically discovered during VFC site visits but may also be self-reported, reported by third parties, or revealed through vaccine ordering and accountability processes. All circumstances are unique, making it difficult to develop a set of rules for handling all situations. VFC providers may be required to replace vaccine lost due to negligence, non-compliance, fraud, or abuse; or incur the cost of re-vaccination due to negligence (see Section 17 for details).

Policy

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

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

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

Escalated Follow-Up – Providers enter escalated follow-up if their non-compliance issue is repetitive (i.e., same issue occurred within the past two site visits), serious, or if a typical follow-up action is not completed within a given time frame. Escalated follow-up puts the provider on probation and involves agreed-upon, written corrective actions with firm deadlines and increased Immunization Program oversight. The provider is also added to the Immunization Program Allegation and Referral Database. Failure to complete an escalated follow up plan results in termination from the VFC Program.

Termination – Termination is the permanent removal of a provider from the program due to uncorrected, non-compliance issues; substantiated instances fraud or abuse; or a permanent condition such as being listed on the "List of Excluded Individuals and Entities."

Terminated providers must account for all VFC vaccine and return State-supplied equipment within 30 days of termination. Once all vaccine and equipment has been accounted for, the Immunization Program issues a memo to the provider finalizing the termination.

Termination from the VFC Program is considered permanent. However, a terminated provider may be allowed to re-enroll if they demonstrate full compliance and complete the enrollment process, including an enrollment site visit.

Referral to Centers for Medicare and Medicaid Services (CMS) for Fraud and Abuse Investigation – The Immunization Program is required to refer to CMS any instances of fraud and abuse (see definitions below) or any non-compliance that appears intentional and results in financial benefits to the provider.

Definitions:

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

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

Examples of Fraud and Abuse

- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC-funded vaccine
- Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen for and document eligibility status at every visit
- Failing to maintain VFC records and comply with other requirements of the VFC program
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match the provider’s profile or otherwise over-ordering VFC vaccine
- Waste of VFC vaccine.

IMMUNIZATION RESOURCES

State

Immunization Program: 444-5580; paper fax 444-2920 digital fax 442-4848

Immunization Program website

Immunization Program Manager: Bekki Wehner 444-0065

Office Manager: Stacy Evens 444-5580

VFC

VFC Coordinator/Vaccine Manager: Lori Hutchinson 444-0277

VFC Quality Specialist: Katie Grady-Selby 444-1613

To report VFC Fraud and Abuse: 444-0277

Online VFC Vaccine Inventory Management (imMTrax):

CDC Public Health Advisor: Carolyn Parry 444-2675

Other State Programs

Assessment Coordinator: Meaghen Kolar 444-6978

Perinatal Hepatitis B Coordinator/Nurse Consultant: Susan Reeser 444-1805

Immunization Information System (IIS) - imMTrax

ImMTrax login

imMTrax Help Desk: 8:00am to 5:00pm, Monday through Friday 406-444-5580 hhsiz@mt.gov

Immunization Information System (IIS) Business Analyst: Michelle Funchess mfunchess@mt.gov 444-2969

IIS Training and Support: Madeleine Barber mbarber@mt.gov 444-2969

IIS Interoperability Coordinator Deb Belleau dbelleau@mt.gov 444-5952

Federal

Centers for Disease Control and Prevention (CDC)

CDC Vaccines and Immunizations

Vaccine Information Statements (VIS)

Immunization Information: (800) 232-4636 English and Spanish

CDC Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)

Other:

Immunization Action Coalition (IAC) (651) 647-9009

IAC produces a newsletter called Needle Tips and Vaccine Information Statements (VIS) in many foreign languages.

Pharmaceutical Companies:

GlaxoSmithKline	(866) 475-8222
MedImmune	(877) 633-4411
Merck Vaccines	(800) MERCKRX
Pfizer (Wyeth)	(800) 666-7248
sanofi pasteur	(800) VACCINE

VFC Forms and Logs

Visit our website to download forms and logs. If the item you are looking for is not available for direct download, contact us, and we will email it to you. (hhsiz@mt.gov 444-5580).

- Vaccine Borrowing Report
- Borrowing Best Practices Poster
- Wasted and Expired Vaccine Report
- Temperature Logs with Storage Unit Trouble-Shooting Log on third page (Not available for direct download. Contact us hhsiz@mt.gov 444-5580)

Vaccine Incident Report

Report temperature excursions and data logger issues through our online Vaccine Incident Report.

VACCINE MANAGEMENT PLAN

VACCINE MANAGEMENT PLAN – INTRODUCTION

Requirement

The CDC requires VFC providers to have written Routine and emergency vaccine management plan, and Sections 11–17 of this handbook serve this function. VFC providers may be held accountable for VFC vaccine wasted due to failure to follow their vaccine management plan (See Section 17 – Vaccine Loss and Replacement).

Customize this plan for your facility:

- Fill-in Section 12 starting on page 37. You can hand-write the information or use a computer editable version found on our website (www.immunization.mt.gov).
- Review the entire *Vaccine Management Plan* (Sections 11–16) with staff involved in the VFC Program.
- Document the completion (or update) and review in the table in Section 12.
- Post a copy of Section 12 on each VFC vaccine storage unit.
- Update, review, and re-post Section 12 as necessary so that the information is accurate.

Update and Review your Vaccine Management Plans with staff once per calendar year:

- Update Section 12, if necessary. Review the entire *Vaccine Management Plan* with staff.
- Document updates and annual reviews in the table.
- Re-post a copy of Section 12 to each VFC vaccine storage unit.

We assess compliance with these requirements during your VFC site visit.

VACCINE MANAGEMENT AND EMERGENCY PLAN

Requirement

Customize your plan by filling in the information below and posting a copy of this section (Section 12) on each vaccine storage unit. Use the information in this section to respond to emergencies that threaten your vaccine supply. A stand-alone version of this section that can be edited on a computer is available on our website.

Provider Information

Provider/Facility Name	VFC #

Designated Vaccine Manager

Requirement

Designate one person primarily responsible for VFC vaccine management and one alternate responsible person for when the primary is not available. A second alternate is optional.

Vaccine Manager (Primary person responsible for vaccine management)	Phone
Alternate Vaccine Manager (Person responsible for vaccine management when primary is unavailable)	Phone
Second Alternate Vaccine Manager (Optional) (Person responsible for vaccine management when primary and alternate are unavailable)	Phone

Emergency Phone Numbers

As appropriate for your facility, provide the phone numbers listed below:

Montana Immunization Program	**444-5580** **hhsiz@mt.gov**	Backup Generator Repair	Phone
Utility Company	Phone	Vaccine Transport	Phone
Building Maintenance	Phone	Other	Phone
Building Alarm Company	Phone	Other	Phone
Refrigerator/Freezer Repair	Phone	Other	Phone

Emergency Power Outage Plan

Backup Generator

Does your facility have a backup generator?

☐ Yes (Provide contact information below) ☐ No (Provide alternate vaccine storage locations, next section).

Contact person for generator maintenance	Phone

Alternate Vaccine Storage Locations

Requirement

If you have no backup generator, identify at least one alternate vaccine storage facility that has proper refrigerator and freezer units, temperature monitoring capabilities, and backup power where vaccine can be stored in the event of a power outage or equipment failure. Designate two locations, if possible.

Alternate Location #1	Contact Name	Phone
Alternate Location #2 (Optional)	Contact Name	Phone

Vaccine Inventory Management

Requirement

You must check expiration dates and remove expired vaccine on a weekly basis. Briefly describe the method you use to ensure that short-dated vaccines are used first:

System for ensuring short-dated vaccines are used first and expired vaccines are removed

Vaccine Management Plan Updates and Reviews

Requirement

Update Section 12 as needed. Document updates in columns one and two below by listing the date and the signature and title of the preparer. Review your *Vaccine Management Plan* with staff annually and anytime Section 12 is updated or you have a change in staff. Document staff reviews in columns three and four.

Updates		**Staff Reviews**	
Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Update Date	Staff Signature and Title	Staff Review Date	Staff Initials

Packing and Transporting Vaccine

The CDC discourages the regular transport of vaccines. Transporting vaccines may be necessary, however, during emergencies, off-site immunization clinics, or to prevent spoiled vaccine due to expiration. The preferred method of transporting vaccine is to use electric coolers that maintain appropriate vaccine storage temperatures. If an electric cooler or electricity is not available, you can use non-electric coolers.

Vaccine Pack-out Supplies/Equipment

Storage Location

To prepare for an emergency, store your vaccine pack-out materials in the location designated below. Quantities should be sufficient to handle your entire vaccine supply.

Location of Vaccine Pack-Out Supplies/Equipment

Supply/Equipment List

- Data logger with glycol-buffered probe – You can use your backup data logger. If you are moving your vaccine out of the original storage unit and temperature monitoring is no longer required in that unit, you can move the data logger with the vaccine.

Electric Option:

- Portable electric coolers that can maintain temperatures between -58°F and +5°F (-50°C and -15°C) for frozen vaccine and 36°F and 46°F (2°C and 8°C) for refrigerated vaccine
- Thin, insulating material to prevent vaccines from touching the interior walls of the cooler (e.g., cardboard, crumpled paper, plastic or wire baskets)

Non-Electric Option:

- Hard-sided cooler with ≥2-inch thick walls (can re-use Styrofoam® shipping containers)
- Cardboard cut to the exact interior, horizontal dimensions of the cooler (2 layers)
- ≥1-inch thick insulating material cut to the exact interior, horizontal dimensions of the cooler (2 layers). DO NOT USE loose material such as packing peanuts that may shift during transport.
- Frozen plastic water bottles, enough for 2 layers inside the cooler
  DO NOT RE-USE cold packs from vaccine shipments.

Steps Common to Electric and Non-Electric Pack-Outs

- Contact your destination storage location to confirm that the storage units have temperature monitoring (continuously monitoring, if possible) and are equilibrated to the proper temperature.
- Start a separate paper temperature logs for your transport coolers and destination storage units (if they don't have logs already).
- Whenever loading or unloading vaccines from a storage unit or cooler always record the date, time, and current temperature on a unit-specific paper temperature logs.
- Do not open storage unit doors until coolers are prepared and read to receive vaccine.

- Pack refrigerated vaccine first.
- Keep vaccine in its original packaging during transport.
- Diluent packaged separately from vaccine should be transported in refrigerated coolers or at room temperature. Diluent packaged with vaccine should remain with vaccine during transport.

Electric Coolers

- Plug the cooler into an electrical supply, set the thermostat to the appropriate temperature, and allow to equilibrate. This may take one to two hours.
    - Maintain refrigerated vaccine coolers between 36° and 46°F (2° and 8°C).
    - Maintain frozen vaccine coolers between -58°F and +5°F (-50°C and -15°C).
- Install data logger and equilibrate to the proper temperature. Only the probe vial should be inside the cooler.
- Line the floor and sides of the cooler so that the vaccine boxes are not in contact with the interior surfaces of the cooler. Cardboard, crumpled paper, bubble wrap, Styrofoam®, or wire or plastic baskets work well.
- Once the data logger shows the temperature is in-range, load vaccine.

Non-Electric Coolers – Refrigerated Vaccine

- Condition frozen water bottles by soaking them in cold water until there is a thin layer of water around the ice and the ice "spins" in the bottle. This takes between three to five minutes.
  Caution: Using unconditioned, frozen water bottles right out of the freezer will result in freezing temperatures in your cooler and will destroy refrigerated vaccines.
    - Pack the cooler according to Figure 1.

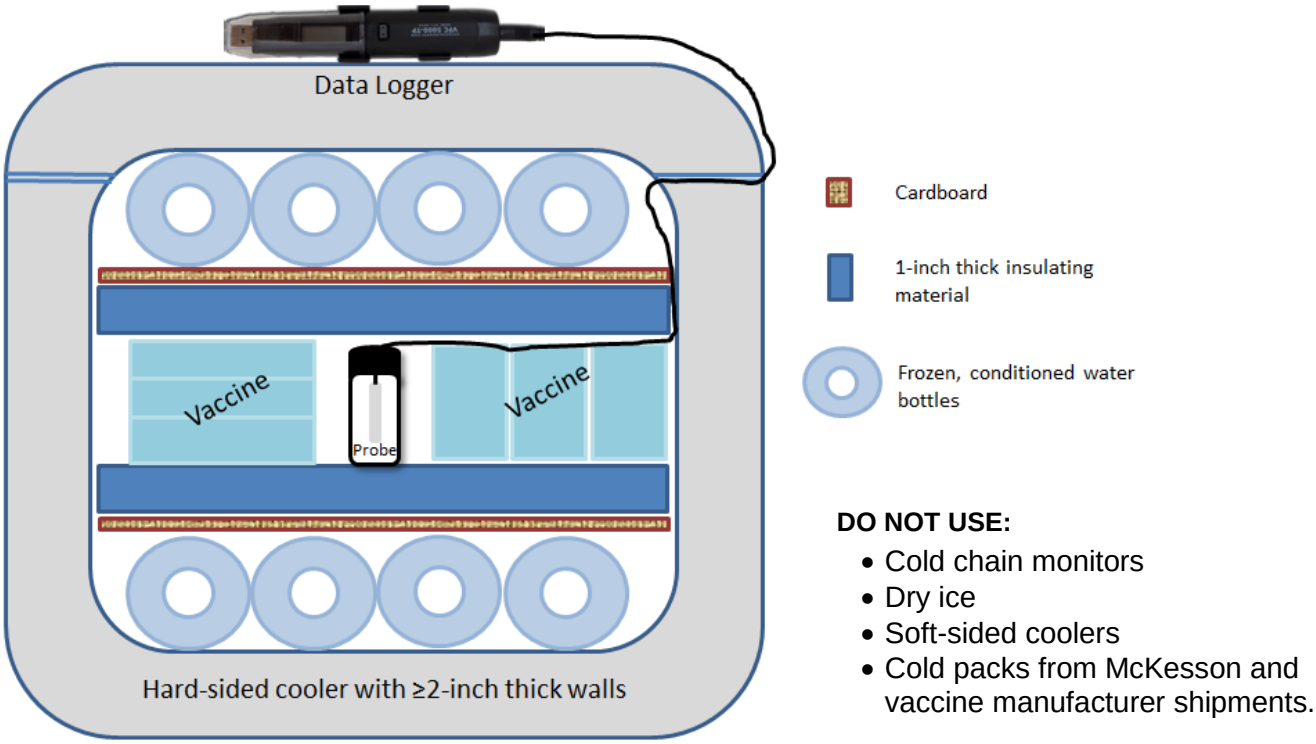


Figure 1 Packing vaccine for transport in non-electric coolers

During Transport

- Monitor the temperature in the transport container hourly if possible, but at least when you load and unload the vaccine. Log temperatures on the cooler-specific paper temperature log.
- Transport containers inside vehicles (not in the trunk) and take the quickest route possible. Do not leave vaccine unattended in vehicles during very hot or very cold weather.

After Transport

- Upon arrival at the destination storage facility, immediately place the vaccine in a storage unit with continuous temperature monitoring maintaining proper temperatures.
- Log temperatures of the alternate storage unit twice daily on the unit-specific paper temperature log.
- Download and review the Data Logger data recorded during the transport.

Reporting Transport Temperature Excursions

- If transport temperatures were outside recommended storage temperatures this is a temperature excursion and must be reported to the Immunization Program. DO NOT USE OR DISCARD the vaccine until you hear from the Immunization Program.
    - Segregate the affected vaccine
    - Mark “Do Not Use”
    - Store under appropriate temperatures
    - Contact the Montana Immunization Program by submitting an online Vaccine Incident Report. Attach data logger data
    - Wait for further instructions from the Immunization Program.

Transporting Varicella-Containing Vaccines

Varicella-containing vaccines must be stored frozen, and Merck does not recommend transporting these vaccines (Varivax®, Proquad®, Zostavax®). If you must transport, the best option is to use an electric cooler set to frozen vaccine temperatures. If an electric cooler or electricity is not available, the following options may be used.

PLEASE NOTE: The these pack-outs will expose your frozen vaccines to out-of-range temperatures that must be reported to the Immunization Program (see section above).

- Pack a separate, non-electric cooler only for frozen vaccines. Use unconditioned frozen water bottles straight out of the freezer. DO NOT USE dry ice. After transport, report the temperature excursion to the Immunization Program and wait for further instructions before using the vaccine.
- Pack frozen vaccine in the same electric or non-electric cooler as refrigerated vaccines with a secure layer of insulating material around the frozen vaccine so that it does not come in contact with the refrigerated vaccines. After transport, report the temperature excursion to the Immunization Program and wait for further instructions before using the vaccine.

Opened, Multi-dose Vials

- Only transport opened, multi-dose vials in an emergency and then only within the same organization/provider.
- NEVER transport opened, multi-dose between organizations/providers or across state lines.

VACCINE STORAGE UNITS

The following information outlines vaccine storage best practices and requirements.

General Requirements

Requirement

Refrigerators and freezers used for storing VFC vaccine must:

- Maintain required vaccine storage temperatures year-round:
  - Refrigerator: 36° to 46°F (2° to 8°C)
  - Freezer: 5°F to -58F (-15° to -50°C)
- Hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- In each unit have a working National Institute for Standards and Testing (NIST)- or American Society for Testing and Materials (ASTM)-calibrated thermometer that complies with the Montana VFC Program thermometer policy (See Section 14)
- Be dedicated to vaccine storage (Food and beverages are not allowed in vaccine storage units.).
- Not be a dormitory-style appliance (see section below).
- If new or replacement unit, must be a CDC recommended storage unit and *cannot* be household/commercial combination units where both the refrigerator and freezer are used to store VFC vaccine (See CDC Recommended Storage Units section below)
- Have the power supply protected by means of "DO NOT DISCONNECT" warning signs on electrical outlets and circuit breakers or a power loss prevention system with appropriate policies/protocols.

Figure 2 Dormitory-Style Refrigerator/Freezer

Dormitory-Style Storage Units are Prohibited

Dormitory-style (also called "bar-style") refrigerator/freezer units are those where the freezer is contained within the refrigerator, and both are accessed by one external door. Please note that the term "dormitory-style" does not refer to the size of the unit. It refers to the location of the freezer within the refrigerator compartment. These units cannot reliably maintain vaccine storage temperatures.

The CDC and the Montana Immunization Program prohibit the use of dormitory-style storage units for storing VFC vaccine. By signing the Provider Agreement each year, you certify that your facility does not use dormitory-style storage units to store public vaccine.

CDC Recommendations for Vaccine Storage Units

Requirement

New or replacement units must comply with CDC recommendations:

1) Pharmaceutical-grade stand-alone or combination units (preferred)
2) Household/commercial stand-alone units
3) Household/commercial combination units using only the refrigerator section

Currently, only varicella-containing vaccines require frozen storage. If you do not administer varicella-containing vaccines at your facility then you do not need a freezer for vaccine storage.

Definitions:

- Combination units have a refrigerator and freezer compartment in one appliance.
- Stand-alone units have just one compartment that is either a refrigerator or freezer.
- Household/Commercial/Domestic quality storage units are those typically found in homes and sold at retail appliance stores.
- Laboratory- or pharmaceutical-grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmacy setting. These are the highest quality option for storing vaccine.

Grandfathered-In Household/Commercial Combination Units

Providers currently using the refrigerator *and* freezer in a household/commercial combination unit can continue to do so as long as the units have been approved by the Immunization Program (see *Storage Unit Approval* later in this section) and the data logger data show that they reliably hold vaccine storage temperatures. However, if you are a new provider or are obtaining new or replacement equipment, you must follow the CDC recommendations as outlined above. We encourage you to contact the Immunization Program before purchasing new or replacement vaccine storage units to ensure they meet requirements.

Precautions when using Household/Commercial Combination Units

Household/commercial combination units regulate temperature by sharing cooled air between the refrigerator and freezer compartments. This makes temperature regulation in both compartments difficult. Please be aware of the following issues when using combination refrigerator/freezers for vaccine storage:

- Avoid units with a single control for both the refrigerator and the freezer. This configuration makes it difficult to maintain appropriate temperatures in both compartments and increases the likelihood of freezing vaccine in the refrigerator.
- Never place vaccine or thermometers (i.e., data logger probe vials) near vents and fans in the refrigerator. These areas may be markedly cooler than the rest of the compartment (even freezing!).
- When making adjustments in one compartment, always carefully monitor temperatures in both compartments. This is especially true when adjusting the freezer as this could cause the refrigerator to drop below freezing.

Freezers – Frost-free vs. Manual Defrost

The Montana Immunization Program allows both frost-free (automatic defrost) and manual defrost freezers for vaccine storage. Definitions:

- Frost-free units cycle to a warmer temperature roughly once every 24 hours to melt ice off the inside of the freezer compartment.
- Manual defrost units do not have a "defrost cycle" and accumulate ice on the inside of the compartment. They require periodic manual defrosting to melt the ice.

There are disadvantages to both defrost scenarios and facilities must decide which feature best fits their situation:

- The temperature cycling parameters in frost-free units must meet Merck specifications (contact the Immunization Program for details).
- Also for frost-free units, temperature monitoring equipment (i.e., data loggers) must be adjusted so the out-of-range alarm is not triggered with each defrost cycle (See the current Data Logger Instruction Manual).
- Manual defrost units typically hold vaccine storage temperatures steady and do not routinely cycle out-of-range, but alternate vaccine storage and temperature tracking must be arranged while you defrost your appliance.

Size Determination

Requirement

Your VFC vaccine storage unit must be able to store the year's largest supply of vaccine (including influenza vaccine) plus ice packs and water bottles used to stabilize temperatures. It also must be large enough to allow spacing between vaccine packages for proper air circulation (See *Vaccine Placement,* page 47).

To determine the size storage unit you need, calculate the largest number of doses you will have on hand during the year for both your refrigerator and freezer. Be sure to include seasonal influenza and private stock if it will all be stored in the same unit. Multiply the maximum doses by 1.25 to account for package spacing. Use this number (maximum doses) and the chart below to determine the minimum cubic feet of storage space you will need.

Table 6 Recommended Minimum Cubic Feet of Storage Space Based on Maximum Doses

Refrigerator		Freezer	
Maximum Doses	**Minimum Cubic Feet Required**	**Maximum Doses**	**Minimum Cubic Feet Required**
1001–2000	40	501–600	7–14.8
900–1000	36	201–500	5–5.6
801–900	21–23	0–200	3.5–4.9
701–800	17–19.5		
401–700	11–16.7		
100–400	4.9–6.1		

Setting Up your Storage Unit

Follow the procedures below when acquiring a new storage unit, moving an existing unit, or reestablishing a unit after a power outage or repair.

Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- Locate the storage unit in a well-ventilated space away from direct sunlight with 4 inches between the unit and surrounding walls, cabinets, and appliances. Follow any minimum clearance guidelines in your appliance documentation. The unit should sit firm and level.
- Do not block the motor compartment, which is usually located on the back or side of the unit.

Electrical Supply

- Place the storage unit near enough to an outlet so that the cord is not a tripping hazard and an extension cord is not necessary.
- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- Make sure the outlet is not controlled by a light switch.
- Protect the power supply to your vaccine storage units: **Requirement**
  - For facilities *without* sophisticated power loss prevention systems, post a "DO NOT DISCONNECT" sign next to the outlet and circuit breaker supplying your storage units. If these are not accessible or visible, place the sign such that anyone accessing the outlet or circuit breaker is likely to see it.
  - Facilities with sophisticated power loss prevention systems do not need "DO NOT DISCONNECT" signs, but must have written policies detailing measures taken to prevent accidental loss of power. Systems should be in working order and tested regularly.
- If you do not have a backup power supply, arrange at least one alternate vaccine storage location that has proper refrigerator and freezer units, temperature monitoring capability, and backup power where your vaccine can be moved in the event of a power outage. Record this information in Section 12. **Requirement**

Temperature Stabilizing

- Plug the unit into the electrical outlet and set the temperature to fall within the following ranges:

  Refrigerator: 36° to 46°F (2° to 8°C)

  Freezer: 5°F or colder (-15°C or colder)

- If the unit has a thermostat, set to the following target temperatures:

  Refrigerator: 40°F or 4°C

  Freezer: -5°F or -20°C

- If the unit has a controller with numbers or words (e.g., "colder"), set as follows:

  Refrigerator: Set slightly warmer than mid-range.

  Freezer: Set to mid-range.

Please note – For most numbered temperature dials, the higher the number the colder the temperature. Check your owner's manual to avoid improper adjustments.

- Place a working certified-calibrated, program-compliant thermometer (data logger) inside each storage compartment in a central location near vaccine, not in the door or crisper drawer and away from ceilings, walls, floors, vents, fans, coils, and cooling plates (stand-alone refrigerators). The Montana Immunization Program supplies data loggers to VFC providers (see Section 14).

Requirement

- Place several containers of water along the inside walls, in door racks, and crisper drawers of the refrigerator, and several frozen packs along the walls and in the door rack of the freezer. These will help stabilize temperatures when the door is open and in the event of a power outage, and prevent vaccine from being placed in areas likely to experience out-of-range temperatures. Do not impede airflow by over-filling with water bottles and ice packs.
- Make sure doors close tightly and seals are intact.
- Allow the unit to stabilize overnight and check temperatures in the morning.
- Adjust the dial or thermostat until the target temperature is achieved and held for at least one week. Log temperatures at least twice a day, and download and review data logger data as needed during the adjustment period (See *Data Logger Instruction Manual*).

Storage Unit Approval

The Immunization Program must approve all storage units and thermometers used to store and monitor VFC vaccine. To have a storage unit/thermometer approved, providers must submit:

Requirement

- One week of temperature data using our online Vaccine Incident Report (See Section 14 and your *Data Logger Instruction Manual* for details)
- One week of paper temperature logs
- Storage unit make/model information.

This requirement applies to:

- New VFC providers
- Providers setting up a new VFC storage unit
- Providers reinstating a VFC storage unit after a repair
- Providers commissioning a new Data Logger or other program-compliant thermometer.

The Immunization Program reviews your temperature data and determines whether your storage unit and thermometers are ready for vaccine. Do not use the storage unit until it has been approved by the Immunization Program.

Vaccine Placement

- Place vaccine in the middle of the compartment away from ceilings, walls, floors, vents, fans, coils, and cooling plates (stand-alone refrigerators).
- In the refrigerator compartment of combined units, keep vaccine away from vents or fans channeling air from the freezer. Consider putting water bottles or empty containers in areas known to deviate from

acceptable temperatures to prevent vaccine from being placed in these areas. However, DO NOT impede airflow.

- Never store vaccine in door racks or crisper drawers. Consider removing crisper drawers to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine "VFC" and keep it physically separated from private stock. **Requirement**
- Keep vaccine in its original packaging and organize by vaccine type. Consider physically separating vaccines with similar names, packaging, or antigens to avoid administration errors.
- Check expiration dates on a weekly basis and organize packages so that only one package is open at a time and short-dated vaccine is used first (record your process in Section 12).
- Immediately remove expired, spoiled, and wasted vaccine from active stock (See *Expired, Spoiled, and Wasted Vaccine* page 70). **Requirement**
- If containers are used to organize vaccine, use only open (no lid) containers that allow air to circulate, such as wire baskets or cardboard boxes.
- Never store food or beverages in vaccine storage units. Other biologicals can be stored in vaccine storage units as long as they are physically separated from vaccine to prevent contamination and administration errors.
- Diluent packaged with the vaccine should be stored at the same temperature as the vaccine. Diluent packaged separately from the vaccine can be stored refrigerated or at room temperatures.

Routine Temperature Monitoring

- VFC providers are required to monitor and log temperatures on VFC vaccine storage units as described below. Providers must use the paper logs provided by the Immunization Program (available on our website). This is required even when your unit has a continuous monitoring chart or data logger, or a temperature alarm (Please refer to the Data Logger Instruction Manual and Section 14 for more information on data loggers). **Requirement**
  - Record the day, time, and initials of the person taking the reading.
  - Record current temperatures twice per day, morning and evening by putting an "X" in the box next to the appropriate temperature.
  - Record minimum/maximum temperatures once per day in the morning by putting an "M" in the box next to the appropriate temperatures.
  - Record the status of the data logger LED light by putting a "Y" for yes or "N" for no in the appropriate box of the "LED Green" row.
  - Respond immediately to red warning lights or out-of-range temperatures (See *Out-of-Range Temperature* below).
  - Respond to requests from the Immunization Program for data logger data and temperature logs. As a quality control measure, the Immunization Program randomly requests temperature-monitoring information from VFC providers.
- Do not make temperature adjustments without informing your Vaccine Manager or Alternate Vaccine Manager. Consider posting a sign discouraging temperature adjustments by unauthorized personnel.

- DO NOT adjust temperatures in the evening or before a weekend when temperatures cannot be monitored.
- When adjusting temperatures, make slight changes to the thermostat or temperature dial and allow the unit to stabilize for 30 minutes. (Check your owner's manual to make sure controller adjustments are in the proper direction.) Check and record the temperature. Repeat, until the temperature is within range and stable.
- Record all storage unit temperature adjustments, issues, and out-of-range events on a Vaccine Storage Trouble-Shooting Log (page 3 of paper temperature logs). Logging these events will communicate vaccine storage issues to all staff and provide documentation that you responded appropriately. **Requirement**
- Retain paper temperature logs, trouble-shooting logs, and data logger data for three years. **Requirement**
- Be proactive in addressing storage unit issues before they result in vaccine wastage or patient recall situations.

Out-of-Range Temperatures

- VFC providers must take action if:
  - They register a red warning light on their data logger or out-of-range indication if using other compliant thermometers.
  - They record a current, minimum, or maximum out-of-range temperatures on their temperature logs.
- Providers experiencing the out-of-range temperature indications listed above must submit an online Vaccine Incident Report. Follow the instructions on the form and wait until you hear back from the Immunization Program before using the affected vaccine. **Requirement**
- Providers must consult with the Immunization Program to determine vaccine viability following a temperature excursion.
- Response to all temperature excursions must be documented through a submitted Vaccine Incident Report and an entry in the Vaccine Storage Unit Trouble-shooting Log (page 3 of paper temperature log).

THERMOMETER (DATA LOGGER) POLICY

Montana VFC Thermometer Requirements

Requirement

The CDC and the Montana Immunization Program require thermometers in all VFC vaccine storage units that meet the following requirements:

- Are certified calibrated/tested as accurate against NIST or ASTM measurement standards annually or within the timeframe recommended by the manufacturer evidenced by a current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report.
- Have alarms for out-of-range temperatures
- Display current, minimum, and maximum temperatures
- Have a low battery indicator
- Are accurate to +/- 1°F (0.5°C)
- Have a memory that stores at least 4,000 readings
- Use a thermocouple probe in a buffered medium such as glycol, glass beads, or aluminum block

State-Supplied Thermometers – Data Loggers

The Montana Immunization Program provides program-compliant digital Data Loggers to all VFC providers in Montana. Data Loggers are electronic thermometers that continuously record and store temperature data and indicate through a warning light when out-of-range temperatures have been encountered. Data Loggers interface with a computer so that data can be removed, reviewed, and saved.

Immunization Program Responsibilities

- The Immunization Program supplies Data Loggers for all public vaccine storage units and one backup free-of-charge to VFC providers in Montana. Each Data Logger comes with:
  - Instrument Calibration Report
  - Data logger cradle and attachment kit for mounting on outside of storage unit
  - Thermocouple probe housed in a glycol-containing bottle and connected to the Data Logger by a 10-foot wire. Acrylic stand for the glycol bottle
  - Extra battery
  - Free EasyLog® Software
  - Montana specific *Data Logger Instruction Manual*
- If a provider chooses to supply their own program-compliant thermometers, they must meet the requirements as defined above. The Immunization Program must approve provider-supplied thermometers and issue a memo exempting the provider from using a State-supplied Data Logger. To obtain thermometer approval, providers must submit to the Immunization Program:

  Requirement

  - One week of temperature recordings for each public vaccine storage unit

  - Thermometer product specifications
  - Current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report that meets CDC requirements.
  - Institutional policies on thermometer calibration, manual checking of temperatures twice daily, and out of range temperature response.
- The Montana Immunization Program provides training, technical support, and written instructions for using the Data Loggers.
- The Montana Immunization Program provides technical assistance to VFC providers in responding to temperature excursions.
- The Montana Immunization Program facilitates a recalibration program for State-supplied Data Loggers at the provider's expense (terms of recalibration may change year to year).
- As a quality control measure, the Immunization Program randomly requests temperature-monitoring information from providers.
- The Immunization Program reviews Data Logger data and approves storage units/thermometers for:
  - New VFC providers
  - Providers setting up a new VFC storage unit
  - Providers reinstating a VFC storage unit after a repair
  - Providers commissioning a new Data Logger or other program-compliant thermometer.

Provider Responsibilities

Listed below are the requirements of the Immunization Program Data Logger Program:

Requirement

- All VFC providers must use a State-supplied Data Loggers in each VFC vaccine storage unit unless they have an Immunization Program-approved thermometer that meets the VFC requirements as defined in this section.
- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software and a storage location for the Data Logger data.
- VFC providers must have all VFC vaccine storage units/thermometers approved for use by following the instructions on page 47 (*Storage Unit Approval*).
- Providers are responsible for Data Logger re-calibration and may use the state-facilitated re-calibration program or a vendor of their choice as long as they offer CDC-compliant calibrations.
- Providers must keep the State-supplied backup thermometer in a well-communicated location ready-to-use if needed.
- Retain paper temperature logs, trouble-shooting logs, and data logger data for three years.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the Immunization Program.

In the routine use of Data Loggers, providers must:

- Prior to first use and after each data download, use the provided software to set up and activate each Data Logger according to Immunization Program guidance.

- After activation, properly install the Data Logger in each VFC vaccine storage unit.
- Manually perform the daily temperature monitoring activities outlined in Section 13, (page 48 – *Routine Temperature Monitoring*) using the state-supplied data logger or other program-complaint thermometer.
- Respond to out-of-range temperature indications as outline in Section 13, (page 49 – *Out of Range Temperatures*).
- At the end of every month (prior to reconciling inventory and ordering vaccine) download, review, and save Data Logger data for the previous month. Save monthly Data Logger data and paper temperature logs for three years.

See the *Montana VFC Data Logger Instruction Manual* for specific details on setting up and using your Data Logger. A copy is available on our website at www.immunization.mt.gov under the "VFC" link.

ORDERING AND RECEIVING VFC VACCINE

Overview

Requirement

VFC providers are required to order and manage vaccine through imMTrax, the State immunization registry.

VFC vaccine orders are exported from imMTrax to the CDC ordering system and placed at McKesson, the CDC-contracted distributor of VFC vaccine. Refrigerated vaccine is shipped directly from McKesson to the provider. Varicella-containing vaccine, which must be kept frozen, ships directly from Merck to the provider and is not shipped from McKesson. Figure 3 is a general outline of the vaccine ordering and receiving process.

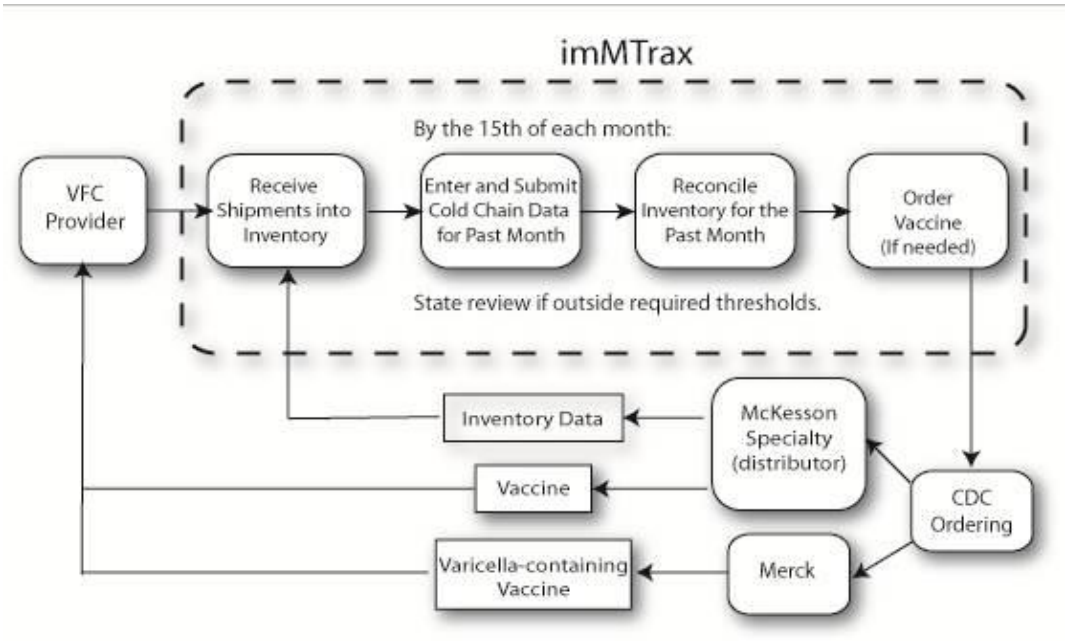


Figure 3 VFC Vaccine Order and Receiving Process

This handbook is not an in-depth imMTrax user's guide and will only outline the steps and policies associated with managing VFC vaccine in the system. Please contact the imMTrax Training and Support at 444-2969 (hhsiz@mt.gov) for more information on using imMTrax.

Ordering VFC Vaccine

Only staff with "Site Administrator" privileges in imMTrax can order and manage vaccine (contact imMTrax Training and Support 444-2969 hhsiz@mt.gov).

Requirement

You must complete two steps in imMTrax before you can order vaccine:

1. Certify cold chain information for the previous month (current to the day of submission)
2. Reconcile your VFC vaccine inventory within the last 14 days.

Cold chain certification, inventory reconciliation, and vaccine orders must be submitted by the 15th of each month. Cold chain certification and inventory reconciliation in imMTrax must be completed monthly regardless of whether you submit a vaccine order.

Requirement

Entering Vaccine Storage Units and Certifying Cold Chain

- To initially set up your storage units in imMTrax click **Manage Cold Chain>>>Add Unit.**
- To certify your cold chain prior to reconciliation and ordering, go to **Manage Cold Chain**, select a cold storage unit from the drop-down list, and click **Certify Temperatures**.
- Select the first option (radio button), if all of the conditions below are met:
  - The digital temperature data has been downloaded, reviewed, and archived with no out-of-range indications.
  - The following has been recorded twice daily on an immunization Program paper temperature log with no out-of-range indications:
    - Time of day
    - Staff initials
    - Status of the data logger LED (green or red)
    - Minimum, maximum, and current temperature every morning
    - Current temperature every evening
  - There have not been any changes, malfunctions, or repairs to this storage unit.
  - There have not been any staff changes to the Vaccine Manager or Alternate Manager positions at your facility.
- Click **Save and Submit**. You can now reconcile your inventory and order vaccine.
- If any of the conditions listed above are not met, you must select the second option and then provide an explanation in the text box at the bottom. Click **Save and Submit**. Your certification will be flagged for review, and you cannot reconcile your inventory until it has been approved by the Immunization Program.

Reconciling Inventory

Reconciling your inventory is simply accounting for the vaccine that was removed from your inventory during the previous month. You must have reconciled inventory within 14 days of placing a vaccine order.

- To reconcile inventory go to **Manage Inventory>>>Show Inventory>>>Reconcile**. You cannot reconcile your inventory if you have outstanding orders or transfers awaiting receipt (See the *Receiving Orders in imMTrax* and *Vaccine Transfer* sections, page 59 and 63, respectively).
- The first step in reconciliation is physically counting the vaccine in your storage units by lot number.
- The next step is entering doses administered into imMTrax for each vaccine by lot number. This can be done one of two ways depending on whether you are an integrated or aggregate user (See page 8 for definitions):
  - **Integrated users** enter patient immunization records into imMTrax throughout the month. During that process, vaccines are selected out of inventory. Integrated users simply have to keep their patient

immunization data entry up to date. During reconciliation, doses administered are automatically pulled into the reconciliation screen.

- **Aggregate users** must manually enter doses administered for the month by vaccine, by lot number, by age cohort. You do not need to enter doses by dose number. All data can be entered under Dose #1.

- Once entered (aggregate) or automatically imported from immunization records (integrated), doses administered will subtract from your starting inventory to give **Inventory on Hand**.
- Next, enter the results of your refrigerator count by vaccine, by lot number into the **Refrigerator Count** field.
- If your **Inventory on Hand** differs from your **Refrigerator Count**, the difference automatically calculates by dose and percentage in the **Adjustment** column. You then must investigate and correct the discrepancy. If it cannot be corrected, select the most appropriate reason for the difference in the **Reason** drop-down list.
- imMTrax will log you out of the system if it is idle for more than 30 minutes. If this happens, you may lose data. During data entry, click **Save and Finish Later** every 15 minutes to prevent this from happening.
- When you have entered your **Doses Administered** (aggregate users), **Refrigerator Count**, and **Adjustment Reasons** (if necessary) for all lots, hit **Save and Submit**.
- If your **Inventory on Hand** differs from your **Refrigerator Count** by more than the threshold set by the State, your reconciliation will be flagged for review. You will not be able to order vaccine until the State has reviewed your reconciliation.
- Once your reconciliation is submitted and approved (if necessary), you can order vaccine.

Placing Orders

Orders are placed online in imMTrax:

- Before placing a vaccine order, submit in imMTrax your cold chain certification and reconcile your inventory. See previous sections. You must have reconciled your inventory within 14 days of when you place your order.
- Order VFC vaccine **no more than once per month** and preferably once every three months. **Place orders between the 1st and 15th of each month**. More than one order per month may be allowed in emergencies. Non-emergency orders submitted after the 15th of the month will be held until the next ordering window (1st of the next month).

Requirement

- To place a vaccine order in imMTrax, under the “Inventory” heading on the left-hand menu, click **Manage Orders**. The “Orders/Transfers” screen will appear. Click **Create Order** in the upper right of the screen.
- A list of public vaccines available to your facility will appear. Enter the number of doses ordered in the **Order Requested** column. (The “Order Recommended” column is not functional at this time.)
- VFC vaccine must be ordered by the dose. Dose amounts ordered must be divisible by the package size listed in the “Packaging” column. Boxes cannot be broken down into smaller quantities.
- Once all vaccine order quantities are entered, click one of the following:
  - **Save Order** – Saves the order for submitting later. The “Orders/Transfers” screen redisplays and the order appears in the “Inbound Orders” section as “Saved, Not Submitted.” To access the order again, check the radio button next to the order on the “Orders/Transfers” screen, and click **Receive/Modify**. The order will reappear and can be edited, re-saved, or submitted.

  - **Submit Order** – Saves the order and submits it to the Immunization Program for review. The order then appears in the "Inbound Orders" section as "Submitted, Under Review."
  - **Cancel** – Does not save the order and returns to the "Orders/Transfers" screen. No order is created.
- Immunization Program reviews orders to ensure that they are:
  - Not over a three-month supply (including current inventory) based on doses administered entered during the month (integrated providers) or during reconciliation (aggregate providers).
  - Not over-ordering a single-antigen presentation when combination vaccines are in inventory (e.g., not over-ordering IPV if you have adequate Pediarix® or Pentacel® on hand).
- The Immunization Program may adjust orders that do not conform to the requirements listed above. We make every attempt to contact providers before modifying orders.
- Issues with order quantities may delay your order. Please strive to order a three-month supply of vaccine (including your current inventory) based on your usage history.
- Be sure to inform the Immunization Program of special circumstances such as campaigns or catch-up clinics where you need more vaccine than your usage history allows (hhsiz@mt.gov 444-5580).

Checking the Status of an Order

- Orders typically ship within 5–10 days from the time they are received at the Immunization Program.
- To check the status of orders, under the "Inventory" heading on the left-hand menu, click **Manage Orders**.
- Saved or submitted orders will appear on the "Orders/Transfers" screen under "Inbound Orders." The status of the order is listed under the "Order Status" column, and includes the following options:
  - **Saved, Not Submitted** – Order is saved, but not submitted to the Immunization Program for review. Provider can still edit order at this point. (See "Save Order" in section above.)
  - **Submitted, Under Review** – Order has been submitted to the Immunization Program for review but has not been placed with the CDC. The order can only be changed by the Immunization Program. To change an order displaying this status, contact the Immunization Program (hhsiz@mt.gov 444-5580).
  - **Approved for Shipment** – Order has been approved by the Immunization Program and sent to the CDC.
  - **Shipped** – Order has been fulfilled by the CDC and shipped to the provider. **DO NOT** "receive" orders in imMTrax until they have physically arrived at your facility and you have inspected the package and inventoried the contents.
- If you have additional questions about the status of your order, call or email the Immunization Program (444-5580 hhsiz@mt.gov).

Receiving Orders

- You must inform the Immunization Program (444-5580 hhsiz@mt.gov) if your vaccine shipping address or times you can receive vaccine shipments change.
- You should receive VFC vaccine 5–10 days after submitting your order. Varicella-containing vaccines ship from the manufacturer (rather than from McKesson) and may take longer to arrive.

- If you have not received your order in 10 days, check the status of your order in imMTrax (see previous section), or contact the Immunization Program (444-5580 hhsiz@mt.gov).

Receiving Vaccine Shipments at your Facility

Follow the procedures below when receiving vaccine shipments at your facility. Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day:

- **DO NOT leave vaccine deliveries unattended.** Check all deliveries immediately to determine if they are perishable vaccine and handle them according to the following instructions:

Requirement

- Inform front desk and supply personnel when vaccine deliveries are expected.
- Contact the designated Vaccine Manager or Alternate Manager when shipments arrive (See Section 12 for contact information).
- Place vaccine in an approved storage unit holding proper temperatures as soon as possible.
- Follow the instructions on the packing slip when unpacking vaccine shipments. Confirm that:
  - The package is not damaged or leaking
  - The shipping time was less than 48 hours (96 hours for varicella-containing vaccines). If the interval between shipment from the supplier and arrival of the product at the facility was more than these time frames, the vaccines could have been compromised during shipment. See “Problems with Orders and Shipments” below.
  - The temperature monitors (if present) are within acceptable temperature range
  - The vaccine quantities, diluents, lot numbers, and expiration dates match the packing list and imMTrax order.
  - Expiration dates are compared to current stock to ensure short-dated vaccines are used first.

Receiving Orders in imMTrax

You must “receive” VFC vaccine orders in imMTrax for them to appear in your inventory.

Requirement

- To electronically receive VFC vaccine orders, under the “Inventory” heading, click **Manage Orders**. The “Orders/Transfers” screen will appear.
- Under “Inbound Orders,” select the radio button next to your VFC vaccine order. The “Order Status” must show as “Shipped” in order to receive it. Click **Receive/Modify**. The list of vaccines approved for order by the Immunization Program will appear, including receipt quantities, lot numbers, and expiration dates.
- Non-varicella-containing vaccines ordered, but not shipped will have an “N/A” in the “Receipt Quantities” column.
- Compare the imMTrax inventory list to your packing slip and the vaccines in the shipment.
- Then click one of the following:
  - **Accept Order** – Click **Accept Order** if the doses in the “Receipt Quantities” column match those on the packing slip and in the shipment. Vaccines not shipped (“N/A” designation) will not be accepted, but will remain in the “Inbound Orders” until shipped.

    Varicella-containing Vaccines:

  - Varivax® and ProQuad® may show as shipped before they arrive at your facility. DO NOT ACCEPT ProQuad® and Varivax® shipments until they physically arrive at your facility. Use the Partially Receive option (below) until they arrive.
  - When accepting varicella-containing vaccines (after they have arrived at your facility), DO NOT EDIT the receipts quantities, lot number, or expiration date. This information imports directly from Merck and should match your packing slip and shipment.
- **Reject Order** – Never reject an order without first contacting the Immunization Program (hhsiz@mt.gov or 444-5580)
- **Partially Receive** – Use this option to accept shipment of refrigerated vaccines when varicella-containing vaccines have not arrived yet. Change the "Receipt Quantities" on the ProQuad® and Varivax® to "0" and then click **Partially Receive**. The varicella-containing vaccines will remain in the Inbound Orders, and can be accepted when they arrive at your facility.
- **Cancel** – To take no action and return to the "Orders/Transfers" screen.

- Accepted/received vaccines will automatically appear in your public vaccine inventory. To confirm that your inventory was added, under the "Inventory Heading," click **Manage Inventory>>>Show Inventory**.

Problems with Orders and Shipments

- Never reject VFC vaccine delivery or discard VFC vaccine shipments.
- If you believe your vaccine order was compromised during shipment, *immediately* store the vaccine under appropriate conditions separate from other stock, mark "DO NOT USE," and call the McKesson Specialty Contact Center (MSCC) at 1-877-836-7123. Viability calls must reach MSCC the same day the vaccine arrived at your facility or the CDC, Immunization Program, and your facility may be liable for vaccine replacement, regardless of the cause of the temperature excursion.

Requirement

- If you encounter problems other than viability issues, call or email the Immunization Program (444-5580 hhsiz@mt.gov).
- Please note that VFC vaccine orders may have been adjusted to conform to the ordering requirements specified in this section. We make every attempt to contact providers before modifying orders. Contact the Immunization Program if you have questions.

Seasonal Influenza Vaccine Orders

The Immunization Program must pre-book seasonal influenza vaccine months in advance and distribute doses during the season as it becomes available. For this reason, we manage influenza vaccine differently than other publicly supplied vaccine:

- The Immunization Program distributes an influenza vaccine order form mid-summer of every year. It lists the vaccine offerings for the coming season and instructions for returning the form to the Immunization Program.
- The influenza vaccine order form must contain your order for the entire season and be returned by the submission deadline in order to reserve your vaccine for the season.

Requirement

- As influenza vaccine becomes available at McKesson, we ship allocations to our providers. Shipments typically begin the first of September and last through December, until all orders are fulfilled. You may not receive your entire order at once.

- After orders are fulfilled, we often have extra doses available on a first come, first serve basis.
- Seasonal influenza vaccine expires in June. DO NOT discard expired influenza vaccine. It must be returned to McKesson following the procedure outlined in Section 16.
- Contact the Immunization Program (444-5580 hhsiz@mt.gov) with questions about influenza vaccine orders.

MANAGING INVENTORY

Please follow the guidelines below in managing your vaccine inventory.

Organizing and Rotating Stock

Requirement

- Physically differentiate VFC vaccine from private and other public stock vaccine.
- Develop a system so that short-dated vaccines (those that expire at the earliest date) are used first. (Record your inventory management process in Section 12).
- Recently received vaccine may outdate sooner than vaccine already in your inventory. Check expiration dates carefully.
- Also see Section 13, *Vaccine Placement* (page 54) for additional guidance on organizing your vaccine inventory within your storage units.

Short-dated Vaccine

Requirement

- Providers must check vaccine expiration dates and remove expired vaccine from viable vaccine weekly.
- Vaccine that will expire in 75 days turns pink in your imMTrax inventory.
- If vaccine is within 3 months of expiring and you will not use it in that timeframe, contact other VFC providers in your area to see if they can use it. If another provider can use the vaccine, follow the guidelines below (Vaccine Transfers) when transferring the vaccine.
- If you cannot find a VFC provider in your area that can use the vaccine, contact the Immunization Program for assistance in rehoming the vaccine.
- Do not transfer short-dated vaccine to providers without first contacting them to see if they can use it before it expires.

Vaccine Transfers

The CDC discourages regular transport of vaccines. “Transport” is defined as the movement of vaccine between VFC providers using private vehicles or couriers where the expected duration of transport is less than eight hours or a regular business day. Transporting vaccine may be necessary, however, during emergencies, for off-site immunization clinics, or to prevent spoiled vaccine due to expiration.

Requirement

Follow the procedure below when transferring vaccine between providers:

- Transfer VFC vaccine between currently enrolled VFC providers only.
- Vaccine transfers between VFC providers must be approved by the Immunization Program prior to physically exchanging the vaccine.
- To request approval, the transferring facility initiates a vaccine transfer in imMTrax by navigating to **“Manage Transfers,”** picking the receiving provider from the drop-down list, and entering the doses of vaccine to be transferred. Click **Submit Transfer**.

- imMTrax notifies the Immunization Program that a transfer is waiting for approval and, if appropriate, approves the transfer. The transferring and receiving providers are notified by email when their transfer is approved.
- Once approved, the receiving provider receives the vaccine in imMTrax by navigating to **Manage Orders**, selecting the radio button next to the inbound transfer and clicking **Receive/Modify**. This transfers the vaccine into the inventory of the receiving facility. Modify the transfer amount if needed.
- Follow the *Vaccine Management Plan* (Section 12) when packing vaccine for transfer.
- Limit transfers to those that can be personally carried and where the vaccine can reach an approved storage unit within 8 hours or a regular business day.
- Montana VFC Providers are prohibited from "shipping" vaccine, which the CDC defines as moving vaccine using a commercial carrier over a longer timeframe than 8 hours. If you have a situation that requires "shipping" vaccine, contact the Immunization Program.
- Do not transfer opened multi-dose vials.

Expired, Spoiled, and Wasted Vaccine

Expired, spoiled, and wasted vaccine is nonviable and should never be administered to patients. Providers must check expiration dates weekly and immediately remove expired, spoiled, and wasted vaccine from active stock.

All nonviable vaccine must be reported to the Immunization Program on a Wasted and Expired Vaccine Form. The reporting process differs depending on the type of nonviable vaccine and is detailed below:

Requirement

Wasted Vaccine – Nonviable vaccine that cannot be returned to McKesson because the packaging has been breached (e.g., broken vials/syringes; vaccine drawn but not administered; nonviable, opened multi-dose vials).

1. Fill in the first table in the Wasted and Expired Form. Leave "10" in the Reason Code column. Use the NDC on the vaccine package or packing slip (not on the syringe/vial).
2. Return form to the Montana Immunization Program.
3. Discard product per your facility guidelines.
4. Account for the wasted vaccine in imMTrax during your monthly reconciliation (See Section 15).

Expired or Spoiled Vaccine–Nonviable vaccine with packaging intact that can be returned to McKesson (e.g., expired/recalled vaccine, vaccine spoiled by cold chain failures). DO NOT DISCARD expired/spoiled vaccine.

1. Fill in the second table in the Wasted and Expired From. Enter the most appropriate number in the Reason Code column. Use the NDC on the vaccine package or packing slip (not on the syringe/vial).
2. Indicate the number of shipping labels needed. One label per shipping container.
3. Return form to the Montana Immunization Program. Once processed, we will email you a print-screen of the return inventory and McKesson Specialty Care Dist will email you a shipping label.

4. Print the print-screen and place in the shipping container with your vaccine. The vaccine in the container must match the information on the print-screen EXACTLY. Print and attach the shipping label to the outside of the container. Call for a UPS pickup.
5. You must return expired/spoiled vaccine within 6 months of the spoilage or expiration.
6. Account for the wasted/expired vaccine in imMTrax during your monthly reconciliation (See Section 15).

Borrowing

Vaccine "borrowing" is the temporary transfer of vaccine between public and private stock at a VFC provider facility in order to avoid a missed opportunity to vaccinate. VFC providers are required to maintain adequate inventory of public and private vaccine to meet the needs of their patients.

Allowed Borrowing Circumstances

Borrowing should not be a routine vaccine management practice and is only allowed under the following circumstances:

Requirement

- Lack of stock due to vaccine shipment delays
- Vaccine not useable on arrival (e.g., vials broken, temperature issue)
- To use short-dated stock before it expires
- Accidental use of wrong stock
- VFC seasonal influenza vaccine not yet available or delayed at the *beginning* of influenza season (any other borrowing of influenza vaccine is prohibited)
- To repay stock when insurance billing reveals that the patient is uninsured or underinsured (FQHC/RHC only) in respect to the vaccine given (See Section 4 for VFC definitions of uninsured and underinsured).

Borrowing VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination.

Borrowing Documentation

Use the following procedures to track vaccine borrowing:

Requirement

- Document borrowing and payback on the VFC Vaccine Borrowing Report, available on our website. The instructions are on the report.
- You must retain borrowing reports for three years and make them available for review during VFC site visits or upon request. Do not submit borrowing reports to the Immunization Program unless requested to do so.
- Retain all vaccine purchase receipts for vaccine used in borrowing payback and make them available for review during VFC site visits or upon request.

Managing Borrowing in imMTrax (Also see Borrowing Cheat Sheets for integrated and aggregate users on our website.)

- imMTrax does not allow the transfer of vaccine between public and private stock. If a vaccine is entered into your inventory as public vaccine, it must remain public vaccine. Private vaccine must remain private vaccine.

- ImMTrax will allow you to administer a public vaccine to a private-pay patient and vice versa, in order to “pay back” the vaccine.
- Private vaccine used to “pay back” borrowed doses must be managed in imMTrax.
- You must have paper borrowing reports to support these transactions.
- All borrowing should be paid back (returned to appropriate stock) within three months of the initial transaction or at the first opportunity, whichever comes first.

Contact imMTrax Training and Support at 444-2969 (hhsiz@mt.gov) for detailed imMTrax support.

VACCINE LOSS AND REPLACEMENT

Requirement

Providers may be required to:

- Replace vaccine lost due to negligence, non-compliance, fraud, or abuse
- Incur the cost of re-vaccination due to negligence.

Providers must consult with the Immunization Program before making determinations about vaccine viability following a temperature excursion.

Situations That May Require Vaccine Replacement

Provider Negligence

Listed below are situation considered to be "provider negligence" and may require vaccine replacement if they result in vaccine loss. This list is not exhaustive. Failure of a provider or staff to adhere to any provision of the current *Montana VFC Handbook/Vaccine Management Plan* may result in a replacement situation. Situations not listed here will be considered on an individual basis by the Immunization Program.

- Failing to log temperatures twice daily during normal operating hours
- Failing to properly install and manage State-supplied Data Loggers or otherwise compliant thermometers (See Section 14 – Thermometer Policy)
- Falsely certifying cold chain documentation in imMTrax
- A contracted alarm/alert company failing to notify the provider of malfunctioning equipment or out-of-range temperatures as required
- Failing to notify the Immunization Program of a change in VFC vaccine management personnel (Vaccine Manager and Alternate VFC Vaccine Manger)
- Preparing vaccine for administration prior to patient screening
- Storing VFC vaccine in prohibited storage units
- Storing VFC vaccine in a storage unit that has not been approved by the Immunization Program.
- Failing to receive and properly store vaccine delivered during designated delivery hours
- Failing to take action to protect vaccine after becoming aware of out-of-range temperatures, equipment malfunctions, or electrical supply issues
- Storing vaccine at improper temperatures (e.g., leaving vaccine at room temperature, storing frozen vaccine in the refrigerator or refrigerated vaccine in the freezer)
- Staff, maintenance workers, or contractors purposefully interrupting storage unit electrical supply without taking action to protect vaccine
- Leaving a storage unit door ajar
- Failing to contact the MSCC (1-877-836-7123) the same day an order arrives at your facility when you suspect it was compromised during shipment

- Failing to provide proof of repair or replacement within 30 days of discovering a storage unit equipment failure
- During a power outage, failing to protect vaccine according to the posted emergency plan when it is safe and possible to do so

Provider Fraud and Abuse

VFC providers are required to replace vaccine lost due to substantiated instances of program fraud and abuse. See Section 9 – Non-compliance, Fraud, and Abuse for more information.

Situations That Do Not Require Vaccine Replacement

Listed below are situations where providers are deemed not at fault and that are not considered "provider negligence." This list is not exhaustive. Providers may be required to produce a letter from the power company or alarm company.

- Vaccine shipments not delivered in a timely manner, delivered outside designated delivery hours, or otherwise damaged or stored improperly during transit and where the provider called the MSCC (1-877-836-7123) as soon as the incident was discovered.
- A provider following their emergency plan in response to a power failure, but their alternate location is inaccessible or without power
- Provider prevented from following their emergency plan due to safety or access issues
- Vaccine accidently broken or dropped
- Vaccine prepared for administration after patient screening but not administered due to parental refusal or a change in physician orders
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Program within 30 days from the date of discovery
- Extraordinary situations not listed above that are deemed by the Immunization Program to be beyond the provider's control.

Procedures for Vaccine Replacement

- The Immunization Program considers the evidence surrounding each situation when determining whether vaccine must be replaced. The evidence includes but is not limited to provider communications, Immunization Program staff observations, data logger data, Vaccine Incident Reports, provider temperature logs, imMTrax cold chain data, wasted and expired forms, imMTrax inventory records, eligibility screening documents/data, and borrowing reports.
- If replacement is required, the Immunization Program will notify the provider in writing including the vaccine, number of doses, monetary value, and reason restitution is requested.
- Providers must reimburse public vaccine dose-for-dose with vaccine from private stock. Monetary payment directly to the Immunization Program is not allowed. Within 90 days, providers must report the replaced doses on a Vaccine Restitution Report and may be required to provide copies of purchase invoices.

Requirement

SPECIALTY PROVIDERS

Specialty providers who serve a unique client base and offer only a subset of pediatric vaccines are eligible for the VFC Program. Specialty providers participating in the Montana VFC Program are listed below along with any special requirements unique to their situation. Unless otherwise noted below, specialty providers must follow all VFC requirements outlined in this handbook.

Requirement

Family Planning Clinics

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

Family planning clinics have the following unique VFC requirements:

- Vaccine offerings at family planning clinics are limited to those relevant to their client base, such as human papilloma virus (HPV) and hepatitis B.
- Family planning clinics can administer VFC vaccine to an additional eligibility category:

  Requirement

  Unaccompanied minors less than 19 years of age who present at family planning clinics for contraceptive services or sexually transmitted disease (STD) treatment who do not know their insurance status or choose not to access their insurance due to the confidential nature of their visit (See note below).
- Family planning clinics must screen for this special eligibility category and document VFC vaccine given to this population per current Immunization Program instructions. The Immunization Program offers a special eligibility screening log for family planning clinics that captures this information. Contact the Immunization Program for current forms and procedures (444-5580 hhsiz@mt.gov).
- **Please Note**: The VFC Program does not regulate the issue of medical consent for the provision of medical care to minors. Clinics are responsible for providing care in conformance with Montana's medical consent laws as they pertain to minors.

Birthing Hospitals

Hepatitis B vaccination is recommended for all infants soon after birth and before hospital discharge. The Montana Immunization Program funds a universal hepatitis B birth dose vaccine program for all infants born in the state. Because this program is partially funded through the VFC Program, Montana birthing hospitals must be enrolled in the VFC Program and fulfill all program requirements in order to receive publicly-supplied vaccine.

- Hepatitis B birth dose is the only publicly funded vaccine available to birthing hospitals.
- Because all newborns qualify for the vaccine, birthing hospitals are not required to screen patients for VFC eligibility prior to administering the vaccine. However, birthing hospitals must track birth dose recipients by VFC eligibility category using one of the methods described in Section 4 – Eligibility.

  Requirement

- Like all VFC providers, birthing hospitals must manage their vaccine orders, inventory, and cold chain in imMTrax either as integrated (entering patient-level information) or aggregate users (entering only aggregate doses administered). See Section 1, page 8 for definitions.
- Birthing hospitals must use State-supplied data loggers in all VFC vaccine storage units or provide their own approved, program-compliant thermometer as outlined in Section 14.

Pharmacies

Montana pharmacies are allowed to provide influenza immunizations to children 12 years and older and must enroll in the VFC Program in order to serve Medicaid (and other VFC-eligible) children.

- Pharmacies must agree to vaccinate all “walk-in” VFC-eligible children and not refuse to vaccinate VFC-eligible children based on a parent’s inability to pay the administration fee. **Requirement**
- Pharmacies must participate in imMTrax as integrated providers or submit immunization records through an electronic data exchange. The timeline for establishing an electronic data exchange with imMTrax depends on the availability of State resources. **Requirement**
- Pharmacies must use State-supplied data loggers in all VFC vaccine storage units or provide their own approved, program-compliant thermometer as outlined in Section 14. **Requirement**

VFC Provider Education Requirements

Montana Immunization Program is required to provide annual education to Vaccines for Children (VFC) providers on the basics of the VFC Program and vaccine storage and handling.

- To fulfill this requirement, vaccine managers and alternate vaccine managers at VFC provider facilities must participate in the Montana Immunization Program Annual Provider Training webinar and submit a knowledge test.

Requirement

- You must complete the education requirement prior to re-enrollment at the turn of each calendar year. Your facility cannot re-enroll in the VFC program until the education requirement is complete.
- Each year, the Immunization Program sends an all-VFC provider email detailing how to complete the annual Provider Education Requirement.

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APPENDIX–SUMMARY OF HANDBOOK CHANGES (2015–17)

VFC requirements underlined and marked with a red arrow ( ) throughout document.	Date of Change	Page
Section 1–Introduction		
Section 2–Provider Enrollment		
• Updated to match current Site Contract in imMTrax	July 2015	9–11
Section 3–Billing		
Section 4–Eligibility		
• Revised eligibility screening documentation guidance	July 2015	17–18
Section 5–ACIP		
Section 6–NCVIA		
Section 7–VFC Compliance Site Visits		
• Revised to include PEAR requirements	July 2015	24
Section 8–VFC Requirement Checklist		
Section 9–Non-Compliance, Fraud, and Abuse		
• Revised to include PEAR definitions and escalated follow-up	July 2015	26
Section 10–Immunization Resources		
• Added online Vaccine Incident Report	July 2015	29
Section 11–Vaccine Management Plan Introduction		
Section 12–Vaccine Management and Emergency Plan		
• Updated to include new pack-out recommendations from CDC	May 2016	39–41
• Revised to include new CDC guidance on refrigerated vaccine temperatures	July 2016	39,41
Section 13–Vaccine Storage Units		
• Revised to include current CDC recommendations	July 2015	43–44
• Revised to include new CDC guidance on refrigerated vaccine temperatures	July 2016	43,46
Section 14–Thermometer (Data Logger) Policy		
Section 15–Ordering and Receiving Vaccine		
Section 16–Managing Inventory		
Section 17–Vaccine Loss and Replacement		
Section 18–Specialty Providers		
Section 19–VFC Provider Education Requirements		
• Revised to remove You Call the Shots and add MT IZ Webinar	May 2016	71
Appendix		
• Removed previous years' changes	July 2015	75
• Added March 2016 revisions	May 2016	73