Montana Department of Public Health and Human Services

Immunization Program

Provider Handbook/ Vaccine Management Plan

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MONTANA
Department of Public Health & Human Services

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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. They 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).

Ordering and Managing Publicly Funded Vaccine - imMTrax

Since November of 2011, Montana's VFC providers are required to order and manage VFC 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 to access the system.

This handbook outlines basics imMTrax procedures as they relate to the VFC Program but 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 contact the imMTrax Training and Support at 444-4560 (hhsiz@mt.gov).

VFC Document Retention

VFC providers must retain all VFC-related documents for three years. This includes eligibility screening documents, temperature logs, borrowing forms, 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 11–16). 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 will notify you through an all-provider memo, provide a copy of the revised section, and post the revised section to our website. It is your responsibility to keep your copy up to date. Please discard outdated sections and replace them with the most 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 homes 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, which involves completing a new site contract in imMTrax, the State immunization registry. The Immunization Program notifies providers when the re-enrollment period begins and ends, and whether there are any special instructions for completing the process. If you do not re-enrolled by the deadline, you will be prohibited from ordering VFC vaccine until you re-enroll. When completing your new site contract you will be asked to provide and/or update the following information:

- **Provider Contact Information** – This information will automatically fill-in from your imMTrax account information. Please review and update, if necessary.
- **List of Providers and Clinicians** – This information will automatically fill-in from your imMTrax account information. Please 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. This information will automatically fill-in from you imMTrax immunization data (integrated users) or from your previous site contract (aggregate users). If you are an integrated user and use imMTrax to document VFC eligibility, then simply use the numbers provided by the system. If you are an aggregate user, please update this information using your eligibility screening documentation from the past year.

- **Vaccine Management Information** – Please review and update, if necessary, the name of your primary and secondary VFC vaccine managers. Please devise a plan for safe guarding your vaccine in the event of an emergency.
- **Provider Agreement** – This portion of the contract lists the federal statutory requirements of the VFC Program as defined in 42 USC § 1396. It 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.

VFC re-enrollment occurs every year for all providers. However, please update your site contract any time during the year if:

- Your providers and clinicians listed in imMTrax change
- Your contact information, vaccine management personnel, or vaccine shipping instructions change
- The number of immunization patients at your facility changes significantly
- Your facility type has changed.

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 you are a good fit.

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 any questions you may have about the program. Ideally, enrollment visits are conducted in person, but depending on the circumstance, they may be done over the phone, through online video conferencing, or online video.
- **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. Once you have access to imMTrax, you can electronically order and manage VFC vaccine. New provider training is available through the imMTrax Training and Support (444-4560).

Please note that the sequence and timing of VFC enrollment 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. 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 return all VFC vaccine and 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 charge to children who might not otherwise be vaccinated because of inability to pay.

There are two costs associated with VFC vaccine – the cost of the vaccine and the administration fee. The billing requirements of the VFC Program are statutorily defined as follows:

- Providers may not charge patients for VFC vaccine.
- Providers may bill an appropriate vaccine administration fee as long as it does not exceed $14.13, the maximum regional charge set for Montana by the Centers for Medicare and Medicaid.
- At facilities that can serve the underinsured, private insurers cannot be billed for VFC vaccine but can be billed for the administration fee.
- VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

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

See “Borrowing” in Section 16, page 60, for options for adjusting inventory to correct for improperly billed vaccine.

4. VFC ELIGIBILITY

Funding for VFC vaccine is based on an estimate of VFC-eligible children in the state. 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 patients for VFC eligibility at every immunization visit. Neglecting to screen for 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:

1. Determining the patient's eligibility status at each immunization visit (screening)
2. Documenting 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 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 or annual visits 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.

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 covers recommended immunizations or covers a portion of all 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.

Special Eligibility Circumstances

In some situations, determining VFC eligibility status can be complicated. This section covers special eligibility situations sometimes encountered. In general, use the following guidelines 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 cannot exceed $14.13 (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
Medicaid as Secondary	Private	Underinsured/ Medicaid Secondary	Medicaid	VFC	No charge	Medicaid

[1] VFC vaccine administration fees cannot exceed $14.13 (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] Reimbursement may be higher under this scenario, and Medicaid can be billed for the balance of unpaid administration fees up to $14.13. 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 less than 19 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 that tracks this information. The form can be found on our website at www.immunization.mt.gov under the VFC link.

Incarcerated Juveniles

Incarcerated juveniles less than 19 years of age who lose access to their health insurance because of 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
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
				VFC	No charge	Insurer

[1] VFC vaccine administration fees cannot exceed $14.13 (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.

Documenting Eligibility Screening

Eligibility screening must occur at every immunization visit. Documenting the screening results is required under the following circumstances:

- At the first immunization visit in the calendar year
- Whenever VFC eligibility status changes.

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.

Each year during the VFC re-enrollment process, you must provide the total number of patients immunized for the year by eligibility category (See Section 2, page 11, Re-enrollment – Current Providers). Therefore, it is important to document eligibility screening throughout the year in way that can be easily tallied during re-enrollment. Simply recording eligibility in individual patient charts is not one of the accepted methods listed below and makes it difficult to tally aggregate immunization numbers by eligibility category during the re-enrollment process.

The Montana Immunization Program accepts four methods for documenting eligibility screening:

1 **imMTrax** – By far, the easiest way to document VFC eligibility is through imMTrax, Montana's Immunization registry. VFC eligibility status can be recorded in each patient's immunization record and can be updated as needed. This information is available to anyone viewing the record. Moreover, during

the annual VFC re-enrollment process, total patients immunized by VFC eligibility category for the previous year will automatically populate the provider profile in your site contract. 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).

2 **Paper-based Eligibility Screening Form – State-Supplied Eligibility Form** – A second way to document VFC eligibility is to use a paper-based log provided by the Immunization Program (found on our website: www.immunization.mt.gov). The instructions for using the form are on the back of the sample. Document the patient's eligibility status at the first immunization visit each calendar year by placing a checkmark in the appropriate category. On subsequent visits, you will leave the eligibility status section blank, unless the patient's status has changed. Each year, the total number of patients immunized by eligibility category can be tallied by adding the checkmarks in the category columns. There are four versions of this form, each taking in to account the different eligibility statuses and vaccine offerings at public, private, and specialty clinics. Be sure to use the form that best suits your practice.

3 **Clinic Computer-Generated Report –** The third approved method for documenting VFC eligibility is to use your clinic charting or billing system to generate a custom report. The report must meet certain criteria and be approved by the Montana Immunization Program before use. The criteria for approval and instructions for submitting a report for review can be found on the Request for Approval of Computer-Generated VFC Screening Report on our website at www.immunization.mt.gov under the VFC link.

4 **Comprehensive Screening Form –** The last option for documenting VFC eligibility screening applies to providers whose client base is exclusively American Indian or Alaskan Native. These providers 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 .

5. Advisory Committee on Immunization Practices (ACIP)

The ACIP is a federal advisory committee 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 the dosage and schedule. 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.

A current list of vaccines provided by the Montana VFC Program can be found at www.immunization.mt.gov under the “VFC” link, document title “Available VFC Vaccines.”

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 new 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 – Exceptions

Health care professionals can deviate from ACIP recommendations under the following circumstances:

- 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 (NCVIA)

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 professional 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 the current print, audio, and foreign language versions on their website at http://www.cdc.gov/vaccines/pubs/vis/default.htm .

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 whereby you are notified through email when VISs have been changed so you are prompted to update your stock.

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 mechanism through which adverse events following immunization can be reported, analyzed, and made available to the public. 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. You may report adverse events even if you are unsure whether a vaccine caused them.

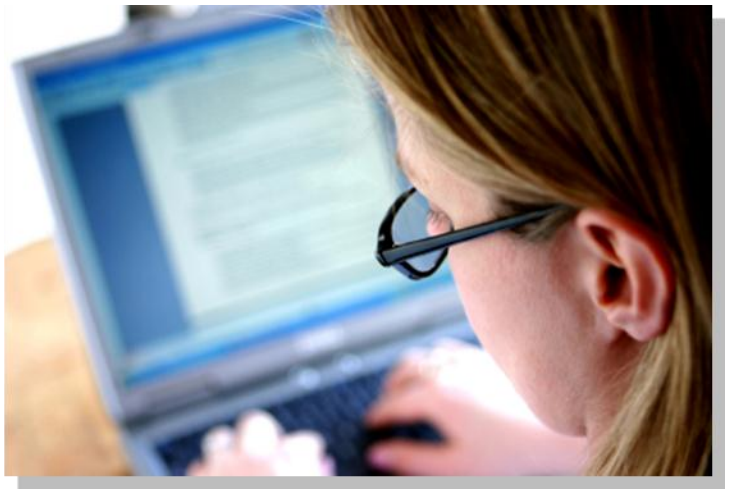
Vaccine Charting Requirements

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 that the Montana Immunization Program 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 that an "audit." Most VFC 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 your 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 are usually combined with another assessment function of the Montana Immunization Program—AFIX visits, where facility immunization rates are determined through chart reviews (AFIX procedures are not covered in this handbook). The general procedure for combined VFC/AFIX site visits is outlined below (AFIX-specific steps are indicated in parentheses.):

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 site visit date and requesting an active patient list (AFIX).

3. After reviewing your active patient list, the Immunization Program will fax or email you a list of charts that will be reviewed during your site visit (AFIX).

During the Site Visit

4. Site visits can take from 1 to 4 hours depending on the size of your clinic, the number of charts to review, and the educational opportunities that arise.

5. 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 and charts
    c. Three months of temperature logs from your vaccine storage units (if not recorded twice daily in imMTrax)
    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. Charts requested in Step 3 above (AFIX).

6. 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.

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

8. At the end of the visit, you will receive feedback on your compliance with the VFC Program and immunization coverage (AFIX) including areas of strength, areas for improvement, and any corrective actions.

Site Visit Follow-Up

9. Approximately one month after your site visit, you will receive a follow-up letter from the Immunization Program detailing the results of your VFC/AFIX visit. It will reiterate any VFC compliance issues and corrective action plans mentioned during your site visit.

10. In order to remain in good standing with the VFC Program, you are responsible for carrying out any corrective actions recommended by the Montana Immunization Program. Immunization Program staff may follow up by telephone and email.

11. Immunization Program staff may return to your facility for an educational site visit to address VFC non-compliance and AFIX issues.

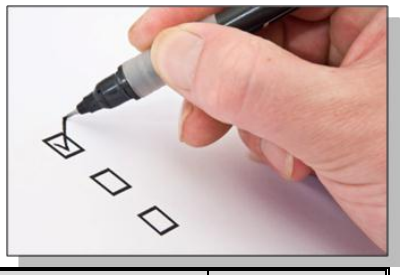
Other Visits from the Montana Immunization Program

- **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. Education 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	Section 2,12
	Receive VFC PIN # and imMTrax Login.	Section 2,15
	Set up vaccine storage units and thermometers according to the *Vaccine Management Plan.* Login to imMTrax and set up cold storage units.	Section 13,14
	Post "DO NOT UNPLUG" signs on outlets and circuit breakers serving vaccine storage units	Section 13
	Copy and post completed Section12 on vaccine storage units. Review *Vaccine Management Plan* with staff. Document the review in Section 12.	Sections 11,12
Every Vaccination Visit		
	Screen for VFC eligibility – Document at first visit in the calendar year and when status changes	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 either in imMTrax or using a 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	Section 11-17
	Re-enroll by submitting a new site contract in imMTrax (per State instructions)	Section 2
Every Other Year		
	Host a compliance site visit from the Montana Immunization Program	Section 7
As Needed		
	Submit Vaccine Incident Report (in response to temperature excursions that threaten vaccine)	Section 13
	Fill out Vaccine Storage Trouble-Shooting Log to document minor storage unit issues (Page 3 of temperature logs)	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

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.

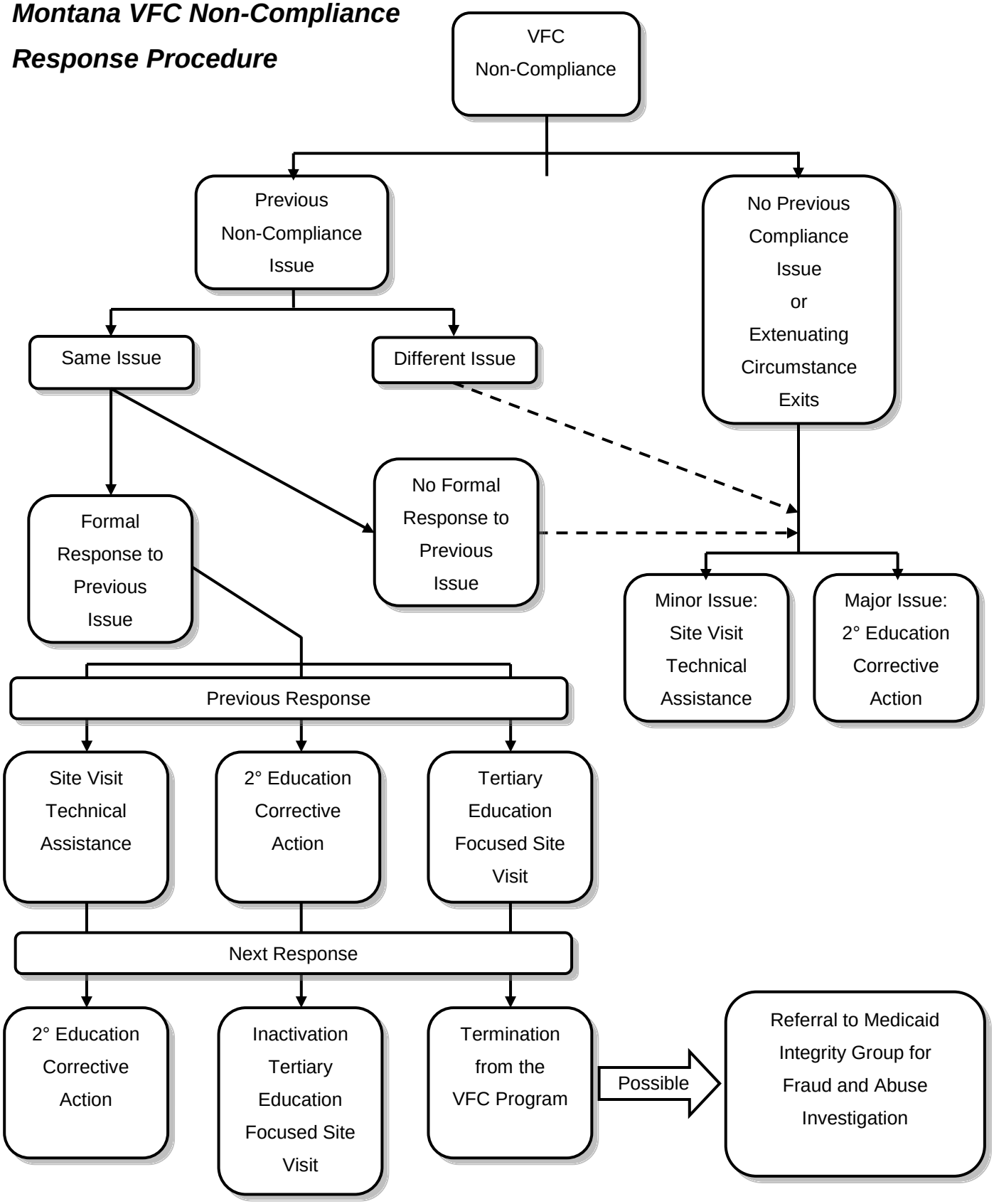
Policy

The primary response of the Montana Immunization Program to non-compliance, fraud, and abuse 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 educational 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 from the VFC Program. When responding to non-compliance issues, the Immunization Program will consider extenuating circumstances, whether it is a major or minor issue, and whether the non-compliance is intentional, negligent, or simply an error due to lack of knowledge. The basic process for Montana VFC non-compliance response is outlined in the diagram on the next page.

Montana VFC Non-Compliance Response Procedure



Definitions

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

Corrective Action Plan – Tasks that must be completed by the provider in order to resolve a noncompliance issue. Corrective action plans are part of secondary and tertiary education sessions.

Extenuating Circumstance – A condition that makes a non-compliance issue excusable or less serious.

Focused Site Visit – An in-person visit from Immunization Program staff that educates a provider on a specific non-compliance issue and ensure that corrective actions have taken place. A focused site visit is separate from a compliance site visit.

Follow-Up – Actions taken by the Immunization Program staff to ensure that a corrective action has taken place and a compliance issue is resolved.

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.

Inactivation – Temporary suspension of vaccine ordering in the VFC Program. Inactivated providers may be required to return VFC vaccine per State instructions.

Intentional – Acting with full awareness of what one is doing and the consequences of the action.

Major Issue – A provider action that results in non-compliance with one of the statutorily defined requirements outlined in the VFC Provider Agreement. (e.g., neglecting to document eligibility screening.)

Medicaid Integrity Group – A division of the Centers for Medicare and Medicaid Services charged with investigating fraud, waste, and abuse in the Medicaid program.

Minor Issue – A provider action, oversight, or mistake that minimally affects compliance with a VFC requirement. (e.g., having an outdated VIS in your VIS supply.)

Negligent – Acting careless, inattentive, neglectful, willfully blind, or reckless.

Non-Compliance – Failure to meet all or part of the requirements of the VFC Program.

Termination – Permanent removal of a provider from the VFC Program. Terminated providers are required to return all VFC vaccine per State instructions.

10. IMMUNIZATION RESOURCES

State

Immunization Program: 444-5580; fax 444-2920 email 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 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. For a detailed view of how VFC administrative processes have changed with imMTrax, please see Section 15.

- 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

Please contact the Montana Immunization Program if you have difficulty finding a form (444-5580 hhsiz@mt.gov).

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.**

Customizing this Plan for Your Facility

Designating a vaccine manager (and alternate) and developing an emergency plan are two 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.

Every 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.
- Retain for three years any old versions of Section 12 that document past reviews/updates.

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

12. 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 is unavailable)	Phone

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

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

Emergency Phone Numbers

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

Utility Company	Phone
Building Maintenance	Phone
Building Alarm Company	Phone
Refrigerator/Freezer Repair	Phone
Backup Generator Repair	Phone
Vaccine Transport	Phone
Other -	Phone
Other -	Phone

Packing and Transporting Vaccine

Emergency 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 as possible to the vaccine making sure that the vaccine does 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.

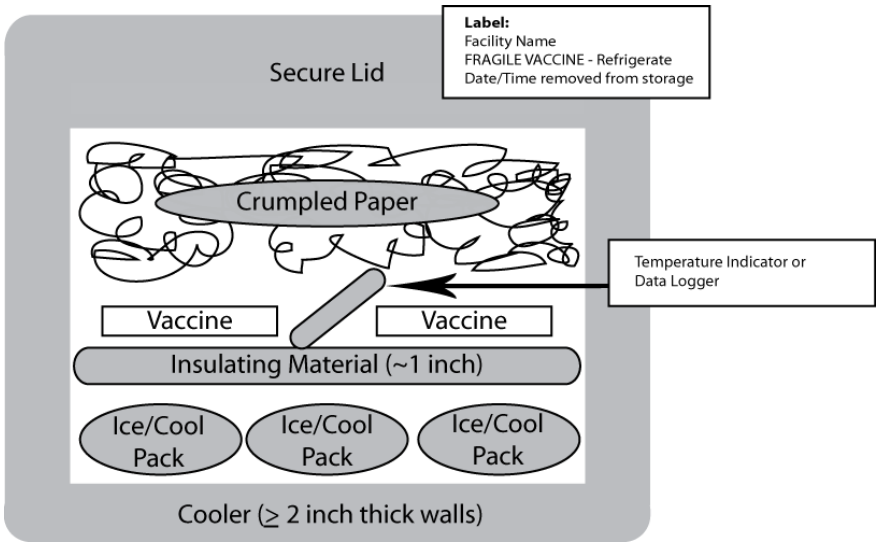


Figure 1 Packing Vaccine for Transport

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 2°C to 8°C (35°F to 46°F).

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 (*VFC Operations Guide*, M-6, page 8):

- 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
- Have a working National Institute for Standards and Testing (NIST)- or American Society for Testing and Materials (ASTM)-calibrated thermometer inside each storage compartment (See Section 14)
- Be dedicated to vaccine storage (Food and beverages are not allowed in vaccine storage units.)

Combined Versus Stand-Alone Units

Two types of storage units are acceptable:

- Combined refrigerator/freezer units that have separate external doors for each compartment
- Stand-alone refrigerators and freezers

Combined units are those that have a refrigerator and freezer compartment in one appliance. Stand-alone units have just one compartment that is either a refrigerator or freezer. In general, stand-alone units are a better choice for vaccine storage because they are better able to maintain proper vaccine storage temperatures

Dormitory-Style Storage Units

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

Figure 2 Dormitory-Style Refrigerator/Freezer

Policy on Dormitory-Style Storage Units:

- Beginning with the 2011 re-enrollment, VFC providers are prohibited from using dormitory-style storage units for permanent storage of VFC vaccine.
- Permanent storage is defined as that involving more than one day's supply of vaccine for longer than one daily work shift (12 hours).
- The practice of using dormitory-style units for *temporary* storage of VFC vaccine is allowed for those providers already using the units in this capacity (as of February 1, 2011) and as long as certain conditions are met.
- Temporary storage is defined as that where only one day's supply of vaccine is stored for one workday (no more than 12 hours). Vaccine is returned to permanent storage at the end of the day.
- Providers wishing to continue to use dormitory-style units for temporary storage of VFC vaccine must agree to certain conditions and obtain written approval from the Montana Immunization Program. Please contact the Immunization Program for more information.
- VFC vaccine storage units acquired for VFC vaccine after February 1, 2011 must not be dormitory-style units regardless of whether they are used for temporary or permanent storage.

Domestic Grade

Domestic (or "household") quality storage units are those typically found in homes and sold at retail appliance stores. Domestic grade appliances can be used 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).

Other desirable features include:

- Separate temperature controls for refrigerator and freezer
- Automatic defrost cycling (i.e., "frost-free")
- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Undesirable features include:

- Manual defrosts—These units accumulate frost and ice on the walls of the freezer and cooling coils, and require periodic "defrosting." If you have a manual defrost unit you must arrange alternate vaccine storage and temperature tracking while you defrost your appliance.
- Single-thermostat units—These are combined units with a single thermostat dial that controls 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. **Please note** that The Montana Immunization Program does not prohibit the use of single-thermostat units. However, such units should be monitored carefully. If temperature excursions and vaccine waste occur, you will be required to upgrade to a dual temperature control model.

Laboratory/Pharmacy-Grade

Laboratory- or pharmacy-grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmaceutical setting. These are the highest quality option for storing VFC 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.

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 Minimum Cubic Feet of Storage Space Based on Maximum Doses

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

Setting Up your Storage Unit

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

Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- 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 in 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: 2° to 8°C (35° to 46°F)
  - Freezer: -15°C or colder (5°F or colder)
- If the unit has a thermostat, set to the following target temperatures:
  - Refrigerator: 4°C or 40°F
  - Freezer: -20°C or -5°F
- 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 NIST- or ASTM-calibrated, continuously monitoring thermometer inside each storage compartment in a central location away from walls, vents, fans, and cooling coils. The Montana Immunization Program supplies thermometers 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 3 days. Log temperatures at least twice a day during the adjustment period.
- Once the temperature is in range and stabilized, your storage unit is ready to receive vaccine.

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 the vent or fan channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins. 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.
- Organize packages so that short-dated vaccine is used first.
- 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.

Temperature Monitoring

- Monitor and record temperatures twice a day for all VFC vaccine storage units. This is required even when your unit has a continuous monitoring chart or data logger, or a temperature alarm (see Section 14 for thermometer requirements).
- Record the twice-daily temperature readings either on a paper temperature log (provided on our website at www.immunization.mt.gov) or through the imMTrax cold chain management module (See Section 15, page 56 for details). Temperatures logged in imMTrax exclusively (not kept on paper) *must be entered twice daily*. Temperatures logged in imMTrax are automatically archived for at least three years and can be reviewed by providers and the State. Paper temperature logs must be kept for 3 years.
- 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 problems and trends with your unit. This will help catch minor problems early before they lead to major incidents that waste vaccine.

- Be proactive in addressing storage unit issues before they result in vaccine wastage or patient recall situations.

Out-of-Range Temperatures

- If vaccine is exposed to out-of-range storage temperatures that threaten your vaccine, immediately obtain a Vaccine Incident Report from www.immunization.mt.gov and follow steps 1–6 on the report. Call or email the Immunization Program immediately 444-5580 or hhsiz@mt.gov.

14. THERMOMETER (DATA LOGGER) POLICY

Montana VFC Thermometer Requirements

The CDC and the Montana Immunization Program require VFC providers to have a certified calibrated, continuously monitoring thermometer in each VFC vaccine storage unit. The Montana Immunization Program supplies thermometers to VFC providers in the state. (Due to budget constraints, the State does not supply thermometers to birthing hospitals and pharmacies at this time.)

Definitions:

- **Certified Calibrated** – A thermometer that has a certificate stating it has been tested and calibrated as accurate against NIST or ASTM measurement standards within the timeframe recommended by the manufacturer.
- **Continuously Monitoring** - A thermometer that measures and permanently records temperatures on a predetermined schedule so that the data can be reviewed and permanently archived for three years.

State-Supplied Thermometers – Data Loggers

The Montana Immunization Program provides certified calibrated, continuously monitoring Data Loggers to all VFC providers in Montana, with the exception of birthing hospitals and pharmacies. Data Loggers are electronic thermometers that continuously record and store temperature readings and indicate through a warning light when out-of-range temperatures that threaten vaccine have been encountered. Data Loggers interface with a computer so that data can be removed and saved.

Immunization Program Responsibilities

- The Immunization Program supplies Data Loggers free-of-charge to VFC providers in the state (with the exception of birthing hospitals and pharmacies and dependent upon budget and supply). Each Data Logger comes with:
  - Certificate of calibration
  - Acrylic stand
  - Extra battery
  - Software for controlling the unit and saving data.
- If a provider chooses to supply their own certified calibrated, continuously monitoring thermometer (as defined above), the Immunization Program must approve the thermometer 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 an annual recalibration program for State-supplied Data Loggers at the provider's expense (terms of recalibration may change year to year).

Provider Responsibilities

- All VFC providers are required to use the State-supplied Data Loggers in each VFC vaccine storage unit unless they have a thermometer that meets the VFC requirements as defined above.
- Birthing hospitals and pharmacies must supply their own thermometers that meet VFC requirements. Contact the Immunization Program for information on qualified thermometers.
- Even with continuously recording temperature monitoring, providers still must manually log temperatures twice daily (see Section 13, page 49 – Temperature Monitoring). If the provider has centralized temperature monitoring that does not included readable temperature displays, then the temperature data must be reviewed twice daily.
- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software.
- Providers are responsible for replacing broken or malfunctioning Data Loggers with an equivalent unit.
- After the first year, providers are responsible for Data Logger yearly calibration. Re-calibration costs approximately 50$/unit and includes a replacement battery and a loaner for use while the unit is being re-calibrated (terms of recalibration subject to change).
- 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 or continuously monitoring.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the State.

In the routine use of Data Loggers, providers must:

- Use the provided software to setup and activate each Data Logger prior to first use.
- After activation, properly place a Data Logger in each VFC vaccine storage unit.
- Check and log the temperature readout and the color of the out-of-range light twice daily. Temperature logging can be on paper (logs provided at www.immunization.mt.gov) or through imMTrax, the Montana immunization information system.
- At the end of every month (prior to reconciling inventory and ordering vaccine) download, review, and save Data Logger data for the previous month. Then enter cold chain data into imMTrax (See Section 15, page 56 for more information on managing cold chain data in imMTrax). Save monthly Data Logger data and paper temperature logs (if used) for three years.
- If out-of-range temperatures that threaten vaccine are encountered, immediately obtain a Vaccine Incident Report, follow steps 1–6, and call the Immunization Program (444-5580).
- 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 information system. Upon enrollment, providers are given access to the system and training on how to manage VFC vaccine. 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 vaccines, which must be kept frozen, ship directly from Merck to the provider and are not shipped from McKesson. Figure 3 is a general outline of the vaccine ordering and receiving process.

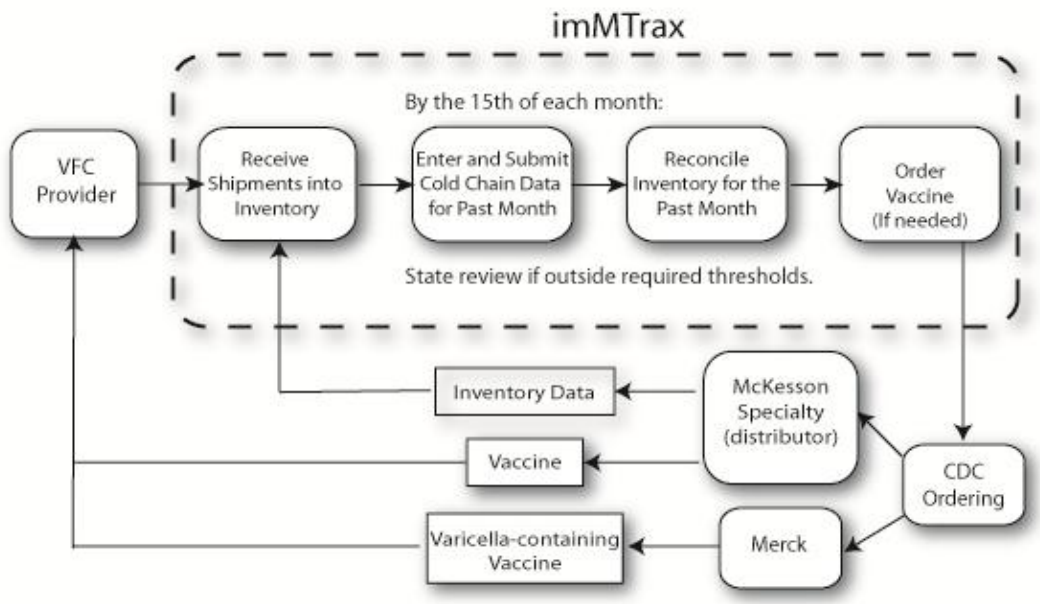


Figure 3 VFC Vaccine Order and Receiving Process

This handbook is not an in-depth imMTrax user's guide and will only outline the steps and policies associated with managing your 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

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

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 51). Temperatures can be recorded in imMTrax or on a paper log (temperature logs can be downloaded from www.immunization.mt.gov).
- Before reconciling inventory and ordering vaccine, you must enter cold chain data (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 are recording twice daily in imMTrax and are not ready to submit your data for the month 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 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. Reconciling inventory in imMTrax replaces the paper reports that were previously submitted to Home IV Pharmacy. You must have reconciled inventory within 14 days to place 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 to enter 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 your inventory. Integrated users simply have to keep their patient immunization data entry up to date. During reconciliation, doses administered data are automatically be pulled into the reconciliation process from patient records.
  - **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** (if necessary), **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

The vaccine ordering function in imMTrax is currently not in use. Until further notice, orders are being processed through Home IV Pharmacy:

- Before placing a vaccine order, submit in imMTrax (before the 15th of the month) your current cold chain data and reconcile your inventory. You must have reconciled your inventory within the last 14 days to place an 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, mail or fax a current order form to Home IV Pharmacy. The current order form can be found on our website (www.immunization.mt.gov under the “VFC” link). The Home IV Pharmacy

address and fax number are on the form. **If you fax the order form, please also send a copy by mail.** Your order will be delayed if faxes are not received or are unreadable.

- The **Doses on Hand** column of your order form must have a complete inventory of all your VFC vaccines (not just those you are ordering).
- VFC vaccine must be ordered by dose and by the minimum order quantities listed on the order form. Boxes cannot be broken down into smaller quantities.
- Orders will be reviewed to ensure that they are:
  - Not over a three–four month supply based on usage history (including current inventory)
  - 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. Issues with order quantities, incomplete order forms, and faxed documents may delay your order.
- Please inform the Immunization Program if there is a special circumstance such as a campaign or catch-up clinic where you need more vaccine than your usage history allows.
- Orders typically ship within 10–14 days from the time they are received at Home IV Pharmacy. To check the status of orders call or email Home IV Pharmacy (723-4099 jerrydotter@bresnan.net) or the Immunization Program (444-5580 hhsiz@mt.gov).

Receiving Orders

- If your vaccine shipping address or times vaccine can be received at your facility change, please inform the Immunization Program (444-5580 hhsiz@mt.gov).
- You should receive VFC vaccine 10–14 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 two weeks, call or email Home IV Pharmacy (723-4099 jerrydotter@bresnan.net) or the Immunization Program (444-5580 hhsiz@mt.gov).
- With the exception of varicella-containing products, VFC vaccine shipments will automatically appear in your imMTrax inventory with the lot number, expiration date, and number of doses.
- For varicella-containing vaccines, please add this vaccine to your inventory as a private lot and call the Immunization Program (444-5580). We will switch it to a public lot. To add the vaccine as a private lot click **Manage Inventory>>>Show Inventory>>>Add Inventory**.
- 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 to determine if they are perishable vaccine.
  - 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.

Problems with Orders

- Never reject VFC vaccine delivery or discard VFC vaccine shipments.
- If you encounter problems with orders or shipments call or email Home IV Pharmacy (723-4099 jerrydotter@bresnan.net) or 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. Contact the Immunization Program if you have questions.

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.
- Organize stock so that short-dated vaccines (those that expire at the earliest date) are used first. Please note that 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

- 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 on our website at www.immunization.mt.gov under the VFC link. The Immunization Program will also send 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. All nonviable vaccine must be reported to the Immunization Program on a Wasted and Expired Vaccine Form. The 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.
- 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. 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.

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.

- Keep the report for your records and make it available for review during VFC site visits. Do not submit borrowing reports to the Immunization Program.
- 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 record the administration of a public vaccine to a private-pay patient and vice versa, in order to "payback" the vaccine. 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. SPECIALTY PROVIDERS

In the past several years, specialty providers who serve a unique client base and offer only a subset of available vaccines have become 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 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, page 20.
- 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).
- Due to budget constraints, the Immunization Program cannot supply certified, calibrated continuously monitoring thermometers to birthing hospitals. Birthing hospitals must supply their own thermometers that meet the requirements outlined in Section 14.

Pharmacies

In 2011, the Montana Legislature passed Senate Bill 189 which 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.

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.

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). However, the Immunization Program reserves the right to conduct a compliance site visit if deemed necessary.

Pharmacies must 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.

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 an additional paper form each month that provides the following information:

- Doses of vaccine administered by VFC eligibility category (See Section 4–Eligibility)
- A statement signed by the pharmacist or cooperative practice provider certifying that no change in VFC Coordinator 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 Coordinator or storage units, the Immunization Program must follow up with the pharmacy before placing their vaccine order.

Due to budget constraints, the Immunization Program cannot supply certified, calibrated continuously monitoring thermometers to pharmacies. Pharmacies must supply their own thermometers that meet the requirements outlined in Section 14.