Montana Department of Public Health and Human Services

Immunization Program

Provider Handbook/ Vaccine Management Plan

PO Box 202951
1400 Broadway
Helena, Montana 59620
406.444.5580
hhsiz@mt.gov
www.immunization.mt.gov

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

Updated 03/2013

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VFC Provider Handbook

1. 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 four main sources: VFC, Section 317 of the US Public Health Service Act (317), State appropriations, and occasionally, Federal grants. 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, however, may differ in vaccine offerings, eligible populations, and reporting requirements, and vary from year to year in response to State and Federal budgets, available grants, and public health concerns. Please contact the Immunization Program for information on current publicly funded vaccine programs in Montana (444-5580 hhsiz@mt.gov).

imMTrax – Ordering and Managing Publicly Funded Vaccine

Montana VFC providers order and manage publicly supplied vaccine through the State's web-based immunization registry, imMTrax. To gain access to imMTrax, providers must sign an imMTrax Memorandum of Agreement for their facility and System Access Requests for each person wanting access to the system.

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

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 must track doses administered and VFC eligibility status outside of imMTrax (see Section 4 for approved tracking methods). Once per month during inventory reconciliation, aggregate providers must 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. Detailed imMTrax instructions can be found in the *imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml). Or you may contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

VFC Document Retention

VFC providers must retain all VFC-related documents and electronic information for three years. This includes eligibility screening records, temperature logs, borrowing forms, data logger (digital thermometer) data, and any forms or reports specific to your facility.

This Document

This handbook is organized in numbered sections and divided into two main parts**:** the ***VFC Provider Handbook*** (Sections 1–10) and the ***Vaccine Management Plan*** (Sections 11–17). Forms used in the VFC Program change frequently and are not included in this handbook. You can find current forms at www.immunization.mt.gov under the VFC link or contact the Immunization Program at 444-5580. A list of forms provided on our website can be found in Section 10 – Immunization Resources.

The Montana Immunization Program provides a paper copy of this document to all enrolled providers and posts the most current version on our website. Sections are revised individually and have a revision date at the bottom of each page. 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.

2. 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. Any Montana health care provider licensed, in good standing, and with independent prescription writing authority for vaccines can enroll in the VFC Program. This includes both public and private facilities and those not registered as Medicaid providers.

VFC providers must have equipment capable of properly storing vaccines as defined by the Montana *Vaccine Management Plan* (contained in this handbook starting with Section 11) and must be willing to implement VFC Program requirements at their facility. Providers should determine if they serve a sufficient number of eligible patients to justify enrollment in the program (see Section 3 – VFC Eligibility).

Individuals and facilities on the "List of Excluded Individuals and Entities" published by the Department of Health and Human Services Office of the Inspector General (http://exclusions.oig.hhs.gov/) are prohibited from participating in federally funded health care programs, including the VFC Program. The Montana Immunization Program must terminate or decline to enroll any provider that is on the list or employs a person on the list.

Re-Enrollment – Current Providers

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

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

- **Provider Contact Information** – This information will automatically fill in from your imMTrax account information. Review and update, if necessary.
- **List of Providers and Clinicians** – This information will automatically fill in from your imMTrax account information. Medical license numbers are required for providers. Review and update, if necessary.
- **Provider Profile** – This portion of the contract contains immunization patient numbers for your facility by age group and VFC eligibility status. Patient numbers will automatically populate in the table. The source of the numbers differs depending on whether you are an integrated or aggregate provider (see page 10 for definitions):
    - **Integrated Providers** – Profile numbers are drawn from immunization records entered over the past year. Integrated providers must have data entry up to date and client VFC eligibility status accurately designated.

- **Aggregate Providers** – Profile numbers come from the previous year's site contract. Please update this information using your eligibility screening documentation from the past year (See Section 4 – Documenting Eligibility Screening).

- **Vaccine Management Information** – Review and update, if necessary, the name of your primary and alternate VFC Vaccine Managers and your plan for safeguarding your vaccine in the event of an emergency. (This is also a good opportunity to update, review, and post information in Section 12. See page 43).
- **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.
- **Fulfillment of Provider Education Requirement** – Beginning in 2014, providers must certify in their site contract that their VFC Vaccine Manager and Alternate Vaccine Manager have fulfilled the annual education requirement. Providers cannot re-enroll until the education requirement has been completed (see Section 19 for more details on the annual education requirement).

Providers must notify the Immunization Program any time during the year if:

- Their contact information, vaccine management personnel, or vaccine shipping instructions change
- The medical director (or equivalent) changes
- Their providers and 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.

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:

- **VFC Enrollment Packet** – A VFC enrollment packet will be mailed to you prior to enrolling and contains information and forms pertaining to the VFC Program. Please review this material before your enrollment visit.
- **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. Ideally, enrollment visits are conducted in person, but they may be done over the phone, through online video conferencing, or online video with a local health department representative inspecting your vaccine storage equipment.
- **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 are required to 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.

- **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 (444-4560).
- **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) on all VFC vaccine storage units and cannot receive VFC vaccine until the Immunization Program reviews the data and approves the storage unit (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.

Inactivation

Inactivation from the VFC Program is defined as a temporary suspension from vaccine ordering. Providers may request to be inactivated or the Montana Immunization Program may inactivate a provider for not complying with program requirements. As long as VFC vaccine is in inventory, facilities must follow the storage and handling requirements described in this handbook.

Inactivation is considered a temporary situation, with the expectation that the situation warranting inactivation can be quickly remedied. Inactivated providers may be required to return all VFC vaccine and State-supplied equipment per State instructions.

Termination

Termination from the VFC Program is the permanent removal of a provider from the program. Providers may choose to be terminated from the VFC Program or the Montana Immunization Program may terminate providers due to repeated non-compliance issues that have not been appropriately addressed or a permanent condition such as being listed on the “List of Excluded Individuals and Entities” (see Section 2 – Provider Enrollment).

Terminated providers are required to account for all VFC vaccine and return State-supplied equipment per State instructions. Once all vaccine and equipment has been accounted for, the Immunization Program will issue 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.

See Section 9 – Non-Compliance, Fraud, and Abuse for more details on program inactivation and termination.

3. BILLING

The main premise of the VFC Program is to supply vaccine at no cost to eligible children.

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:

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.
- 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.

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, page 62, for options for adjusting inventory to correct for improperly billed vaccine.

4. VFC ELIGIBILITY

Our budget depends on VFC vaccine being administered only to eligible children. Screening for eligibility is the foundation of accountability in the program**.**

VFC providers are required to screen ALL patients for VFC eligibility and document the results at every immunization visit. 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).

[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.

To find your nearest FQHC go to: http://findahealthcenter.hrsa.gov/Search_HCC.aspx?byCounty=1.

To find your nearest RHC go to: http://www.mtpca.org/rhc.htm.

Insured Children

Insured children are not eligible for the VFC Program. For purposes of the VFC Program, a child is considered insured if he or she has private health insurance that fully or partially covers the cost of recommended immunizations—even if some combination vaccines are excluded. Insured children are not eligible for the VFC Program even when claims for vaccination services are denied because of unmet deductibles.

Documenting Eligibility Screening

Eligibility screening and documenting must occur at every immunization visit. Federal law requires the maintenance of eligibility screening records for three years and that this information be made available to Montana Immunization Program staff on request and during site visits.

Acceptable Methods of Documenting Eligibility Screening

Integrated Providers

imMTrax – Integrated providers document VFC eligibility status when recording patient immunizations in imMTrax. This information is available to anyone viewing the record and is attached to each immunization. It can be updated if eligibility status changes.

Aggregate Providers (including providers on electronic data feeds)

Aggregate providers cannot document VFC eligibility in imMTrax, and electronic data feeds do not send eligibility information at this time. Therefore, these clinics must document VFC eligibility outside imMTrax in a manner that is traceable to the patient's paper or electronic health record. Eligibility documentation must be recorded at every immunization visit.

Clinics no longer maintaining paper charts and unable to capture this information in their electronic health record (EHR), can use the State-supplied paper screening logs to document eligibility screening as long as they capture ALL immunization visits, not just VFC-eligible patients.

Special Circumstance – Comprehensive Screening Form

Providers whose client base is exclusively Medicaid-eligible or American Indian/Alaskan Native can submit a comprehensive screening form once per year during their enrollment. Submission of this form releases them from having to screen for eligibility at each immunization visit.

Contact the Montana Immunization Program if you would like additional information about eligibility screening and documentation options – 444-5580 hhsiz@mt.gov.

Provider Profiles – 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, by VFC eligibility category (See Section 2 – Re-enrollment–Current Providers). This information constitutes your "Provider Profile" and must be derived from actual immunization data. Providers must document eligibility screening throughout the year so the information can be used to estimate your provider profile. The Immunization Program recommends using one of the methods below to determine provider profile numbers.

Integrated Providers

For integrated providers, imMTrax automatically calculates provider profile numbers based upon immunization records entered throughout the year. For the numbers to be accurate, integrated providers must document VFC eligibility properly and keep data entry up to date. For more information on using imMTrax to document VFC eligibility please see the *imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

Aggregate Providers

Aggregate providers can use one of the following methods to determine provider profile numbers:

State-Supplied Eligibility Form – The Immunization Program provides paper-based eligibility tracking logs on our website (www.immunization.mt.gov). To use the log, for each immunization visit enter patient name, date of birth, VFC eligibility status, and administered vaccines. From this information, you can tally patient numbers for re-enrollment and doses administered for order quantities.

There are four versions of this form based on facility type. Be sure to use the form that best suits your practice.

Clinic Computer-Generated Report – For clinics on EHRs or electronic billing systems, the recommended method for determining provider profile numbers is to generate a custom report from you clinic electronic charting or billing system. The report must be able to tally immunization patient numbers by ALL VFC eligibility categories for a given period of time.

Special Eligibility Circumstances

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 1 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.

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 2 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

Population	Facility Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee[1]
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 know their insurance status 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. This information is not captured in imMTrax and must be tracked manually. The Immunization Program has a special eligibility screening form for family planning clinics to track this information. The form can be found on our website at www.immunization.mt.gov under the VFC link.

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) are often 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 3 VFC Eligibility for American Indian and Alaskan Native Populations

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

Population	Facility Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee[1]
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.

5. Advisory Committee on Immunization Practices

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 (http://www.cdc.gov/mmwr/) 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 website at http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm.

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. As a VFC provider, you will be notified when new and amended ACIP recommendations and VFC resolutions become available.

ACIP Recommendations

VFC providers agree to comply with immunization schedules, dosages, and contraindications established by the ACIP and included in the VFC program unless:

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

6. 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.**

VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on their website at http://www.cdc.gov/vaccines/pubs/vis/default.htm .

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. The VAERS website is: http://vaers.hhs.gov/professionals/index.

Reportable Events – Required

The NCVIA requires health care providers to report:

- 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 (http://www.immunize.org/handouts/document-vaccines.asp) provides free immunization charts (downloadable as PDFs) that capture all the information required by the NCVIA.

7. 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 advanced stages of corrective action. Please refer to Section 9 for more 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

VFC providers in Montana can expect a site visit from the Montana Immunization Program **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.

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. A work space large enough for a laptop computer
    c. Three months of temperature logs and Data Logger data from your vaccine storage units
    d. Your completed and annually reviewed *Vaccine Management Plan*
    e. VFC eligibility screening documentation (if not recorded in imMTrax)
    f. Borrowing reports (if applicable)
    g. Your paper stock or electronic source of VISs
    h. Any VFC-related documentation requested during the visit.

5. Approximately one hour of the site visit will be one-on-one with your vaccine manager. Immunization Program staff will ask questions pertaining to the practices at your facility for implementing the VFC Program. They will also inspect your vaccine storage units.

6. After the one-on-one with the vaccine manager, the Immunization Program staff can work independently as they enter data into their computer.

7. At the end of the visit, you will receive feedback on your compliance with the VFC Program and a list of any required corrective action plans and deadlines for completion.

Site Visit Follow-Up

8. Within one month of your visit, you will receive a follow-up letter from the Immunization Program detailing the results of your VFC visit. It will reiterate any VFC compliance issues, corrective action plans, and deadlines from your site visit.

9. In order to remain in good standing with the VFC Program, you must carry out corrective actions by the deadline. Immunization Program staff will follow up by telephone and email.

10. Immunization Program staff may return to your facility for an educational site visit to address major or complex VFC non-compliance issues.

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. The visit will take no longer than 30 minutes and will focus on vaccine storage and handling practices, including an inspection of the VFC vaccine storage units at your facility.
- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance.

- **Provider Request** – Providers may request an educational visit from the Montana Immunization Program at any time. Educational visits are useful when there has been a change in staff, location, or management. Educational visits are dependent on availability of Immunization Program staff and can also be conducted by telephone or web conferencing.
- **Non-Compliance Response** – An educational visit may occur in response to provider non-compliance. The visit will focus on correcting the specific compliance issue.

- **Enrollment Visits** – Enrollment visits occur during the enrollment process, See Section 2 – Provider Enrollment for more information on VFC Program enrollment.

8. VFC Requirement Checklist

Below is a checklist of VFC requirements by frequency, which can be used to assess your compliance with the program.

Table 4 VFC Requirement Checklist by Frequency

X	VFC Requirement by Frequency	More Information
Once (upon enrollment or as needed)		
	Submit Site Contract, imMTrax MOA, and System Access Requests.	Sections 2,12
	Receive VFC PIN # and imMTrax login credentials.	Sections 2,15
	Set up vaccine storage units/thermometers according to the *Vaccine Management Plan.* Submit one week of temperature data for approval. Login to imMTrax and set up cold storage units.	Sections 13,14
	Post "DO NOT UNPLUG" signs on outlets and circuit breakers serving vaccine storage units.	Section 13
	Review *Vaccine Management Plan* with staff. Document the review in Section 12. Copy and post completed Section12 on vaccine storage units.	Sections 11,12
	Fulfill Vaccine Manager and Alternate Manager education requirement.	Section 19
Every Vaccination Visit		
	Screen for VFC eligibility and document using an approved method.	Section 4
	Distribute 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 (paper logs can be downloaded from www.immunization.mt.gov).	Sections 13,14
Monthly (by the 15th of every month)		
	Download and save Data Logger (thermometer) data for the previous month.	Section 14
	Enter monthly cold chain data into imMTrax (if not entered twice daily) and submit to the State.	Section 15
	Reconcile inventory in imMTrax for the previous month.	Section 15
	Order vaccine per State instructions (must have reconciliation 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		
	Document all storage unit temperature excursions either with Vaccine Incident Report or entry in trouble-shooting log.	Section 13
	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 one week of temperature data for new or repaired storage units prior to using appliance.	Sections 13,14

9. Non-Compliance, Fraud, and Abuse

By submitting a Site Contract in imMTrax and accepting shipment of VFC vaccine, you are agreeing 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 must enforce compliance.

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 data. All circumstances are unique, making it difficult to develop a set of rules for handling all situations. We also recognize our obligation to communicate effectively to providers about VFC Program requirements and incidents of non-compliance.

Policy – Non-Compliance

The primary response of the Montana Immunization Program to non-compliance is education, which progresses through three levels as defined below:

- **Site Visit Technical Assistance** – Site visit technical assistance occurs when minor compliance issues are corrected during a site visit and no corrective action from the provider is required. If subsequent follow-up indicates that the issue has not been corrected, the compliance issue progresses to the secondary education level.
- **Secondary Education** – Secondary education focuses on a specific non-compliance issue and includes a corrective action plan for the provider. Secondary education can occur in person during a regular compliance site visit but may occur via telephone or email. If the corrective action plan is not completed and/or the issue is not corrected, providers are inactivated from vaccine ordering, and the issue progresses to the tertiary education level.
- **Tertiary Education** – Tertiary education involves a focused site visit directed at a specific non-compliance issue and a corrective action plan for the provider. If the corrective action plan is not completed and/or the issue is not resolved at this level, the provider is terminated from the VFC Program and possibly referred to the Medicaid Integrity Group for investigation for fraud and abuse.

In general, providers are given three opportunities to correct non-compliance issues before being inactivated or terminated. When responding to non-compliance issues, the Immunization Program considers extenuating circumstances, whether it is a high-priority issue, and whether the non-compliance is intentional, negligent, or simply an error due to lack of knowledge. The Immunization Program reserves the right to elevate the education level of serious or repeated instances of non-compliance or categorize intentional non-compliance as fraud and abuse.The basic process for Montana VFC non-compliance response is outlined in the diagram on page 33.

Policy – Fraud and Abuse

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.

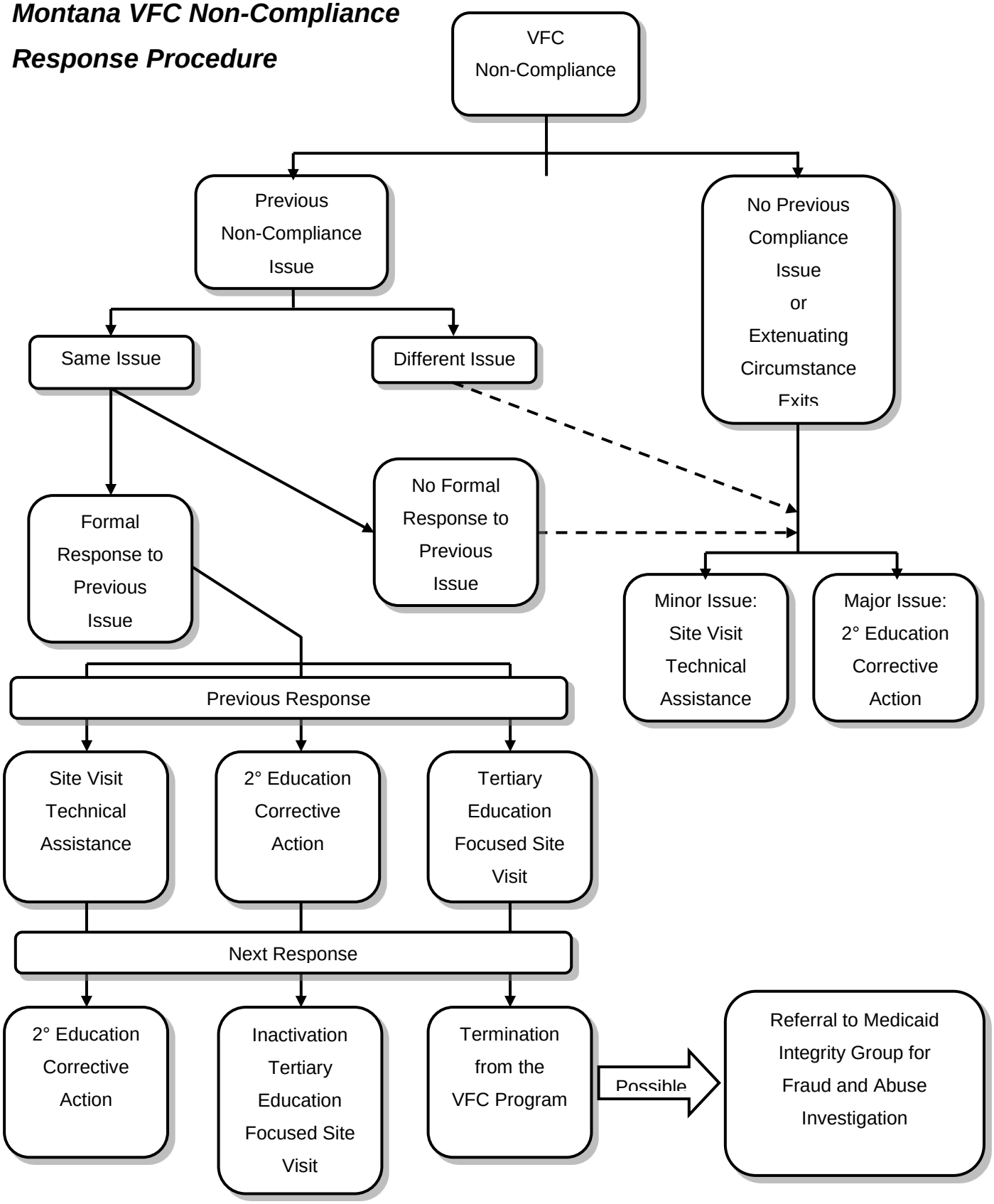
Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement 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.

If the non-compliance, fraud, or abuse appears intentional and has resulted in financial gain to the provider, the Immunization Program must refer the situation to the Medicaid Integrity Group for further investigation.

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.

Montana VFC Non-Compliance Response Procedure



10. IMMUNIZATION RESOURCES

State

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

Immunization Program website: http://immunization.mt.gov

Immunization Program Manager: Lisa Underwood 444-0065

Office Manager: Melody Lee 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): https://www.immtrax.mt.gov/wir

CDC Public Health Advisor: Carolyn Parry 444-2675

Other State Programs

Adolescent/Adult and School/Daycare Coordinator: Laura Baus 444-6978

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

Immunization Information System (IIS) - imMTrax

Immunization Information System (IIS) Manager: Lisa Rasmussen 444-9539

IIS Training and Support: Stacy Russell 444-4560

IIS Interoperability Coordinator Deb Belleau 444-5952

imMTrax password resets: 1-855-631-9190 OR 444-9500

imMTrax Help Desk: 8:00am to 5:00pm, Monday through Friday.
1-855-631-9190 support_services@stchome.com

ImMTrax website: https://www.immtrax.mt.gov/wir

Federal

Centers for Disease Control and Prevention (CDC) website: http://www.cdc.gov/

CDC Vaccines and Immunizations website: http://www.cdc.gov/vaccines/

Vaccine Information Statements (VIS): http://www.cdc.gov/vaccines/pubs/vis/default.htm

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

CDC Vaccine Safety website: http://www.cdc.gov/vaccines/vac-gen/safety/default.htm

Vaccine Adverse Event Reporting System (VAERS): http://vaers.hhs.gov/index

Other:

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

IAC produces a newsletter called Needle Tips

Vaccine Information Statements (VIS) are available in English and many foreign languages.

IAC website: http://www.immunize.org/

National Network for Immunization Information (NNii): (409) 772-0199

NNii website: http://www.immunizationinfo.org/

Pharmaceutical Companies:

GlaxoSmithKline	(866) 475-8222	http://www.gsk.com/products/vaccines/index.htm
MedImmune	(877) 633-4411	http://www.medimmune.com
Merck & Co.	(800) MERCKRX	http://www.merckvaccines.com
Novartis	(800) 244-7668	http://www.novartisvaccines.com
Pfizer (Wyeth)	(800) 666-7248	http://www.wyeth.com/vaccines
sanofi pasteur	(800) VACCINE	http://www.vaccineshoppe.com

VFC Forms

Most paper-based processes in the Montana VFC Program are now handled online through imMTrax. However, some paper forms are still used and can be downloaded from our website at www.immunization.mt.gov.

- Paper-Based Eligibility Screening Form (multiple clinic-specific versions)
- Borrowing Form
- Wasted and Expired Vaccine Report
- Temperature Logs with Storage Unit Trouble-Shooting Log on third page (Celsius and Fahrenheit versions)
- Vaccine Incident Report
- Request Form for Approval of Clinic Computer Report
- Pharmacy Monthly Report Statement

Vaccine Management Plan

11. VACCINE MANAGEMENT PLAN – INTRODUCTION

Vaccines are fragile and expensive, and proper storage and handling practices are critical to providing effective immunizations. The CDC requires VFC providers to have a written vaccine management plan, and Sections 11–17 of this handbook serve this function. When you submit a site contract each year and accept VFC vaccine shipments, you are agreeing to abide by the vaccine management practices outlined in this plan**. 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).**

Customizing this Plan for Your Facility

Designating a vaccine manager (and alternate) and developing vaccine management and emergency plans are critical components to vaccine management. **You are required to customize this plan for your facility by documenting this information in Section 12.**

To customize this plan for your facility:

- Fill-in Section 12 starting on page 41. You can hand-write the information or use a computer editable version of Section 12 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 review in the table in Section 12, page 41.
- Post a copy of Section 12 on each VFC vaccine storage unit.
- Update and re-post Section 12 as necessary so that the information is accurate.

You must review your *Vaccine Management Plan* with staff once per calendar year:

- Review the entire *Vaccine Management Plan* with staff. Update Section 12, if necessary.
- Document the annual review in the table on page 41.
- Re-post a copy of Section 12 on each VFC vaccine storage unit.

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

12. VACCINE MANAGEMENT AND EMERGENCY PLAN

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

Provider Information

Enter provider-specific VFC information below

Provider/Facility Name	VFC #

Designated Vaccine Manager

Designate one person primarily responsible for 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

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

You must check expiration dates and segregate 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

Vaccine Management Plan Review

Review your *Vaccine Management Plan* annually and anytime you have a change in staff. Update this section (Section 12), if necessary. Document reviews and updates below by listing the date, circling whether it was a review, update or both, and listing the initials of the staff involved.

Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials

Packing and Transporting Vaccine

Vaccine Packing Supplies

To prepare for an emergency, store the following supplies at your facility in the location designated below. Quantities should be sufficient to handle your entire vaccine supply.

Location of Emergency Packing Supplies

- Insulated coolers with ≥2 inch thick walls (separate coolers for refrigerated and frozen vaccines)
- Cool packs (refrigerated), 2–3 per cooler (winter)
- Ice packs (frozen), 2–3 per cooler (summer)
- If available, a portable freezer unit that maintains temperature between -58°F and +5°F (-50°C and -15°C)
- Temperature indicators or Data Loggers from your storage units
- Insulating material (e.g., cardboard, crumpled paper, bubble wrap, Styrofoam)
- Flashlight with spare batteries

Vaccine Packing Procedure

- Contact your alternate vaccine storage location to confirm transfer.
- Do not open storage unit doors until coolers are prepared and ready to receive vaccine
- Keep vaccine in original boxes when packing in coolers
- 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.
- Record the date/time and temperature of vaccine storage units at the time you remove the vaccine for transport.
- Prepare transport coolers as follows:

  Refrigerated Vaccine (See Figure 1)

  - Pack refrigerated vaccine first.
  - Maintain refrigerated vaccine between 35° – 46°F (2° – 8°C).
  - Place ice packs (summer) or cool packs (winter) in the bottom of the cooler followed by an approximately 1-inch layer of insulating material such as cardboard, crumpled paper, bubble wrap, or Styrofoam.
  - Place the vaccine and a continuously monitoring thermometer (Data Logger) on top of the insulated material and as close to the vaccine as possible making sure that the vaccine and thermometer do not touch ice packs or cool packs. In summer, a second layer of insulating material on top of the vaccine followed by ice packs may be required.
  - Fill the remaining open space at the top with crumpled paper or insulating material to prevent the vaccine from shifting while in transport.

- Close and secure the lid.
- Label the container with your facility name and “Fragile Vaccines – Refrigerate” and the date and time the vaccine was removed from the permanent storage unit.

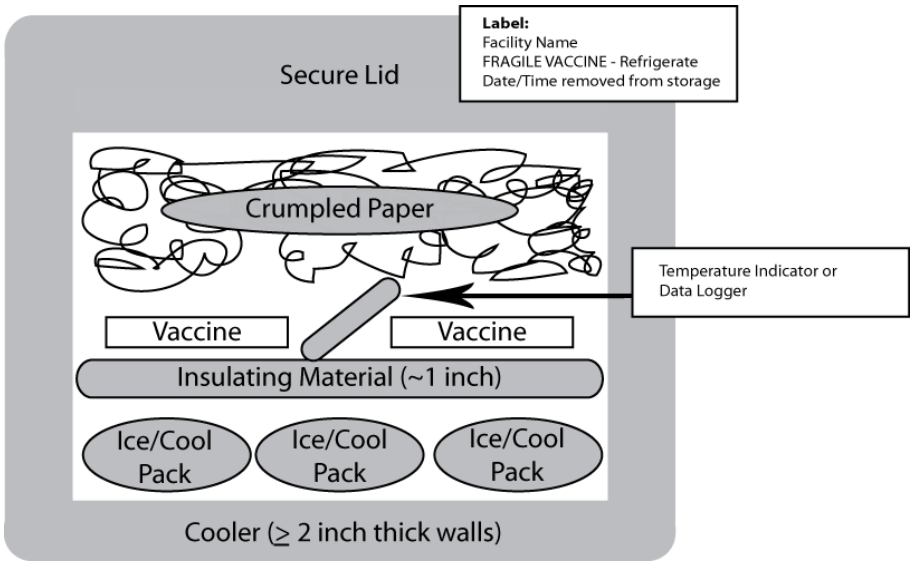


Figure 1 Packing Vaccine for Transport

Frozen Vaccine

- **DO NOT transport frozen vaccine on dry ice.** If available, pack frozen vaccine in a portable freezer unit that maintains temperature between -58°F and +5°F (-50°C and -15°C).
- If a portable freezer unit is not available, pack frozen vaccine as you would refrigerated vaccine (see previous section). Frozen and refrigerated vaccine can be transported in the same container as long as they are physically separated within the container.

During Transport

- Monitor the temperature in the transport container with a continuously monitoring thermometer (Data Logger). Document the time and temperature at the beginning and end of transport.
- Avoid prolonged temperature extremes by transporting containers inside vehicles and taking the quickest route possible. Do not leave vaccine unattended in vehicles during very hot or very cold weather.
- Upon arrival at the alternate storage facility, immediately place the vaccine in a storage unit maintaining proper temperatures. Freezer -58°F to +5°F (-50°C and -15°C). Refrigerator 35°Fto 46°F (2°C to 8°C).

While in Alternate Storage

- Download and review the Data Logger data recorded during the transport.
- If transport temperatures were outside recommended storage temperatures this is considered a temperature excursion**.** Segregate the affected vaccine and mark “Do Not Use.” Contact the Montana Immunization Program (444-5580 hhsiz@mt.gov) and obtain a Vaccine Incident Report. Follow the procedure on the report to determine vaccine viability.
- Monitor alternate storage unit temperatures twice daily.

13. VACCINE STORAGE UNITS

The following information outlines the storage unit requirements of the Montana VFC Program.

General Requirements

Refrigerators and freezers used for storing VFC vaccine must:

- Maintain required vaccine storage temperatures year-round:
  - Refrigerator: 35° to 46°F (2° to 8°C)
  - Freezer: 5°F or colder (-15°C or colder)
- Hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- In each compartment 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 below).
- Storage units can be combined refrigerator/freezers, but stand-along units are recommended (see Combined vs. Stand-alone Units below).

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.

Figure 2 Dormitory-Style Refrigerator/Freezer

The CDC and the Montana Immunization Program prohibit the use of dormitory-style storage units for storing VFC vaccine.

During the re-enrollment process each year, VFC providers must certify that they do not use dormitory-style storage units to store VFC vaccine.

Combined vs. Stand-Alone Units

Definitions:

- Combined units have a refrigerator and freezer compartment in one appliance.
- Stand-alone units have just one compartment that is either a refrigerator or freezer.

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.

The CDC-recommended best practice for vaccine storage is to use stand-alone refrigerators and freezers. This can be accomplished using a stand-alone refrigerator and stand-alone freezer or by using just the refrigerator in a combined unit and a stand-alone freezer. If freezer storage is not required, you can just use the refrigerator in a combined unit. The combined units cannot be dormitory-style.

The Montana Immunization Program allows the use of combined refrigerator/freezers as long as they are not dormitory-style units (see above). However, if you are a new provider or are obtaining new or replacement equipment, we encourage you to follow the best practice and obtain stand-alone units.

Combined 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 combined 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 loggers) 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.

Domestic Grade vs. Pharmaceutical Grade

Domestic (or “household”) quality storage units are those typically found in homes and sold at retail appliance stores. The Montana Immunization Program allows the use of domestic-grade appliances to store VFC vaccine as long as combined refrigerator/freezer units have a separate external door for the refrigerator and freezer compartments and are not dormitory-style units (See *Dormitory-Style Units* above).

Laboratory- or pharmacy-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. Laboratory-grade appliances come with safety, temperature control, and security options typically not found on domestic units. Although usually more expensive, they come in a wide variety of sizes, configurations, and prices, including moderately priced under-counter models ideally suited for small clinics.

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.

Other Recommended Features:

- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Size Determination

Your VFC vaccine storage unit must be able to store the year’s largest supply of vaccine including 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 51).

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 5 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		

Refrigerator		Freezer	
Maximum Doses	**Minimum Cubic Feet Required**	**Maximum Doses**	**Minimum Cubic Feet Required**
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).
- For proper cooling and heat exchange, locate the storage unit in a well-ventilated space away from direct sunlight and with 4 inches between the unit and surrounding walls, cabinets, and appliances.
- 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.
- Make sure the outlet is not controlled by a light switch.
- Place a “DO NOT UNPLUG” sign next to the outlet ***and its controlling circuit breaker***. If these are not accessible or visible, place the sign as near as possible so that anyone accessing the outlet or circuit breaker is likely to see it.
- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- If you have a backup power supply for your facility, make sure it is in working order, tested regularly, and that your storage units are connected to the system.
- 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 of this document.

Temperature Stabilizing

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

  Refrigerator: 35° 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 program-compliant thermometer (data logger) inside each storage compartment in a central location near vaccine but away from walls, vents, fans, and cooling coils. The Montana Immunization Program supplies data loggers to VFC providers (see Section 14).
- Place several containers of water along the inside walls, in door racks, and vegetable bins (“crispers”) 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. Do not impede air flow 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 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:

- One week of temperature (data logger) data (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, vents, fans, and coils. In the refrigerator compartment of combined units, keep vaccine away from vents or fans channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins (i.e., “crispers”). Consider removing vegetable bins to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine “VFC” and keep it physically separated from private stock.
- 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 short-dated vaccine is used first (record your process in Section 12).
- 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 log forms provided by the Immunization Program (available on our website at www.immunization.mt.gov). 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).
  - 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.
- 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 comfortably within range and stable.

- Record all temperature adjustments and issues with your storage unit on a Vaccine Storage Trouble-Shooting Log (page 3 of the State-supplied temperature logs). Logging these events will communicate vaccine storage issues to all staff, and document recurring events before they lead to major vaccine loss.
- 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 or min/max out-of-range temperature on their temperature logs.
- Providers experiencing the out-of-range temperature indications listed above should immediately obtain a Vaccine Incident Report from www.immunization.mt.gov and follow steps 1–6 on the report. Then call or email the Immunization Program immediately–444-5580 or hhsiz@mt.gov. Do not complete the entire Vaccine Incident Report until you have consulted with the Immunization Program.
- All temperature excursions must be documented either through a completed and submitted Vaccine Incident Report or an entry in the Vaccine Storage Unit Trouble-shooting Log (third page of paper temperature log), depending on the circumstances and guidance from the Immunization Program.

14. THERMOMETER (DATA LOGGER) POLICY

Montana VFC Thermometer Requirements

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

- Certified calibrated/tested as accurate against NIST or ASTM measurement standards annually or within the timeframe recommended by the manufacturer.
- Continuously monitoring by measuring and permanently recording temperatures on a predetermined schedule so that the data can be reviewed and permanently archived for three years.
- Capable of recording and saving temperature readings at a minimum of every 15 minutes.
- Uses a thermocouple probe in a glycol or glass bead buffer medium
- Capable of displaying current temperature and minimum/maximum temperatures without having to open the storage unit door.

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 current and min/max temperature readings 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 free-of-charge to VFC providers in the state. Each Data Logger comes with:
  - Certificate of calibration
  - 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 4-foot wire. Acrylic stand for the glycol bottle
  - Extra battery
  - Software for controlling the unit and saving data
  - Montana VFC Program 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.
- The Montana Immunization Program and the Data Logger supplier provides training, technical support, and written instructions for using the Data Loggers.
- 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).

- 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

- All VFC providers are required to use the 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 above.
- 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 50 (Storage Unit Approval).
- Providers are responsible for replacing broken or malfunctioning Data Loggers with an equivalent unit.
- 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 equivalent services.
- Providers must have an emergency backup thermometer on hand in the event that the Data Logger breaks or malfunctions. Backup thermometers must be working and reliable but are not required to be certified calibrated, continuously monitoring, or have a thermocouple probe in glycol.
- 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 place a Data Logger in each VFC vaccine storage unit.
- Manually perform the daily temperature monitoring activities outlined in Section 13, (page 54 – Routine Temperature Monitoring) using the state-supplied data logger or other program-complaint thermometer.
- 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.
- Respond to out-of-range temperature indications as outline in Section 13, page 55 Out of Range Temperatures.
- Make Data Logger data and temperature logs available for review during VFC site visits from the Montana Immunization Program.

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.

15. Ordering and Receiving VFC Vaccine

Overview

VFC providers are required to order and manage vaccine through imMTrax, the State immunization registry. Upon enrollment, providers are given access to the system and inventory management training. Cold chain data, inventory reconciliations, and vaccine orders (if needed) must be received by the 15th of each month. Providers are required to enter cold chain data and reconcile inventory each month regardless of whether they order vaccine.

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.

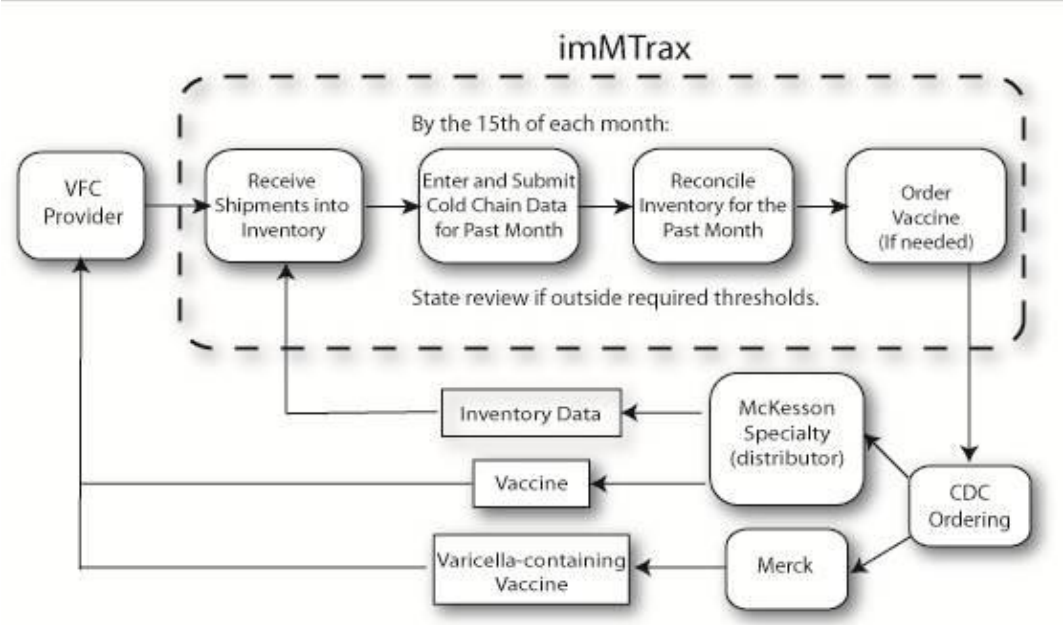


Figure 3 VFC Vaccine Order and Receiving Process

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 refer to the *imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (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 444-4560 hhsiz@mt.gov).

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

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

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

Entering and Submitting Cold Chain Data

- All VFC providers must log temperatures for VFC vaccine storage units twice daily (See Section 13, page 54). Temperatures must be recorded on the paper log provided by the Immunization Program (downloaded from www.immunization.mt.gov).
- Before reconciling inventory and ordering vaccine, you must enter cold chain data (current temperatures from your twice daily monitoring) for the previous month into imMTrax (up to the day of submission) and submit it to the State. This process is outlined in the following steps:
- To initially set up your storage units in the system click **Manage Cold Chain>>>Add Unit.**
- After your storage units are in the system, record temperature data by going to **Manage Cold Chain>>>Record Temperatures.** If you enter temperature data in imMTrax throughout the month and are not ready to submit your data, click **Save**. If you have data for ALL storage units entered and are ready to submit your data, click **Save and Submit**.
- In order to proceed to the reconciliation function, submitted cold chain data must meet two requirements:
  - There must be two temperature readings for each day your facility is open up to the day of your data submission
  - All temperatures must be in range.
- If either of these criteria is not met, you will not be able to reconcile your inventory until you provide all required data (missing data) and/or the State reviews and approves your cold chain data (out-of-range temperatures). Contact the Immunization Program if you have problems submitting your cold chain data (444-5580 hhsiz@mt.gov).
- Contact the Immunization Program immediately when you discover out-of-range temperatures that threaten your vaccine. This will safeguard your vaccine supply *and* facilitate the quick review of your out-of-range data in imMTrax. If submitting out-of-range temperatures, enter a brief description of the incident and the date you contacted the Immunization Program into the comment box before submitting your cold chain data for the month.
- Once cold chain data is submitted and approved by the State (if necessary), you can then reconcile your vaccine inventory.

Detailed imMTrax instructions can be found in *the imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

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**.
- 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:
  - **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 administered 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 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 45 minutes. If this happens, you may lose data. During data entry, clicking **Save and Finish Later** every 15 minutes will prevent this from happening.
- When you have entered your **Doses Administered** (aggregate users), **Refrigerator Count**, and **Adjustment Reasons** 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.

Detailed imMTrax instructions can be found in *the imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

Placing Orders

As of August 1, 2013, orders are placed online in imMTrax:

- Before placing a vaccine order, submit in imMTrax your current cold chain data (twice-daily temperature readings from paper logs) 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 less frequently if you are a low-volume provider. **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).
- 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.
  - **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 circumstance such as a campaign or catch-up clinic 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 section above), 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:
  - Inform front desk and supply personnel when vaccine deliveries are expected. **DO NOT leave vaccine deliveries unattended.** Check all deliveries immediately to determine if they are perishable vaccine and handle them accordingly.
  - 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 temperature monitors (if present) are within acceptable temperature range
    - The vaccine quantities, lot numbers, and expiration dates match the packing list
    - 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.

- 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* call the MSCC at 1-877-836-7123. This number is printed on the temperature monitors packed with the vaccine.
- 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.
- 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 order form must contain your influenza order for the entire season and be returned by the submission deadline in order to guarantee your vaccine for the season.
- 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.

Detailed imMTrax instructions can be found in the *imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

16. MANAGING INVENTORY

Please follow the guidelines below in managing your vaccine inventory.

Organizing and Rotating Stock

- Physically separate VFC vaccine from private stock vaccine and label the boxes accordingly.
- 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 51) for additional guidance on organizing your vaccine inventory within your storage units.

Short-dated Vaccine

- Providers must check vaccine expiration dates and segregate expired vaccine from viable vaccine weekly.
- Vaccine that is soon to expire will be listed in imMTrax on the **Manage Inventory** screen. You can customize this screen by going to **Manage Inventory>>>Update Alert Prefs**.
- 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 you cannot find a VFC provider in your area that can use the vaccine, contact the Immunization Program to have it placed on our Short-Dated Vaccine List. The Short-Dated Vaccine List can be found in the "Announcements" section on your imMTrax homepage ("Vaccine Available"). The Immunization Program also sends out an all-provider email of available short-dated vaccine.
- If another provider can use the vaccine, follow the guidelines below (Vaccine Transfers) when transferring the vaccine.
- Do not transfer short-dated vaccine to providers without first contacting them to see if they can use it before it expires.
- If vaccine on our Short-Dated Vaccine List is transferred to another provider, please notify the Montana Immunization Program (444-5580 hhsiz@mt.gov) so we can remove it from the list.

Vaccine Transfers

- Transfer VFC vaccine between currently enrolled VFC providers only.
- Follow the *Vaccine Management Plan* (Section 12, page 45) 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 4 hours. Commercial carriers may be used in emergencies. Contact the Immunization Program if you have an emergency.
- Do not transfer opened multi-dose vials.
- VFC vaccine that has been physically transferred to another provider must also be virtually transferred in imMTrax. To transfer vaccine in imMTrax, go to **Manage Transfers.** Pick the receiving facility from the drop-down list and enter the doses of vaccine to be transferred. Click **Submit Transfer**. To receive a

transfer, go to **Manage Orders**, select the radio button next to the transfer and click **Receive/Modify**. This will transfer the vaccine into the inventory of the receiving facility. Modify the transfer amount if needed.

Expired, Spoiled, and Wasted Vaccine

Expired, spoiled, and wasted vaccine is nonviable and should never be administered to patients. Immediately segregate expired, spoiled, and wasted vaccine from viable vaccine to avoid administration errors. Providers must check expiration dates weekly.

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:

Wasted Vaccine–Any nonviable vaccine that cannot be returned to McKesson, including broken vials/syringes, vaccine drawn but not administered, and nonviable opened multi-dose vials.

- Fill out a Wasted and Expired Vaccine Form. Enter “10” in the Reason Code column. NDC number is required and can be found on the vaccine package or packing slip.
- Return the form to the Immunization Program.
- Discard product per your facility guidelines.

Expired or Spoiled Vaccine–Any nonviable vaccine that can be returned to McKesson, including expired vaccine or vaccine spoiled due to cold chain failures or recalls. DO NOT DISCARD EXPIRED/SPOILED VACCINE. Do not return viable vaccine to McKesson.

- Fill out a Wasted and Expired Vaccine Form. Enter the most appropriate number in the Reason Code column. NDC number is required and can be found on the vaccine package or packing slip.
- Indicate the number of shipping labels needed. One label per shipping container.
- Return the form to the Immunization Program.
- Once the Immunization Program receives the form, McKesson will mail the requested number of UPS shipping labels within 7–10 business days and the Immunization Program will FAX or email a printout of the McKesson return information. Include this printout in the shipping container with your vaccine. PLEASE NOTE: The vaccine in the shipping container must match the information on the printout.
- Arrange a UPS pickup for your packaged vaccine.
- Expired/spoiled vaccine must be returned to McKesson within six months of the spoilage or expiration.
- Account for the wasted/expired vaccine in imMTrax during your monthly reconciliation (See Section 15, page 54).

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. Borrowing should not be a routine vaccine management practice. Limited borrowing is allowed in the VFC Program in response to unexpected

circumstances such as delayed or spoiled vaccine shipments, order miscalculations, and billing corrections.

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

Borrowing influenza vaccine between seasons is not allowed.

Use the following procedures to track vaccine borrowing:

- Document borrowing and payback on the VFC Vaccine Borrowing Report, available on our website at www.immunization.mt.gov. The instructions are on the report.
- You must retain borrowing reports for three years and make them available for review during VFC site visits. Do not submit borrowing reports to the Immunization Program.

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 within three months of the initial transaction or at the first opportunity, whichever comes first.

Detailed imMTrax instructions can be found in the *imMTrax Provider Handbook* (https://immtrax.mt.gov/users.shtml) or contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

17. VACCINE LOSS AND REPLACEMENT

VFC providers are entrusted with publicly supplied vaccine to immunize eligible children at no cost; however, 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 a determination about vaccine viability.

Situations That May Require Vaccine Reimbursement or Replacement

Provider Negligence

Listed below are situation considered to be "provider negligence" and may require financial restitution 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 restitution 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)
- Failing to notify the Immunization Program of a change in VFC vaccine management personnel (Vaccine Manager and Alternate VFC Vaccine Monitor)
- 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 or reimburse 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 Financial Restitution

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 contracted alarm/alert company failing to notify the provider of malfunctioning equipment or out-of-range temperatures as required
- 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

- When making determinations about vaccine restitution, the Immunization Program considers the evidence surrounding each situation, which 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 restitution 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 can choose a dose-for-dose replacement with vaccine from private stock or monetary payment directly to the Immunization Program. In accordance with Federal requirements, vaccine reimbursement paid directly to the Immunization Program will be used in its entirety to purchase pediatric vaccines for administration to eligible children.
- Providers choosing dose-for-dose replacement must provide the Immunization Program a copy of the purchase invoice and manage the replaced vaccine in imMTrax.

18. 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.

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:

  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 due to the confidential nature of their visit.
- Family planning clinics must screen for this special eligibility category and document VFC vaccine given to this population per current Immunization Program instructions. 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).

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, they must track birth dose recipients by VFC eligibility category using one of the methods described in Section 4 – Eligibility.
- 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 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

In 2011, the Montana Legislature passed Senate Bill 189 that allows pharmacists to provide influenza immunizations to children 12 years and older. Montana Medicaid currently does not reimburse claims for vaccine administered to Medicaid-eligible children 0 through 18 years of age due to the VFC Program providing vaccine free-of-charge to this population.

Pharmacies must enroll in the VFC Program in order to administer vaccine to VFC-eligible children and 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.

Because pharmacists only administer influenza vaccine, they qualify for streamlined oversight in the VFC Program if they:

- Received a documented enrollment visit prior to receiving vaccine
- Have a current site contract (signed by the pharmacist *and* cooperative practice provider)
- Have ordered vaccine within the calendar year
- Submit one month of temperature data from VFC vaccine storage units prior to storing vaccine.

Providers who qualify for streamlined oversight must implement all VFC program requirements. However, they are exempt from having a routine biennial compliance site visits (detailed in Section 7). The Immunization Program reserves the right to conduct a compliance site visit if deemed necessary.

Pharmacies must participate in imMTrax as integrated providers and submit to the Immunization Program on a monthly basis:

- Storage unit temperature logs
- An inventory report that includes:
- Doses on hand by vaccine at beginning of reporting period
- Doses received by vaccine during reporting period
- Doses administered by age cohort during the reporting period
- Doses of vaccine wasted/lost due to mishandling by vaccine for reporting period
- Doses on hand by vaccine at the end of reporting period
- Doses of vaccine administered by VFC eligibility category (See Section 4–Eligibility)

This information is automatically submitted to the Immunization Program when providers manage their VFC vaccine inventory in imMTrax, the state immunization registry.

In addition to participating in imMTrax, pharmacists must submit each month a statement signed by the pharmacist or cooperative practice provider certifying that no change in VFC Vaccine Manager or storage units has occurred since the last report submission. A standard form is available from the Immunization Program for this purpose.

If the required documentation is not submitted or it shows wasted/lost or unaccounted for vaccine greater than 5%, temperature excursions, or a statement of change in VFC Manager or storage units, the Immunization Program must follow up with the pharmacy before placing their vaccine order.

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.

19. VFC Provider Education Requirements

Information will be released in June 2013.

APPENDIX–2013 SUMMARY OF HANDBOOK CHANGES

2013 VFC Provider Handbook Summary of Changes (Highlighted in yellow in body of Handbook)	Page
Section 1–Introduction	
• Added definitions of integrated and aggregate provider in imMTrax	7–8
Section 2–Provider Enrollment	
• Added education requirement for re-enrolling and newly enrolling providers	10–11
• Added requirement - providers must notify Immunization Program if info changes	10
• Added storage unit approval requirement for newly enrolling providers	11
Section 3–Billing	
• Revised to include new vaccine administration fee cap and guidance from the CDC	13
Section 4–Eligibility	
• Updated to require documenting eligibility screening at every visit	15
• Added websites that give locations of FQHCs and RHCs	16
• Updated to distinguish documentation requirements from methods used to determine provider profiles	16–17
• Updated table footnotes to include new billing guidance	18–20
Section 5–ACIP	
• Reworded to clarify that VFC providers agree to comply with ACIP schedules, dosages, and contraindications	21
Section 6–NCVIA	
• Updated to include electronic management of VISs	23
Section 7–VFC Compliance Site Visits	
• Removed reference to AFIX activities throughout	25–27
• Added Unannounced Storage and Handling Visit requirement	26
Section 8–VFC Requirement Checklist	

• **Once (upon enrollment or as needed)** –
  • Added submission of one week of data logger data for storage unit approval
  • Added enrollment education requirement for Vaccine Manager and Alternate
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• **Every Vaccination Visit** – Revised eligibility screening to include documenting at every visit	
• **Twice Daily** – Revised to require the use of State-supplied paper temperature logs	29
• **Yearly** – Added annual education requirement for Vaccine Manager and Alternate	29
• **As Needed** – Added requirement to have storage units approved by submitting one week of data	29
Section 9–Non-Compliance, Fraud, and Abuse	
• Updated policy to include CDC definitions and obligation to refer fraud and abuse to third party for investigation	31–32
Section 10–Immunization Resources	
• Updated with current staff contact information	35
Section 11–Vaccine Management Plan Introduction	
• Added reference to Section 17 – Vaccine Loss and Replacement Policy	39

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• Added heading to emphasize requirement to review Vaccine Management Plan once per calendar year	39
Section 12–Vaccine Management and Emergency Plan	
• Added Immunization Program contact information to Emergency Contact table	41
• Added space to describe method of rotating stock and that expiration dates must be checked weekly	42
Section 13–Vaccine Storage Units	
• Included all requirements under “General Requirements” heading	46
• Updated policy prohibiting the use of dormitory-style storage units	46
• Clarified policy allowing combined domestic units, but that the CDC recommends stand-alone units	46–47
• Clarified policy on manual defrost versus frost-free freezers	47–48
• Added section requiring approval of storage units before use	50
• Added requirement that expiration dates must be checked weekly and to record process for rotating vaccine in Section 12	51
• Updated routine temperature monitoring to comply with CDC recommendations	51
Section 14–Thermometer (Data Logger) Policy	
• Updated entire section to include new thermo-couple Data Loggers, storage unit approval policy, and temperature monitoring requirements	53–54
Section 15–Ordering and Receiving Vaccine	
• Added section on seasonal influenza vaccine orders	58
• Added requirement to call MSCC the same day of receipt, when vaccine shipments are suspected of being compromised	59
Section 16–Managing Inventory	
• Added requirement to check expiration dates weekly and that inventory management process must be recorded in Section 12	61
• Added instructions to immediately segregate expired, wasted, and spoiled vaccine from viable vaccine	62
• Added requirement that expired/spoiled vaccine must be returned to McKesson within six months of spoilage or expiration	62
• Added restriction that borrowing influenza vaccine across seasons is not allowed	63
• Added “borrowing cheat sheet” resource	63
• Added that private payback vaccine must be managed in imMTrax	63
Section 17–Vaccine Loss and Replacement	
• New section added that describes vaccine restitution policy	65–66
Section 18–Specialty Providers	
• Added requirement that pharmacies must vaccinate “walk-in” clients and cannot refuse to vaccinate VFC-eligible children based on a parent’s inability to pay the administration fee	68
• Added that pharmacies must submit one month of temperature data before receiving vaccine in order to qualify for streamlined oversight	68

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• Added requirement that birthing hospitals and pharmacies must use State-supplied Data Loggers	67 and 69
Section 19–VFC Provider Education Requirements	
• Added new section but information will not be available until June, 2013	71
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• Added as a place to include the 2013 Summary of Changes	73