Montana Department of Public Health and Human Services

Immunization Program

Provider Handbook/ Vaccine Management Plan

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PublicHealth IN THE 406

MONTANA DPHHS DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

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VFC PROVIDER HANDBOOK

1. INTRODUCTION

Vaccines for Children (VFC) is a federal program providing no-cost vaccines to children who might not be able to afford them. 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. Eligible children through 18 years of age can receive VFC vaccine through a network of enrolled VFC providers. Since its inception in 1994, the VFC Program has improved vaccine availability, increased immunization coverage, and reduced disparities in access to healthcare.

VFC in Montana

The Montana Immunization Program (Immunization Program) implements the VFC Program within the state. We manage the budget, distribute vaccines, enroll and educate providers, and ensure program compliance through provider site visits.

Funding

As a Medicaid entitlement program, the VFC budget adjusts annually to cover all Advisory Committee on Immunization Practices (ACIP)-recommended childhood vaccines for Montana's VFC-eligible children.

Ordering and Managing VFC Vaccine—imMTrax

Requirement

Montana VFC providers order and manage VFC vaccine through the state's web-based immunization information system, imMTrax. Persons needing access to imMTrax must submit a System Access Request Form and an imMTrax User Memorandum of Agreement.

For in-depth imMTrax training, information, and forms, visit the imMTrax website, the Document Center in the application, or contact imMTrax Support at 406-444-5580 (hhsiz@mt.gov).

Document Retention Requirements

VFC-related Documents

Requirement

VFC providers must retain all VFC-related documents and electronic information for three years. This includes, but is not limited to VFC eligibility screening documentation, temperature logs, data logger (digital thermometer) data, borrowing forms, billing records, medical records that verify vaccine administration, and vaccine purchase and accountability records.

Immunization Records

Montana law requires hospitals to retain immunization records for at least 10 years (ARM 37.106.402), healthcare facilities other than hospitals to retain immunization records for at least 6 years (ARM 37.106.314), and pharmacies to retain immunization records for 7 years from the date the immunization was administered or until 7 years after the individual reaches 18 years of age, whichever is later (MCA 37-7-105).

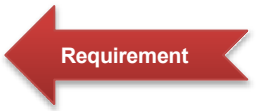
Medicaid Billing Records

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

This Document

This handbook contains immunization best practices, recommendations, and requirements of the Montana VFC Program. Requirements are underlined and marked with red arrows: 

We provide a paper copy of this document to all enrolled providers and post the most current version on our VFC Resources webpage. When revisions are made, we notify providers through an all-provider memo, provide a copy of the revised section(s), and post the revised version to our website. It is your responsibility to keep your paper handbook up to date by discarding outdated sections and replacing them with current versions.



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2. PROVIDER ENROLLMENT

Who can enroll?

The VFC Program was created to increase access to healthcare and allow children to remain in their medical homes for immunizations.

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

Requirement

- Has a medical director or equivalent to sign the Provider Agreement who has a valid license to administer vaccines in Montana and the authority to ensure the facility and all providers listed on the agreement adhere to the requirements of the program.
- Agrees to all program requirements, including participation in site visits and education requirements, and providing all ACIP-recommended vaccines for the populations they serve.
- Has the capacity to order, manage, and store public vaccine, including proper vaccine storage and temperature monitoring as described in Sections 12–18.
- Does not have providers or staff included on the Office of Inspector General List of Excluded Individuals and Entities (LEIE).
- Is on site with appropriate staff available to receive vaccine at least one day a week other than Monday and Friday, and for at least four consecutive hours during that day.

VFC providers can be both public and private facilities and those not registered as Medicaid providers. Pharmacies can enroll but are limited to administering influenza vaccines to children 12 through 18 years of age and ACIP-recommended immunizations under a collaborative practice agreement to children 7 through 18 years of age.

VFC Provider Agreement

The Provider Agreement lists the federal statutory requirements of the VFC Program. It must be signed by the medical director or equivalent at your facility. By signing a Provider Agreement and accepting shipment of VFC vaccine, you agree to abide by the requirements of the VFC Program.

Requirement

All VFC providers must submit a Provider Agreement annually. New providers do so during the enrollment process. Current providers complete a new Provider Agreement each year during annual re-enrollment.

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

Re-enrollment – Current Providers

Requirement

Each year, all current VFC providers must re-enroll in the VFC Program by completing a new Provider Agreement. The Immunization Program notifies providers when the re-enrollment period

begins and provides instructions for completing the process. All Provider Agreements must be reviewed and approved by the Immunization Program.

Enrollment – New Providers

Healthcare providers wishing to enroll in the VFC Program should contact the Immunization Program at 406-444-5580 (hhsiz@mt.gov).

New provider enrollment involves the following steps: Requirement

- Submitting a provider profile and signed VFC Provider Agreement
- Completing the required provider training
- Obtaining and setting up VFC-compliant vaccine storage units and digital thermometers (data loggers)
- Submitting a routine and emergency vaccine management plan
- Obtaining imMTrax access and training
- Receiving an enrollment visit from the Immunization Program.

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

Change Notification Requirement

Current providers must notify the Immunization Program if: Requirement

- Their contact information, vaccine management personnel, or vaccine shipping instructions change
- The medical director (or equivalent) who signed the Provider Agreement changes
- The number of immunization patients at the facility changes significantly
- The facility type changes
- They add or acquire new VFC vaccine storages unit and/or data loggers.

Termination

VFC providers may terminate the Provider Agreement at any time, and the Immunization Program may terminate the Provider Agreement due to provider inactivity, non-compliance, fraud, abuse, or being listed on the “List of Excluded Individuals and Entities.” (see Section 9 – Non-compliance, Fraud, and Abuse for more information).

Terminated providers agree to return unused public vaccine as directed by the Immunization Program. Requirement

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3. BILLING

There are two charges associated with immunization services—one for the vaccine and one for an administration fee.

The following are billing requirements of the VFC Program: Requirement

Vaccine

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

Administration Fee

- Providers agree to accept the administration fee set by the state Medicaid agency for Medicaid patients.
- Providers can charge non-Medicaid VFC-eligible patients an administration fee up to $21.32 per vaccine (not per antigen in combination vaccines).
- 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.
    - Unpaid administration fees cannot be sent to collections, and providers cannot refuse to vaccinate an eligible child whose parent or guardian has unpaid vaccine administration fees.
- Providers who bill for the vaccine administration fee of a non-Medicaid VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not affect VFC vaccine administration fees billed to Medicaid for Medicaid-eligible children.

Refer to the tables in Section 4 – VFC Eligibility – Special Eligibility Circumstance for additional billing information.

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

4. VFC ELIGIBILITY

VFC providers must screen all patients for VFC eligibility and document the results at every immunization visit. **Requirement**

VFC eligibility documentation must be retained for three years. **Requirement**

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

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

Determining VFC Eligibility Status

Basic Eligibility Criteria

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

- **Medicaid eligible:** A child who is eligible for the Medicaid program. For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably. (Healthy Montana Kids Plus)
- **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 health insurance, but coverage does not include any vaccines
  - A child who has health insurance, but coverage does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) (underinsured for non-covered vaccines)
  - A child who has health insurance but there is a fixed dollar limit or cap for vaccines (underinsured after limit or cap is reached).

*Underinsured children are only eligible to receive VFC vaccine at Federally Qualified Health Centers[1] (FQHC) or Rural Health Clinics[2] (RHC). If providers cannot verify vaccine insurance coverage, underinsured children are considered insured and not VFC eligible.

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

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

For patients eligible under more than one category, providers should select the category that requires the least out-of-pocket expense to the parent or guardian.

Fully Insured Children

Fully insured children are not eligible for VFC vaccines. Fully insured is defined as having health insurance that covers the cost of vaccine and its administration even if the insurance includes a high deductible or co-pay or if a claim would be denied because of an unmet deductible. Table 1 summarizes VFC eligibility determinations based on various insurance situations.

Table 1 Quick View of VFC Eligibility and Insurance Situations (From: *VFC Operations Guide*, page 21. CDC June 2018)

Child's Insurance Status	VFC Eligible?	VFC Eligibility Category
Enrolled in Medicaid (Healthy Montana Kids Plus)	Yes	Medicaid
Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Yes	Insured until the fixed dollar limit is met Underinsured after the fixed dollar limit is reached
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured. Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare.
Enrolled in a Health Care Sharing Ministry	Depends	Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan Insured if plan is recognized by the state insurance department and covers vaccines Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines
Enrolled in a separate Children's Health Insurance Program (Healthy Montana Kids)	No	Insured. The state CHIP program is responsible for vaccine payment for its members.
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN. However, provider should choose the eligibility category most cost-effective for the child and family.
Has Medicaid and is AI/AN	Yes	Medicaid or AI/AN. Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.

Special Eligibility Circumstances

This section covers special VFC eligibility situations. In general, when selecting between eligibility categories select the option requiring the least out-of-pocket expense to the child's parent or guardian.

Non-US Citizen Children

Non-U.S. citizen children are VFC eligible, if they meet the basic VFC eligibility criteria (≤18 years and AI/AN, Medicaid eligible, uninsured, or underinsured). Additionally, while citizenship is not a requirement for VFC eligibility, VFC vaccines are not intended to be used for children who are simply visiting the United States, temporarily traveling in the United States or tourist.

Healthy Montana Kids

For VFC eligibility purposes:

- Healthy Montana Kids children are considered insured and not VFC eligible.
- Healthy Montana Kids Plus children are Medicaid enrolled and therefore VFC eligible.

Medicaid as Secondary Insurance

Any insured or underinsured child who has Medicaid as secondary insurance is eligible for the VFC Program but is not required to participate. There are two options for billing. Children with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

The following are billing options when Medicaid is the secondary insurance:

- Use private vaccine and bill the primary insurer for the vaccine and the administration fee. If the claim is denied, bill Medicaid for the administration fee and repay the private dose with a VFC dose. Document the repayment as described in Section 16 – Borrowing.
- Use VFC vaccine and bill the primary insurer for the administration fee. If the claim is denied, bill Medicaid for the administration fee.

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.

Family Planning Clinics and Sexually Transmitted Disease (STD) Clinics

Unaccompanied minors through 18 years of age who present at family planning or STD clinics for contraceptive services or STD treatment are considered uninsured and VFC-eligible if they do not want to access their insurance due to the confidential nature of their visit. This special eligibility status is restricted to family planning and STD clinics. These facilities must track VFC vaccine given to patients in this eligibility category using a form that can be obtained by contacting the Immunization Program. Clinics are responsible for providing care in conformance with Montana's medical consent laws as they pertain to minors.

Incarcerated Juveniles

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

Dual Eligibility – American Indians/Alaska Natives

American Indians and Alaska Natives (AI/AN) can be eligible for VFC vaccine under more than one category. The following table outlines the 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 2).

Table 2 VFC Eligibility for American Indian and Alaska Native Populations at Facilities Other than Indian Health Service, Tribal, and Urban Indian Clinics

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

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

[2] Insured AI/AN children are not required to participate in the VFC Program. The decision whether to participate should be based on what is most cost effective for the patient. AI/AN children with high-deductible insurance plans requiring the parent to pay out of pocket for vaccines, should be considered VFC-eligible if the family has not yet reached its deductible.

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

Documenting Eligibility Screening

Requirements

Eligibility screening results must be:

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

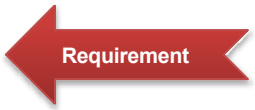
Methods of Documenting Eligibility Screening

Below are typical methods used to document eligibility although any method or combination of methods that meets the criteria above is acceptable.

imMTrax

Providers who hand-key administered immunizations into imMTrax and deduct doses from their inventory document VFC eligibility as part of this process, and this can serve as eligibility documentation. If data entry is current and accurate, imMTrax automatically calculates Provider Profile numbers for annual re-enrollment. If you do not manage your private vaccine in imMTrax, you must document eligibility screening for privately insured patients outside of imMTrax. Providers on data feeds or only entering "historic" immunizations do not capture eligibility and cannot use imMTrax to document eligibility.

Paper Eligibility Logs



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

Electronic Health Records

Most electronic health records (EHRs) can capture VFC eligibility information. EHRs can be used to document eligibility as long as the information is associated with an immunization or visit date and is not solely in the demographic/personal information fields. You must be able to extract Provider Profile numbers from the system for all VFC eligibility categories for re-enrollment, including privately insured and AI/AN.

Face Sheets and Patient Check-in Questionnaires

Patient-completed face sheets and questionnaires can be used to document eligibility as long as they are completed for each immunization visit (dated), screen for all eligibility categories you serve, can be used to determined Provider Profile numbers, and are archived for three years.

Provider Profile – Immunization Patient Numbers for Re-enrollment

Your Provider Profile is the number of VFC-eligible children and non-eligible children you served in the most recent 12 months by age and eligibility category. Each year during VFC Program re-enrollment, you must submit your Provider Profile derived from actual eligibility screening data from the previous year.

Be sure you are documenting eligibility throughout the year in a way that can be easily tallied for your Provider Profile.

5. Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory panel that recommends routine immunization practices for children and adults in the United State (US). The ACIP approves vaccines for use in the VFC Program.

VFC Resolutions

The ACIP approves new and amended recommendations for inclusion in the VFC Program by passing a VFC Resolution. VFC Resolutions determine what vaccines are available through the VFC Program, including dosage, schedule, and contraindications. The CDC publishes current VFC Resolutions on their VFC Resolution webpage.

Please note the following about VFC resolutions:

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

The Immunization Program notifies VFC providers when new and amended ACIP recommendations and VFC Resolutions become available.

ACIP Recommendations

Requirement

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

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

6. National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act (NCVIA) provides a cost-effective arbitration and compensation system for vaccine injury claims and a system for reporting and tracking adverse events related to vaccinations. Healthcare professionals who provide immunization services must adhere to the following NCVIA requirements when administering vaccinations. 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 a vaccine. You must provide a current vaccine-specific VIS to your patient or your patient's legal guardian at each vaccination visit.

Requirement

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

Whether managed as electronic files or paper handouts, you must provide *current* VISs to your patients. It is your responsibility to ensure VISs are kept up to date. We recommend storing paper VISs in one location and designating one person responsible for updating them. VISs managed through an EHR may require IT assistance to keep them up to date. The CDC VIS webpage offers a "Get email updates" function that notifies you by email when VISs are changed. Another option is to download VISs directly from the CDC website as needed so they are always up to date.

Vaccine Adverse Event Reporting System (VAERS) and MedWatch

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines. For nirsevimab when not co-administered with other vaccines, VFC providers should report all suspected adverse reactions to MedWatch. Providers should report suspected adverse reactions following co-administration of nirsevimab with any vaccine to the Vaccine Adverse Event Reporting System (VAERS).

Requirement

Reportable Events – Required

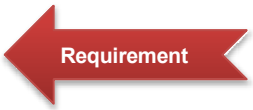
The NCVIA requires healthcare providers to report to VAERS:

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

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

Reportable Events – Voluntary

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



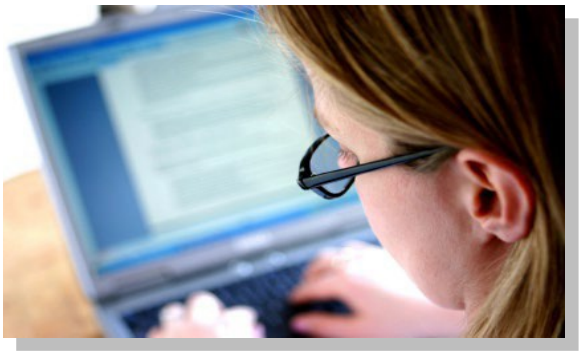
Vaccine Charting Requirements

The NCVIA requires vaccination records be in a patient's permanent medical record and 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.

Most EHRs capture the required charting elements for immunizations. If charting on paper, the Immunization Action Coalition website provides free immunization charts (downloadable as PDFs) that capture all the information required by the NCVIA.

7. VFC COMPLIANCE SITE VISITS



Overview

A compliance site visit is when an Immunization Program staff member—a site visit reviewer—visits your clinic and assesses the implementation of the VFC Program at your facility.

VFC providers receive a compliance site visit within 12 months of enrollment and at least every 24 months after that.

Requirement

Site Visit Process

VFC site visits may be combined with other assessment functions of the Immunization Program. Only VFC compliance site visit procedures are outlined in this handbook.

Site Visit Preparation

1. Approximately one month prior to your visit, the site visit reviewer will contact you by telephone or email to schedule the visit.
2. After the visit is scheduled, you will receive a letter confirming the date and detailing items needed before and during the visit.

During the Site Visit

3. Site visits can take from one to three hours depending on the size of your clinic, whether other assessment activities are performed, and the issues that arise during the visit.
4. Providers must make the following available during the visit:
    a. The vaccine manager or alternate and any key staff involved in the VFC Program
    b. Three months of temperature logs, trouble-shooting logs, and temperature data from your vaccine storage units
    c. The calibration certificates for all data loggers including your backup
    d. Your completed and annually reviewed *Vaccine Management Plan* (Section 12 of this Handbook)
    e. VFC eligibility screening documentation for the last year
    f. Borrowing reports (if applicable)
    g. Your paper stock or electronic source of VISs
    h. The circuit breaker for your vaccine storage units or your facility power loss prevention policy
    i. The vaccine administration fee charged to non-Medicaid, VFC-eligible patients
    j. Any VFC-related documentation requested during the visit.
5. Approximately one hour of the site visit is a one-on-one conversation with your vaccine manager or alternate. The site visit reviewer asks questions pertaining to the VFC Program and provides a list of public vaccines shipped to your facility over the last year.
6. The site visit reviewer also inspects your vaccine storage units.

7. After one-on-one with the vaccine manager or alternate and storage unit inspection, the site visit reviewer may work independently as they review documents, take notes, fill-out forms, and enter data into a computer or tablet

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

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

Requirement

Site Visit Follow-up

10. You must complete follow-up actions by the deadline in the Follow Up Plan. The site visit reviewer will be in contact by telephone, email, or fax or may return to your facility for a follow-up visit.

Requirement

Other Visits from the Immunization Program

Requirement

- **Unannounced Storage and Handling Visits** –Throughout the year, the Immunization Program performs unannounced visits that focus on vaccine storage and handling. Any active VFC provider may receive an unannounced visit. They take approximately 30 minutes and include an inspection of your vaccine storage units.
- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance. Providers may request an educational visit from the Immunization Program at any time (subject to staff availability). Education can also be conducted by telephone or webinar.
- **Enrollment Visits** – Enrollment visits occur during the enrollment process. See Section 2 – Provider Enrollment for more information on VFC Program enrollment.
- **Immunization Quality Improvement for Providers (IQIP) Visits** – IQIP visits are a VFC activity designed to support implementation of provider-level quality improvement (QI) strategies leading to increased vaccine uptake. Enrolled VFC providers should receive an IQIP visit at least every 5 years. New providers enrolled in the VFC program will receive an IQIP visit within 12 months of enrollment. IQIP visits may be held remotely or in-person.

8. VFC REQUIREMENT CHECKLIST

Requirements

Table 3 VFC Requirement Checklist by Frequency

X	VFC Requirement by Frequency	More Information
Once (upon enrollment or as needed)		
	Submit signed Provider Agreement, imMTrax MOA, and imMTrax System Access Requests.	Sections 2
	Receive VFC PIN # and imMTrax login credentials.	Sections 2,15
	Set up vaccine storage units and data loggers. Submit at least 24-hours of temperature data and calibration certificates for data loggers for approval using online Vaccine Storage Incident Report.	Sections 13,14
	Post "DO NOT DISCONNECT" signs on outlets and circuit breakers or if you have a backup generator/power, establish written electrical loss prevention policy.	Section 13
	Complete *Vaccine Management Plan* (Section 12). Review with staff. Document the review in the table in Section 12. Post completed Section12 on or near vaccine storage units. Fax to 406-442-4848.	Sections 11,12
	Complete vaccine manager and alternate vaccine manager enrollment education requirements.	Section 2
Every Vaccination Visit		
	Screen for VFC eligibility and document using a compliant method.	Section 4
	Distribute current Vaccine Information Statements (VISs) to patients.	Section 6
	Chart required vaccination information.	Section 6
Once Daily (preferably in the morning before vaccinating)		
	Log min/max temperatures and data logger alarm status.	Sections 13,14
Monthly (preferably around the end of the month)		
	Download, review, and save data logger data for the month (if applicable to your data loggers).	Section 14
	Vaccine manager or alternate review and sign completed temperature and borrowing logs	Sections 14,16
	Reconcile inventory in imMTrax for the month.	Section 15
	Order vaccine in imMTrax (must have reconciled within the last 30 days to order).	Section 15
Yearly		
	Review *Vaccine Management Plan* (Section 12) with staff. Document the review, update/re-post/re-fax (406-442-4848), if necessary.	Sections 11–18
	Re-enroll by submitting a new Provider Agreement (per IZ Program instructions).	Section 2
	Fulfill annual vaccine manager and alternate vaccine manager education requirement.	Section 19
Every 24 Months		
	Host a compliance site visit from the Immunization Program.	Section 7
As Needed		
	Report all storage unit temperature excursions using the online Vaccine Storage Incident Report	Section 14
	Document all issues with vaccine storage units on your trouble-shooting logs.	Section 14
	Submit VAERS incidents.	Section 6
	Document borrowing and repayment on VFC Vaccine Borrowing Report.	Section 16
	Update, re-post, and re-fax (406-442-4848) Section 12 of the *Vaccine Management Plan* if information changes.	Sections 11-12
	Retain VFC documents/data for three years (e.g., eligibility screening logs, temperature data).	Sections 1,4,14
	Submit temperature data for new or repaired storage units for approval prior to using appliance. Submit calibration certificates and sample data for new or replacement data loggers for approval.	Sections 13,14
	Immunization Quality Improvement for Providers (IQIP) Visits	Section 7

9. NON-COMPLIANCE, FRAUD, AND ABUSE

Requirement

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

Non-compliance, fraud, and abuse is typically discovered during VFC site visits but may also be self-reported, reported by third parties, or revealed through vaccine ordering and accountability processes. All circumstances are unique, making it difficult to develop rules for handling all situations. VFC providers may be required to replace vaccine lost due to negligence, non-compliance, fraud, or abuse; or incur the cost of re-vaccination due to negligence (see Section 18 for details on vaccine replacement).

Policy

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

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

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

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

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

Terminated providers must return any unused public vaccine as directed by the Immunization Program. Once all vaccine has been accounted for, the Immunization Program issues a memo to the provider finalizing the termination.

A terminated provider may be allowed to re-enroll if they complete the enrollment process, including an enrollment site visit, and demonstrate full compliance.

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

Definitions

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

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

Examples of Fraud and Abuse

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

10. IMMUNIZATION RESOURCES

Montana Immunization Program

Immunization Program main phone and email: (406) 406-444-5580 hhsiz@mt.gov

Paper fax (406) 406-444-2920 Digital fax (406) 442-4848

Immunization Program website | Montana VFC webpage | Vaccine Storage Incident Report

Immunization Program Staff

Federal

CDC Vaccines and Immunizations

CDC VFC | Vaccine Information Statements (VIS)

CDC Vaccine Safety | Vaccine Adverse Event Reporting System (VAERS)

Vaccine Package Inserts (Prescribing Information)

FDA Product Approval: View All (immunize.org)

Other

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

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

Manufacture Stability Calculator

- GlaxoSmithKline: Vaccine Stability Calculator | GSK US Medical Affairs
- Merck: Merck Vaccine Temperature Stability Calculator (merckmedicalportal.com)
- Sanofi Pasteur: https://www.sanofimedicalinformation.com/s/stability-calculator?language=en_US&CN=US
- Pfizer: https://www.pfizermedicalinformation.com/stability-calculator
- Moderna: https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page

VACCINE MANAGEMENT PLAN

11. VACCINE MANAGEMENT PLAN – INTRODUCTION

Requirement

VFC providers must have written routine and emergency vaccine management plans. Section 11–18 of this handbook serves this function. Providers may be held accountable for VFC vaccine wasted due to not following their vaccine management plans (See Section 18 – Vaccine Loss and Replacement).

Customize, Review, and Submit your Plan

Requirement

- Fill-in Section 12. You can hand-write the information or use a computer fillable version obtained by request from the Immunization Program.
- Review the plan with your staff involved in immunization services.
- Document the completion and review by filling in the table at the end of Section 12.
- Fax a copy of the completed Section 12 to 406-442-4848.
- Post a copy of the completed Section 12 on or near your VFC vaccine storage units.

Keep Your Plan Up to Date

Requirement

- Review your plan with staff at least annually. Document the reviews in the table at the end of Section 12.
- Any time the information on pages 35–38 changes, update the plan, review with staff, re-post, and re-fax to 406-442-4848.

12. Routine and Emergency Management Plan Template

Customize your plan by filling in the information below and posting a copy of this section on or near your vaccine storage units. Fax a copy to 406-442-4848 upon initial completion and whenever information on pages 35–38 changes. See Section 11 for details on keeping your vaccine management plans up to date.

Requirement

Facility Information

Provider/Facility Name	VFC #

Designated Vaccine Managers

Requirement

Designate one person primarily responsible for VFC vaccine management and one alternate for when the primary is not available. Notify the Immunization Program if staff in these positions change.

Vaccine Manager	Email	Phone
Alternate Vaccine Manager	Email	Phone

Important Phone Numbers and Emails

As appropriate for your facility, provide important phone numbers and email addresses below.

Montana Immunization Program	**406-444-5580** hhsiz@mt.gov	Data Logger Calibration/Support	
Utility Company		Vaccine Transport	
Facility Maintenance/Landlord		Other	
Appliance Repair		Other	
Alarm Company		Other	

Power Supply

Circuit Breaker Location

Contact person if access to circuit breaker is restricted	Phone/Email

DO NOT DISCONNECT Signs

Requirement

Posted to:

☐ Refrigerator Outlet(s) ☐ Freezer Outlet(s) ☐ Circuit Breaker(s)

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 testing/maintenance	Phone/Email
Date and Result of Last Test (e.g., pass/fail, issues, repairs)	

Emergency Plan

Alternate Vaccine Storage Locations

Requirement

Identify at least one alternate vaccine storage facility that has compliant storage and backup power where vaccines can be stored in the event of a power outage or equipment failure. We recommend signing a Memorandum of Agreement (MOU) with the alternate location. Designate two locations, if possible.

Alternate Location #1	Contact Name	Phone	MOU/Agreement Date
Alternate Location #2 (Optional)	Contact Name	Phone	MOU/Agreement Date

Location of Emergency Transport/Pack-out Materials

Location of Emergency Transport/Pack-Out Materials

Storage Units and Data Loggers

Inventory

Storage Unit Make/Model/Identifier	Ref or Freezer	Location	Data Logger Make/Model/Identifier	Calibration Due Date

Storage Unit Make/Model/Identifier	Ref or Freezer	Location	Data Logger Make/Model/Identifier	Calibration Due Date

Location of Storage Unit User Manuals

Location of Backup Data Logger

Location of Data Logger Accessories

User Manual
Calibration Certificates
Computers with Software or System Access
Archived Temperature Logs and Trouble-shooting Logs
Archived Temperature Data Files or Reports (NA if using cloud or centralized server storage)

Vaccine Inventory Management

Receiving Shipments

Describe the process for receiving vaccine shipments at your facility.

Rotating Stock and Removing Expired Vaccine

Describe the process for ensuring short-dated vaccines are used first and expired vaccines are removed from storage.

Separating Public and Private Vaccine

Describe the process for separating public and private vaccine stock.

Responsible Persons

Vaccine Ordering	Responsible Person	Phone/Email
Receiving Shipments	Responsible Person	Phone/Email
Organizing/Managing Storage Units	Responsible Person	Phone/Email
Rotating Stock so Short-dated Vaccines are Used First	Responsible Person	Phone/Email
Accounting for Doses Administered	Responsible Person	Phone/Email
Removing Expired Vaccine from Storage Units	Responsible Person	Phone/Email
Returning/Disposing of Wasted, Spoiled, and Expired Vaccine	Responsible Person	Phone/Email
Managing and Documenting Borrowing	Responsible Person	Phone/Email
Managing Data Loggers	Responsible Person	Phone/Email
Handling and Reporting Temperature Excursions	Responsible Person	Phone/Email

Vaccine Management Plan Updates and Reviews

Update Section 12 as needed. Document updates in columns one and two below by listing the date and the signature and title of the preparer.

Requirement

Review your *Vaccine Management Plan* with staff annually and anytime Section 12 is updated, or you have a change in staff. Document staff reviews in columns three and four

Anytime the information on pages 35–38 changes, fax a copy to 406-442-4848.

Updates **Staff Reviews**

Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials

Faxed: Date________________ Date________________ Date________________ Date________________

Date________________ Date________________ Date________________ Date________________

13. VACCINE STORAGE UNITS

General Requirements

Refrigerators and freezers used to store VFC vaccine must be:

Requirement

- Stable enough to maintain vaccine storage temperatures year-round.
- Large enough to hold the year's largest inventory.
- Equipped with a calibrated, digital data logger[3] or equivalent for recording temperatures. See Section 14.
- A CDC-recommended appliance type. Either:
  - A. Pharmaceutical-grade[4] stand-alone[5] or combination[6] units, or
  - B. Household-grade[7] stand-alone units, or
  - C. Household-grade combination units using only the refrigerator section and a stand-alone freezer.

A. B. C.

- **Prohibited**: Dormitory-style storage units[8] or using the freezer of a household-grade combination unit.

Requirement

[3] A digital, continuous monitoring thermometer

[4] Designed to store pharmaceuticals in a laboratory or pharmacy setting

[5] An appliance that is either a refrigerator or freezer

[6] An appliance with both a refrigerator and freezer chamber

[7] Appliances typically found in homes and sold at retail appliance stores

[8] A refrigerator with a small freezer inside the refrigerator chamber and only one external door

New or replacement units must be CDC-recommended storage units and *cannot* be household/commercial combination units where both the refrigerator and freezer are used to store VFC vaccine.

We strongly recommend VFC providers have the Immunization Program review vaccine storage units *before purchase* to ensure they meet requirements.

Requirement

Precautions when using Household-grade Combination Units

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

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

Freezers – Frost-free vs. Manual Defrost

Both frost-free (automatic defrost) and manual defrost freezers are allowed for storing vaccines.

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

There are disadvantages to both types of freezers:

- The temperature cycling parameters in frost-free units must meet Merck specifications (contact the Immunization Program for details), and data loggers must be adjusted to accommodate the temperature spikes, so they do not activate the alarm.
- Manual defrost units hold vaccine storage temperatures steady, but alternate storage must be arranged when the unit is defrosted.

Size Determination

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

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

Requirement

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 4 Recommended Minimum Cubic Feet of Storage Space Based on Maximum Doses

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

Setting Up your Storage Unit

Unit Location

- Place the unit close to a reliable electrical outlet (see *Electrical Supply* below) in a well-ventilated, climate-controlled space away from direct sunlight.
- Follow the minimum clearance guidelines for your appliance taking care not to block vents to the motor compartment.
- The unit should sit firm and level.

Electrical Supply

- If possible, do not plug more than one appliance into the outlet to avoid overloading the circuit and tripping the circuit breaker.
- Make sure the outlet is not controlled by a light switch and is not GFCI protected.
- Do not use extension cords, battery packs, or surge protectors.
- Protect the power supply:
  - Facilities *without* sophisticated power loss prevention systems, must post “DO NOT DISCONNECT” signs next to the outlets and circuit breakers supplying vaccine storage units.

    Requirement
  - Facilities with sophisticated power loss prevention systems do not need “DO NOT DISCONNECT” signs but must have written policies detailing measures taken to prevent accidental loss of power. Systems should be in working order and tested regularly.
- Arrange at least one alternate vaccine storage location that has compliant storage units and backup power where you can move your vaccine in the event of a power outage or equipment failure. Record this information in Section 12.

  Requirement

Temperature Stabilizing

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

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

  Freezer: -58ºF to 5°F (-50°C to -15°C)

Requirement

- For most numbered temperature dials, the higher the number the colder the temperature. Check your appliance manual to avoid improper adjustments.
- Place the buffered probe of a calibrated, VFC-compliant data logger inside each chamber in a central location near vaccines and away from ceilings, walls, floors, vents, fans, coils, and cooling plates. See Section 14 for more information on data loggers.

Requirement

- If using a household-grade appliance, consider putting water bottles in the refrigerator or ice packs in the freezer in areas inappropriate for vaccine storage (e.g., door racks, crisper drawers, near cooling plates). This helps maintain the temperature in the event of a power outage and prevents vaccine from being placed in inappropriate areas. However, DO NOT impede airflow with the water bottles or icepacks.
- Make sure doors close tightly and seals are intact.
- Allow the unit to stabilize at least several hours.
- Adjust the temperature controller until the target temperature is achieved and the unit remains stable and in range.
- Once the unit has remained stable and in range for at least 24-hours, submit storage unit temperature data for approval (see below).

Storage Unit Approval

The Immunization Program must approve all storage units used to store VFC vaccine. To have a storage unit approved, submit:

Requirement

- Data logger data showing at least 24-hours of stable, in-range temperatures. Use our online Vaccine Storage Incident Report to submit the data and select “Sending Approval Data” as the “Reason for Contact.”

This requirement applies to:

- New VFC providers
- Providers setting up new VFC storage units
- Providers reinstating a VFC storage unit after a repair.

The Immunization Program will reply by email approving or disapproving your storage unit. Do not use the storage unit for public vaccine until it has been approved.

Vaccine Placement

- Keep vaccines in their original boxes with the lids closed.
- Place vaccine in the middle of the compartment away from the ceiling, walls, and floor of the chamber.

- Keep vaccine away from vents, fans, cooling coils or cooling plates where temperatures may be too cold. (You can test these locations with your data logger before loading your vaccines.)
- Never store vaccine in door racks or crisper drawers. Consider removing crisper drawers to facilitate air circulation.
- If containers are used to organize vaccine, use only open (no lid) containers that allow air to circulate around the vaccine boxes. Baskets work well for this.
- Clearly label VFC vaccine and keep it physically separated from private and other public stock. **Requirement**
- Never store food or beverages in vaccine storage units. Other medications and biologicals can be stored as long as they are clearly marked and physically separated from vaccine. Store potentially contaminated items below vaccines.
- In general, 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. Consult Section 16 of the product prescribing information for proper diluent storage conditions.
- See Section 16 for more guidance on managing vaccine inventory.

14. TEMPERATURE MONITORING

Montana VFC Data Logger Policy

Providers must monitor temperatures in their vaccine storage units with VFC-compliant digital thermometers called data loggers and have one backup onsite at each clinic location.

Requirement

To be VFC-compliant, a data logger must:

- Be a continuous recording device that takes a reading at least every 30 minutes
- Read temperatures from a buffered probe
- Display the current, minimum, and maximum temperatures on the outside of the storage unit (exceptions for organization-wide monitoring systems)
- Generate data that is reviewable, archivable (3 years), and able to be sent to the Immunization Program
- Alarm to indicate temperatures outside proper vaccine storage temperatures
- Have a current calibration performed within the last two years evidenced by a certificate of calibration.

Purchasing Data Loggers

Providers can purchase data loggers from a vendor of their choice as long as the devices meet the requirements listed above. Contact the Immunization Program for a list of data loggers used by other providers in the VFC Program. We strongly recommend having the Immunization Program review data logger specifications *before purchase* to ensure they meet requirements.

Data Logger Approval

The Immunization Program must approve all data loggers used to monitor VFC vaccine. To have data loggers approved, submit the following by using our online Vaccine Storage Incident Report and selecting "Sending storage unit approval data" as the reason for contact:

Requirement

- Data logger data from each device showing the data loggers are properly configured and that storage units are stable and in-range
- Calibration certificate for each device showing the data logger is currently calibrated.

This requirement applies to:

- New VFC providers
- Current providers acquiring new data loggers

The Immunization Program will reply by email approving or disapproving your data loggers. Do not use data loggers to monitor your public vaccines until they have been approved.

Calibrating Data Loggers

"Calibration" is checking the data logger's accuracy by comparing its temperature readings to those of a known standard. Calibration testing must adhere to international standards and be documented with a certificate of calibration. Calibration costs from $50 to $100 per device and typically involves shipping the device to a

calibration lab or having a calibration service come to your facility. Calibrations can also be done by your bioengineering or facilities department as long as they follow international standards and issue a certificate.

Calibration Interval

Requirement

Data loggers must be calibrated at least every two years. Some calibration labs may specify how long the calibration is valid with a "due date" for the next calibration. This is called the calibration interval. Be sure to clarify the calibration interval with the lab and always try to get a calibration valid for two years.

- If the certificate has a due date less than or equal to two years from the testing date, recalibrate by the due date.
- If the certificate has a due date greater than two years from the testing date, recalibrate within two years of the testing date. We do not allow calibration intervals longer than two years regardless of the due date on the certificate.
- If the certificate does not have a due date, recalibrate within two years of the testing date.

Certificates of Calibration

Requirement

To show compliance with international standards, the certificate of calibration must either:

- Indicate the testing was done by an ILAC MRA[9] calibration lab OR
- Include a statement saying the testing adhered to one of the following standards:
  - ISO IEC 17025
  - ASTM Standard E2877 tolerance Class F
  - NIST traceability
  - Other Immunization Program approved accuracy validation method (Contact us).
- Certificates must include:
  - The name of the calibration lab or entity
  - Device make/model and unique identifier (e.g., device number, serial number etc.)
  - Date of calibration testing
  - Confirmation that the device passed testing with an accuracy of ±1°F or ±0.5°C.
  - Optional: Calibration due date. Some calibration labs may include a calibration "due date" indicating how long the calibration is valid (i.e., calibration interval).

Providers are responsible for calibration certificates and must make them available for review by request and during VFC site visits.

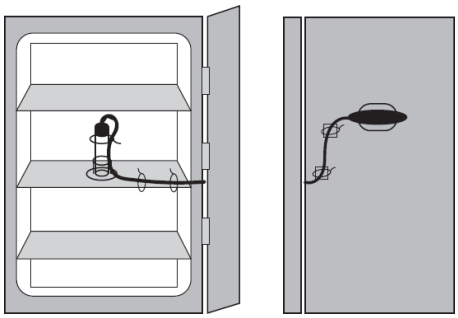
Calibration Labs

To find a calibration lab, start by contacting the manufacturer or distributor of your data logger. They may offer calibration services or be able to recommend a lab. Another option is to choose a lab from this list of accredited calibration labs compiled by the California Immunization Program.

[9] International Laboratory Accreditation Cooperative – Mutual Recognition Arrangement

Installing Data Loggers

Refer to the instructions that came with your data logger for proper installation.



- Place the buffered probe in the center of the chamber near vaccine but away from vents, coils, cooling plates, walls, ceilings, and floors. We recommend securing the probe in place. **Requirement**
- Equilibrate the buffered probe for at least two hours before beginning to monitor temperatures.

Data Logger Settings

Use the following settings when configuring your data loggers: **Requirement**

Sampling Rate/Recording Interval

Data loggers must take a temperature reading at least every 30 minutes.

Alarms

Set alarms to activate 1° (F) or 0.5° (C) outside proper vaccine storage temperatures.

Vaccine storage temperatures:

Refrigerators	36° to 46°F	(2° to 8°C)
Freezers	-58° to 5°F	(-50° to -15°C)

Alarm thresholds:

Refrigerator	Lower 35°F (1.5°C)	Upper 47°F (8.5°C)
Freezer	Lower -59°F (-50.5°C)	Upper 6°F (-14.5°C)

Alarm Delays

Some devices allow you to set a period of time or number of readings out-of-range before activating the alarm. We allow up to 15-minute alarm delays on refrigerators and freezer. Auto-defrost (frost-free) freezers can have an alarm delay up to 1 hour to accommodate defrost cycles.

Managing Data Logger Data

Data logger data must be archived for three years just like other VFC documentation and must be made available to the Immunization Program by request and during VFC site visits. **Requirement**

Routine Temperature Monitoring

Requirement

VFC providers are required to manually check their calibrated data loggers once per day—preferably in the morning—each day their facility is open. The following information must be captured:

- Clinic name
- Storage unit being monitored
- Entry date and time
- Initials of person making the entry
- Alarm status
- Minimum and maximum temperature since the last check.

Requirement

Providers must also keep a trouble-shooting log for each storage unit that includes:

- Date/time of issue
- Description of the issue
- Action taken
- Outcome
- Vaccine Storage Incident Report number
- Initials of staff making the entry.

Providers can use any method for logging temperatures and troubleshooting as long as all required elements are captured (lists above) and there is a place on the form for the Vaccine Manager or Alternate to sign (see below). The Immunization Program offers once-daily and twice-daily paper temperature logs that capture all required information. Contact us (406-444-5580 hhsiz@mt.gov) if you would like a copy or visit our website.

Requirement

Once-daily temperature documentation must be archived for three years and made available to the Immunization Program during VFC site visits and by request.

Requirement

At the end of each month and prior to archiving, the Vaccine Manager or Alternate must review and sign the temperature logs certifying that the information is accurate, and all issues have been reported and resolved.

Adjusting Temperatures

- Do not make temperature adjustments without informing your vaccine manager or alternate vaccine manager. Consider posting a sign prohibiting temperature adjustments by unauthorized personnel.
- DO NOT adjust temperatures in the evening or before a weekend when you will not be around to monitor the results.

Temperature Excursions

A temperature excursion is an event where vaccine is exposed to temperatures outside the acceptable range for vaccine storage.

Requirement

VFC providers must report temperature excursions involving public vaccine to the Immunization Program.

Follow the steps below when responding to temperature excursions:

1. Do not administer or discard the vaccine.
2. Notify the vaccine manager or alternate vaccine manager at your facility.
3. Label the affected vaccine DO NOT USE so it is not administered while the incident is investigated.
4. Stabilize the situation by returning the vaccine to appropriate storage temperatures.
    a. If the duration of the event is likely to be less than 4 hours, keep the vaccine in the storage unit with the door closed.
    b. If the duration of the event is unknown or likely to last longer than 4 hours, move the vaccine to the alternate storage location designated in Section 12.
5. Download the temperature data for the timeframe of the excursion.
6. Use the online vaccine stability calculators or contact information for manufactures of each vaccine to determine if the vaccine(s) are viable. You will need the following information before contracting manufactures:
    a. Duration unit(s) were out or range
    b. Max/Min temperature reached
    c. Vaccine(s) affected
7. Report results by submitting an online Vaccine Storage Incident Report. Complete all required fields and upload downloaded digital data logger data. The Immunization Program will reply by email with confirmation it was received within 2 business days.
8. If vaccine(s) must be wasted or disposed of follow the steps using the wasted and expired form.
9. Save any relevant documents related to your VIR.
10. Report on your trouble shooting log.

15. Ordering and Receiving VFC Vaccine

Overview

Providers order and manage VFC vaccine in imMTrax, the state immunization registry. **Requirement**

Managing private stock vaccine in imMTrax is optional.

You must have access to the Vaccine Order and Management System (VOMS) in imMTrax to order vaccine and manage inventory. For in-depth imMTrax training and information, visit the imMTrax website, the Document Center in the application, or contact imMTrax Support at 406-444-5580 (hhsiz@mt.gov).

Reconciling Inventory

Reconciling inventory is accounting for the vaccine used or otherwise removed from inventory since the last reconciliation. To reconcile go to **VOMS>>>Reconciliation.** For more guidance on reconciliation, visit the imMTrax website, the Document Center in the application, or contact imMTrax Support at 406-444-5580 (hhsiz@mt.gov).

When reconciling, you must: **Requirement**

- Reconcile monthly
- Account for all doses
- Select accurate reasons for inventory adjustments.

Ordering Vaccine

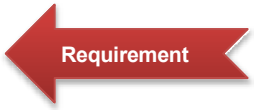
- Place orders in imMTrax by using the order form found at **VOMS>>>Orders & Transfers>>>New Order**.
- Before placing a vaccine order, you must have reconciled your inventory within the last 14 days.
- Place orders between the 1st and 15th of each month.
- Order vaccine no more than once per month. **Requirement**
- Order vaccine by the dose with the order amount divisible by the number of doses in a minimum order.
- The Immunization Program reviews orders to ensure they are:
  - Not over a two-month supply based on past usage (including current inventory)
  - Not over-ordering a particular antigen when taking into account combination vaccines.
- The Immunization Program may adjust orders that do not conform to the requirements listed above. We attempt to contact providers before adjusting orders but will adjust and place orders if we do not hear back from the provider.
- Inform the Immunization Program of special circumstances such as off-site clinics and campaigns where you need more vaccine than your usage history allows (hhsiz@mt.gov 406-444-5580).
- Inform the Immunization Program (406-444-5580 hhsiz@mt.gov) if your vaccine shipping address or times you can receive vaccine shipments change.

Checking the Status of an Order

- Orders typically ship one to three days after placing them in imMTrax.
- Check the status of an order by going to **VOMS>>>Orders & Returns>>>Orders & Transfers>>>Inbound Orders & Transfers** tab>>>**Status** column.
- If you have questions about the status of your order, call or email the Immunization Program (406-444-5580 hhsiz@mt.gov).

Receiving Vaccine Shipments at your Facility

Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday and Friday, and for at least four consecutive hours during that day.



If you have not received your order in five days, check the status of your order in imMTrax (see previous section), or contact the Immunization Program (406-444-5580 hhsiz@mt.gov).

Refrigerated vaccines ship from McKesson. Varicella-containing vaccines and Pfizer Covid vaccines that are stored frozen ship from either Merck or Pfizer, respectively. Frozen vaccines may arrive at a different time than your refrigerated vaccine.

Follow the steps below when receiving vaccine at your facility:

- The Immunization Program will send an email to the vaccine manager and alternate manager at your facility the morning of the day you are expected to receive a *refrigerated* vaccine shipment. We cannot warn you about frozen vaccine shipments from Merck and Pfizer.
- Inform the front desk and supply personnel when vaccine deliveries are expected.
- DO NOT leave vaccine deliveries unattended. Check all deliveries immediately to determine if they are perishable vaccine and handle them accordingly.
- Contact the designated vaccine manager or alternate when shipments arrive.
- Place vaccine in an approved storage unit holding proper temperatures as soon as possible.
- Follow the instructions on the packing slip when unpacking vaccine shipments. Confirm that:
    - The package is not damaged or leaking
    - The shipping time was less than 48 hours for refrigerated vaccines and less than 96 hours for frozen vaccines. If the interval between shipment from the supplier and arrival at your facility is more than the allowed time, the vaccines could have been compromised during shipment. See *Problems with Orders and Shipments* below.
    - The temperature monitors (if present) are within acceptable limits.
    - The vaccine quantities, diluents, lot numbers, and expiration dates match the packing list and imMTrax order.
    - Review expiration dates to current stock to ensure short-dated vaccines are used first.

Receiving Orders in imMTrax

Orders should be received in imMTrax within 24-hours of them physically arriving at your facility.

- To receive a vaccine shipment in imMTrax, go to **VOMS>>>Orders & Returns>>>Orders & Transfers>>>Inbound Orders & Transfers**. Enter the quantity received in the column and click **Receive**.

- Received vaccines will automatically appear in your public vaccine inventory. To confirm your order was added to your inventory, go to **VOMS>>>Inventory>>>Search/Add**.

Problems with Orders and Shipments

Requirement

- Never reject a vaccine delivery or discard a VFC vaccine shipment.
- If you believe your vaccine was compromised during shipment, *immediately* store the vaccine under appropriate conditions, separate from other stock, mark "DO NOT USE," and call the McKesson Specialty Contact Center (MSCC) at 1-877-836-7123. Viability calls must reach MSCC the same day the vaccine arrived at your facility or the CDC, Immunization Program, and your facility may be liable for vaccine replacement.
- If you encounter problems with shipments other than viability issues, call or email the Immunization Program (406-444-5580 hhsiz@mt.gov).
- 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.

Seasonal Influenza Vaccine Orders

The Immunization Program pre-books seasonal influenza vaccine months in advance and distributes doses during the season as they become available. For this reason, we manage influenza vaccine differently than other publicly supplied vaccine:

Requirement

- The Immunization Program distributes an influenza vaccine order form early summer each year. It lists the vaccine offerings for the coming season and instructions for returning the form to the Immunization Program.
- The influenza vaccine order form must contain your order for the entire season and be returned by the submission deadline in order to reserve your vaccine for the season.
- As influenza vaccine becomes available at McKesson, we ship allocations to our providers. Shipments typically begin the first of September and last through December until all orders are fulfilled. You may not receive your entire order at once.
- After orders are fulfilled, we often have extra doses available on a first come, first serve basis.
- Seasonal influenza vaccine expires in June. DO NOT discard expired influenza vaccine. It must be returned to McKesson following the procedure outlined in Section 16.
- Contact the Immunization Program (406-444-5580 hhsiz@mt.gov) with questions about influenza vaccine orders.

16. MANAGING INVENTORY

Organizing and Rotating Stock

- Physically differentiate VFC vaccine from private and other public stock vaccine.
- Check expiration dates on a weekly basis and immediately remove expired, spoiled, and wasted vaccine from storage units.

Requirement

- Organize packages so that short-dated vaccines are used first and only one package is actively used at a time.
- Recently received vaccine may outdate sooner than vaccine already in your inventory. Check expiration dates carefully.
- See Section 13, *Vaccine Placement* for additional guidance on organizing your vaccine inventory within your storage units.

Short-dated Vaccine

- Vaccine that will expire in 90 days turns orange in your imMTrax inventory.
- If vaccine is within three months of expiring, you will not use it in that timeframe, and it has not experienced any temperature excursions, contact other VFC providers in your area to see if they can use it. If another provider can use the vaccine, follow the guidelines in Section 17 to transfer the vaccine.
- If you cannot find a VFC provider in your area that can use the vaccine, contact the Immunization Program for assistance in rehoming the vaccine.
- DO NOT TRANSFER short-dated vaccine to providers without first contacting them to see if they want it and can use it before it expires.
- DO NOT TRANSFER opened, multi-dose vials or vaccine that has experienced a temperature excursion.

Expired, Spoiled, and Wasted Vaccine

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

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

Requirement

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

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

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

1. Fill in the second table in the Wasted and Expired From. Enter the most appropriate number in the Reason Code column. Use the NDC on the vaccine package or packing slip (not on the syringe/vial).
2. Indicate the number of shipping labels needed. One label per shipping container.
3. Return form to the Immunization Program. Once processed, we will email you a print-screen of the return inventory and McKesson Specialty Care Distribution will email you a shipping label.
4. Print the print-screen and place in the shipping container with your vaccine. The vaccine in the container must match the information on the print-screen EXACTLY. Print and attach the shipping label to the outside of the container. Call for a UPS pickup.
5. You must return expired/spoiled vaccine within six months of the spoilage or expiration by the end of the current year.
6. Account for the wasted/expired vaccine in imMTrax during your monthly reconciliation.

Borrowing

Vaccine "borrowing" is the temporary transfer of vaccine between public and private stock in order to avoid a missed opportunity to vaccinate. VFC providers are required to maintain adequate inventory of public and private vaccine to meet the needs of their patients. Borrowing should not be a routine vaccine management practice.

Allowed Borrowing Circumstances

Requirement

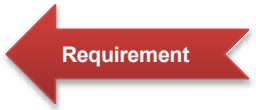
Borrowing is only allowed under the following circumstances:

- Lack of stock due to vaccine shipment delays
- Vaccine not useable on arrival (e.g., vials broken, temperature issue)
- To use short-dated stock before it expires
- Accidental use of wrong stock
- VFC seasonal influenza vaccine not yet available or delayed at the *beginning* of influenza season (any other borrowing of influenza vaccine is prohibited)
- To repay stock when insurance billing reveals a patient is a different eligibility than what was presented/determined during screening (See Section 4 for definitions of uninsured and underinsured).

CDC issues a separate threshold for allowable borrowing instances by category. A VFC provider may have permissible borrowing instances but may still have a follow-up action item assigned during a site visit if the set threshold is crossed.

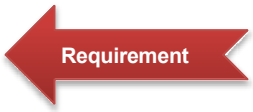
Borrowing VFC vaccine must not prevent a VFC-eligible child from receiving a needed immunization.

Borrowing Documentation



Use the following procedures to track vaccine borrowing:

- Document borrowing and payback on the VFC Vaccine Borrowing Report, available on our website. Follow the instructions on the report.
- You must retain borrowing reports for three years and make them available for review during VFC site visits and upon request. Do not submit borrowing reports to the Immunization Program unless requested to do so.
- Prior to site visit or when log is complete, the Vaccine Manager or Alternate must review and sign completed borrowing logs, certifying that all transactions are accurately documented and all borrowed VFC doses have been repaid.



- Retain all vaccine purchase receipts for vaccine used in borrowing payback and make them available for review during VFC site visits or upon request.

Managing Borrowing in imMTrax:

- imMTrax does not allow transferring vaccine between public and private stock. If a vaccine is entered into your inventory as public vaccine, it must remain public vaccine. Private vaccine must remain private vaccine.
- ImMTrax will allow you to administer a public vaccine to a private-pay patient and vice versa, in order to “pay back” the vaccine.
- Private vaccine used to “pay back” borrowed doses must be managed in imMTrax.
- You must have paper borrowing reports to support borrowing transactions in imMTrax.
- All borrowing should be paid back (returned to appropriate stock) within three months of the initial transaction or at the first opportunity, whichever comes first.

17. VACCINE TRANSFER, TRANSPORT, AND OFF-SITE CLINICS

Vaccine Transfers

VFC vaccine should be direct shipped to the end-user whenever possible. However, it may be transferred between providers to resolve short-term supply issues and prevent wastage due to expiration.

Follow the procedure below when transferring vaccine between providers: **Requirement**

- Only transfer VFC vaccine between currently enrolled VFC providers.
- Limit transfers to those that can be personally carried and where the vaccine can reach an approved storage unit within eight hours or a regular business day.
- Vaccine transfers must be approved by the Immunization Program prior to physically exchanging the vaccine. Follow the steps below when transferring vaccine in imMTrax:
    1. To initiate a transfer, navigate to **VOMS>>>Orders & Returns>>>Orders & Transfers>>>New Transfer**. Pick the receiving organization and facility from the drop-down lists and enter the doses of vaccine to be transferred. Enter a comment in the comment box (required). Click **Submit Transfer**.
    2. Immediately after submitting the transfer, email kgrady-selby@mt.gov that a transfer is ready for approval (required).
    3. Once approved, the sending and receiving clinic will receive an email that the transfer is ready to be received at the receiving clinic.
    4. Before receiving the transfer in imMTrax, the receiving clinic must confirm the vaccine, lot numbers, expiration dates, and number of doses physically transferred to them matches what is transferred in imMTrax. If it does not, do not accept the transfer and contact kgrady-selby@mt.gov 406-444-1613. If it does, receive the transfer.
- Follow the guidance in the section below (Vaccine Transport) when physically moving the vaccine.
- DO NOT TRANSFER opened, multi-dose vials or vaccine that has experienced a temperature excursion.

Vaccine Transport

Policy

"Transport" is defined as the physical movement of vaccine using coolers where the expected duration out of regular storage is less than eight hours or a regular business day. The CDC discourages the regular transport of vaccines, but it may be necessary when moving vaccine between providers, during off-site clinics, and during emergencies. Providers should have validated protocols for routine and emergency transport.

The following cold chain documentation must be maintained during transport: **Requirement**

- Transport-specific inventory list
- Container-specific temperature log
- Data logger data.

Data loggers are not required for transports lasting less than 30 minutes when using a validated (tested) process.

Temperature excursions during transport should be reported using our online Vaccine Storage Incident Report as described in Section 13.

Providers are prohibited from “shipping” vaccine, which the CDC defines as moving vaccine using a commercial carrier over a longer timeframe than eight hours.

Procedure

The preferred method of transporting vaccine is to use *electric coolers* that maintain appropriate vaccine storage temperatures. If an electric cooler or electricity is not available, you can use a validated (tested) pack-out using non-electric coolers.

Alternate/Destination Storage Location

Contact your alternate/destination storage location to confirm the storage units are being actively monitored with data loggers, are equilibrated to the proper temperature, and ready to receive your vaccines.

Pack-out Equipment List

For emergency transport, the quantity of pack-out materials/equipment should be sufficient to handle your entire vaccine supply.

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

Electric Option:

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

Non-electric Option:

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

Steps Common to Electric and Non-electric Pack-outs

- Start a separate paper temperature log for your transport coolers.
- Create a transport-specific inventory list of vaccines in the coolers.
- Record the date, time, and current, minimum, and maximum temperatures whenever loading or unloading vaccines from a transport container. Log temperatures hourly during transport, if possible.
- Do not open storage unit doors until coolers are prepared and ready to receive vaccine.

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

Electric Coolers

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

Non-electric Coolers – Refrigerated Vaccine

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

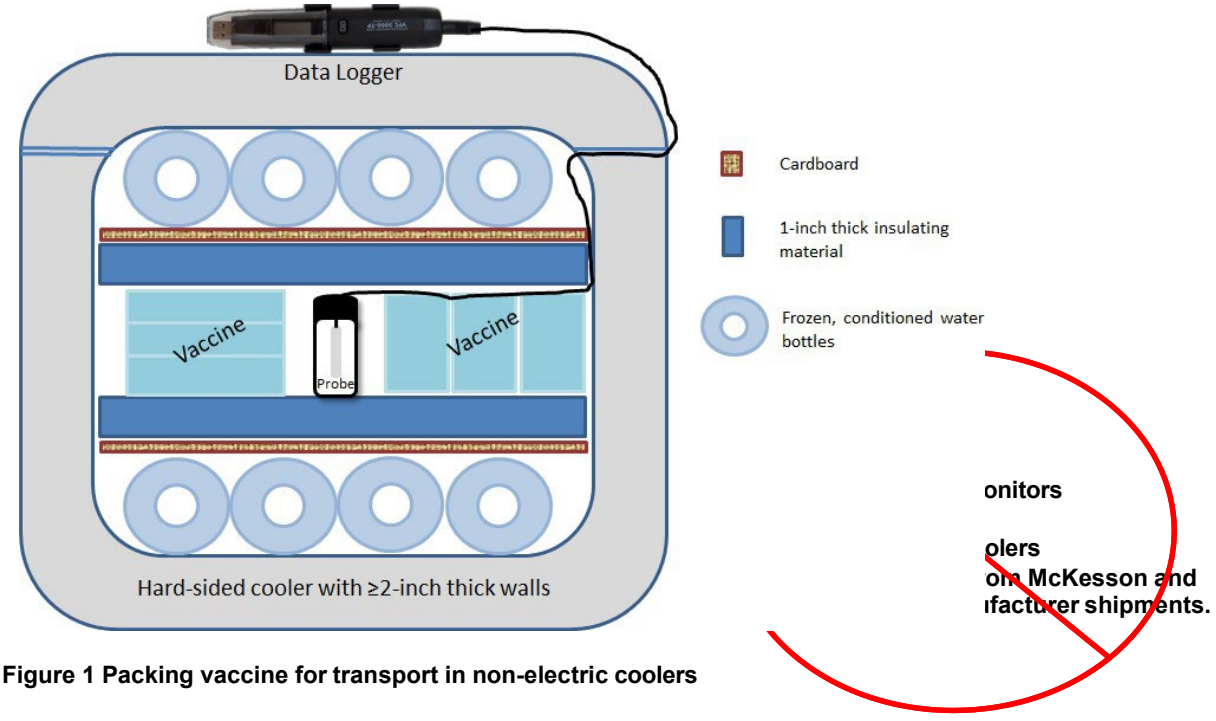


Figure 1 Packing vaccine for transport in non-electric coolers

During Transport

- Log temperatures hourly, if possible, on the container-specific temperature log.
- Transport coolers inside vehicles (not in the trunk) and take the quickest route possible. Do not leave vaccine unattended in vehicles during very hot or very cold weather.

After Transport

- Upon arrival at the destination, immediately place vaccine in a storage unit with continuous temperature monitoring maintaining proper temperatures.
- Log temperatures on the unit-specific temperature log when you load the vaccines and at least once daily for as long as the vaccine is in alternate storage.
- Download and review the data logger data recorded during the transport.

Reporting Transport Temperature Excursions

- If transport temperatures were outside recommended storage temperatures this is a temperature excursion and must be reported to the Immunization Program using our online Vaccine Storage Incident Report as described in Section 14 —Temperature Excursions. DO NOT USE OR DISCARD the vaccine.

Transporting Varicella-containing Vaccines

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

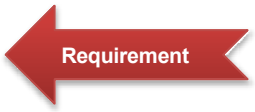
PLEASE NOTE: These pack-outs will expose your frozen vaccines to out-of-range temperatures that must be reported to the Immunization Program (see section above).

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

***Opened*, Multi-dose Vials**

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

Off-site Clinics



VFC providers conducting off-site clinics must adhere to the following vaccine practices:

- Screen for VFC eligibility prior to administering vaccines.
- Estimate the number of vaccines needed and only transport that amount to the clinic.
- Adhere to good transport practices and maintain cold chain documentation as outlined in the previous section.
- If necessary, each person administering vaccines may pre-draw at their station up to one multi-dose vial or 10 doses. Monitor patient flow to avoid drawing up unnecessary doses.
- Assess temperature data prior to returning vaccines to regular storage and report any excursions using our online Vaccine Storage Incident Report. See Section 14 – Temperature Excursions.

18. VACCINE LOSS AND REPLACEMENT

Requirement

Providers may be required to:

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

Providers must consult vaccine manufacturers (online stability calculators or contact directly) before making determinations about vaccine viability following a temperature excursion. Once completed, submit a Vaccine Storage Incident Report and the Immunization Program will review.

Situations That May Require Vaccine Replacement

Provider Negligence

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

- Failing to log temperatures once daily during normal operating hours
- Failing to properly install and manage data loggers or other compliant temperature monitoring system (See Section 14 – Thermometer Policy).
- A contracted alarm/alert company failing to notify the provider of malfunctioning equipment or out-of-range temperatures as required.
- Failing to notify the Immunization Program of a change in VFC vaccine management personnel (vaccine manager and alternate vaccine manager).
- Preparing vaccine for administration prior to patient screening.
- Storing VFC vaccine in prohibited storage units.
- Storing VFC vaccine in a storage unit that has not been approved by the Immunization Program.
- Failing to receive and properly store vaccine delivered during designated delivery hours.
- Failing to take action to protect vaccine after becoming aware of out-of-range temperatures, equipment malfunctions, or electrical supply issues.
- Storing vaccine at improper temperatures (e.g., leaving vaccine at room temperature, storing frozen vaccine in the refrigerator or refrigerated vaccine in the freezer).
- Staff, maintenance workers, or contractors intentionally interrupting storage unit electrical supply without taking action to protect vaccine.
- Leaving a storage unit door ajar.
- Failing to contact the MSCC (1-877-836-7123) the same day an order arrives at your facility when you suspect it was compromised during shipment.
- Failing to provide proof of repair or replacement within 30 days of discovering a storage unit equipment failure.

- During a power outage, failing to protect vaccine according to the posted emergency plan when it is safe and possible to do so

Provider Fraud and Abuse

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

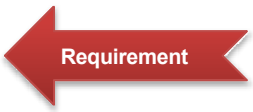
Situations That Do Not Require Vaccine Replacement

Listed below are situations where providers are deemed not at fault and that are not considered "provider negligence." This list is not exhaustive.

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

Procedures for Vaccine Replacement

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



19. SPECIALTY PROVIDERS

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

Requirement

Family Planning and Sexually Transmitted Disease 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 or choose not to access their insurance due to the confidential nature of their visit (See note below).

  Requirement

- 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 (406-444-5580 hhsiz@mt.gov).
- **Please Note**: The VFC Program does not regulate the issue of medical consent for the provision of medical care to minors. Clinics are responsible for providing care in conformance with Montana's medical consent laws as they pertain to minors.

Birthing Hospitals

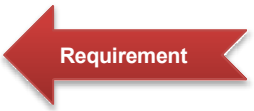
Birthing hospitals in the VFC Program are limited to two immunizations: Hepatitis B vaccine as part of our Universal Hepatitis B Birth Dose Program and nirsevimab (Beyfortus®).

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

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

  Requirement

Nirsevimab is a monoclonal antibody product indicated for the prevention of RSV disease in neonates, infants, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Nirsevimab is available to birthing hospitals but can only be administered to VFC-eligible patients as defined in Section 4. Birthing hospitals must carry private stock for their privately insured patients and screen for and document VFC eligibility. See Section 4 for details.



Pharmacies

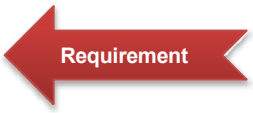
Montana pharmacies are allowed to provide influenza vaccines to children 12 through 18 years of age and ACIP-recommended immunizations under a collaborative practice agreement to children 7 through 18 years of age. Pharmacies must enroll in the VFC Program in order to serve Medicaid and other VFC-eligible children.

- Pharmacies must agree to vaccinate all "walk-in" VFC-eligible children and not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.
- Pharmacies must offer the patient the opportunity to have the immunization information reported to imMTrax, the state immunization information system.
- Pharmacies must adhere to state law when administering immunizations (MCA 37-7-1).

20. VFC Provider Education Requirements

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

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



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

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21. APPENDIX–SUMMARY OF HANDBOOK CHANGES

Section and Substantive Changes	Date of Change	Page
Section 1–Introduction		
• Added new pharmacy information pertaining to immunization record retention	June 2019	8
Section 2–Provider Enrollment		
• Added new information on who pharmacists can immunize	June 2019	9
Section 3–Billing		
• Added prohibition on billing administration fees or sending to collections	June 2019	11
Section 4–VFC Eligibility		
• Added must verify vaccine coverage for underinsured category	June 2019	13
• Non-US Citizen Children	July 2024	15
Section 5–ACIP		
Section 6–NCVIA		
• Added MedWatch	July 2024	21
Section 7–VFC Compliance Site Visits		
• Added providers will receive a site visit within 12 months of enrollment	June 2019	23
• Added Immunization Quality Improvement for Providers (IQIP) Visits	Feb 2024	24
Section 8–VFC Requirement Checklist		
• Removed requirement to register data loggers	November 2020	25
• Changed routine temperature monitoring from twice to once daily	November 2020	25
• Added requirement to have data loggers approved before use	October 2021	25
• Added requirement that vaccine manager or alternate review and sign temperature and borrowing logs	October 2021	25
Section 9–Non-compliance, Fraud, and Abuse		
Section 10–Immunization Resources		
• Added Manufacture stability calculator links	July 2024	29
Section 11–Vaccine Management Plan – Introduction		
• Added requirement to fax completed/updated Section 12 to IZ Program	June 2019	33
Section 12–Routine and Emergency Management Plan Template		
• Moved non-electric pack-out protocol to Section 17	June 2019	60–62
• Reiterated requirement to fax completed/updated Section 12 to IZ program	June 2019	35,39
• Expanded Section 12 template to comply with CDC requirements	June 2019	35–39
• Added email field to Section 12 template	September 2023	35
Section 13–Vaccine Storage Units		
Section 14–Temperature Monitoring		
• Rewrote to incorporate new data logger policy	June 2019	47–50
• Change routine temperature monitoring from twice to once daily	November 2020	49, 50
• Removed requirement to register data loggers	November 2020	47
• Added requirement to have new and replaced data loggers approved before use	October 2021	47
• Added requirement for vaccine manager or alternate to review and sign temperature logs each month before archiving	October 2021	50

Section and Substantive Changes	Date of Change	Page
• Added language about Provider responsibility to Vaccine Storage Incident Reports	July 2024	50, 51
• Added that each clinic needs to have a backup data logger on site	October 2024	47
Section 15–Ordering and Receiving VFC Vaccine		
• Updated to incorporate new imMTrax platform	June 2019	51–53
• Updated allowed ordering interval from every three months to every month • Increased allowed supply on hand	November 2024	52
• Added Covid Pfizer vaccine to frozen vaccines	September 2023	53
Section 16–Managing Inventory		
• Updated to incorporate new imMTrax platform	June 2019	55–57
• Added DO NOT TRANSFER vaccine with prior temperature excursion	June 2019	55
• Added requirement for vaccine manager or alternate to review and sign completed borrowing logs before archiving	October 2021	57
• Added language for threshold CDC allows	July 2024	56
Section 17–Vaccine Transfer, Transport, and Off-site Clinics		
• Created new section with recommendations and requirements	June 2019	59–63
• Changed twice-daily temperature monitoring to once-daily.	November 2020	62
Section 18–Vaccine Loss and Replacement		
• Changed twice-daily temperature monitoring to once-daily.	November 2020	65
• Added language about Provider responsibility to Vaccine Storage Incident Reports	July 2024	65
Section 19–Specialty Providers		
• Added new pharmacy information	June 2019	68
• Added that nirsevimab (Beyfortus®) is available at birthing hospitals but only for VFC eligible newborns.	September 2023	67-68
Section 20–VFC Provider Education Requirement		
Appendix		
• Edited to include only substantive 2019 changes	June 2019	71
• Added once-daily temperature monitoring and removal of data logger registry changes	November 2020	71
• Added data logger approval requirement and requirement for vaccine manager and alternate to review and sign temperature and borrowing logs	October 2021	71
• Add updates marked yellow in the book and on the appendix	February 2025	24, 25

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