



MICHIGAN VACCINES FOR CHILDREN (VFC) PROVIDER MANUAL

www.michigan.gov/vfc

ABOUT THIS MANUAL

This document serves as a Michigan immunization provider's manual to understand and implement state and federal requirements of the VFC program and all publicly funded Michigan vaccine programs. The Local Health Department (LHD) provides local oversight and is a provider's VFC point of contact. The LHD may provide additional support or expectations.

Adult Vaccine Program information can be found in [Section 9](#).

This manual combined with ALL documents within the Michigan VFC program/website and CDC requirements is the provider's responsibility to obtain and utilize the most up-to-date information available. This information can be found at www.michigan.gov/vfc. The VFC Resource Guide website has templates, tip sheets, and additional resources for implementing the VFC program.

All sections with a **corresponding tip sheet** online are identified by a star symbol:



CONTACTS & SUPPORT



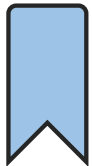
VFC Questions? Contact your [Local Health Department](#) or the [VFC Resource Guide](#)

MCIR Questions? Contact your [MCIR Regional Contacts](#) or the online Healthcare Immunizing Providers [MCIR Reference Guides](#)



Looking for specific guidance within this manual? Along with using the clickable "Table of Contents" and/or "Navigation Bar" on the left, you may search the entire document for key words. To do this, hold down "CTRL" and the letter "F". A search bar will display to "find" key words.

PROVIDERS are REQUIRED to SAVE OR "BOOKMARK" THE WEBSITE LINK FOR THIS MANUAL & THE ONLINE VFC RESOURCE GUIDE: WWW.MICHIGAN.GOV/VFC.



THIS ENSURES ACCESS TO THE MOST CURRENT GUIDANCE. TO QUICKLY CREATE A BOOKMARK (IN MANY BROWSERS): VIEW WEB PAGE, HOLD DOWN "CTRL" AND THE LETTER "D"!

Thank you for all that you do to protect against vaccine-preventable diseases!

RECENT REVISIONS

Revision Date	Description of Revision	Pages
10/18/2023	Added Beyfortus and COVID-19 vaccine to ACIP recommended vaccine list	7

REQUIRED TO POST

Michigan VFC Providers are required to maintain, utilize, display, and/or have available the most up-to-date documents listed below:

These are available at www.michigan.gov/vfc

1. The [Vaccine Management & Emergency Response Plan](#) posted in a prominent location
2. Temperature Log for each storage unit: options available at www.michigan.gov/vfc
3. Vaccine [Borrowing Log](#)
4. Up-to-date **Michigan** [versions of VISs](#)
5. “Do Not Unplug” [signs](#) (must post at outlet and circuit breaker)
6. MDHHS [Storage & Handling Table](#) (must post on storage units)
7. MDHHS [Preparation & Administration Table](#) (must post in vaccine preparation area)

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QUICK CLICKS: FREQUENTLY USED RESOURCES

VACCINE DOCUMENTATION

[MCIR MiLogin](#)

MCIR Reference Guides

[MDHHS Medicaid Manual](#)

Michigan VISs

[CPT—CVX Codes](#)

VACCINE ADMINISTRATION

[CDC Vaccine Administration E-Learn](#)

CDC Immunization Schedules

[MDHHS Vaccine Quick Looks](#)

Vaccine Adverse Event: Reporting System (VAERS)

VFC ANNUAL TRAINING

[You Call the Shots: VFC](#)

You Call the Shots: Storage & Handling

[How to Get CE for You Call the Shots](#)

FREE MATERIALS FOR ORDER

[MDHHS Clearinghouse](#)

CDC Info on Demand

STORAGE & HANDLING

[CDC Storage & Handling Toolkit](#)

CDC Vaccine Labels

VACCINE EDUCATION RESOURCES

[FREE MDHHS Immunization Nurse Education Presentations](#)

CDC Immunization Online Trainings

[Immunization Action Coalition](#)

[I Vaccinate](#)

[AIM: Alliance for Immunization in Michigan](#)

MDHHS: Hepatitis A

[MDHHS: Perinatal Hepatitis B](#)

MDHHS: Measles

[MDHHS: Influenza](#)

FREQUENTLY ASKED QUESTIONS

★ For Michigan VFC-related **Frequently Asked Questions (FAQs)**, see [this resource](#)!

Section 1: VFC PROGRAM & VACCINES

IN THIS SECTION:

Introduction & Overview
Michigan-Specific Requirements
Vaccines Available to VFC Providers
Vaccination Standards

INTRODUCTION & OVERVIEW

The Vaccines for Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Michigan providers have participated in VFC since 1995. The success of this program is built upon the cooperation and collaboration of many agencies. Your participation is vital to increasing Michigan's immunization rates and ensuring all children are protected against vaccine-preventable diseases.

- VFC Providers work with their Local Health Department to obtain support in ensuring that VFC requirements are followed per CDC and MDHHS requirements.
- The LHD is a provider's main contact for VFC-related questions and can also offer additional support on partnering to improve vaccination rates and practices.

Additional Public Vaccine Providers

Qualifying providers may participate in additional publicly-funded Michigan vaccine programs. These programs **must implement all VFC Requirements** within this manual including storage, handling, and inventory management of vaccine (unless stated otherwise). In some instances, additional or modified requirements are indicated. Information specific to these programs is linked here:

- [Local Health Departments as VFC Providers](#)
- [Adult Vaccine Program \(MI-AVP\)](#)
- [Universal Hepatitis B Vaccine Provider Program](#)
- [High-Risk Hepatitis A & B Vaccine Provider Program](#)

MICHIGAN-SPECIFIC REQUIREMENTS

VFC providers must comply with all CDC requirements, which are utilized to develop this manual. Additionally, state requirements must be assessed for compliancy. Both are assessed regularly (VFC site visits, monthly documentation review, etc.). Many requirements are also indicated in the Provider Agreement ([Sample here](#)). Below are requirements specific to Michigan:

- ❖ Bookmark/save this VFC Provider Manual and VFC Resource Guide: www.michigan.gov/vfc.
- ❖ Twice daily temperatures must be assessed and documented: AM current temp + min/max and PM current temp, including name/initials, time, and exact temperature documented as displayed on the DDL (to the tenth's place rather than rounded to whole number)
- ❖ Data loggers must be downloaded, reviewed, and saved at least weekly (keep for 3 years)
- ❖ Submit temperature logs monthly and supporting docs per LHD frequency required (MCIR reports and borrowing log). Supporting documents MUST be submitted with all orders, and it is recommended that these are submitted every month regardless of ordering. If you do not place monthly orders, follow your LHD policy for supporting document submission.
- ❖ Vaccines must be stored in original packaging
- ❖ Michigan-specific VISs must be used, containing information on MCIR. These can be located on the MCIR home screen or [available here](#).
- ❖ Ensure up-to-date postage of documents "[Required to Post](#)."
- ❖ Report changes to the LHD immediately: changes in the medical director, new providers within the practice, changes in the VFC Primary and/or Backup contacts, shipping address
- ❖ Enter vaccine information into MCIR within 72 hours of administration, regardless of whether the patient receives VFC or private stock.
- ❖ Manage inventory appropriately, both physically and in the IIS:
 - a. Monthly balancing and submission of reports
 - b. MCIR VIM training for primary and backup
 - c. Proper rotation of stock
 - d. Proper demonstration of return/waste reporting
 - e. Notification to LHD within 3-6 months for soon-to-expire vaccines, etc.
- ❖ Private stock vaccines must be stored, handled, and inventory managed in the same manner as VFC vaccine if any movement occurs or is expected to occur between inventories. Any vaccine that is used for VFC but originated in private (i.e., borrowing, replacement of VFC borrowing, replacement of VFC expiration, loss, etc.) must follow VFC requirements.
- ❖ Combination household units are NOT recommended. If a household combination unit has been approved for use, only the refrigerator section can be used if temps have remained in-range. The ONLY time the freezer section can be utilized is for providers enrolled prior to Jan 1, 2013 with a unit that has maintained temperatures in both the refrigerator and freezer. Provider should be aware of risks associated with such unit and plan to replace the unit as soon as possible. If a household combination unit goes out of range, it must be replaced with stand-alone refrigerator and freezer units or a combination pharmaceutical unit with separate condensers. Detailed guidance on these units is [available here](#).
- ❖ Immediately contact the LHD in the event of excursions, suspected vaccine loss or for questions about storage or viability of vaccine.
- ❖ MDHHS requires dose for dose replacement with private stock vaccine for VFC vaccine wasted due to expiration, negligence, or improper vaccine storage and handling practices.
- ❖ Implement jurisdictional requirements that may apply, as indicated by the LHD.

VACCINES AVAILABLE TO VFC PROVIDERS

The following vaccines are available through the VFC Program. Providers **must stock and offer all routine ACIP-recommended vaccines** for their populations served, according to their Provider Profile.

Please be aware that in the event of a vaccine shortage leading to unavailability of a certain brand or presentation, if another brand or presentation of vaccine is available for that antigen, VFC providers are expected to order the available presentation to ensure patients maintain access.

★ For chart showing vaccines available in our public vaccine programs as well as Adult Medicaid and Medicare B and D, see this document [Vaccine Resources for Eligible Populations](#).

VFC Vaccines Available

The following VFC vaccines are available for order via MCIR E-ordering:

COVID-19		MMRV
DTaP	Hib	PCV15
DTaP-IPV	HPV9	PCV20
DTaP-IPV-Hep B (Pediarix)	Influenza [†]	PPSV23*
DTaP-IPV-Hib (Pentacel)	IPV/polio	Rotavirus
DTaP-IPV-Hib-HepB	Meningococcal ACWY	RSV
(Vaxelis)	Meningococcal B*	Td
Hepatitis A	MMR	Tdap
Hepatitis B		Varicella

[†] Refers to influenza-specific guidelines indicated; see guidance below.

* Refers to non-routine vaccines available; see guidance below.

[†] Influenza Vaccine: VFC providers must stock and offer flu vaccine for patients six months and older. Ordering flu vaccine is unique in that it involves annual “pre-booking” for the upcoming season.

- **Flu pre-booking:** Flu vaccine is pre-booked via MCIR annually, typically each January. This allows providers to place orders for the upcoming flu season. Providers must ensure the same type and presentation is booked for both private and VFC flu pre-book.
 - Pre-booked flu vaccine is automatically shipped to providers, often beginning late August.
 - Providers are expected to pre-book enough flu vaccine for 70-100% of their patient population; The LHD can assist providers in accurately placing flu prebook orders.
 - See [Flu Prebooking](#) for full details.
- Providers **may not borrow VFC flu vaccine** for private pay patients under any circumstances.

*Non-routine VFC Vaccines

VFC Providers must ensure that VFC-eligible children have access to non-routine vaccines as needed. The following non-routine vaccines may be ordered as needed, based on clinical decision-making and according to the following guidelines:

***PPSV23 (Pneumococcal 23-valent polysaccharide) Vaccine after PCV13:** This includes PPSV23 (Pneumovax) vaccine available for ordering single doses as needed for high-risk children 2-18; For guidance on pneumococcal vaccination based on certain risk groups: see [Pneumococcal Vaccination](#).

***Meningococcal B (MenB) Vaccines:** MDHHS highly encourages providers to stock and offer MenB vaccine. These include Trumenba and Bexsero vaccines; Trumenba arrives as boxes of 10 doses, while Bexsero can be ordered as 1 dose or boxes of 10. The same MenB vaccine brand must be used for all doses to complete the series. MenB vaccine is forecasted as a general routine vaccine series for persons 16 through 23 years of age with a due date of the 16th birthday.

- LHDs must stock and offer MenB vaccine.
- Providers are highly encouraged to stock MenB vaccine. Providers with limited VFC-eligible patients may order this vaccine as-needed or refer to another provider (such as an LHD). If a parent requests MenB vaccine, it must be provided.
- MenB vaccination may be provided to patients 16-23 without a risk factor and should be discussed for all eligible patients. The preferred age is 16-18 years.
- MenB vaccine may be indicated beginning at age 10 for increased risk.
- Guidance on MenB vaccination: Quick Look at [Meningococcal Serogroup B Vaccine](#).

Additional Public Vaccine Providers & Vaccines

There may be differences in vaccine expectations for specialty providers such as Local Health Departments, the Adult Vaccine Program, Universal Hepatitis B Vaccine Providers or High-Risk Hepatitis A and B Vaccine Providers. For these details, please see [Additional Public Vaccine Providers](#).

VACCINATION STANDARDS

VFC Providers must adhere to the recommendations outlined by the Advisory Committee on Immunization Practices (ACIP) and Standards for Pediatric Vaccination Practices. Additionally, MDHHS has easy-to-follow “Quick Looks” for vaccination guidelines: www.Michigan.gov/VaccineQuickLooks

ACIP Recommendations

ACIP is a federal advisory group of medical and public health experts that develops recommendations on the use of vaccines in the United States. They also vote on VFC Resolutions to include vaccines in the VFC program.

- ACIP recommendations are utilized in the [CDC Immunization Schedules](#)
- Detailed guidelines of the ACIP [are available here](#).
- Providers must comply with the immunization schedule, dosage, and contraindications established by the Department of Health and Human Services (DHHS) and ACIP unless:
 - (a) a physician, when making a medical judgment in conformance with accepted medical practice, deems compliance to be medically inappropriate; or
 - (b) a requirement is not in compliance with state law, including laws relating to religious beliefs or other exemptions.
- Contraindications
 - For a contraindications summary, see this [Immunization Action Coalition tool \(Immunize.org\)](#).
 - For a detailed guidance on contraindications, see [this ACIP guidance](#).

Standards for Pediatric Vaccination Practices

These are published by the National Vaccine Advisory Committee and define appropriate vaccination practices. [The standards](#) address priorities such as ensuring vaccine availability, providing effective communication, proper storage and handling, and improving coverage rates.

1. Immunization services are readily available.
2. There are no barriers or unnecessary prerequisites to the receipt of vaccines.
3. Immunization services are available free or for a minimal fee.
4. Providers utilize all clinical encounters to screen and, when indicated, vaccinate children.
5. Providers educate parents and guardians about immunization in general terms.
6. Providers question parents or guardians about contraindications and, before vaccinating a child, inform them about the risks and benefits of the vaccinations their child is to receive.
7. Providers follow only true contraindications.
 - a. For a detailed guidance on contraindications, see [this ACIP guidance](#).
 - b. For a summary of contraindications, see this [Immunization Action Coalition tool](#).
8. Providers administer simultaneously all doses for which a child is eligible at the time of visit.
9. Providers use accurate and complete recording procedures.
10. Providers co-schedule immunization appointments with appointments for other services.
11. Providers report adverse events following vaccination promptly, accurately, and completely.
12. Providers operate a tracking system.
13. Providers adhere to appropriate procedures for vaccine management.
14. Providers conduct semi-annual audits to assess immunization coverage levels and to review immunization records in the patient populations they serve.
15. Providers maintain up-to-date, easily retrievable protocols where vaccines are administered.
16. Providers practice patient-oriented and community-based approaches.
17. Vaccines are administered by properly trained persons.
18. Providers receive ongoing education regarding current immunization recommendations.

Refusal to Consent to Vaccination

Document vaccine refusal both in the patient medical record **and** MCIR. For the document to include in patient records, see refusal forms within the “Document” section of the Aim Toolkit [located here](#).

Section 2: ENROLLMENT & ANNUAL RE-ENROLLMENT

IN THIS SECTION:

Provider Agreement & Provider Profile

How to Enroll

Enrollment Training & Site Visit

Annual Re-enrollment

Enrollment into the VFC Program is completed via MCIR. All currently enrolled VFC providers must also complete annual re-enrollment and communicate any changes to the LHD and MDHHS.

PROVIDER AGREEMENT & PROVIDER PROFILE

The VFC Enrollment collects basic information on a practice, personnel, and patient population data. The enrollment consists of a Provider Agreement as well as a Provider Profile.

Provider Agreement

The Provider Agreement is a CDC-developed contract between the healthcare provider (HCP) and MDHHS outlining compliancy with VFC program requirements to receive publicly funded vaccines. The Provider Agreement is within the enrollment and re-enrollment, which occurs in MCIR. This must be **signed (electronically) by the VFC Medical Director**. The VFC Medical Director takes responsibility for the practice's use of VFC vaccines and agrees that all staff will follow the outlined requirements.

- The VFC Medical Director must be licensed to administer pediatric vaccines in Michigan.
 - MD, DO, or pharmacist
 - For Universal Hepatitis B Vaccine Providers (birthing hospitals), the pharmacist may serve as the VFC Medical Director.
- If the VFC Medical Director changes after submission of enrollment in MCIR, the LHD must be notified; MDHHS will provide a blank Provider Agreement to sign and submit.
- The provider signing the Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity.
- Enter all licensed health care providers and their corresponding professional license numbers on the Provider Agreement within the "Providers" tab. Do not enter *educational limited* licenses (MCIR will display an error message). Providers that can be added are as follows:
 - If MD, license number must be a 10-digit number of the format '4301xxxxxx'
 - If DO, license number must be a 10-digit number of the format '5101xxxxxx'
 - If NP, license number must be a 10-digit number of the format '4704xxxxxx'
 - If PharmD, license number must be a 10-digit number of the format '5302xxxxxx'
 - If PA, license number must be a 10-digit number of the format '5601xxxxxx'
- The provider agreement can be terminated at any time by the provider, LHD, or MDHHS.
- A sample provider agreement is also available at the VFC Online Resource Guide.

Provider Profile

The Provider Profile captures the number of VFC-eligible and non-VFC-eligible children served in the past 12 months. Provider Profile data allows MDHHS to estimate vaccine needs and monthly ordering patterns. New VFC providers should work with their LHD to complete the profile.

- The Profile data is **automatically populated** for current VFC providers during re-enrollment.
- For new providers, the profile data may be estimated, but rationale must be stated.
- For Specialty Providers such as MI-AVP, Universal Hepatitis B, and High-Risk Hepatitis A and B, a Doses Administered Report is utilized to enter Provider Profile data.
- Provider Profile reports may be generated in MCIR (Reports→Vaccine→Provider Profile Data)

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

HOW TO ENROLL

Prospective VFC Providers and others interested in providing publicly-funded vaccine (Universal Hepatitis B, Adult Vaccine Providers, etc.) must contact their Local Health Department and enroll in MCIR via the link “Enroll in VFC Program”. By selecting this link and submitting a *completed enrollment*, it triggers the Local Health Department (LHD) to initiate contact for becoming a provider.

1. Before enrolling in VFC, please review program information within this manual and at www.michigan.gov/vfc. If you have any questions, contact your [local health department](#).
2. Designate a VFC Primary and Backup Coordinator. They must have MCIR IDs and be associated to the provider site. The provider’s MCIR Site Administrator can perform these functions:
 - a. Guidance on MCIR registration is [available here](#).
 - b. Guidance on adding registered users to the MCIR site is [available here](#).
3. Complete an online enrollment by accessing the “Enroll in VFC Program” link from the provider’s MCIR home page. Completing this [enrollment](#) triggers the LHD to contact your site.
 - a. *Important:* Partially completed enrollments are not viewable by the LHD. Therefore, the LHD may not be aware of intent to enroll if not submitted. To ensure follow-up, please ensure your enrollment is **fully completed and submitted in MCIR**.
4. The LHD reviews enrollment for completion and contacts the provider to verify information and review the VFC program. The provider may begin working towards preparing to participate, as detailed below (30 days of temperatures, vaccine management plan, etc.)
5. The LHD approves enrollment at the local level and submits to MDHHS, who assigns a VFC PIN. Once a PIN is assigned, **the enrollment process below must be completed within 3 months**.
6. LHD staff will continue follow-up to coordinate training and an enrollment site visit. Once all enrollment requirements have been met, E-order contacts must be added, inventory activated, shipping contact assigned, as well as E-order approver assigned. MDHHS VFC staff will perform final activation.

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

ENROLLMENT TRAINING, PREPARATION & SITE VISIT

After contacting the LHD, the provider may prepare for the enrollment process and schedule an enrollment visit with the LHD. Before a provider can order VFC/publicly-funded vaccines, the provider must complete the initial enrollment visit and trainings. All enrollment expectations must be fulfilled **within 3 months** of provider activation/PIN assignment. This includes the enrollment site visit, **30 days of temperature monitoring**, and any follow-up not met at the time of the visit. Providers should be confident in meeting this timeline, as the process will start over if not completed within 3 months.

Training

Training is coordinated by the LHD and Regional MCIR staff. While recommended that all staff involved with vaccine receive thorough training, the designated **Primary and Backup Vaccine Coordinator must be trained on:**

1. Vaccines for Children Program
2. Vaccine Storage & Handling
 - The above two topics are also required yearly for [VFC annual training](#).
3. Training on MCIR Vaccine Inventory Module (VIM): Contact your [MCIR Regional Coordinator](#).

Preparation/Enrollment Site Visit

After enrollment in MCIR, coordination occurs with the LHD to complete the enrollment process. An enrollment visit is performed by the LHD to review VFC requirements such as: screening and eligibility, storage units, temperature devices, vaccine management plan, etc. Providers can work toward reviewing this manual and completing the checklist below to prepare for the visit and complete follow-up in a timely manner.

- The entire enrollment process must be completed **within 3 months**. This includes enrollment site visit, any follow-up to be completed by the provider and MDHHS notification for final activation. If this is not completed within 3 months, the process must start over.

Checklist for Enrollment Visit and Provider Follow-up:

- ☐ Key staff identified: Primary vaccine coordinator, backup, and how to report changes
 - MCIR should reflect staff and any updates. The Primary and Backup should be listed on the “Enrollment” tab as well as designated as “E-order Contacts”.
- ☐ Trainings completed as outlined above (VFC and MCIR training)
- ☐ A [Vaccine Management & Emergency Response Plan](#) completed & meets VFC requirements
- ☐ Appropriate storage units and data loggers; sufficient space; appropriate vaccine and data logger placement; certificates of calibration;
 - “[Do not disconnect](#)” labels on plugs and circuit breakers
 - Knowledge of what to do in the event of a temperature excursion
- ☐ **Thirty (30) days of accurate temperature monitoring and documentation** submitted to the LHD before first order. This includes temperature logs with daily documentation as well as data files/graphs (to demonstrate weekly downloads).
 - Temperature logs are available at www.michigan.gov/vfc.
- ☐ Understanding of VFC eligibility, [screening](#), and billing; borrowing guidelines
- ☐ Understanding of routine expectations such as: monthly balancing, annual re-enrollment, provider profile, provider agreement, annual training, etc.
- ☐ Processes in place to: maintain a separate VFC inventory; place orders on time to maintain stock to serve populations; offer all ACIP-recommended vaccines
- ☐ Record maintenance (documents to maintain for three years)
- ☐ Understanding of [Michigan-specific VISs](#) and reporting to VAERS
- ☐ Review and understanding of this manual and the VFC Resource Guide: www.michigan.gov/vfc
- ☐ Be aware of LHD contact for orders, VFC support, etc.

Following the Enrollment Visit:

All follow-up requirements must be met and training verified (VFC annual training and MCIR VIM training). E-order contacts must be added, inventory activated, shipping contact assigned, as well as E-order approver assigned. LHD will notify MDHHS for final activation and assist with the first order.

Following the enrollment visit, a full/initial VFC **compliance visit will occur in 3-6 months**. Then, these compliance visits occur at least every 24 months, but in many regions, visits are yearly.

- Before the first full compliance visit, providers must be enrolled in the VFC program for at least three to six months and have experience ordering and administering VFC vaccines. CDC recommends the site visit occur **at the 3-6-month time frame**. Regardless, the visit **must** be completed within 12 months of enrollment.

The Local Health Department (LHD) provides support for program implementation. The *LHD must be informed of changes* such as to the primary/backup coordinator, medical director, address, etc.

ANNUAL RE-ENROLLMENT

All VFC Providers must re-enroll annually, which requires an updated Provider Agreement, Provider Profile, and ensuring that all information is up-to-date and accurate in MCIR. This process is also necessary for Universal Hepatitis B Vaccine Providers, AVP Providers, High-Risk, LHDs, etc.

- Re-enrollment is completed in MCIR via “Enroll in VFC program” link.
- Re-enrollment in the VFC Program begins in January every year.
 - This must be completed and approved by the LHD by April 1st. However, LHDs may indicate an earlier due date to ensure appropriate processing.
 - LHDs will notify their providers when the link to re-enroll is available.
- MDHHS provides final review and will suspend providers not re-enrolled by April 1st.
 - Suspended providers have 30 days to contact their LHD to get re-enrolled before disenrollment occurs. Once disenrolled, they must re-apply as a new provider.

Important Reminders for Re-enrollment:

- Review ALL tabs in MCIR for accuracy (contact information, storage units, etc.)
 - **Notify the LHD for changes** to primary/backup, VFC Medical Director, address, etc. This notification should be provided to the LHD as soon as the change occurs.
 - The LHD will notify MDHHS to ensure MCIR VFC tabs are accurately updated
- The last step of enrollment requires an electronic signature—**This must be of the VFC Medical Director**. Rejection will occur if the signature is not that of the VFC Medical Director.

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

DISENROLLMENT

The LHD, MDHHS or VFC provider may disenroll and/or terminate the VFC Provider Agreement at any time, with indication of rationale and communication with MDHHS. Disenrollment may occur if:

- An enrolled VFC provider has not ordered vaccine in the past 12 months. The provider is considered inactive and should be disenrolled.
- The provider seeks disenrollment and communicates with LHD accordingly.
- Repeated and/or un-resolved non-compliance or provider actions determined as fraud or abuse: See [Non-compliance, Fraud & Abuse](#)
- Immediate termination by MDHHS if notified by the state Medicaid agency that a provider is on the List of Excluded Individuals and Entities (LEIE).

The above may also lead to temporary suspension. This is outlined in the [Non-compliance, Fraud & Abuse](#) section. Providers that will be disenrolled must ensure inventory is maintained and vaccines stored appropriately until the LHD is in possession of VFC vaccine.

Disenrollment Process

1. Provider communication with the LHD is essential. A date for vaccine pickup must be identified as well as rationale for disenrollment.
2. The LHD notifies MDHHS VFC and MDHHS Field Rep advising that a provider is leaving the program. Include the rationale and date of termination.
3. The provider must perform a final VFC vaccine balance, ensuring all admin./expired/wasted doses have been entered. Ensure losses are processed and replaced as required, prior to disenrollment. Submit Ending Inventory Report(s) to the LHD.
4. Provider must provide temperature logs (and data files upon request) to the LHD at time of pickup (and earlier if requested), along with any remaining MCIR reports that may be due.
5. When vaccine pickup occurs, the LHD will perform a final count.
6. The LHD and/or MCIR staff will work with the provider to “zero out” the provider’s inventory.
 - Remove doses from provider’s inventory via **“Returned to LHD: Excess Inventory”** with comments included. Quantities become “0”. Balance at “0” until the checkbox next to “Active” is no longer greyed out. It may take multiple balances achieve this.

The diagram illustrates the process of making the 'Active' checkbox modifiable. On the left, under the 'Inventory Details' header, the 'Name' is 'VFC/Public' and the 'Active' checkbox is greyed out. A red arrow points to the right, where the 'Active' checkbox is now checked and no longer greyed out, indicating it is now modifiable.

7. Once this checkbox appears as modifiable, inactivate all individual VFC lots.
8. The “Default” checkbox can be un-checked, but the “Active” checkbox does not have to be unchecked yet (this creates issues if flu pre-book needs to be cancelled by MDHHS staff). If the LHD and/or MCIR staff are certain no pre-book was created, *both* boxes can be un-checked.

The screenshot shows the 'Inventory Details' form. The 'Name' is 'VFC/Public'. The 'Default' checkbox is unchecked and highlighted with a red box. The 'Active' checkbox is checked.

9. The LHD will add the doses to their inventory via **“Transfer in: Add to Inventory”** with detailed comments and VFC PIN. The LHD will absorb inventory or re-distribute to another provider, provided vaccines have been stored and handled appropriately.
10. Notify MDHHS VFC staff, MCIR Regional Staff, and Field Rep when vaccine has been removed physically and electronically. Please include the date and reason for disenrollment.
11. If pre-book flu was created, MDHHS VFC staff will cancel this. The “Default” and “Active” checkboxes will be un-checked, and the provider assigned in the VFC tab as “inactivated”. The provider VFC status is inactivated in MCIR, PEAR, and VTrckS.

Section 3: ELIGIBILITY & DOCUMENTATION

IN THIS SECTION:

Eligibility & Insurance Criteria
Administration Fees & Billing Scenarios
Vaccine Documentation
VFC Documents to Maintain

VFC eligibility must be reviewed and documented at every immunization visit. VFC vaccines can be administered only to children who meet eligibility requirements of the program.

ELIGIBILITY & INSURANCE CRITERIA

Screening and Documentation

VFC providers must screen and document patient eligibility at each immunization visit. Before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccines. If a child presents with health insurance and coverage for vaccine *is not known* (i.e., not verified) by the provider, the child must be treated as though they are insured for all vaccines. It cannot be assumed that a patient is VFC-eligible due to lack of insurance screening and/or verification.

- Screening eligibility tool [available here](#).
- Document eligibility appropriately in the patient record/EMR **and** in MCIR.
- Providers should select the eligibility requiring the least out-of-pocket expense to the family.
- Documentation related to screening and eligibility must be retained for 3 years.

Eligibility Criteria

Children through 18 years of age (under 19) who meet at least one of the following criteria are eligible to receive VFC vaccine:

1. **American Indian or Alaska Native:** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603). (AI/AN children are VFC-eligible under any circumstance.)
2. **Medicaid-eligible:** Children eligible for the Medicaid program (For purposes of VFC, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably.)
3. **Uninsured:** Children not covered by any health insurance plan
4. **Underinsured:** Has health insurance, but coverage does not include ACIP-recommended vaccines or covers only selected vaccines (VFC-eligible for non-covered vaccines only).
 - OR there is a fixed cap for vaccines (underinsured after cap: see below)

Table: Quick View of Insurance Situations and VFC Eligibility

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in Medicaid	Yes	Medicaid
Has private health insurance with Medicaid as secondary insurance	See note	Note: See section below outlining two options
Has insurance covering all vaccines, but has not met plan's deductible	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and administration because the plan's deductible has not been met.
Has insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	See note	Note: Insured until the fixed dollar limit is met Underinsured after dollar limit is reached
Has an insurance plan that does not cover all ACIP-recommended vaccines	See note	Note: Underinsured for the vaccines not covered by insurance plan.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare.
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is AI/AN	Yes; see note	Note: AI/AN are VFC-eligible. <i>However</i> , 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 expense for the family.
Enrolled in a Health Care Sharing Ministry	Yes; see note	Uninsured. A health cost sharing ministry is not considered health insurance (not recognized by the state insurance department), so any age-eligible child is eligible for VFC vaccine.

Eligibility: Detailed Definitions

1. American Indian or Alaska Native

AI/AN children are VFC-eligible under any circumstance. If an AI/AN child also fits a second eligibility, always choose the category that costs less for the family.

2. Medicaid and Medicaid-Eligible

"Medicaid-eligible" is defined as a child entitled to medical assistance under a Medicaid state plan. MI-Child has merged with Medicaid and eligible for VFC vaccine under the Medicaid eligibility code.

- According to the Medicaid Provider manual, "When a provider contracts with a health plan to provide primary care (which includes immunizations), the provider should immunize the beneficiaries assigned to them by the plan. MHP providers enrolled in VFC are encouraged to immunize and are discouraged from referring beneficiaries to a LHD for these services."
- For a list of Medicaid Health Plans in Michigan by county, see [this resource](#).
- The Medicaid Provider Manual is [available here](#).

Medicaid Spend-Down: Children with Medicaid spend-down are considered *uninsured* until amount is met. Once spend-down amount is met and eligible for Medicaid, eligibility becomes *Medicaid*.

3. Uninsured

A child who has no health insurance coverage is VFC-eligible.

4. Underinsured

Underinsured children are VFC-eligible. Underinsured designation is for patients with health insurance, but the insurance policy:

- Does not cover any ACIP-recommended vaccines
- Does not cover all ACIP-recommended vaccines (underinsured for vaccines not covered) **OR**
- Covers ACIP-recommended vaccines but has a fixed dollar limit or cap for vaccines (considered underinsured once the fixed dollar amount is reached).

5. Insured (Privately Insured): NOT eligible for VFC vaccines

Insured is defined as having health insurance that covers the cost of the vaccinations—**not eligible for VFC vaccines**. A child is considered insured if all or a part of the vaccine is covered by insurance.

- This applies even for plans with a high deductible that has not yet been met
 - Co-pays, deductibles (even large ones) or other charges associated with cost of vaccines are considered routine costs and the child would not qualify for VFC vaccine.
- A child with insurance that has a cap on preventive care is considered *insured* until the cap is met. Once the cap has been met, the child is then considered *underinsured* and VFC-eligible.

Note: As required by the Affordable Care Act, insurance plans purchased through the Health Insurance Marketplace are required to cover ACIP-recommended vaccines (including seasonal flu vaccine) for children of all ages, without charging a deductible, copayment, or billing coinsurance.

ADMINISTRATION FEES & BILLING DETAILS

There are two costs associated with vaccine—the cost of the vaccine and the administration fee. VFC providers **may not** charge patients, Medicaid, or other third-party payer for the **cost of VFC vaccine**.

Cost of Vaccine

- Do not charge patients, Medicaid, or other third-party payer for the cost of VFC vaccine.

Administration Fees

A provider may charge a “vaccine administration fee” when vaccinating VFC-eligible children. Administration fees are per vaccine, not per antigen (i.e., as in combination vaccines).

- For Medicaid VFC-eligible patients, providers must accept the reimbursement for vaccination set by the state Medicaid agency or the contracted Medicaid health plans. See “Billing Details below for more information.”
- For non-Medicaid VFC-eligible patients, providers cannot charge the child’s family an administration fee that exceeds the maximum regional charge. The **maximum regional charge** for the Michigan VFC vaccine administration fee is **\$23.03** per vaccine (not per antigen in combination vaccines). The provider must establish a process to waive the fee if the patient or parent remains unable to pay the vaccine administration fee. Unpaid administration fees may not be sent to collections, and providers may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.
 - Providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child **after the date of service** may issue **only a single bill to the patient, and this bill must be issued within 90 days** of vaccine administration. This **does not** apply to administration fees billed to Medicaid. This is effective as of January 1, 2020.
- See the next section for more details on billing for administration fees.

Billing Details

Billing Medicaid VFC-Eligible Administration

Providers must bill only Medicaid for the administration fee for Medicaid-enrolled children. Bill the state Medicaid agency for the administration fee for Medicaid-eligible VFC children immunized by a Medicaid-enrolled VFC provider. Medicaid agencies have the authority to reimburse at a lower level than the set vaccine administration fee. Providers must accept the reimbursement for vaccination set by the state Medicaid agency or the contracted Medicaid health plans. If the provider bills Medicaid the regional maximum charge instead of the Medicaid agency's allowable rate, the provider will be reimbursed only the allowable rate and not the amount billed. The difference between the allowable rate and the amount billed **cannot** be collected from the parents of the child.

- According to the MI [Medicaid Provider Manual](#): Immunizations must be reported using administration fee code(s) and the code identifying type of vaccine given. Each vaccine/toxoid given must be reported in addition to the appropriate CPT administration code(s). Immunizations included in the Vaccine for Children (VFC) Program are free to providers so the charge for these vaccines must be reported as \$0.00. Medicaid FFS or the appropriate Medicaid Health Plan can be billed directly for immunizations provided to a child even if other insurance resources are available. The preventive pediatric diagnosis code(s) must be included to avoid rejection.
- MDHHS Medical Clinic Fee Schedule and correlating CPT Code is [available here](#).
- Michigan Medicaid billing information: 1-800-292-2550 or providersupport@michigan.gov
- AAP FAQ for Pediatric [Immunization Codes](#)

Medicaid as Secondary Insurance

Some children may have private primary insurance with Medicaid as their secondary insurance. There are billing options and the provider should choose the option that is **most cost-effective** for the family. The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Option 1: The provider administers VFC vaccines and bills Medicaid for the administration fee.

- In most situations, Medicaid is the “payer of last resort.” This means that claims must be filed with and rejected by all other insurers before Medicaid will consider payment: This is *not true of the vaccine administration fee* for Medicaid-eligible VFC children. Medicaid must pay the administration fee because vaccines are a component of Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT). However, once a claim is submitted to Medicaid, the state Medicaid agency may seek reimbursement for the administration fee from the primary insurer.

Option 2: The provider administers private stock vaccines and bills the primary insurance carrier for both the cost of the vaccine and the administration fee.

- If the primary insurer reimburses less than Medicaid for the administration fee, the provider can bill Medicaid for the balance, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of a vaccine and administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee (only in these instances where the child has Medicaid as secondary insurance). The provider must document this in MCIR and on the VFC borrowing form.

Billing Non-Medicaid VFC-Eligible Administration

VFC providers may charge up to, but not exceeding, the vaccine administration fee for non-Medicaid children who are eligible for federal vaccine. **In Michigan, this cap is \$23.03.** Providers cannot charge a patient/parent for the cost of the vaccine itself.

- Providers who choose to bill for the vaccine administration fee of a **non-Medicaid, VFC-eligible child after the date of service** may issue **only a single bill to the patient and this bill must be issued within 90 days** of administration. This policy **does not** apply to administration fees billed to Medicaid. The provider must establish a process to waive the fee if the patient/parent remains unable to pay the administration fee. Unpaid administration fees may not be sent to collections, and providers may not refuse to vaccinate an eligible child with unpaid administration fees. This is effective as of January 1, 2020.

If Unable to Pay Administration Fee

- VFC vaccines cannot be denied to a VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee. The provider must establish a process to waive the fee if the patient or parent remains unable to pay the vaccine administration fee.
- Unpaid administration fees may **not** be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.
- Note: Providers *may* charge an office visit fee in addition to the vaccine administration fee.

Billing Rejection

If at the time of service the child was reported as fully insured, private pay vaccine administered and insurance was billed with eligibility code of “private pay/fully insured” recorded in MCIR, but vaccine payment was rejected by insurance, VFC will replace the private vaccine doses with VFC vaccine doses. This is because the child at the time of service was actually VFC eligible as “underinsured” but parent/guardian was unaware. Replacing doses for underinsured rejections must be completed in 6-8 months from time of service or as soon as rejection is received.

- Provider office staff must change this child’s eligibility in MCIR for the doses rejected from “private pay” to “underinsured”, which will create a borrow appropriately.
- Now VFC owes vaccine to the private stock: Go into MCIR VFC inventory and create a “Transfer out - Replace Borrowed” transaction for the doses that were rejected. Add notes with patient name/MCIR ID, rejection information, and date of service. Go to Private Inv and add this dose via “Transfer In—Replace Borrowed” with the same notes added.
- Ensure the vaccine is also physically re-located in the units.
- Document this (and all borrows) on the [Vaccine Borrowing Log](#) and submit to LHD.

VACCINE DOCUMENTATION & VIS

Required Documentation for Vaccination

Providers must follow federal requirements for documenting vaccines administered to your patients, listed below. Providers must also follow state requirements and ensure MCIR documentation is complete and accurate within 72 hours of administration.

Patient Record/EMR documentation

The following documentation must be included per federal requirements:

1. Date vaccine dose given
2. Address of clinic where vaccine was given
3. Date Vaccine Information Statement (VIS) given (Use Michigan-Specific VIS)
4. VIS publication date
5. Vaccine manufacturer
6. Vaccine lot number*
7. Signature/name and title of person administering the vaccine
8. Eligibility (VFC, private pay, etc.) recorded within the chart and in MCIR.

*Best practice is to also include *site and route* of administration.

Providers utilizing EMRs must assure all above required fields are within their EMR. Paper version of the MDHHS vaccine administration record is [available here](#). Provide an updated MCIR record after administration of vaccines.

MCIR documentation

State law **requires documenting immunizations in the MCIR within 72 hours of vaccination** regardless of VFC or private stock vaccine administration. This may be performed via direct entry into MCIR or by Electronic Medical Record (EMR) data transfer

- Correct eligibility, lot, manufacturer, etc. must be correctly documented to ensure accurate vaccine inventory deduction, doses administered report, and other MCIR reports.
- Frequent review of deductions and reports should occur to ensure proper documentation in MCIR; For example, providers with EMR HL7 Transfer, the HL7 Transfer Report identifies data transferred from the EMR to MCIR. This allows providers to identify and correct errors. This report and correction should occur at least three times per week to meet the 72-hour reporting rule. It should be generated and reviewed before balancing/counting vaccine.

Lot Documentation If Lot Differs Between Box and Vial/Syringe

Nearly all vaccines have matching lot numbers between the box and the vial/syringe which allows seamless inventory deductions. However, some vaccines (such as those with multiple components) may have a lot number on the box which differs from the vial/syringe. This is of significant importance for all providers, particularly those using 2D scanners. For these instances, the documented lot number must **match the lot number uploaded in MCIR VFC inventory** to ensure deduction. This difference typically affects the following VFC vaccines and is uploaded as follows*:

- ActHIB: uploaded inventory reflects the lyophilized/freeze-dried vial
- IPV: uploaded inventory reflects the box
- Menveo: uploaded inventory reflects the box
- Pentacel: uploaded inventory reflects the lyophilized/freeze-dried vial

**Lot uploads are based on information provided by CDC. MDHHS is evaluating lot schemes to work toward a consistent approach (i.e. for upload to always match vial). At this time, this method is not consistent and therefore this guidance is current practice. If this changes, guidance will be updated.*

Reminder: Lots documented on packing slips reflect the BOX; If you receive a shipment for one of the above vaccines and the packing slip differs/box differs from MCIR upload, it may be because the upload reflects the vial/syringe instead of the box. Verify this before contacting the LHD.

Refusal to Consent to Vaccination

See [MDHHS Guidance](#) for documenting vaccine refusal both in MCIR and the patient medical record.

Vaccine Information Statements (VIS)

In Michigan, it is important that vaccine recipients, their parents, or their legal representatives be given the **Michigan versions of VIS** because they include information about the Michigan Care Improvement Registry (MCIR). By state law in Michigan, parents must be informed about MCIR and VISs from other sources (e.g., CDC or IAC) do not contain information about MCIR. Federal law requires VISs to be given to all vaccine recipients or their parent/guardian prior to vaccination. VISs are available at the [Michigan VIS website](#) (also from MCIR Home Screen). You may also contact your Local Health Department for copies of VISs.

- The [Important VIS Facts handout](#) includes all the current VIS dates.
- VIS publication date and date the VIS is provided must be documented in EMR/patient chart.

VFC DOCUMENTS TO MAINTAIN

Maintain the following VFC program documentation for 3 years:

- Screening & eligibility forms/documentation
- Documentation of administration and billing
- Temperature logs and data file downloads, including any excursion follow-up documents
- Annual training documentation/certificates
- Vaccine accountability records: packing slips, borrowing logs, wastage reports, etc.

Section 4: VFC SITE VISITS

IN THIS SECTION:

Site Visit Preparation

Type & Frequency

VFC site visits are essential to the success of the VFC Program. The data collected from these visits help CDC assess our state's overall compliance with federal VFC Program requirements.

SITE VISIT PREPARATION

Site visits are performed by LHD and MDHHS staff. They provide opportunities to answer questions about the VFC Program as well as work to develop an action plan for any issues found during the visit. The VFC Primary and Backup Coordinators are expected to be present for VFC Compliance Visits.

Some areas assessed at a site visit include:

- Identifying VFC-eligibility criteria
- Providing billing information, including vaccine administration fees
- Eligibility and screening documentation
- Vaccine Management Plan & Emergency Plan review
- Randomized chart review for documentation required and VIS review
- Borrow logs for review, all logs since last site visit
- Three months of temperature logs for review
- Storage unit and vaccine inventory assessment
- Certificates of calibration for all data loggers and backup data logger
- Appropriate signs posted as required (Do Not Disconnect signs, MDHHS required handouts "Storage & Handling" and "Preparation & Administration")

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

TYPE & FREQUENCY

Enrollment Visit

Providers new to the VFC Program will receive an initial [enrollment site visit](#). This visit includes an assessment of the site's vaccine storage and monitoring equipment, vaccine management and emergency response plan, and an overview of the VFC Program requirements.

- All expectations for VFC enrollment must be **completed within 3 months** of the enrollment visit. If not completed within 3 months, the process will be re-initiated from the beginning.
- Providers receive comprehensive training at the VFC enrollment site visit. Trainings include:
 - Vaccines for Children Program
 - Vaccine Storage & Handling
 - MCIR VIM Training
- A full compliance visit will then be completed **3-6 months** after the enrollment visit. Before the first compliance visit, providers must be enrolled for at least 3-6 months and have experience ordering and administering VFC vaccines. CDC recommends the site visit occur at this 3-6 time frame. Regardless, the compliance visit **must be completed within 12 months of enrollment**.

VFC Compliance Visits

VFC providers receive CDC-required VFC compliance visits, at minimum, every 24 months (and yearly in many areas). LHDs work to visit as many providers as possible **yearly**. Following a compliance visit, follow-up correspondence reviews compliancy and identifies any areas that require provider action. Due dates are included in this plan and must be followed appropriately.

- LHDs are responsible for conducting VFC site visits within their jurisdiction to provide support for VFC Providers across the state and assess VFC implementation. Providers can prepare for site visits by utilizing the [Site Visit Preparation Checklist](#).
- All eligible providers must also have a Quality Improvement visit that occurs just before the VFC compliance visit: see below
- The VFC Primary and Backup Coordinators are expected to be present for VFC Compliance Visits; The VFC Medical Director is encouraged to attend whenever possible.
 - In addition, to make the most of your VFC visit and Quality Improvement portion of the visit, please ensure any other key staff are present.

Unannounced Storage & Handling Visits

CDC requires MDHHS to conduct unannounced site visits throughout the state every year. These visits may be randomly selected; However, priority is given to providers with ongoing compliance issues.

Immunization Quality Improvement Visits

In conjunction with VFC compliance visits, providers are required to receive an Immunization Quality Improvement visit if they have any 2-year-old, 13-year-old or 17-year-old patients at their practice (according to the MCIR provider site id). This Quality Improvement (QI) visit occurs on the same date but prior to the VFC compliance visit and it promotes provider-level strategies that can lead to improving on-time vaccination and enhance practice workflow.

- The QI visit reviews the workflow of immunization delivery at the practice
- The LHD consultant and the provider staff collaborate together to select two QI strategies that can improve administration of timely vaccines to patients.
- The QI visit is a 12-month cycle, including the initial site visit, a 2-month and a 6-month check-in and a 12-month follow up.
- The LHD consultant will provide technical assistance (resources, training, & guidance) throughout the 12-month cycle.
- QI visits will be conducted at VFC enrolled provider sites that regularly administer vaccines to the VFC-age patients all year.

Section 5: VACCINE MANAGEMENT & TRAINING

IN THIS SECTION:

VFC Vaccine Coordinators
Initial & Annual Training
Communication & Contact Changes
Vaccine Management & Emergency Response Plans

VFC VACCINE COORDINATORS

At minimum, providers must designate one **Primary Vaccine Coordinator** and one **Backup (Secondary) Vaccine Coordinator** per facility. Coordinators are responsible for day-to-day operation of the VFC Program within the facility. They must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management. The VFC Primary Coordinator is physically on-site during clinic hours and is responsible for day-to-day operation of the VFC Program and storage and handling. The backup coordinator must be readily available to perform the same tasks whenever the VFC Primary is not present. If any responsibility is delegated to another staff member, the VFC Coordinators must ensure adequate training occurs and remain accountable for tasks.

Providers **must report contact changes to the Local Health Department** (LHD) and ensure training is coordinated with the LHD and MCIR staff. **Notify the LHD for changes** to primary/backup, VFC Medical Director, address, etc. Notification should be provided as soon as the change occurs. Failure to notify the LHD of changes in a timely manner may result in suspension from the VFC Program.

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

Coordinator Responsibilities

- Develop a [Vaccine Management & Emergency Response Plan](#).
 - Ensure staff understand the plan, and ensure it is reviewed and updated **at least yearly** (and prior to VFC Site Visits). If changes occur, it must be updated at this time.
 - Assess and document temperatures twice daily:
 1. AM: Current temp **and min/max** assessed and documented* when clinic opens
 2. PM: Current temp assessed and documented 30-60 minutes before leaving
- *Document exactly as displayed; For decimals, includes the tenth's place (i.e., 40.1 F) and do not round to the nearest whole number.
- Must include temps, exact time, date, and name/initials of the person
 - If more than one device in place, such as alarm system and DDL—document weekly calibration checks to compare accuracy (REQUIRED FOR LHDs).
 - Temperature logs are available at www.michigan.gov/vfc.
 - Ensure temperature devices meet MDHHS data logger requirements and are not expired.
 - Maintain certificate of calibration and re-calibrate before expiration
 - Ensure a **backup/extra digital data logger** is readily available
 - Download, review, and save temperature data files **at least weekly**; Immediate download and review must also occur anytime an out-of-range temperature is identified.

- Submit temperature logs to the LHD **monthly**, along with required documents/reports.
- Respond to temperature excursions appropriately and notify the LHD immediately.
- Manage vaccine inventory appropriately:
 - Place VFC vaccine orders in MCIR and submit supporting documentation to the LHD.
 - Ensure proper receipt and immediate storage of vaccine deliveries.
 - Rotate stock **at least weekly** so vaccines with earliest expiration are used first.
 - Balance/count vaccine inventory **monthly** (or more often if indicated by LHD) in MCIR.
- Document and process all vaccine loss, waste, borrows, returns, etc.
 - All vaccine loss, waste, and borrows must be documented and replaced as needed. Borrowing **must be rare and unplanned**; All borrows and replacements must be documented in MCIR and on the [borrowing log](#).
 - Generate and submit a Return/Waste Report in MCIR **monthly or sooner** for any loss, waste or return (expiration, temperature excursion/emergency, etc.) For guidance on generating the Return/Waste Report, see this [tip sheet](#).
- Ensure all staff that handle vaccine are adequately trained on vaccine storage and handling.
 - This includes not only those who administer vaccines, but also anyone who accepts vaccine deliveries or may have access to the unit(s) where vaccines are stored
- Understand VFC eligibility, screening documentation, and billing (administration fees)
- Primary and Backup coordinators must complete **annual training (see next section)**.
- The VFC Primary & Backup Coordinators are expected to be present for VFC Compliance Visits
- Maintain all VFC program documentation for 3 years:
 - Screening & eligibility forms/documentation
 - Documentation of administration and billing
 - Temperature logs and data files, including excursion details and follow-up
 - Annual training documentation/certificates
 - Vaccine accountability records: packing slips, borrowing logs, waste reports, etc.
- Contact your local health department for any VFC questions or concerns
- **Notify the LHD for changes** to primary/backup, VFC Medical Director, address, etc. This notification should be provided to the LHD as soon as the change occurs.

INITIAL & ANNUAL TRAINING

Providers must receive VFC training every 12 months and at enrollment. This includes training on (1) The VFC Program and (2) Vaccine Storage & Handling (and any Michigan updates at www.michigan.gov/vfc). At minimum, **the primary and back-up coordinators** must complete annual training. However, all personnel who work with VFC vaccine are encouraged to receive annual training. Primary/backup must also complete **MCIR VIM training** at least once and as needed. Maintain training documents for a minimum of three years and provide at VFC Compliance Site Visits.

Training is accomplished via one or more indicators below completed annually (within 12 months):

- Two CDC [You Call the Shots](#) web trainings (instructions below)
 - Attending Immunization Nurse Education (INE) sessions for VFC and/or Vaccine Management
 - Combination of the above, ensuring training on (1) VFC and (2) Vaccine Storage & Handling
- OR**
- Attending and participating in an entire VFC Compliance Site Visit

The LHD/MDHHS may require a training be repeated, supplemented, or done at a particular time (i.e.: following a vaccine loss, displaying challenges with requirements, during annual re-enrollment, etc.).



Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

CONTACT CHANGES & COMMUNICATION

Any changes in the medical director, new providers within the practice, shipping address, or changes to VFC Primary and/or Backup contacts **must be reported to the local health department (LHD) as soon as they occur**. Failure to notify the LHD of changes in a timely manner may result in suspension.

- The LHD will submit that information to MDHHS VFC, who will then make the appropriate changes to the VFC Enrollment tab in MCIR (pictured below).
- LHD will provide support in coordinating any required training on VFC or MCIR VIM.
 - Guidance on MCIR registration is [available here](#).
 - Guidance on adding registered users to the MCIR site is [available here](#).
- If the VFC Medical Director has changed after annual re-enrollment information was submitted, MDHHS will provide a blank Provider Agreement to sign and submit.

Maintain up to date MCIR information

- **The E-ordering tab** should be maintained by the provider's MCIR Site Administrator. E-order contacts should minimally include the Primary and Backup. These contacts should sign up to receive important emails such as expiration warnings, shipping notifications, etc.
- **Enrollment tab** is maintained by the MDHHS VFC team. Enrollment tab includes information regarding VFC Primary, Backup, Medical Director, or other providers. The Primary VFC Contact is the contact that receives vaccine return labels and is considered primary communication contact. Any updates must be reported.
 - If providers have changes to these staff, notify the LHD
 - The LHD will submit the information to MDHHS for update
 - If medical director changes, a new Provider Agreement must be signed (obtained from MDHHS VFC team)
- **Shipping tab, Storage tab:** Providers must maintain these tabs for accuracy.
 - If shipping address changes, notify the LHD.

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

Edit My Site → VFC Tab:

Contact Information	MCIR Users	Site Contacts	VFC	Business Hours	Transfer Interfaces
VFC Name*			Facility Type*	Private Provider	
VFC Pin*	VFC Status*	Active	Last Site Visit		
E Ordering		Shipping	Storage	Enrollment	
Enroll Date 02/23/1999		Renewal Date 03/08/2018		<input type="checkbox"/> Check, if considered a Specialty Provider ?	
Contact Information					
VFC Medical Director:		Notify LHD for contact changes, shipping address, etc.			
VFC Primary Contact:					
VFC Backup Contact:					
Providers					
Name	Phone	Email	Lic#/State	Type	

MONTHLY REPORTS & SUPPORTING DOCUMENTS

These are considered the minimal reporting requirements for document submission and review. “Supporting documents” must be submitted with all VFC vaccine orders, but **monthly balancing** in MCIR is required. The LHD may therefore require that **these reports be sent monthly for LHD review**. Follow the LHD requirement for monthly documents. The LHD may also request more frequent submission if provider infrequently orders, has trouble balancing appropriately, order issues, temperature issues, etc. Supporting documents include:

- Ending Inventory Reports (EIR)
 - Look at the date on the EIR: this reflects each balance cycle. Ensure submission of EIRs for all balances since last document submission. Choose the same dates when running the Doses Administered Report.
- Doses Administered Report (DAR) – must MATCH dates of the EIR(s) generated.
- Temperature Logs*** (*Must be sent **monthly** to LHD for review)
- Borrowing Log
- Return/waste report generated and submitted in MCIR for any loss/waste/expiration

02/21/2019 **Ending Inventory Report** Page: 1

Inventory: VFC/Public Report Period: 01/16/2019 - 02/15/2019

DTaP (pediatric)									
Lot Number	Expiration Date	Begin Balance	Doses In	Doses Out	Admins	Brdw/ Rpted	Unusable LW	Balance	Dose Count
X565R	07/12/2020	0	0	0	0	0	0	0	0
3N42N	10/23/2020	15	0	0	15	0	0	0	0
42RC4	10/23/2020	0	0	0	0	0	0	0	0
CX59C	10/23/2020	10	0	0	3	0	0	7	7
5553K	02/01/2021	0	20	0	0	0	0	20	20

02/21/2019 **Doses Admin Report** Page: 1

Report Period: 01/16/2019 - 02/15/2019

Provider Type: Family Practice (Private) VFC Pin: 500047 Funding Type: MI-VFC Funds
Eligibility: All Age Range: All Ages

DTaP (pediatric)												
<1	1	2	3-5	6	7-10	11-12	13-18	19-24	25-44	45-64	65+	Total
2	9	3	3	1	0	0	0	0	0	0	0	18

DTaP-Hep B-IPV (Pediatric)												
<1	1	2	3-5	6	7-10	11-12	13-18	19-24	25-44	45-64	65+	Total
22	0	0	0	0	0	0	0	0	0	0	0	22

Month/Year: VFC PIN #: Primary VFC Coordinator: Backup VFC Coordinator: Phone: Fridge: Stand-Alone: Combo:

REFRIGERATOR TEMPERATURE LOG (FAHRENHEIT): 36.0° to 46.0° F

Send logs monthly and with all orders. Download data weekly (or if alarm triggered), review, and save to computer.

For all checks, write exact temperature. Cross off days that your clinic is not open.

AM Check: 1. Write initials, exact time and current temperature. Assess if within range. 2. Write min/max. Ensure it is cleared/reset daily (if applicable). Assess if within range.

PM Check: 1. Write initials, exact time and current temperature. Assess if within range. *LHDs must also perform weekly calibration and documentation.

CIRCLE any out of range temperature. Refer to back of page for excursion response and NOTIFY LHD.

Day	Int.	Time	Current	Min	Max	In-range? (36-46.0) (YES/NO)	Comments/Calibration
01	M.L.	8:07	39.4	38.2	40.6	X	Called Health Dept. & Manual.
1	F.B.	4:11	40.6				
2							

VACCINE BORROWING LOG

VFC PIN: Clinic Name: Date Range or Month/Year:

Use this form when: 1. A dose of VFC vaccine is administered to a non-VFC-eligible child OR 2. A dose of privately-purchased vaccine is administered to a VFC-eligible child. Submit with orders and maintain for 3 years. All borrowings must be recorded on this form and in MCIR. VFC providers must maintain adequate inventory of private vaccine for patients not VFC-eligible. Borrowing should only occur as a rare, unplanned circumstance such as a delay in private shipment. As a reminder, VFC flu vaccine should NOT be borrowed under any circumstance. Detailed guidance can be found at www.michigan.gov/vfc.

BORROW							REPLACEMENT			
Date Dose Borrowed	Patient's MCIR ID or Name*	DOR	Dose Used from: VFC or Private	Vaccine Type (ie: MMII, if flu, specify type/dose)	Manufacturer	Lot # of Borrowed Dose	Reason # (option below)	Date Dose Replaced	Vaccine Type	Lot # of Replacement Dose

Reminder: Ensure replacement occurs in MCIR and unit.

Return/Waste Report Details

Report Date: MDHHS Submit Date: Report ID:

Action Plan: Increase flu vaccination efforts; expired flu will be returned.

Notes:

☒ 07/02/2019 **FLUARIX** NDC: 58160-898-52 Quantity: 7
Note: Vaccine expired, pulled from inventory. Lot No: 9455T

Dose Size	Inventory Effect	Transaction Id	VFC Code	State	Reason	Opt Out Flag
0	-7	63877167		Reconciled	Expired Vaccine	N

★ Need assistance in how to run the MCIR reports? See [VFC MCIR Reports](#).

VACCINE MANAGEMENT PLAN & EMERGENCY RESPONSE

All VFC providers must have a written vaccine management plan in place. Providers must also utilize the Emergency Response Plan to indicate backup locations and contact information. Both must be posted in a prominent area (ex: storage unit) and accessible to all staff. Ensure staff is trained on the plan and that the Primary and Backup are experts in implementation. Templates are [available here](#).

These plans must be **reviewed, updated, and signed at least annually** or any time there is a change in staff responsible for vaccine management or a change in procedure. A 'review date' and signature are required on all plans to verify that they are current. These documents are reviewed at site visits.

The **Emergency Response Plan** quickly outlines emergency information such as:

- Contacts notified in emergency (power outage, unit failure, etc.)
- Backup location to transport vaccine (cannot be a home/residence)
 - Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment.
 - Ensure 24-hour access to this facility. Some options may include hospitals, pharmacies, other VFC providers, long-term care facilities, etc.
 - Alternative storage locations should be inspected prior to an emergency to validate that proper vaccine storage conditions can be maintained.
- A fillable worksheet to track vaccines transported or affected by temperature excursion
- Vaccine manufacturer contact information for viability decisions

Section 6: VACCINE STORAGE, HANDLING & PREPARATION

IN THIS SECTION:

Vaccine Preparation & Administration
Vaccine Placement & Organization
Storage Units
Freezers & Defrosting
Power Supply Protection
New, Repaired, or Re-located Units

Temperature Monitoring Devices
Temperature Documentation
Alarm Systems & Backup Power Supply
Excursion Protocol for Out-of-Range
Temperatures
Transport

VACCINE PREPARATION & ADMINISTRATION

Vaccines must be prepared immediately prior to administration: Do not pre-draw doses. Prepare vaccines in a designated, clean medication area, away from where potentially contaminated items are placed. Post the MDHHS [Preparation & Administration](#) table in the area of vaccine preparation.

Ensure these additional preparation and administration practices:

- Follow ACIP recommendations, Standards of Pediatric Immunization Practices, and vaccine package inserts.
- When indicated, utilize appropriate medical contraindications:
 - For a 1-page contraindications summary, see this [Immunization Action Coalition tool](#).
 - For a detailed guidance on contraindications, see [this ACIP guidance](#).
- Never administer expired vaccines or diluent. Always check expiration dates for vaccines and diluent prior to preparation.
- Discard any un-used prepared doses no later than the end of the workday or per the manufacturer package insert, which may be much sooner (reconstitution time limits)
 - For guidance on when vaccines must be used after reconstitution, see [this resource](#).
- Only use the diluent provided by the manufacturer for that vaccine.
- Provide updated MCIR record after administration of vaccines.
- A single-dose vial contains **one** dose and should only be used for **one** patient.

Multi-dose vials: A multidose vial (MDV) contains more than one dose of vaccine. Only the number of doses indicated in the package insert should be withdrawn. After the maximum number of doses have been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached. MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a BUD noted in the package insert.

- **Beyond-use Date:** For some vaccines, the manufacturer specifies that once the multidose vial has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of days. This is commonly referred to as the "**beyond-use date**" (**BUD**). Any vaccine not used within the BUD should be discarded. For example, for some inactivated influenza vaccine, once the stopper of the multidose vial is pierced, the vial must be discarded within 28 days. For others, such as IPV or Fluzone MDV, a maximum of 10 doses may be withdrawn, even if there is remaining vaccine in the vial. For vaccine-specific details, see [package inserts](#).

- Opened vials may not be returned to McKesson (whether expired, compromised, etc.).
 - They must be removed from inventory as “Non-return open MDV”

For educational resources on preparation and administration, see the [MDHHS Quick Look](#) resources page and additional guidance at the [CDC Vaccine Administration Resource Library](#).

VAERS: Vaccine Adverse Events Reporting System

Vaccine Adverse Event Reporting System (VAERS) VAERS is a national vaccine safety surveillance program. VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines. The link for reporting is [available here](#).

The National Childhood Vaccine Injury Act (NCVIA) requires healthcare providers to report:

1. Any adverse event listed by a vaccine manufacturer as a contraindication to further doses; **OR**
2. Any adverse event listed in the [VAERS Table of Reportable Events](#) following vaccination that occurs within the specified time period after vaccination.

In addition, CDC encourages reporting **any clinically significant adverse event** that occurs in a patient following a vaccination, even if you are unsure whether a vaccine caused the event.

Administration Errors & Administration of Non-Viable Vaccine

Administration of non-viable vaccine may include: incorrect vaccine, wrong age group, improper administration, using non-viable vaccine following temperature excursion, expiration, improper transport, etc. **Such instances must be communicated to the LHD for follow-up.** The LHD provides appropriate actions to take and ensures MCIR documentation reflects correctly. When a vaccine is administered in error and the patient is required to be re-vaccinated, a provider must re-vaccinate with privately purchased vaccine as soon as possible. Serologic testing (titers) may not be performed instead of re-vaccination. Per ACIP General Best Practice [Guidelines](#), “*vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated*.” Clinicians should consult promptly with state or local health departments in these situations.” To ensure appropriate re-vaccination is performed and to properly indicate a dose as compromised in MCIR, **contact your Local Health Department**. Providers will see these doses with a “Y” next to them, and upon hovering over the dose, will see the detailed reason. These reasons include vaccine administration errors, vaccine efficacy concerns, etc.

Providers must **notify and re-vaccinate affected patients** as soon as possible, with privately purchased vaccine as follows:

- VFC patients must be re-vaccinated at no cost to them.
- To determine patients requiring revaccination:
 - LHD and/or MCIR staff will assist in identifying affected patients and doses.
 - The LHD and/or MCIR staff will designate these affected doses in MCIR appropriately.
- Providers must notify patients as soon as possible (e.g. mailed letters). The LHD should review letters to ensure they are complete and accurate before sending.
- Patients must be revaccinated as soon as possible (and as medically appropriate), using privately purchased vaccine that is stored and handled appropriately. If the re-vaccination is due to temperature excursions, it must be ensured that this privately purchased vaccine is newly purchased and was not affected by the excursion. If the vaccine is a live vaccine and follows the live-live rule, wait at least 28 days before repeating this dose.
- Serologic testing (titers) may not be performed instead of re-vaccination.
- If a provider does not perform these tasks, corrective actions will be implemented.

VACCINE ORGANIZATION & PLACEMENT

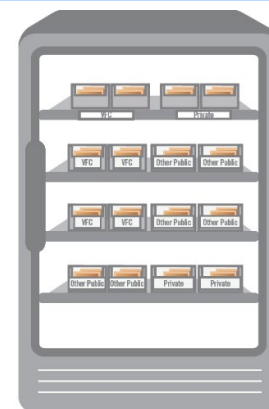
Overall Unit Organization

- Post the [MDHHS Storage & Handling](#) table on your unit.
- Units must be large enough to accommodate your maximum inventory without crowding.
- No food or drink may be stored within the vaccine units.
- No vaccine may be stored in the door, drawers/bins, or directly in front of vents.
- Place water bottles throughout unit: against walls, back, floor, and in door.
 - These are areas of greatest temperature instability
 - Water bottles assist in stabilizing temperatures and provide a blockade for areas where vaccines should not be stored
 - The only exception is if your unit manufacturer indicates that this may negatively impact unit functionality.
- Freeze several *additional* water bottles: The bottles should be utilized for transport packing when “conditioned” under water. This is outlined at [CDC Transport Guidance](#).



Vaccine Organization & Separation of Stock

- Private stock and VFC stock must be clearly marked and stored separately. Label bins and packaging to identify which box belongs to which stock. This can reduce accidental borrowing.
- Vaccines must be stored in **original packaging** with lids closed until preparation per manufacturers and CDC’s guidance.
 - Loose vials/syringes may be exposed to light and reduce potency; loose vaccine may also cause difficulty in tracking expiration, increase errors, and impact inventory management.
 - The only exception to storing in original packaging is when this is not feasible due to the unit manufacturer. For example, certain purpose-built units involve storing vaccines outside of the packaging for purposes of auto-dispensing (i.e. “Accuvax”). Always follow the manufacturer’s guidance. If using these units, save the original boxes in case of transport. For guidance on these units, see this [section](#).
 - If necessary, vaccine may be stored in a light-sensitive plastic bag labeled with appropriate vaccine information, including beyond-use-date (BUD) and time if applicable. The plastic bags must be amber light sensitive bags which protect from being damaged by ultraviolet light. This is not a recommended method of storage. Regular Ziploc bags do not protect contents from light and should **NOT** be used.
- Utilize open baskets, especially basket-weave bins, for vaccine organization and air circulation.
- Providers may choose to use [CDC pre-created labels](#) for vaccines
- Arrange vaccines/diluent in rows, allowing space for air circulation.
- Arrange vaccines/diluents centrally at least 2-3 inches from walls, ceiling, floor and door.



Images: CDC Storage & Handling Toolkit

DTaP-IPV-HepB (Pediarix)

Ages: 6 weeks through 6 years
Use for: DTaP and IPV: Doses #1, #2, and/or #3
 HepB: Any dose in the series
Do NOT use for HepB birth dose
Route: Intramuscular (IM) injection
Syringe tip cap of prefilled syringe contains latex

- If using a household-grade unit, do not store vaccines/diluents in unstable areas: directly under cooling vents (top shelf and back), in drawers, or in door shelves. The instability in these areas may expose vaccines to inappropriate storage temperatures.
- If using pharmaceutical units, follow manufacturer's guidance whether vaccines can be safely stored on the top shelf.
- Ensure inventory is monitored and stock rotated according to [Vaccine Inventory](#) guidelines.

Private Stock Vaccine Management: Private stock vaccines must be stored, handled, and inventory managed in the same manner as VFC if any movement occurs or is expected to occur between inventories. Any vaccine that is used for VFC but originated in private (i.e., borrowing, replacement of VFC borrowing, replacement of VFC expiration, loss, etc.) must follow VFC requirements.

Expired, Spoiled, and Wasted vaccine

Remove expired, spoiled, or wasted vaccines from the unit and place affected vaccines in bag labeled "Do Not Use". Ensure inventory transactions are made in MCIR. For details, see [this section](#).

- After inventory transactions, a Return/Waste Report must be generated in MCIR. Return/Waste Reports must be generated and submitted at least monthly and with orders. These reports allows action plans to be indicated, and ensure a return label is generated.
- For Michigan guidance on vaccine disposal, see [this resource](#).
- Replacement is outlined in [Loss, Waste & Non-compliance](#), as well as determined by the LHD.
- Return spoiled/expired vaccines within six months of the spoilage/expiration date. These VFC vaccines must be returned to McKesson and replaced, but *opened* vials cannot be returned.

★ Tip sheet available! For step-by-step guidance on ret/waste reporting, see [this tip sheet](#).

STORAGE UNITS

Proper storage units must be implemented to ensure that VFC vaccine potency is maintained. This protects your patients' health and your facility against costly vaccine replacement, inadvertent administration of compromised vaccine, and other consequences. Investing in reliable units and monitoring devices is often less expensive than replacing vaccines wasted due to improper storage.

General Unit Requirements

- The use of dormitory-style refrigerator/freezers is prohibited at all times for VFC providers.
- A household combination refrigerator/freezer is NOT recommended and the freezer cannot be used. Additional requirements for these units are outlined below.
- Units must have room to store the largest inventory a provider may have, without crowding.
- Units must maintain vaccine storage temperatures for refrigerated and frozen vaccine:
 - **Refrigerator:** 36.0° F to 46.0° F (2.0° C to 8.0° C), Aim for mid-range of 41.0° F (5.0° C).
 - **Freezer:** -58.0° F to +5.0° F (-50.0° C to -15.0° C)
 - **Ultra-Cold Freezer:** -90.0°C to -60.0°C (-130.0°F to -76.0°F)
- Units must be dedicated to vaccine storage: NO food or drink in vaccine units.
- Place water bottles throughout unit: against walls, back, floor, and in the door. The only exception is if unit manufacturer indicates this may negatively impact unit functionality.
- Certain unit-types have additional VFC requirements and guidance (household units, freezers, etc.). Therefore, ensure all details are reviewed below for each unit type considered.

- Units are assessed regularly: at site visits, with monthly temperature submission, inventory reports, etc. The LHD may indicate a need to replace units due to such indications (unstable temperatures, unit too small for inventory needs, etc.).
- LHDs may indicate a need to replace/supplement units based on a variety of factors.

Unit Placement & Maintenance

- Post the [MDHHS Storage & Handling](#) table on your unit.
- Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment.
- Make sure the unit door functions well and secures properly; If not secured properly, doors pose a particular risk to maintaining appropriate internal temperatures.
- Most units work best in an area with standard room temperatures, 20° to 25°C (68° to 77°F).
- Check the manufacturer owner's manual for additional guidance on placement and spacing.
- Maintain a log to document testing and repairs/maintenance for units and power backups.
- Conduct routine maintenance for all vaccine storage units and related equipment:
 - Check seals and door hinges.
 - Clean coils and other components per manufacturer direction.
 - Defrost manual-defrost freezers.
 - Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
 - Test any backup generator quarterly and have it serviced annually.

Unit Size

Consider the largest amount of vaccine used (back-to-school/flu season), including private stock:

MAXIMUM DOSES (LARGEST INVENTORY)	MINIMUM CUBIC FEET
>2,000	May require multiple units
1,000-2,000	40 cu. ft.
800-1,000	21 - 36 cu. ft.
400-800	16-20 cu. ft.
< 400	5 cu. ft.

Unit Types

Units vary by stand-alone versus combination units. Units also vary by grade: pharmaceutical and purpose-built, commercial, or household. For questions on a specific unit and its ability to meet VFC requirements, contact your Local Health Department and review the information below.

Unit types in order of highest to lowest preference:

1. Pharmaceutical Purpose-Built Units

MDHHS **highly recommends** purpose-built or pharmaceutical units. These are designed for storage of biologics, including vaccines, and they maintain temperatures most consistently.

- These vary in size from a compact, under-the-counter style unit to a large, stand-alone unit.
- Some purpose-built pharmaceutical units may be a refrigerator/freezer combination with separate temperature controls in each section.

Advantages of a pharmaceutical-grade refrigerator or freezer:

- Good temperature recovery when the unit has been opened to get vaccines
- Nearly all the internal space in the unit can be used to store vaccines.

- Pharmaceutical *freezers* typically allow auto-defrost with minimal rises in temperature.
- Offer the option of alarm and safety features to alert you to temperature excursions
- Includes key locks so doors cannot be opened by unauthorized staff

These units typically also feature:

- Microprocessor-based temperature control with a digital sensor (thermistor)
- Fan-forced air circulation multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.
- May have a temperature device like digital data loggers (DDLs). Before utilizing for primary temperature monitoring/documentation, this must be approved by the LHD. If not approved, a separate DDL must be utilized.
- Follow manufacturer's guidance whether vaccines can be safely stored on the top shelf
- For alternative purpose-built units (auto-dispensing), see [Variations in Purpose-Built Units](#).
- For freezer guidance and defrost specific guidance, see [Freezers and Defrost](#)

2. Commercial-Grade Units (Stand-Alone)

These are not built for vaccine storage and instead intended for commercial food use. They are typically larger and more powerful than combination household units.

- These are acceptable but may not provide as consistent temperatures as purpose-built units and are not built for vaccine storage.
- These units may have a temperature display on the unit, but this display typically reflects AIR temperature rather than DDL-required temperature data. Therefore, please ensure any temperature display on these unit is NOT utilized for temperature documentation. These do not reflect data logger standards with probes, calibration, etc.
- For freezer guidance and defrost specific guidance, see [Freezers and Defrost](#).

3. Household Refrigerator/Freezer Units (Combination) **ONLY** refrigeration section

CDC and MDHHS **do not recommend** these units and do not allow use of the freezer* in these.

- **ONLY** the refrigeration section of a combination household unit can be utilized for vaccine storage, and **ONLY** as long as temperatures are maintained in both sections. A separate **stand-alone freezer** must be utilized for frozen vaccine.
- If the unit experiences out-of-range temperatures, the provider must replace the unit by purchasing stand-alone or pharmaceutical units (#1 and #2 above).
- Household combination units are not an acceptable new equipment purchase.
- Providers must understand the risks associated with these units if they are in place and may be required to replace these units at any time based on temperatures, storage capacity for inventory needs, etc. Consideration for replacement is assessed regularly: at site visits, with monthly temperature submission, inventory reports, etc. The LHD may indicate a need to replace such units for a variety of reasons.
- Remove any deli/fruit/vegetable drawers and place water bottles instead.
- Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow: directly under cooling vents (top shelf and back), the floor, or in the door of these units. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
- Ensure water bottles are placed on the top shelf, floor, door, and all areas where vaccine should not be stored. For freezer guidance and defrost guidance, see [Freezers and Defrost](#).

- If a newly-enrolled VFC provider has an existing household combination unit in place for vaccine storage, **only the refrigeration** portion can be utilized for vaccine storage, and only if temperatures are within range at all times. Other assessments are also made by the LHD such as ability to support inventory needs. Before storing VFC vaccine in this unit, the provider must send data logger graphs showing 7 days of in-range temperatures. A separate, **stand-alone freezer** must be utilized for frozen vaccine.

*VFC providers enrolled prior to 1/1/2013 with a household combination unit may use the refrigerator and freezer portions *only as long as they maintain appropriate temperatures in both sections*. If the unit experiences out-of-range temperatures, the provider must replace by purchasing stand-alone or pharmaceutical units (#1 and #2 above).

Variations in Purpose-Built Units

Some purpose-built units take a non-traditional form such as door-less auto-dispensing units. For questions on a unit's ability to meet requirements, contact your LHD. General guidance is as follows:

Purpose-Built Variations in Inventory

- Must have the ability to separate public and private stock physically or virtually
 - If stock is separated virtually, an inventory printout must be accessible
- If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccine inaccessible.
- For certain purpose-built units, it may be recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's guidance for storage.

Purpose-Built Variations in Temperature Monitoring

- May have built-in digital data loggers that track temperatures and provide min/max temperatures. Contact the LHD to see if it satisfies MDHHS data logger requirements.
- May have multiple temperature probes or sensors
 - These probes or sensors must have current Certificates of Calibration.
 - May utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a *buffered* probe is not essential.
 - Many purpose-built units have undergone testing and temperature mapping so that the probe is in the most appropriate location.
- Although purpose-built units can have multiple temperature probes, a **backup DDL** is still needed in case of transport.
- Many purpose-built units do not need water bottles to serve as thermal ballast.
- Providers must ensure daily required temperature assessment and documentation (twice daily checks, min/max once daily, initials and times.)

FREEZERS & DEFROSTING

Freezer Types

The above guidance on unit types also applies to freezer types (pharmaceutical, commercial, household). Additional guidance on freezers is as follows:

- Freezers must maintain temperatures of -58.0 F to +5.0 F (-50.0C to -15.0C).
- All new VFC providers must utilize stand-alone freezers or a freezer within a purpose-built combination pharmaceutical unit.
 - New providers may not store vaccine in the freezer section of a household combo unit

- If a household unit is used by providers enrolled prior to 1/1/2013, it may be used for storage in both compartments *only as long as temperatures are maintained*. See full [guidance here](#).
- Freezers may differ in their defrost cycles (manual or auto-defrost). Consider this before purchase, and review “Freezer Defrost” below. Because manual defrost freezers require a backup plan for defrosting, a frost-free unit with an automatic defrost cycle may be preferred.

Freezer Defrost

Providers may utilize a **manual defrost** or a **frost-free automatic defrost** freezer. In many instances, automatic defrosts are preferred to reduce the need for a defrost plan, as required for manual defrost units. All freezers must be defrosted according to the unit manufacturer instruction. See the following section outlining both options and their requirements for use.

Manual Defrost Freezer & Defrost Plan

If a manual defrost freezer is used, providers **MUST** have a plan for vaccine storage during defrost.

- The provider must submit an **acceptable defrost plan** that uses a monitored storage unit or portable freezer that accurately holds freezer temperature.
- While defrosting a unit, ensure that vaccine is always monitored in an appropriate freezer and with a certified calibrated digital data logger.

Frost-Free Automatic Defrost Units: Defrost Cycle Guidance

Providers utilizing a frost-free freezer may experience regular defrost cycles which cause a brief temperature fluctuation. All out of range temperatures require data review, and the following guidance may be utilized to evaluate if a defrost fluctuation is considered supported or unsupported. *Supported* cycles do not require standard excursion follow-through if all criteria are met. They do, however, require documentation of details provided to the LHD. *Unsupported* cycles require standard excursion follow-through (stop vaccination, contact manufacturers and LHD, etc.).

This guidance is **only applicable to automatic defrost cycles of frost-free freezers** (Not manual defrost or household units). For temperatures briefly out of range on automatic defrost freezers, providers must download and review data to evaluate the cycle as follows:

Supported: A defrost cycle is considered supported if **all the following criteria are met:**

- The maximum temperature reached during cycle does not exceed 0C/32F.
- The number of defrost cycles within 1 day does not exceed 4 cycles.
- Each defrost cycle does not exceed 60 minutes.
- Temperatures must be documented as assessed, with notes added to temperature logs.
- Notes should indicate “defrost: max temp reached, length of time” (If notes are not included, VFC orders may be delayed)
- LHD may request graphs/data to support provider assessment of defrost cycles

Unsupported: A defrost cycle is unsupported if it **does not meet all above criteria**.

- Unsupported cycles require follow through according to [excursion protocol](#).
- Provider must contact manufacturer, and all documents, including follow-up, must be provided to the LHD immediately following the excursion.
- As with all excursions, do not use vaccine until LHD has provided guidance.
- Unsupported cycles should be investigated for cause: consider having unit serviced or replaced, water bottles added or removed, etc.

POWER SUPPLY PROTECTION

Precautions must be taken to protect the storage unit's power supply. Providers must implement the following measures to protect their power supply, and these measures are reviewed at site visits.

- Post **"DO NOT UNPLUG"** warning signs at outlets.
- Post **"DO NOT UNPLUG"** warning sign at circuit breakers.
 - Signs are [available here](#).
- It is highly recommended to plug in only one storage unit per electrical outlet.
- Additional measures may be in place to prevent accidental disconnection from power:
 - Plug guards are in place if possible (required for LHDs).
 - Units may be hard-wired into power supply, with no outlet.
 - Comprehensive policy on measures taken to prevent accidental disconnection.

Do NOT use the following:

- Multi-outlet power strips or surge protectors
- Extension cords
- Power outlets that can be tripped or switched off
- Built-in circuit switches (may have reset buttons)
- Outlets that can be activated by a wall switch

REQUIRED BACKUP UNIT/LOCATION

ALL VFC Providers **must identify a backup location** even if a generator is on-site. This is to ensure there is a location for vaccine storage if the actual unit fails and vaccine must be transported. Alternative storage locations should be inspected prior to an emergency to validate that proper vaccine storage conditions can be maintained.

- Ensure 24-hour access to the alternative facility.
- Vaccine must be transported, stored, and handled appropriately when re-located.
 - See [Transport](#) and the [Vaccine Management Plan & Emergency Response Plan](#).
- All staff should be aware of location of the backup unit and the Vaccine Management & Emergency Response Plan.
- Practicing the emergency plan and backup location is imperative to prevent losses. Keep a log of testing your emergency response and incorporate into regular staff training. There is a staff training section in the [Vaccine Management & Emergency Response Plan](#).

NEW, REPAIRED, OR RE-LOCATED UNITS

A new unit or unit that has been re-located or repaired requires close monitoring. Documentation must be submitted to the LHD before using unit for vaccine storage. This may also be implemented for units experiencing repeated fluctuations (though replacement and/or repair is most likely needed). Monitoring must be according to VFC requirements outlined in [Temperature Monitoring](#).

- It may take 2-7 days to stabilize temperatures in a newly installed, re-located, or repaired refrigerator and may take 2-3 days for a freezer.
- Monitor such a unit with a certified calibrated data logger for stabilization as follows:
 - Check and record temperatures twice daily, including min/max.
 - According to LHD, submit temperature data graphs for approval before storing vaccine in the unit. A minimum of two consecutive days of in-range temperatures is required; However, a full seven days may be indicated based on unit and/or LHD policy.
 - At the LHD's discretion, additional days of monitoring may be required.

TEMPERATURE MONITORING DEVICES

All VFC providers must use continuous temperature monitoring devices, typically known as digital data loggers (DDLs), to monitor vaccines administered to VFC eligible children. Routine review and accessibility of temperature data is critical for determining whether vaccine has been properly stored and for assessing usability of vaccine that was involved in a temperature excursion. Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached, a DDL provides detailed information on all temperatures recorded at preset intervals. **Providers must also have at least one extra/backup data logger readily available.**

Private Stock Vaccine Monitoring Reminder

Private stock vaccines must be stored, handled, and inventory managed in the same manner as VFC vaccine if any movement occurs or is expected to occur between inventories. Any vaccine that is used for VFC but originated in private (i.e., borrowing, replacement of VFC borrowing, replacement of VFC expiration, loss, etc.) must follow VFC requirements. This management includes calibrated data loggers, temperature checked twice daily, inventory management, etc. This is inspected during VFC site visits.

General Data Logger/Continuous Monitoring Requirements

- VFC providers must use a DDL with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit.
- DDLs must be used for monitoring of ALL vaccine storage: during routine, on-site vaccine storage, vaccine transport, emergency transport, mass vaccination clinics, etc..
- Providers using wireless electronic systems, wi-fi systems, etc., refer to [this section](#).
- Providers with alternate purpose-built units such as door-less units, see [this section](#)

Device Capabilities Required

To meet VFC program requirements, the DDL must be equipped with:

1. An active temperature display that can be easily read from the outside of the unit
2. The capacity for continuous monitoring and recording capabilities where the data can be routinely downloaded and analyzed for review
 - Must download and save data weekly and anytime an alarm is triggered or out-of-range temperature is identified
3. Alarm for out-of-range temperatures
4. Current, minimum, and maximum temperatures display
5. Low battery indicator
6. Accuracy of +/- 1°F (0.5°C)
7. Memory storage of at least 4,000 readings
8. Logging interval that can be programmed by the user to measure and record temperatures **at least every 30 minutes** (every 5 minutes is highly recommended).
9. Use of buffered probe that best reflects the temperature of the vaccine (e.g. buffered with glycol, glass beads, sand, or Teflon®)
 - Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.

Data Logger Use & Placement

- Must utilize valid, up-to-date calibrated DDLs for all temperature documentation

- Download, review, and save data **weekly**, or anytime an alarm or out-of-range temperature is identified. Ensure these files, and any excursion documents are saved for three years.
- Ensure you have batteries on-hand for replacement as needed
- Alarms must be set appropriately if temperatures go outside of the required ranges.
- Ensure appropriate logging interval is setup; It must log temperatures **at least every 30 minutes**. It is recommended that intervals be more frequent, such as every 5 minutes. Keep in mind that if an excursion occurs and data reviewed, the data is calculated according to logged temperature data; therefore, if settings show logged temperatures every 30 minutes, and one interval is out-of-range, it is considered out-of-range for 30 minutes. Setting intervals more frequent can allow more accurate data (but may require more batteries).
- Probe must be placed **centrally** in unit
 - The only exemption is for units with a built-in DDL that cannot be moved centrally (but meets all other DDL requirements), **OR** a dedicated port that dictates probe placement.
- Ensure device is re-calibrated according to the timeline indicated for your device.

Calibration Testing & Certificate of Traceability

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

- Calibration testing should be done **every two to three years or according to the manufacturer's suggested timeline**. Devices can experience a "drift" over time, affecting accuracy. This testing ensures the accuracy conforms to nationally accepted standards.
- The back- up DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time.

The calibration certificate must have the following components:

- | | |
|--|---|
| 1. Device name | 5. Issued by appropriate entity* |
| 2. Serial number | 6. Uncertainty of +/- 0.5°C (1F) |
| 3. Date of calibration | ○ If not within +/- .5°C (+/-1°F), DDL must |
| 4. Confirmation of test passed (or "in tolerance") | be replaced; adjustment of such a DDL is not recommended. |

*To determine issuance by an appropriate entity, it must indicate **one or more** of the following:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- Traceable to the standards of the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Backup Data Logger

- Must have **at least one backup data logger** with current calibration certificate
- This device must meet the same DDL requirements as indicated above.
- A back-up DDL must be readily available in case a DDL fails, primary device is being re-calibrated, and/or to be utilized in situations such as emergency transport.

- The back-up DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time.
- Ensure backup can be setup in emergency (i.e., power outage). Probes must be kept in refrigerator or freezer to be pre-conditioned. If only one back up, store in refrigerator.
- Providers should maintain the backup on-site. If not physically on-site, it must be accessible 24 hours per day and no more than thirty minutes from the site. Plans for accessing this backup device must be approved by the LHD/MDHHS and included in the vaccine management plan.

ELECTRONIC OR WIRELESS MONITORING SYSTEMS

Wireless or electronic continuous temperature monitoring systems allow a clinic to monitor temperatures in real-time on a remotely connected PC. Electronic or wireless systems must meet all VFC temperature monitoring DDL requirements. Providers must ensure the VFC Primary and Backup Coordinator are trained on these systems and have login accessibility for temperature assessments.

- These systems do not preclude providers from temperature documentation: Providers utilizing a wireless system must **perform all required temperature assessments and documentation, detailed in the Temperature Documentation Requirements section below** (twice daily temperatures with min/max, excursion protocol compliancy, etc.).

Providers with these systems must ensure all requirements are followed, including:

- Calibration certificates for probes
- A backup data logger is required
- Weekly review of temperature graphs/trends to review the unit trends
- Training provider staff on proper use and interpretation of data
- Testing alarm function monthly
- Creation of appropriate reports generated if electronic documentation is utilized
- Excursion follow-up as required, with notification to the LHD.

For these systems, daily temperatures may be documented either:

1. Via **handwritten log**: Log into system daily and hand-document required temperatures: current temp twice daily and min/max once daily (AM), initials, and times.
2. Via **electronic log**: Log into system daily and *electronically* documenting required temperatures: current temp twice daily and min/max once daily (AM), initials, and times. This is allowable **if** the electronic log/report contains all of these required elements and can be printed and provided monthly, with orders, and as needed.
 - Such electronic temperature assessment should generate reports that indicate evidence of logging into the system twice daily and documenting required temperatures with time stamp and user login identification.
 - Generating reports/graphs retroactively does not supersede daily temperature documentation requirements. While graphs/reports may indicate temperatures were in-range, daily assessment and documentation is required.

TEMPERATURE DOCUMENTATION

Providers must ensure all staff who store and handle vaccine understand cold chain management and temperature requirements. Vaccines must be stored within these ranges:

REQUIRED REFRIGERATOR TEMPERATURES:
36.0° F - 46.0° F (2.0° C – 8.0° C) Aim for 41.0°F (5.0°C)

REQUIRED FREEZER TEMPERATURES:
-58.0° F to +5.0° F (-50.0° C to -15.0° C)

Any reading outside of these ranges is known as a temperature excursion. Exposure to inappropriate temperatures may affect potency of vaccine and lead to costly vaccine losses and/or revaccination if administered. All excursions require follow-up and notification to the LHD (excursion protocol below).

Temperature Documentation

- Temperature logs are available at www.michigan.gov/vfc.
- Temperature logs must be submitted to LHD monthly and with order documentation to reflect time frame between orders.
- Temperature logs and associated documentation must be retained for at least three years.
- Temperatures must be taken from digital data loggers (DDLs) or approved continuous monitoring devices which meet all DDL requirements.
- Generating reports/graphs does not supersede the requirement of daily temperature documentation requirements. While graphs or reports may indicate temperatures were in-range, daily assessment and documentation is required.
- Document exactly as displayed; For decimals, includes the tenth's place (i.e., 40.1 F) and do not round to the nearest whole number. Decimals are included in excursion adherence: For example, if a provider has documented the temperature of a refrigerated storage unit as 46.1° F, the vaccine is out of range, and the provider must follow the temperature excursion policy.
- CDC also recommends checking the current temperature prior to accessing vaccine.

Regardless of the temperature monitoring system used, all VFC providers (including Hepatitis B Providers, MI-AVP, etc.) must **assess and document temperatures twice daily** as follows:

Required Temperature Assessment & Documentation*

1. AM temperatures taken when clinic opens
 - a. Current temp AND
 - b. Min/max temp
 - c. Exact time, date, and name/initials of the person assessing the temperature
2. PM temperatures taken 30-60 minutes before leaving for the day
 - a. Current temp
 - b. Exact time, date, and name/initials of the person assessing the temperature
3. If more than one device in place, such as alarm system and DDL—must document weekly calibration checks. **REQUIRED FOR LHDs.**
4. Any actions taken related to excursions and follow-up

*Document exactly as displayed (to the tenth's place, rather than rounded to the nearest whole)

Importance of Morning MIN/MAX

Min/max provides the highest and lowest temperature reached since min/max was last checked or since device was cleared.

- Allows you to identify an out-of-range temperature, even if “current” temperatures recovered. You can then initiate excursion follow-up and investigate *before* vaccination.
- Some devices require that min/max is physically CLEARED after each assessment of min/max (ex: VFC5000). Please ensure you understand these intricacies of your device features.
- Some devices automatically “clear” or reset the min/max at a time period such as at midnight. Ensure that your staff toggle back to review all data since last min/max was assessed.

Excursion Documentation

Out-of-range temperatures (current, min, or max) are considered excursions. These must be documented on the temperature logs and require immediate action.

- Providers must report all excursions to the LHD immediately and follow [Excursion Protocol](#).
- Stop vaccination while investigating any excursions.
- Do not use the vaccine/unit until guidance is provided by the LHD.
- Provide the LHD with all requested documentation, including data files and manufacturer reports for all affected vaccines.
- Lack of documentation provided to LHDs will delay approval of vaccine orders.
- Ensure that the unit is considered for replacement, repair, etc.

New, Repaired, or Re-located Units

See [this section](#) for guidance.

ALARM SYSTEMS & BACKUP POWER SUPPLY

Alarm Systems

Providers may utilize an external temperature alarm system for notification if a temperature excursion occurs (especially outside of business hours, weekends, etc.). LHDs are required to implement these systems. An external temperature alarm system will alert when the temperature goes out of the set range, however, it may not provide a permanent record. Therefore, it cannot replace a data logger and must be used **in conjunction** with data loggers.

- Alarm system limit settings: 36.0°F to 46.0°F (2.0°C to 8.0°C) for the refrigerator and -58.0°F to +5.0°F (-50.0°C to -15.0°C) for the freezer.
- Alarm systems must be co-located centrally with primary certified DDL.

Weekly Calibration: Alarm systems must be calibrated weekly to the certified device (such as DDL) to ensure the two devices function compatibly and accurately.

- Documented on temperature logs or a separate calibration log.
- Occasional slight discrepancies may occur due to the data logger capturing temperatures at specific intervals (e.g., every 30 minutes.) If the discrepancy is more than 3°F (1.5°C) from the reading on the certified DDL, make adjustments and document all actions taken.

Monthly testing: Test alarm systems at least monthly: Expose probe to temperatures out of range and verify notifications work as expected (correct staff notified, prompt notification, etc.).

Generators and Backup Battery Power Sources

Generators: A back-up generator may be an option for an extra layer of protection. Backup generators should be of a sufficient capacity to run continuously for 72 hours if necessary.

- Test generators quarterly and service annually or per manufacturer specifications. Maintain a log to document testing and repairs/maintenance for units and power supply backups.

- Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.

Battery backup: A backup battery power source can be used in lieu of a generator.

- Test battery backups quarterly and service annually or based on manufacturer specifications.
- Backup batteries should also supply at least 72 hours of power supply
- Maintain a log to document testing and maintenance for units and power supply backups.

Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment. Make sure you have 24-hour access to this facility.

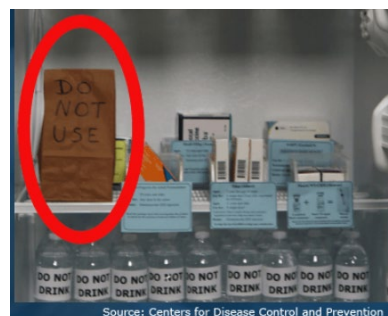
Backup Location

See [Backup Unit/Location](#). This must be identified in the Vaccine Management & Emergency Response Plan. Ensure that staff practice the emergency response plan! Keep a log of testing your emergency response and incorporate into regular staff training. There is a staff training section of the [Vaccine Management & Emergency Response Plan](#).

EXCURSION PROTOCOL FOR OUT-OF-RANGE TEMPERATURES

ANY out-of-range temperature is considered a temperature excursion and requires immediate action. If you are not confident in identifying an excursion or any part of this process, contact your LHD for assistance. Providers are responsible to follow through on excursions and **notify their LHD immediately**. Do not utilize vaccine exposed to excursions until the LHD advises.

Each event is unique and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar. Therefore, all excursions require appropriate notification and follow-up to ensure viability determinations are made.



If any temperature is out of range, follow these steps:

IDENTIFY & NOTIFY

1. Stop vaccination from the unit in question or vaccine in question.
2. Implement immediate correctional action if able (shut door if left open, resupply power, etc.).
3. Place exposed vaccine in a separate paper bag within the unit and label "DO NOT USE". Do not discard these vaccines.
4. Notify your clinic's Primary VFC Vaccine Coordinator and/or supervisor.

DOWNLOAD AND EVALUATE DETAILS OF EVENT

5. Download data logger and review all data. If multiple excursions have occurred, manufacturers will utilize the cumulative exposure time/temperatures.
6. Document all details of the event and ensure the LHD is notified and provided this data.
7. If unit is not stabilizing, implement Emergency Plan for transport to backup location/unit. Utilize CDC's guidance when [packing for transport](#) and always transport with a data logger.

CONTACT MANUFACTURERS AND LOCAL HEALTH DEPARTMENT

8. Contact all vaccine manufacturers for decisions on stability. They will request excursion temperatures/time/vaccines, etc. Contact info is in the Emergency Response Worksheet

9. Contact the LHD and provide all documentation, including manufacturer reports. Details for vaccine losses can be reviewed in the [Loss Policy](#).
 - a. If any dose is administered, see [Administration of non-viable vaccine](#).

Manufacturer Contact Info:

Dynavax: 1-844-375-4728
GlaxoSmithKline: 1-888-825-5249 or
www.gskusmedicalaffairs.com
Medimmune: 1-877-633-4411

Merck: 1-800-672-6372
Pfizer: 1-800-438-1985
Sanofi Pasteur: 1-800-822-2463
Seqirus: 1-855-358-8966

Post-Excursion Follow-Up

If any vaccines are considered non-viable/not supported, providers must replace with privately purchased vaccine, dose-for-dose. Provide invoices and temperature documentation for this vaccine to the LHD. Replacement and details of the loss policy are located in the [Vaccine Loss Policy](#).

- Nonviable VFC vaccine must be returned to the distributor (McKesson, Merck).
 - For vaccine return, remove from MCIR inventory and complete a [return/waste report](#).
- If doses have been administered, follow “[Administration of Non-Viable Vaccine](#)”
- Ensure that the unit is considered for replacement, repair, etc.
- If the unit undergoes maintenance, the LHD must approve before using for vaccine storage: Submit to the LHD at least 2 consecutive days of stable in-range temperatures via graph/files.
- The provider must work with the LHD throughout this process for any replacement, revaccination, and/or ensuring the unit has stabilized accordingly.
- Any loss exceeding \$1500 requires education from the LHD on Vaccine Accountability.
- If the unit is a household combination unit, it must be replaced with stand-alone or other acceptable (pharmaceutical or purpose built) units.

Excursion and Subsequent Administration of Non-Viable Vaccine

- When vaccine has been determined as unsupported but is subsequently administered to patients, the provider must notify and re-vaccinate the patient(s) with privately purchased vaccine as soon as possible. If the vaccine is a live vaccine and follows the live-live rule, re-vaccination must occur at least 28 days later.
- VFC patients must receive this vaccine at no cost to them.
- Serologic testing (titers) may not be performed instead of re-vaccination. Per ACIP General Best Practice Guidelines, “*vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be **repeated***” (CDC Storage & Handling [Toolkit](#), 2019 and General Best Practice [Guidelines](#)). To ensure appropriate re-vaccination is performed and to properly indicate a dose as compromised in MCIR, contact your Local Health Department.
- For full guidance, see [Administration of Non-Viable Vaccine](#).

TRANSPORT

MDHHS and CDC do NOT recommend routine transport of vaccines. If transport does occur, vaccines should only be transported using appropriate packing materials that provide maximum protection. This guidance outlines such materials and the importance of maintaining appropriate storage conditions during transport.

General Transport Requirements and Reminders

Transporting vaccine is **not recommended** and should only occur in an emergency. In instances where transport of vaccine is necessary, take appropriate precautions to protect your supply.



It is important to understand that ***different transport situations necessitate different methods for packing (detailed on page 2)***. Improper packing is as risky for vaccines as a failed storage unit.

Providers should ensure appropriate steps are outlined in their [Vaccine Management & Emergency Response Plan](#). All staff should be aware of this plan and familiar with transport materials needed and appropriate packing. The Vaccine/VFC Primary and Backup Coordinators are expected to be experts in its implementation.

- Vaccine transfers can only occur:
 - With approval and guidance from the LHD if enrolled in a public vaccine program such as the Vaccines for Children Program, Michigan Adult Vaccine Program, Universal Hepatitis B Vaccine Program, and High-Risk Hepatitis A & B Program. If transport occurs after-hours in an emergency, notify the LHD as soon as possible.
 - When a process is in place to ensure vaccine viability, as outlined below and in [CDC's Vaccine Storage and Handling Toolkit](#). This must include use of a current certified, calibrated DDL for temperature monitoring during transport, as well as other appropriate equipment below.
 - Ensuring total time for transport or transport plus off-site clinic cannot exceed 8 hours (e.g., if transport to off-site clinic is 1 hour each way, the clinic may run up to 6 hours).
- If any excursion occurs during transport or off-site clinics, follow the [Excursion Protocol](#) and do not use vaccine until viability information is obtained and the LHD has provided guidance.

Transport Situations and Packing Methods

When transporting vaccines, it is recommended that the manufacturers and CDC's guidance always be followed. Transporting vaccine is not recommended and should not occur routinely. Follow your Vaccine Management & Emergency Response Plan if transporting.

CDC recommends transporting vaccines in their original packaging with lids closed until ready for administration. Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. This may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines.

If necessary, vaccine may be transported in a light-sensitive plastic bag labeled with appropriate vaccine information, including beyond-use-date (BUD) and time if applicable. The plastic bags must be amber light sensitive bags which protect contents from being damaged by ultraviolet light. Regular Ziploc bags do not protect contents from light and should **NOT** be used.

Transport packing methods differ between 1) Emergency transport and 2) Planned transport such as for off-site clinics, satellite facilities, or re-location of stock. A portable refrigerator/freezer is always the preferred method. Do not utilize original shipping containers or food/beverage coolers for transporting vaccine.

Emergency transport requires either portable vaccine storage units (portable vaccine refrigerator/freezer), qualified containers and pack-outs, or the conditioned water bottle transport system.

- For step-by-step guidance on packing a cooler for emergencies using the conditioned water bottle method, see CDC's [Packing for Emergency Transport](#).

Planned transport requires either portable refrigerators/freezers or qualified containers and pack-outs (e.g., Cool Cubes, TempArmour, etc.). The conditioned water bottle method **cannot be used for planned transport**.

- Follow instructions specific to the portable refrigerator/freezer or qualified container/pack-out.

Transport Method Requirements

Transport Method	Emergency Transport	Planned Transport (Off-site clinic, Satellite Facility, or Relocation of Stock)
1. Portable Vaccine Refrigerator/Freezer (preferred)	Yes	Yes
2. Qualified Container and Pack-out*	Yes	Yes
3. Conditioned Water Bottle Transport System [†]	Yes	No

1. Portable Vaccine Storage Unit - A type of **powered** refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Some active units are “qualified” to maintain desired temperatures for a set amount of time in the event of a power loss. For proper use, follow directions stated in manufacturer instructions.

2. Qualified Container and Pack-out: A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are “qualified” through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time (i.e., Cool Cubes, TempArmour, etc.). For proper use, follow directions stated in manufacturer instructions.

3. Conditioned Water Bottle Transport Method: Method outlined according to CDC's [Packing for Emergency Transport](#). This is for **emergency transport only**; it cannot be used for planned transport such as off-site clinics, transport to a satellite facility, or relocation of stock. If packed correctly, this method can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

1. Portable Vaccine Storage Unit (PREFERRED)



Planned or
Emergency

2. Qualified Container & Pack-Out



Planned or
Emergency

3. Conditioned Water Bottle Transport



Emergency
ONLY

Do not utilize original shipping containers nor food/beverage coolers for transporting vaccine.

Materials for Transport

Maintain sufficient materials for transport of your largest inventory. Keep these available at all times, and detail their use in your [Vaccine Management & Emergency Response Plan](#). Materials include:

- ☐ Portable vaccine storage units (refrigerator/freezer units - preferred)
- ☐ Qualified vaccine-specific coolers or pack-out containers (Cool Cube, TempArmour, etc.)
- ☐ Coolant materials such as phase change materials (PCMs) for vaccine-specific coolers above
- ☐ Hard-sided insulated containers or Styrofoam™
- ☐ Frozen water bottles that can be conditioned to maintain appropriate vaccine storage ranges
 - Conditioned water bottle transport method is for **emergency** transport only
- ☐ A digital data logger for **each** cooler/refrigerator (certified and up-to-date calibration)
- ☐ Insulating materials: bubble wrap and cardboard
- ☐ Printed out guidance on [Packing for Emergency Transport](#)
- ☐ Pen and paper for temperature documentation before, during, and after transport
- ☐ Printed MDHHS [Vaccine Transport Temperature Logs](#)

Do **NOT** use dry ice, coolant packs from shipments, or soft-sided food/beverage coolers.

Packing & Monitoring Vaccine in Transport

- Follow manufacturer's guidance if using a portable refrigerator/freezer or a qualified container and pack-out designed for vaccine transport (includes specific materials and "conditioning" processes).
- Never freeze diluents, not even during transport.
- Place calibrated temperature monitoring device (preferably a digital data logger with a buffered probe) in the container. Place the device/probe as close as possible to vaccine(s).
- **Document:**
 - Time and temperatures at the start, during, and end of transport - if longer than 1 hour, document hourly. If device displays min/max temperatures, review and record information.
 - Utilize the **NEW** MDHHS Vaccine [Transport Temperature Log](#).

If any excursion occurs during transport or off-site clinics, follow [MDHHS Guidance for Responding to Temperature Excursions](#). Do not use vaccine until viability information is obtained and the LHD has provided guidance.

Transporting Opened Multidose Vials: A partially used vial **cannot be transferred from one provider to another** ([CDC Storage & Handling Toolkit](#)). If necessary, a partially used vial may be appropriately transported to or from an off-site/satellite facility *operated by the same provider*.

Guidance Specific to Frozen Vaccine

MDHHS, CDC, and Merck **do NOT recommend transporting varicella-containing vaccines** (VAR, ZVL, MMRV). If these must be transported in an emergency:

- [A portable freezer is BEST practice. All other options may cause a vaccine excursion.](#)
- Use a portable vaccine freezer or qualified container and pack-out that maintains temperatures between -58.0° F to +5.0° F (-50.0° C to -15.0° C).
- Do NOT use dry ice, even for temporary storage or emergency transport.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -58.0° F to +5.0° F (-50.0° C to -15.0° C).

Backup Location

Identify a backup location even if a generator is on-site. This is required for VFC providers. In case of power disruption or unit failure, a backup location allows temporary storage and monitoring. This location should be listed on the [Vaccine Management & Emergency Response Plan](#) and inspected

prior to an emergency to validate proper conditions can be maintained. Providers should have 24-hour access to the backup location.

Image Sources:

- Portable Vaccine Refrigerator/Freezer Image: <http://www.accucold.com/product/SPRF26M>
- Qualified Container & Pack-out Image: <https://www.vericormed.com/product/cooler-cool-cube-08-vaccine-transport-cooler-at-refrigerated-temperatures-fresh-vaccine-vt-08/>
- Conditioned Water Bottle Method Image: <https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

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Section 7: INVENTORY, ORDERING & TRANSACTIONS OVERVIEW

IN THIS SECTION:

Physical Inventory Management
Vaccine Ordering & Receiving
Electronic Inventory: Transactions & Reports Overview

PHYSICAL INVENTORY MANAGEMENT

Inventory management is crucial to VFC accountability and success. VFC vaccines that expire, are borrowed, mishandled or otherwise lost/wasted are to be replaced dose-for-dose (See VFC Loss Policy). The following requirements are expected for inventory management:

Inventory Comparison and Stock Separation

VFC providers must stock and offer **all routine ACIP-recommended vaccines** for their patient population served and for which there are federal [VFC resolutions](#). The CDC [Immunization Schedules](#) identify routine recommendations by age and recommendation.

- Ensure stock is clearly labeled to differentiate VFC and private stock inventory.
- VFC providers must maintain adequate inventory of private stock vaccine as well.
- Keep vaccines in original packaging to maintain expiration and lot information together, as well as to prevent borrowing.
 - If utilizing an auto-dispensing unit, follow manufacturer requirements.
- Borrowing vaccine must be a rare, unplanned occurrence.
 - Ensure all borrows are documented in MCIR and the borrowing log, as well as replacement: See [Balancing & Borrowing](#).
 - VFC flu vaccine is an exception to the borrowing rule – VFC flu vaccine cannot be used on private pay patients under any circumstances.

Stock Rotation & Avoidance of Borrows and Expiration

- **Weekly:** Review stock and rotate to ensure soonest-to-expire is up front and used first.
- **Monthly:** All providers must “balance” inventory monthly, which consists of counting and reporting vaccine inventory in MCIR. Monthly balancing is required even if an order is not being submitted. See “Balancing” in the next section.
- Notify the LHD if vaccine will expire within 3-6 months and you may not use in time. Before LHD is expected to re-locate vaccines, provider must perform Reminder/Recall in MCIR to notify patients coming due/overdue. Additional details in [VFC Loss Policy](#) below.
- **Expired** vaccine must be removed immediately: both in the unit and MCIR
 - Expired vaccine must be returned to McKesson via return labels after generating a return/waste report in MCIR.
 - Expired or mishandled vaccine must be replaced dose-for-dose.
 - Guidance on expiration is included in the [VFC Loss Policy](#).

Multi-Dose Vials

A multi-dose vial (MDV) contains more than one dose of vaccine. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses have been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached. A multidose vial of vaccine that has been stored and handled properly can be used through the expiration date printed on the vial *unless otherwise stated* in the manufacturer's information, such as the "beyond use date" discussed below. Vaccines are exempt from the Joint Commission ruling on the discard of open multi-dose vials 28 days after opening. The Joint Commission statement is [available here](#). MDVs cannot be transported between providers.

Beyond Use Date: Additionally, some vials must be used within a certain time frame after the first time a needle is inserted, after reconstitution, or if the manufacturer deems it is necessary to shorten the expiration date ([Pink Book](#)). This time frame is called the "**beyond use date**" or **BUD**. For example, with some inactivated influenza vaccine, once the stopper of the multidose vial is pierced, the vial must be discarded within 28 days. If the vial is entered on 06/01/2019, the BUD is 06/29/2019. The vaccine should not be used after the BUD.

- The BUD is the date or time after which the vaccine should not be used. The BUD varies among vaccines and can be found in [package inserts](#).
- The BUD replaces the manufacturer's expiration date and should be noted on the label along with the initials of the person making the calculation.
- **Reconstituted vaccines** have a limited period for use once the vaccine is mixed with a diluent. This period or BUD is listed in the package insert. Guidance is available from Immunization Action Coalition on "[Vaccines with Diluents: How to Use Them](#)," including the time limits.

Opened vials **may not be returned to McKesson** (whether expired, compromised, etc.). These must be removed from MCIR inventory with a special transaction: Non-return opened MDV. Waste appropriately rather than returning.

VACCINE ORDERING & RECEIVING

Completion of the MCIR Vaccine Inventory Module (VIM) training is required before ordering VFC vaccine. The VFC Primary and Backup must receive VIM training. Contact your [MCIR coordinator](#) for primary and backup, or any new staff that will be placing orders or managing inventory, to ensure they receive the required VIM training before submitting vaccine orders.

E-order Contacts

E-order contacts must be assigned in your MCIR site before an order can be placed. The order link is only visible to staff that are assigned as e-orders. This should at least include the VFC Primary and Backup Coordinator. Your MCIR "Site Administrator" can add users, edit user, and designate E-order contacts. See the [MCIR Provider Site Administrator Guidance](#).

- a. Guidance on MCIR registration is [available here](#).
- b. Guidance on adding registered users to the MCIR site is [available here](#).

After training on MCIR VIM, the Primary and Backup must be "E-Order Contacts" in MCIR to allow ordering privileges. This also allows these contacts to receive notifications such as emails regarding orders, shipments, lot expiration emails.

How to Place an Order

VFC orders are placed via MCIR E-ordering. VFC providers must submit orders and required paperwork to LHD. The LHD may require more frequent submission of supporting documents, particularly for providers who are on a less frequent ordering schedule or have issues with temperature monitoring, balancing, etc. Step-by-step guidance is available here for the [Provider Guidance on E-Ordering](#).

Contact Information	MCIR Users	Site Contacts	VFC	Business Hours	Transfer Interfaces
VFC Name*			Facility Type*	Local Health Department ▼	
VFC Pin*	VFC Status*	Active ▼	Last Site Visit		
E Ordering		Notes	Shipping	Storage	Enrollment
<input checked="" type="checkbox"/> VFC eOrdering		Approver:		MDHHS VFC Program ▼	
<input type="checkbox"/> All Hazard eOrdering		Vaccine Approver:		▼	
		Non-Vaccine Approver:		▼	
E-Order Contacts					
Name	E-Mail Address		Phone	Notify	
Add New E-Order Contact					

Ordering Amount & Frequency

Providers should submit vaccine orders based on the ordering schedule set up by their LHD and based on doses administered, unit capacity/type, and current needs. Monthly orders are recommended and should be the default frequency. CDC recommends placing orders with a four-week supply on-hand to allow for shipping time and unexpected delays. Vaccine units must be able to support quantities ordered. If ordering more than typical need, providers must communicate need to the LHD. Providers can maintain no more than a one to three-month supply of vaccines.

- Place smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss should an incident occur in the vaccine storage unit.
- Monthly ordering is recommended and should be the default ordering frequency, as monthly inventory balancing is required.

Priority Orders: Priority orders may be requested by LHDs only and pre-approved by MDHHS. A priority order is an order that will be shipped overnight if communicated in time for CDC processing same day; This order request is acceptable under emergency circumstances, primarily for a disease outbreak. Forgetting to order enough vaccine does not warrant a priority order.

Order Modification/Rejection

The LHD/MDHHS reviews quantities and appropriateness of orders, considering doses administered, unit capacity/type, patient population, etc. The LHD may therefore modify quantities when indicated. Additionally, orders may be rejected for a variety of reasons such as inadequate or no supporting documents provided, balance not performed, excursion without follow-up, or other reason.

Documentation Required for Orders

VFC has two levels for data submission: VFC Private Providers to LHDs and LHDs to MDHHS. The following guidelines, highlight which documents are needed for submission. These are considered the minimal reporting requirements for document submission and review. The LHD may require additional documents. For all orders, the “**count date**” must be within 10 days of placing an order.

Submit with Order	Submission Frequency
<ol style="list-style-type: none"> 1. Doses Administered Report 2. Ending Inventory Report 3. Temperature Logs 4. Borrowing Logs 5. Data logger documentation (if temps are out of range) 	<p>Reports must be generated within 10 calendar days of the order and sent to the LHD based on the ordering schedule set up by the LHD (monthly, bi-monthly, or quarterly, etc.).</p> <p>The LHD may require that reports be sent monthly, regardless of ordering. Balancing must be done monthly, therefore submission of reports can typically occur at this time.</p>

LHDs Processing and Submitting Provider Orders to MDHHS

Approving and processing VFC Provider Orders:

- Prior to placing a VFC provider's vaccine order, LHDs must review supporting documents, reviewing and approving for accuracy. This must be done before the order is approved in MCIR VIM and submitted to MDHHS for processing.
- LHD staff should check MCIR for pending vaccine orders at a minimum of twice a day to ensure vaccine orders are reviewed and approved by MDHHS in a timely manner.

LHDs Submitting LHD Order to MDHHS:

Submit with Order	Submission Frequency
<ol style="list-style-type: none"> 1. Doses Administered Report 2. Ending Inventory Report 3. Temperature/Calibration logs including satellites 4. Borrowing Logs 5. Data logger documentation (if temps out of range) 	<p>LHDs should submit their vaccine order and supporting documentation to MDHHS at the same time. Do not send supporting documents unless ordering. Supporting documents must be generated within 10 calendar days of order.</p>

Flu Pre-booking Orders

Seasonal VFC flu vaccine is pre-booked in MCIR in January or February. LHDs will contact providers to begin flu pre-booking process. All VFC providers are expected to maintain an ample supply of VFC flu vaccine for VFC-eligible children 6 months and older as recommended by ACIP. Accurate flu pre-booking quantities are vital to ensuring providers can vaccinate throughout the season, until flu vaccine expires. Work with the LHD to order appropriate pre-book quantities (70 – 100% population).

- Pre-booking VFC flu vaccine is a commitment to accept the vaccine when it becomes available. Providers must be prepared to receive/store VFC flu vaccine as early as August.
 - If a provider incurs temporary closure and cannot receive automatic flu shipments (such as school-based health centers), notify the LHD in advance to prevent delivery.
- Providers who enroll in the VFC Program after the pre-booking process should contact their LHD to request VFC flu vaccine doses.
- VFC flu vaccine is shipped directly to providers from McKesson as soon as it becomes available
- VFC flu vaccine is shipped separately from other VFC vaccines and may arrive in small, multiple allocations as provided by CDC throughout the flu season.
- Order the same VFC vaccine product (type and presentation) as private vaccine stock.
- Providers **may not borrow VFC flu vaccine** for private pay patients under any circumstances.

★ Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

SHIPPING TIMELINE AND PRESENTATION

Refrigerated VFC vaccine is shipped from McKesson, usually via FedEx. Frozen vaccine is shipped from Merck, usually via UPS. If correctly identified in MCIR to receive notifications, staff will receive emails upon shipment of vaccine orders!

McKesson Shipping Timeline & Presentation

- Orders are typically received within 24 hours from date of **shipment** (and inventory upload).
- The box is much larger than the amount of vaccine inside.
- Validated to maintain 2 - 8° C (36 - 46° F) for up to 72 hours. The box will include a **temperature monitor** – either a 3M MonitorMark or FREEZEmarker indicator.
- McKesson shipping days are Mon-Thurs (excluding holidays) for delivery on Tues-Friday, but also takes into consideration *provider* hours for vaccine deliveries.

McKesson Routine Vaccine Shipping Timeline

MDHHS Order Approval Date in MCIR*:	Order Shipped by:
Monday	The following Monday
Tuesday	Monday
Wednesday	Tuesday
Thursday	Wednesday
Friday	Thursday

* To view when an order was approved, review “**Order History/Status**” on MCIR Home Screen. Select the “**Order Log**”. Look for the date the order was “batched for processing” by MDHHS. Orders may ship more quickly than the “Order shipped by” day shown in this table. Keep in mind that provider delivery hours play a role in CDC shipping to ensure vaccine can be received in viable condition.

McKesson **Flu Vaccine** Order Shipping Timeline

MDHHS Flu Order Approval Date in MCIR:	Order Shipped by:
Monday	Tuesday
Tuesday	Wednesday
Wednesday	Thursday
Thursday	Monday
Friday	Monday

Pre-booked flu vaccine is shipped automatically from McKesson as soon as it becomes available. VFC flu vaccine is shipped separately from other VFC vaccines and may arrive in small, multiple allocations as provided by CDC throughout the flu season. Keep in mind that provider delivery hours play a role in CDC shipping to ensure vaccine can be received in viable condition.

Merck Shipping Timeline & Presentation

- Diluent is in the package lid: Store diluent appropriately but do not freeze diluent!
- Rather than a strict timeline, Merck provides a delivery date based on shipping temperature requirements for each package of your order (typically 1-4 days from shipment date).
- No temperature *monitor* is included in the box. Instead, an insert is included with acceptable shipping time for transit. Check this insert compared to the packing slip shipment date. If received outside this time-frame, refer to How to Report a Problem with an Order below.



RECEIVING VACCINES

Providers must never refuse a vaccine delivery. Providers should post signage directing delivery personnel to not leave deliveries unattended. **Do not implement “Signature on File”** for vaccine orders. This could result in the carrier leaving a vaccine box unattended, which could cause a vaccine loss. It is a CDC requirement that all providers must be open with the appropriate staff onsite to receive and immediately store vaccine **orders at least one weekday other than Monday for at least four consecutive hours**. Please ensure MCIR Shipping Hours reflect this.

- Vaccines must be shipped directly to the provider site of administration.
- Each provider office should have at least 2 people trained for vaccine ordering and receiving.
- DO NOT leave the vaccine shipment unattended. Vaccine deliveries require immediate attention. Staff who do not routinely handle vaccines but who accept shipments should alert the primary vaccine manager or the back-up manager as soon as vaccine shipments arrive.
- Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive.
- Do not place an unopened and/or unpacked shipment box in a vaccine storage unit.
- Failure to appropriately store vaccine upon delivery could result in a vaccine loss that requires replacement with private stock vaccine.

Checking Vaccine Deliveries Received

When vaccine arrives, review the following at minimum:

- ☐ Review the packing slip and verify that this matches contents received (Reminder: maintain packing slips for three years). **Discrepancies between the packing slip and contents received is the provider’s responsibility if not reported to the LHD within 1 hour of delivery.**
- ☐ Review any temperature indicators associated with the order and verify appropriate temperatures were maintained. Follow guidance below to report problems.
- ☐ Expiration dates match and should be at least 6 months from date of receipt.
- ☐ Presentation of vaccine (vials vs syringe) matches.
- ☐ The package and the vaccine boxes should not be damaged.
- ☐ Remove vaccines from the box and bags and store according to VFC guidelines.
- ☐ Compare packing slip and contents to MCIR VIM. If you find any discrepancies, contact your local health department immediately.
- ☐ **If problems are identified**, follow the guidance below immediately.

Note on single dose orders: Providers may order a single dose of pediatric Td, PPSV23 or DT (with MDHHS approval). These are shipped in 6” x 8” Amber UV bags. Since these come directly from the distributor, they are considered original packaging and offer protection for light-sensitive vaccines. They should remain in these bags until they are ready to be administered.

How to Report a Problem* with a VFC Vaccine Order

**Report order-related issues within 1 hour of receipt.*

Temperature/Viability Issues/Spoiled in Shipment

If you receive a VFC vaccine delivery that is damaged/compromised, shows a temperature indicator issue, etc., store the vaccine appropriately, label it **DO NOT USE**, and **immediately** contact:

- **McKesson's Vaccine Viability Line: 1-877-836-7123**
 - Call McKesson at the phone line above and notify the LHD. Once McKesson has been contacted, the provider and LHD must work with MDHHS for guidance and follow-up. If replacement vaccine is needed, the distributor will work with the provider to email a return label *directly to the provider* (rather than MCIR ret/waste report), as well as send a replacement order. This may require MCIR inventory be adjusted to remove the spoiled shipment and re-enter the new shipment with correct inventory information.
- **Merck Call Center: 1-800-637-2579**
 - Call Merck at the phone line above and notify the LHD. Once Merck has been contacted, the provider and LHD must work with MDHHS for guidance and follow-up. If replacement vaccine is needed, the distributor will work with the provider to email a return label *directly to the provider* (rather than MCIR ret/waste report), as well as send a replacement order. This may require MCIR inventory be adjusted to remove the spoiled shipment and re-enter the new shipment with correct inventory information.

Discrepancies in Vaccine Lot Numbers

If you receive a different lot/expiration date from the lot/expiration date listed on your packing slip, provide the following information via email to LHD/MDHHS VFC staff within 1 hour of receipt.

1. The VFC PIN
2. The vaccine NDC
3. The correct lot and expiration date

Manually remove the incorrect lot and add the correct lot. MDHHS VFC staff will send the discrepancy to McKesson so they can fix their records. **Reminder:** for certain vaccines, the lot may differ between box and MCIR upload. See [this section](#) before contacting the LHD.

Discrepancies in Vaccine Quantities Received

If you receive your vaccine order and the amount you received is different from what is listed on the packing slip, please submit the following information to the LHD/MDHHS, within 1 hour of receipt:

1. The VFC PIN
2. Names of both staff persons who looked through all packing materials and counted vaccine
3. Assure the packing slip lists the provider's correct name & address
4. A copy of the packing slip with discrepancy marked (email preferred)
5. The tracking number from the shipping label on the box
6. The number from the sticker on the back of the packing slip – should begin with an E. If this number cannot be found on the back of the packing slip then it will be on the cardboard packaging that surrounds the vaccine inside the cooler.
7. What exactly is wrong with the order: for example – ordered 30 doses of hepB, the packing slip indicates 30 doses, but only received 20 doses.

Once MDHHS receives this information, MDHHS will notify McKesson and the warehouse conducts an inventory count. If their count supports the shortage, they will ship out the missing vaccine. Please be confident in this determination before indicating such discrepancies (as they are rare).

ELECTRONIC INVENTORY: TRANSACTIONS & VFC MCIR REPORTS

VIM & VIM Training

The Vaccine Inventory Module, VIM, is the system within MCIR used to account for vaccine. Accurate dose documentation allows inventory to deduct and allows provider to manage loss/waste. Providers use the MCIR VIM to regularly count, report on, and order VFC inventory. This section will overview commonly-used VFC functions in VIM. There is also a MCIR Reference Guide for [VIM](#).

The VFC Primary and Backup Coordinators must be trained in MCIR VIM before placing VFC orders. This is provided by the [regional MCIR](#) staff.

Viewing Inventory: VFC Inventory

- VFC/MI-AVP Vaccines will be automatically uploaded into the public VIM Inventory
- To view VFC inventory: From MCIR Home Screen, within Vaccine Mgmt, select Manage Inventory. Ensure the drop-down shows “VFC/Public” and inventory will display.

(Pneumovax)				doses
RV5 (Rotateq)	Merck (ROTATEQ)	N030174	06/13/2019	2 doses
RV5 (Rotateq)	Merck (ROTATEQ)	R002521	09/18/2019	6 doses
RV5 (Rotateq)	Merck (ROTATEQ)	R021216	04/25/2020	50 doses

- Utilize MCIR VIM for review of expiration dates frequently
 - Green indicates expiration in 6 months; purple indicates expiration in 3 months; red indicates EXPIRED vaccine which must be removed immediately.
- Utilize MCIR VIM to make adjustments to doses that have been wasted, broken, expired, etc.

Viewing Inventory: Private Inventory

- Private vaccines must be **manually** entered in the private VIM inventory.
- To view private inventory: From MCIR Home Screen, within Vaccine Mgmt, select Manage Inventory. Ensure the drop-down shows “Private” and inventory will display.
 - Select “Add New Lot” for entering new vaccine.
- Maintenance of private stock inventory in VIM is a requirement of all VFC providers to assure borrowing transactions are complete.
 - This includes balancing, adjustments, and appropriate inventory transactions.
- Same lot in both VFC and Private? When entering the administration, the private lot will have an asterisk next to it, identifying it was given from private stock.

Immunization Information - (Lots marked with '*' are from private stock)			
Type	Admin	Date	04/15/2019
Mfr.	Merck (GARDASIL 9)	Vaccine	R017457 (Expires: 04/10/2021) R020947 (Expires: 05/04/2021) R003557* (Expires: 11/20/2020) R024264* (Expires: 10/29/2019)
		Lot	

Using VIM to Avoid Expiration

- Utilize MCIR VIM for review of expiration dates frequently
 - Green indicates expiration in 6 months; purple indicates expiration in 3 months; red indicates the vaccine is EXPIRED and must be removed immediately.

- Ensure key staff receive Lot Expiration emails for upcoming notifications.
- Use the [Reminder/Recall](#) function in MCIR to administer doses that will soon expire. **Recalls must be done before** requesting your LHD redistribute soon-to-expire vaccine.
 - Notify LHD if vaccine will expire within 3-6 months and you may not use in time. Additional details are available in [Loss, Waste & Non-compliance](#).
- The Vaccine Lot Expiration report generates automatically in your “Retrieve Results” area of MCIR and sent via email to those designated for notifications in E-order contacts.

Administrations and Inventory Effects

Doses are automatically deducted from inventory if entered correctly into MCIR (or via EMR transfer). All required fields must be completed to ensure proper inventory deductions and data entry.

- Per state law, doses must be entered within 72 hours of administration (required for ALL patients under 20 years old)
- Document: date, manufacturer, lot, eligibility. Site and route are highly recommended.
- Same lot in both inventories? The private lot number will have an **asterisk (*)** next to it.
- Ensure the “Admin” field is selected as it is “administered” by you. This ensures the dose deducts from inventory and appears on Doses Administered Reports.
- Doses given by another provider: Enter as “Historical” to avoiding impact to inventory
- For step-by-step instruction on MCIR documentation, see pg. 23 of the [User Reference Guide](#).
- If doses are not entered/deducted correctly, providers will have difficulty balancing.
- With EMRs that transfer to MCIR, providers must ensure accuracy. This involves regular review of reports such as the “HL7 Transfer Report” in MCIR. This should be run at least 3 times per week to ensure corrections within 72 hours. It should be run prior to all balances.

VIM: TRANSACTIONS OVERVIEW & SCENARIOS

VIM Transactions Overview

Beyond administrations, providers create adjustments to their inventory if vaccine is re-distributed, broken, drawn but not used, etc. These require manual adjustments to the MCIR inventory and may involve either adjusting a current inventory or adding a new lot/vaccine to an existing inventory.

Most adjustments involve active inventory and occur via Manage Inv → Vaccine Name → Add New Transaction. This section provides an overview of these.

Adjustments that indicate a loss/waste or a need for a return label such as expired vaccines, are detailed in the [VFC Loss Policy](#). There is also a MCIR Reference Guide for [VIM](#).

All transactions require an “Action” and a “Reason”. For example, the action may be Return to Distributor, while the reason could be expired, equip failure, power outage, etc. Example:

Action*	<input type="text"/>	Reason*	<input type="text"/>
Inventory Effect:	<input type="text"/>	LWB Effect:	<input type="text"/>
Comment	Adjustment		Equip Failure - too Warm
Created By:	Returned to Distr		Equip Failure - too Cold
	Transferred In		Expired Vaccine
	Transferred Out		Failure to Store Properly
	MCIR Opted-Out		Power Outage
	Non-Return Opened MDV		Recalled
	Vaccine Short Dated		Spoilage in Shipment
	Returned to LHD		
		Cancel	

Questions about which adjustments to use and how it affects inventory? In addition to VIM training, ensure utilization of the MCIR Reference Guides: There is a dedicated [VIM Reference Guide](#).

- A helpful table is available which highlights how each adjustment affects inventory (p. 24).

Transaction for Vaccine Re-Located/Transferred

If you receive vaccine from the LHD or other provider via redistribution, manual transactions must be entered into MCIR to reflect all movement of the vaccine.

- A provider giving up doses must ensure transactions reflect all movement:
 - The LHD must be notified, approve, and the provider or transporter must ensure that vaccine is re-located according to MDHHS and CDC requirements.
 - From provider's site, select Add New Transaction → **"Return to LHD"**. Select appropriate reason; ensure detailed comments with provider PINs are involved.

Transaction Detail			
Date*	02/19/2019	Doses*	10
Action*	Returned to LHD	Reason*	
Inventory Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A
Comment: LHD picked up vaccine from PIN 990080, transport to PIN 990133			
Created By:	Date: 02/20/2019		

- The clinic receiving the vaccine will perform the transactions:
 - Manage Inventory → Add New Lot → **"Transferred In" — "Add to Inventory"**. Add notes with detailed descriptions and both VFC provider PINs.
 - If not immediately re-located, the LHD must enter vaccine in their LHD inventory.

Transaction Detail			
Date*	02/20/2019	Doses*	10
Action*	Transferred In	Reason*	Add to Inventory
Inventory Effect:	<input type="radio"/> Subtract <input checked="" type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment: Received vaccine from PIN 990000. LHD notified and approved.			
Created By:	Date: 02/20/2019		

Transaction for Opened Multi-Dose Vials

Regardless of reason, there is a specific transaction used for multi-dose vials. Whether the vaccine expired or was compromised, opened vials CANNOT be returned to McKesson. They also cannot be transported to another provider or LHD. Open MDVs must be removed from inventory as follows:

- Utilize transaction **"Non-return opened MDV"** and add comments describing reasons.

Transaction Detail			
Date*	02/20/2019	Doses*	4
Action*	Non-Return Opened In		
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment: Expired vial open multi-dose polio. Sent reminder/recalls and notified LHD. Vaccine wasted appropriately.			
Created By:	Date: 02/20/2019		

Transaction for Short-Dated Vaccine

This does not apply to EXPIRED or SOON-TO-EXPIRE vaccine. *Short-dated vaccine* may apply if vaccine is exposed to inappropriate storage conditions. The manufacturer may determine the vaccine can still be used but will expire on an earlier date than the date on the label. If this occurs,

- Utilize transaction “**Vaccine Short Dated**”, subtracted from inventory with documentation in Comment field (e.g. exposed to temps out of range, new expiration date xx/xx/xxxx).
- The same vaccine, now with new shortened expiration date, must be added back into inventory as Transferred In, with correct data entered in required fields.

Transaction Detail	
Date*	02/20/2019
Doses*	4
Action*	Vaccine Short Dated
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A
LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment	Manuf short-dated vaccine after temp excursion. Will re-add this lot to inv. with updated exp. 3/16/19
Created By:	Date: 02/20/2019

Transactions Due to Loss/Waste, Expiration/Return

- See [Loss Policy](#)

Transactions Due to Borrowing

- See [Balancing & Borrowing](#)

VFC MCIR REPORTS

Below is an overview of frequently used reports. These are reviewed in MCIR VIM training and detailed MCIR Resource Guides [available here](#).

➡ **MCIR reports to submit for orders:** Ending Inventory Report, Doses Administered Report and Return/Waste Report if applicable (as well as temp logs and vaccine borrow log)

Physical Inventory Report (PIR)

The **Physical Inventory Report (PIR)** generates a report of all doses in your inventory according to MCIR. It creates a “worksheet” to count your inventory and compare to the counts on the PIR.

- To generate: From MCIR Home Screen, go under the Reports section and select “Inventory”. From the drop-down options, select “Physical Inventory Report” and choose inventory (VFC). Submit. All reports generate in a queue: Retrieve by selecting the “Retrieve Results” link in the upper banner or from MCIR Home Screen.

Ending Inventory Report (EIR)

The **Ending Inventory Report (EIR)** accounts for the movement of all vaccine lots in a specific balance period. The EIR can only be generated for a completed/closed inventory. Therefore, an EIR cannot be generated for an inventory still in the process of being balanced.

- The EIR dates must **match the DAR dates** generated (see below).
- **If you’ve completed multiple balances since last order, generate an EIR for each cycle and submit all EIRs with orders.** For example, if I balance weekly and last ordered 5 weeks ago, I will generate 5 EIRs and submit to the LHD.
- To generate: From MCIR Home Screen, within the Reports section, select “Inventory”. From the drop-down options, choose “**Ending Inventory Report**”. Choose the date of the balance

cycle needing an EIR for. Submit. All reports generate in a queue: Retrieve by selecting the “Retrieve Results” link in the upper banner or from MCIR Home Screen.

Doses Administered Report (DAR)

The **Doses Administered Report (DAR)** indicates the number of doses administered by age groups for each vaccine. It is specific to a purchase type (VFC doses), and a specific time frame. This is to be submitted with orders, for VFC doses administered since last order or document submission.

- When generating the DAR, the dates must reflect the **date range since the last order and match the dates of the EIR(s)**.
- After generating the EIR(s) as indicated above, utilize the SAME date range for the DAR. If multiple balances were performed since last order/document submission, ensure that the DAR reflects the total date range reflective of all EIRs generated.
- To generate: From MCIR Home Screen, within the Reports section, select “**Vaccine**”. From the drop-down options, select “**Doses Admin Report**”. Choose a start and end date. For VFC inventory, VFC is defaulted. Submit. All reports generate in a queue: Retrieve by selecting the “Retrieve Results” link in the upper banner or from MCIR Home Screen.

Return/Waste Report

- If you had a loss/waste/exp/unable to locate/etc., a return/waste report must be generated.
- This allows a return label to be generated for any returns needed.
- See [this section](#) for details.

Transfer Reports for Sites with EMR Transfer (HL7)

The Transfer Report or Electronic Submission Summary Report is used by sites that have transfer capabilities between their EMR and MCIR (HL7). The report details EMR/HL7 transactions and the corresponding MCR effects.

- The report allows the user to identify doses that were entered in the EMR but did not “transfer” to MCIR due to data entry error. This allows the user to make corrections that will then update in MCIR. Please review HL7 section of MCIR [available here](#).
- The transfer report is recommended to run 3X weekly and before all balances.
- To generate: On the MCIR home page, click the “**Reports**” tab, and then click “**Transfer**”. Select the desired date parameters. Submit. All reports generate in a queue: Retrieve by selecting the “Retrieve Results” link in the upper banner or from MCIR Home Screen.

BALANCING & BORROWING: POLICY & MCIR GUIDANCE

Balancing Overview

Balancing of vaccine is **required monthly (minimally)** for all VFC providers, even if an order is not placed. Balancing involves counting and reporting inventory in MCIR.

- Primary and Backup must receive MCIR VIM Training by [MCIR Regional staff](#).
- A balance “count date” must be within 10 calendar days of an order.
- Balancing allows you to generate Ending Inventory Reports needed for orders.
- Balancing is performed in MCIR, within “Manage Inventory”.
- It is recommended that balancing be done at the start of a day, before vaccination.
- To perform a balance, a Physical Inventory Report is utilized to perform a count of your vaccines and ideally, the MCIR counts should match your on-hand counts.

- **Count date:** If counted in AM before vaccination, use **yesterday's** date. If counting at the end of the day after administrations, use today's date as the count date.
- When there are discrepancies, this is an opportunity to correct errors in data entry (wrong lot, manufacturer, etc.). After these corrections are made, your inventory will update and you will be able to "complete" your balance in MCIR.

★ After being trained on VIM, the MCIR [VIM Reference Guide](#) is a helpful resources which includes detailed guidance on balancing, troubleshooting discrepancies, etc.

Borrowing and Replacement

Borrowing is only allowable in rare, unplanned occurrences. **VFC flu vaccine is an exception to the borrowing rule – VFC flu vaccine cannot be used on private pay patients under any circumstances.**

Private inventory management reminder: Private stock must be stored, handled, and inventory managed in the same manner as VFC vaccine if any movement occurs or is expected to occur between inventories. Any vaccine used for VFC but originated in private (i.e., borrowing, replacement of VFC borrowing, replacement of VFC expiration, loss, etc.) must follow VFC requirements.

Borrowing Overview

- Providers must maintain adequate vaccine inventories for *both* privately insured and VFC-eligible children. VFC CANNOT serve as a replacement system for private vaccine inventory.
- CDC allows borrowing of vaccine between two vaccine inventories only as a rare, unplanned occurrence. According to CDC, borrowing can occur only when there is:
 - A lack of private-stock vaccine due to unexpected circumstances such as a delayed shipment, vaccine spoiled in-transit, or new staff calculated ordering time incorrectly.
 - Regardless of reason, all borrows must be documented and reason indicated.

Borrow Documentation & Replacement

- Borrows must be replaced as soon as private stock is available, and within 90 days.
- Borrowing and replacement must be documented in MCIR, and on the handwritten [MDHHS Borrowing Log](#). Submit this log with orders and have available at site visits. The MCIR "borrow" deduction is triggered once a dose is documented as given to the incorrect eligibility. To perform the replacement, see below.
- Vaccine doses must be replaced with like-kind vaccine (e.g., if one dose of VFC ActHIB vaccine is used, one dose of privately purchased vaccine stock ActHIB must be used for replacement).
- Providers must not borrow VFC vaccine that they are unable to replace with private stock.
- Invoices may be requested to verify private vaccine was used to replace borrowed VFC vaccine.
- If a provider replaces VFC vaccine with privately purchased vaccine: vaccine storage, handling, and inventory management must comply with all VFC requirements.

MCIR Transaction for Replacement of Borrows

If a dose is given from VFC inventory but the patient eligibility is non-vfc, a "borrow" triggers in MCIR. This also must be documented on the [borrow log](#) and replaced as follows. Below are transactions for the direction OUT of PRIVATE and INTO VFC inventory (Ensure it is moved in the unit, too!)

1. From Private Inventory, select the lot used to replace the borrowed VFC dose. "Add new transaction" as: Action → Transferred Out → Reason → Replaced Borrowed. Comment with MCIR ID or name and DOB, and date of service/borrow. "Copy" comment text and submit.

Transaction Detail			
Date*	02/20/2019	Doses*	1
Action*	Transferred Out	Reason*	Replaced Borrowed
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment*	Replacing 1 borrowed dose for patient 12345678 on DOS. On borrow log and replaced in unit.		
Created By:	Date: 02/20/2019		

2. From VFC/Public Inventory add the replacement doses in as “Add new lot” (or add to existing lot if that lot number already exists in your VFC inventory) under add a transaction:
 Action→Transferred In→Reason→Replaced Borrowed. Comment = PASTE copied comment.

Transaction Detail			
Date*	02/20/2019	Doses*	1
Action*	Transferred In	Reason*	Replaced Borrowed
Inventory Effect:	<input type="radio"/> Subtract <input checked="" type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A
Comment*	Replacing 1 borrowed dose for patient 12345678 on DOS. On borrow log and replaced in unit.		
Created By:	Date: 02/20/2019		

For step-by-step guidance on which adjustments to utilize, also see the [VIM Reference Guide](#).

Specific Borrowing Scenarios

Flu Vaccine Borrowing

- For seasonal flu vaccine, VFC flu vaccine must not be borrowed. However, providers may use private stock flu vaccine to vaccinate VFC children if VFC seasonal flu stock is not yet available.
 - Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available. The replacement must be for the exact same product including the same presentation (Fluzone for Fluzone, syringe for syringe, etc.).
 - You should not borrow more private stock vaccine than what you have pre-booked through VFC. VFC flu vaccine should never be used on private pay patients.
 - This one-directional borrowing exception is unique to seasonal flu vaccine.**

Private Billing Rejection:

- See [Vaccine Rejection](#).

Section 8: LOSS, WASTE & NON-COMPLIANCE

IN THIS SECTION:

VFC Loss Policy
Types of Vaccine Loss, Actions, & MCIR Guidance
Non-compliance, Fraud & Abuse

VFC LOSS POLICY

Providers must ensure accountability for publicly-funded vaccines as outlined in the Loss Policy below. Providers also agree to comply with the VFC program requirements outlined in the [Provider Agreement](#) and discussed during the enrollment and subsequent site visits. Lack of adherence could lead to suspension, removal, and/or fraud and abuse charges for the provider.

The Vaccine Loss Policy applies to all providers actively enrolled in the Michigan VFC Program. This policy supersedes all policies previously issued by the Michigan Department of Health and Human Services (MDHHS) addressing lost, wasted or borrowed VFC vaccine.

MDHHS, the Centers for Disease Control and Prevention (CDC), and VFC providers share a common interest in ensuring that all eligible children receive immunizations. It is important that VFC providers account for and store VFC vaccine appropriately to avoid loss of vaccine due to expiration, storage and handling issues, and administration errors. This helps ensure that all Michigan's VFC-eligible children have access to an adequate supply of vaccine.

MDHHS requires replacement with privately purchased vaccine for all VFC vaccine that becomes non-viable due to expiration and improper storage and handling. Under the VFC Program [Provider Agreement](#) which providers sign at the initial enrollment into the program and at every annual re-enrollment, #13 specifically states "I agree to replace vaccine purchased with state and federal funds (VFC, 317) that are deemed nonviable due to provider negligence on a dose-for-dose basis."

Provider negligence minimally includes:

- Allowing VFC vaccine to expire
 - Due to the seasonal nature of flu vaccine and the difficulty of accurately predicting distribution of the vaccine and public demand for the vaccine, dose for dose replacement of expired flu vaccine is not required. However, providers should continue to offer flu vaccine to their patients up to the expiration date.
- Not being available to accept a vaccine delivery during stated vaccine delivery hours
- Not storing the vaccine promptly upon arrival
- Storing vaccine in a dormitory refrigerator
- Storing vaccine in a refrigeration or freezer unit that cannot consistently maintain the required temperature range
- Not checking and documenting temperatures twice a day
- Not downloading and reviewing your data logger if the temperature went out-of-range
- Not correctly programming or testing an alarm system
- Not appropriately responding to an alarm

- Not following your emergency response plan for a power outage or unit failure; or following a response plan that is identified as not in compliance with MDHHS & CDC guidance
- Not using a data logger appropriately when transporting vaccine in an emergency

Replacement of Vaccine Loss:

- Replacement must occur within 90 days of the vaccine loss and reported to the LHD. If private vaccine was stored in the same storage unit as the compromised VFC vaccine, the provider must submit a paid invoice and packing slip for private vaccine used to replace lost VFC doses.
- If a provider is unable to use the replaced doses, the doses may be shipped directly to a local health department for administration to VFC-eligible children
- Providers with losses that exceed a VFC dollar value of \$1500 are required to complete a Vaccine Accountability training session before the loss is resolved. If the provider site received a Vaccine Accountability INE session within 90 days of the vaccine loss, this requirement may be waived unless the LHD feels the provider staff would benefit from a repeated training.

All VFC loss/waste/return require the following steps for processing:

1. If applicable, remove vaccine from unit (expired vaccine must be removed immediately).
2. Complete appropriate transaction to remove the dose(s) from inventory.
3. Return/waste report created and submitted in MCIR.
4. If vaccine requires return, obtain return label in email and send back to distributor.
5. If replacement indicated, replacement must occur within 90 days of loss and reported to LHD.

TYPES OF LOSS/WASTE/RETURN, ACTIONS, & MCIR GUIDANCE

All wasted and spoiled VFC doses must be handled appropriately, documented in MCIR inventory and ret/waste report, and doses replaced as indicated and outlined below. To support documentation of VFC doses wasted, expired, or otherwise spoiled, providers may wish to use the [Return & Wastage Log](#).

Expiration

Avoiding Expiration & Actions to Take

1. Be diligent when rotating stock weekly, to ensure soonest-to-expire vaccine is placed up front to be used first. Also review expiration dates in MCIR and at time of balance.
2. Weekly, there is a Lot Expiration Warning Report generated in the Retrieve Results area of your MCIR site. This is also emailed to those identified as the Primary & Backup in MCIR.
3. Use the Reminder/Recall function in MCIR to administer doses that will soon expire. Recalls must be done before requesting LHD redistribute soon-to-expire vaccine. Reminder letters can generate letters for patients coming due for vaccines, while recalls are for patients overdue. For details on these reports, see the [MCIR Reminder/Recall Manual](#).
4. If you believe your site will not be able to administer vaccines before expiration, notify your LHD **three to six months prior to expiration**. The LHD can assist in running reports for overdue patients and may redistribute or absorb the provider's VFC inventory if the provider notified the LHD at least three to six months prior to expiration.
 - a. The LHD is obligated to receive the VFC vaccine and either use it within their clinic or redistribute to another clinic. This is required if the provider has provided at least three to six months' notice and has exhibited appropriate inventory management, stock rotation, and has sent MCIR recall notices. The vaccine must also have been stored and handled appropriately (as evidenced by temp logs and/or data logger files).

- b. If the provider vaccine is redistributed or absorbed by the LHD but some doses remained un-used and subsequently expired, the original provider is responsible for replacement of the doses that remained and must be returned. The ret/waste report can be generated with detailed notes, identifying the VFC PIN of the **original** provider.
- c. If the LHD receives notification from a provider about expiring vaccine and it is less than three months from expiration date and the doses subsequently expire, the LHD is not obligated to receive the vaccine but should assist in attempting to redistribute or use in their own clinic if feasible. If this is not feasible and doses expire, the original provider is responsible for replacement of the expired doses.
- **Redistribution of Short-Dated Doses:** If vaccine has been assigned a shortened expiration date by the manufacturer (i.e. following an excursion), the vaccine cannot be redistributed unless the receiving clinic is aware and agrees to accept the vaccine. If the receiving clinic is unable to administer the vaccine prior to the shortened expiration date, the **original provider** is responsible for replacement of that vaccine.
- **Flu vaccine:** Due to the seasonal nature of flu vaccine and difficulty of accurately predicting distribution and demand, dose for dose replacement of expired flu vaccine is not required.
- **Multi-Dose Vials and Open Vials:** Vaccines are exempt from the Joint Commission ruling on the discard of open multi-doses vials 28 days after opening unless otherwise stated on the manufacturer insert. Complete Joint Commission information on this is [available here](#).
 - MCIR transaction: “Non-return open MDV” is used for vials that expire without full utilization of all doses in time (such as open IPV vial with 1 dose left at expiration).
 - Opened vials CANNOT be returned, and instead must be [wasted appropriately](#).

Expired VFC Vaccine & Actions to Take

This includes nonviable vaccine in its original container (vial or syringe) that is able to be returned to distributor. This includes expired vaccine or vaccine spoiled due to expiration, temperature excursions, improper transport conditions, etc.

- MCIR transaction: This depends if it is an **unopened vial/syringe** or an **opened multi-dose vial**:

A: Unopened/full vial/syringe: MCIR Transaction: Return to Distr → Expired

Transaction Detail			
Date*	02/20/2019	Doses*	2
Action*	Returned to Distr	Reason*	Expired Vaccine
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input checked="" type="radio"/> Add <input type="radio"/> N/A
Comment	Vaccine expired. Ran reminder/recall and notified LHD. Will do ret/waste report and replace doses.		
Created By:	Date: 02/20/2019		

B: Opened multi-dose vial (polio, flu): MCIR Transaction: Non-return Open MDV (Expired vaccines create a “return” report for return labels, but opened vials CANNOT be returned.)

Transaction Detail			
Date*	02/20/2019	Doses*	1
Action*	Non-Return Opened MDV		
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment	Vaccine expired. Ran reminder/recall and notified LHD. Will do ret/waste report and waste appropriately.		
Created By:	Date: 02/20/2019		

One more step! Generate a [return/waste report](#) once the inventory transactions are complete. The closed vials must be returned to the distributor. This return/waste report will ensure a return label is emailed to the VFC Primary listed in the “Enrollment” section of the MCIR “VFC” tab.

Replacement of Expired Vaccine

Expired VFC vaccine is replaced **dose for dose** with privately purchased vaccine. CDC requires dose for dose replacement with privately purchased vaccine **within 90 days** of the expired vaccine loss.

- MCIR transaction: Add to Inventory → Replace loss/waste. Add notes regarding loss.

Loss Due to Improper Storage & Handling

Vaccine must be stored, handled, administered, and transported according to VFC vaccine storage and handling guidelines. Whenever viability is in question due to improper storage and handling, vaccine manufacturer(s) must be contacted for decisions on viability.

- If the manufacturer(s) determines that the vaccine is non-viable, the doses must be handled appropriately: Remove vaccine from the unit and marked DO NOT USE.
- Transfer out of MCIR VFC inventory using the correct MCIR transaction depending on whether the vaccine is unopened vials or opened MDV:

A. Unopened/full vials/syringes: Return to Distributor → choose appropriate reason. Contact the LHD if you are unsure of which “reason” to select; A helpful table is also available on page 24/25 of the MCIR VIM Reference Guide [located here](#).

Transaction Detail			
Date*	02/20/2019	Doses*	2
Action*	Returned to Distr	Reason*	
Inventory Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	
Comment	Manuf deemed unsupported. Will do ret/waste report, return, and replace		
Created By:	Date:	02/20/2019	

B. Opened multi-dose vials: Non-Return Open MDV (CANNOT return; must waste)

Transaction Detail			
Date*	02/20/2019	Doses*	3
Action*	Non-Return Opened M		
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A	LWB Effect:	<input type="radio"/> Subtract <input type="radio"/> Add <input checked="" type="radio"/> N/A
Comment	Manuf deemed unsupported. Will do ret/waste report, and waste appropriately (open vial).		
Created By:	Date:	02/20/2019	

One more step! Generate a [return/waste report](#) once the inventory transactions are complete. The closed vials must be returned to the distributor. This return/waste report will ensure a return label is emailed to the VFC Primary listed in the “Enrollment” section of the MCIR “VFC” tab.

Replacement of Loss Due to Storage & Handling

Expired VFC vaccine is replaced **dose for dose** with privately purchased vaccine. CDC requires dose for dose replacement with privately purchased vaccine **within 90 days** of the expired vaccine loss.

- MCIR transaction: Add to Inventory → Replace loss/waste. Add notes regarding loss.

If a provider has vaccinated using non-viable vaccine (expired or non-viable from a temperature excursion), they must re-vaccinate the child with private stock vaccine. Under the VFC Program, running titers is not acceptable. See “[Administration of Non-viable Vaccine](#)”

Loss Due to Waste/Breakage/Drawn Not Used

This includes wasted or broken vaccine, which **cannot be returned**. This includes vaccine in an open vial, drawn into a syringe but not used, or compromised because it was dropped/broken.

- Adjustment → choose appropriate reason: “breakage” or “drawn not used”*

Transaction Detail	
Date*	02/20/2019
Doses*	1
Action*	Adjustment
Reason*	Breakage
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A
LWB Effect:	<input type="radio"/> Subtract <input checked="" type="radio"/> Add <input type="radio"/> N/A
Comment	Syringe malfunction when drawing up vaccine for MCIR ID 12345678 on DOS. Will do ret/waste report.
Created By:	Date: 02/20/2019

* “Breakage” may include vaccine dropped, broken or defective and not usable.

* “Drawn Not Used” may include vaccine drawn up but not used such as parent changing mind, reconstituted vaccine to be used by manufacturer limit, patient moved and unable to administer, etc.

One more step! Generate a [return/waste report](#) once the inventory transactions are complete.

Wasted and broken vaccines cannot be returned but must be disposed of appropriately.

Replacement of Wasted and Broken Vaccine

Dependent upon the LHD requirements and/or practices conducted by the provider, dose for dose replacement may not be required for the above losses. An educational training/intervention may be required if a provider has an above average occurrence of losses.

Loss Due to Lost/Missing/Unable to Locate Vaccine

Vaccine for which the physical vaccine vial or syringe is missing at the time of inventory balance.

- Must obtain approval from LHD before choosing transaction “Unable to locate.” LHDs and MDHHS may withhold orders until improved accountability is demonstrated.
- While performing a balance, when on-hand counts do not match MCIR counts, this is often an indicator of a data entry error that should be corrected. When corrected, the MCIR dose counts will be updated with this correction so that counts should then match. If you are unable to perform or identify these corrections, contact your LHD or MCIR Regional staff.
- Providers must review the administration history of vaccines and determine if all data has been entered into MCIR and if a data entry error has occurred regarding doses administered or wasted. It is also recommended that you physically re-count your vaccines.
- Every effort should be made to reconcile unaccounted for doses of VFC vaccine. In those circumstances where you are unable to reconcile your current vaccine inventory with what is reflected in MCIR, doses that cannot be accounted for are considered lost doses.
- MCIR transaction: Adjustment → Unable to Locate

Transaction Detail	
Date*	02/20/2019
Doses*	1
Action*	Adjustment
Reason*	Unable to Locate
Inventory Effect:	<input checked="" type="radio"/> Subtract <input type="radio"/> Add <input type="radio"/> N/A
LWB Effect:	<input type="radio"/> Subtract <input checked="" type="radio"/> Add <input type="radio"/> N/A
Comment	LHD approved. Ran reports, reviewed records. Unable to locate dose or data error. Will continue to review.
Created By:	Date: 02/20/2019

One more step! Generate a [return/waste report](#) once the inventory transactions are complete.

Wasted and broken vaccines cannot be returned but must be disposed of appropriately.

Replacement of “Unable to Locate” Vaccine

Dependent upon the LHD requirements and/or practices conducted by the provider, dose for dose replacement may not be required for the above losses. An educational training/intervention may be required if a provider has an above average occurrence of losses.

Losses Not Replaced within 90 Days

- The LHD and MDHHS have the authority to withhold VFC vaccines from a clinic with an open, unresolved (90 days or older) vaccine loss until doses are replaced and all corrective action to avoid occurrence of another loss is completed.

Medical Errors Requiring Revaccination

- See [Administration of Non-Viable Vaccine](#)

Return/Waste Report

- a. Create and submit Return/Waste reports, at minimum, monthly or anytime a loss transaction is completed (expired, broken, drawn not used, etc.).
- b. From MCIR home screen → Vaccine Mgmt → **Return/Waste Reporting** → “**Create a New Return/Waste Report**”. It may take a few moments to generate the report.
- c. Check the boxes of all vaccine being reported. Add a corrective action plan, including information (lot, expiration, date of replacement) for replacement of the vaccines. Submit for approval. This report also ensures a return label is generated and emailed. Return labels are emailed to the Primary VFC Contact.
- d. If you are expecting a return label and do not receive an email with this label within 7 business days of submitting ret/waste report, contact your LHD.



Tip sheet available! For step-by-step guidance, see [this tip sheet](#).

What if I Performed the Wrong Transaction for Loss/Waste/Expire?

If you have questions about inventory transactions, contact your LHD. If a transaction has been performed incorrectly, call the LHD for guidance on reconciliation. The LHD will assist to ensure any adjustments are made to correct inventory deductions and perform the correct transaction needed. If the incorrect transaction generated a ret/waste report that is inaccurate, add detailed comments about what was entered incorrectly and what vaccine was involved in the *actual* waste/expiration.

Returning Vaccine & Obtaining Return Labels

- Return expired or spoiled vaccines in their original vials or manufacturer pre-filled syringes.
- Opened vials (such as opened multi-dose vials of polio or Fluzone) cannot be returned (these also have a special inventory transaction, detailed in the section above).
- Once the report has been processed at the MDHHS level, a return label **will be emailed to the VFC Primary Contact’s email address** within the provider’s VFC “Enrollment” Tab.
- Most importantly, emailed return labels are **only valid for 30 days. Please retrieve the return label immediately**. If you do not receive a label within 7 days, contact your LHD.

NON-COMPLIANCE, FRAUD & ABUSE

Non-compliance

Providers agree to comply with the VFC program requirements outlined in the Provider Agreement and this Provider Manual, as well as discussed during site visits. Failure to comply with VFC requirements is defined as any VFC provider who does not implement and maintain the federal

and/or state requirements of the Michigan VFC program. Non-compliance is grounds for suspension and/or termination. However, lack of adherence could also lead to fraud and abuse charges.

Suspension and/or Termination

Providers may be suspended from the VFC Program for a variety of program violations. Upon suspension, no VFC vaccine will be delivered to the provider until the suspension is lifted. Failure to adequately correct deficiencies can result in termination and removal of the provider from the VFC Program. Vaccine pickup and inactivation are outlined in the [Disenrollment](#) section.

Reasons for VFC Program Suspension and/or Termination (this list is not exhaustive)

- Not re-enrolling annually according to the [Enrollment & Re-enrollment](#) guidance
- No order placed in the last 12 months
- Vaccine loss not replaced within 90 days of VFC vaccine loss
- Demonstration of noncompliance with program requirements such as those outlined in this manual, the provider agreement, online VFC Resource Guide or identified at VFC site visits or via routine communication/order submission to the LHD (monthly reports, balancing, etc.)
- Repeated or unresolved actions within the Fraud & Abuse list

Suspension will be lifted upon demonstration of compliance and notification to LHD and MDHHS.

Michigan VFC Fraud & Abuse Policy

This outlines the policy and procedures to prevent, detect, investigate, and resolve fraud and abuse within Michigan's VFC Program. For reporting any suspected fraud and abuse, contact:

- Your Local Health Department
- MDHHS Fraud & Abuse hotline: 517-335-8159 (staffed Mon-Fri, 8 am to 5 pm),
- Medicaid Fraud & Abuse hotline at 1-855-MI-FRAUD (643-7283), or
- Medicaid Online Fraud & Abuse [reporting website](#)

Roles & Responsibilities: Fraud and Abuse

Provider Role/Responsibility

- Complete educational trainings regarding the VFC Program as provided by the LHD. These trainings include education on VFC program requirements, ACIP immunization recommendations, reporting requirements, and vaccine storage and handling.
- Complete training requirements for MCIR VIM as provided by Regional MCIR staff.
- Comply with all VFC Program requirements as outlined in this Provider Manual, the VFC Provider Agreement and the VFC Resource guide at www.michigan.gov/vfc.
- Be observant of indicators of fraud and abuse within your practice. Reports are confidential.

LHD Roles/Responsibilities

- Provide training and education to new and existing VFC providers regarding requirements.
- Conduct VFC/QI site visits.
- Be observant of indicators of fraud and abuse.
- Conduct on-site reviews of providers who have vaccine storage and handling problems and assist them in the resolution of these problems.
- Review incoming vaccine orders, inventory reports, doses administered reports, and temperature logs. If inconsistencies are found (e.g., ordering more vaccines than usual, reports of wasted/expired vaccines), follow-up with the provider to resolve any issues.
- Follow-up on problems until improvements are made and maintained.

- If additional provider education is indicated regarding the VFC Program and/or vaccine safety, storage and handling concerns, make referrals to the MDHHS INE program.
- If fraud and/or abuse is suspected, make referral to MDHHS Field Representative and MDHHS VFC Program Staff.

Division of Immunization Role/Responsibilities

- Develop VFC Program policy, including annual update of the VFC Resource Guide and Manual.
- Conduct site visits and educational trainings with LHD staff.
- Monitor the VFC Program at the LHD level.
- Screen VFC providers for suspended, revoked licenses or exclusion from CDC contracts.
- Act as a resource to LHD inquiries regarding the VFC Program.
- Collaborate with Medicaid staff on fraud and abuse policies.
- Substantiate reported fraud and abuse incidents.
- Report suspect fraud cases to Medicaid and CDC for further investigation.

Identification

Fraud, as defined in 42 CFR 455.2, is “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.”

Abuse is defined as “provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care...”

Examples of fraud and abuse*:

- Failure to comply with any part of the Provider Agreement or program requirements
- Providing VFC vaccine to a non-VFC-eligible patient
- Providing VFC vaccine to clinics or persons for which it is not intended or to individuals not enrolled in the VFC Program
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum vaccine administration fee for an eligible child
- Refusal to provide VFC vaccine to an eligible child due to a parents’/guardian’s inability to pay the administration fee
- Failure to implement provider enrollment requirements of the VFC Program
- Failure to screen for and document eligibility status at each visit
- Failure to maintain VFC records for three years
- Failure to fully account for VFC vaccine
- Failure to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that does not match provider profile or involves excessive ordering of VFC doses
- Wastage of VFC vaccine

**This list provides examples only and should not be considered comprehensive.*

Unintentional abuse: Incidents involving unintentional abuse (clearly excusable lack of knowledge or understanding of the VFC Program) are nevertheless unacceptable. The response to unintentional

abuse will vary depending on the circumstances of the incident and whether other instances of fraud or abuse (either intentional or unintentional) have previously occurred.

- In most circumstances, education will be the proper response in lieu of criminal enforcement. However, the investigative/enforcement referral requirements of *42 CFR 455.15* shall be followed to determine if an educational intervention is appropriate.
- If determined to result from an excusable lack of knowledge or understanding of the program requirements, then secondary education and a corrective action plan should be implemented

Referral, Investigation & Documentation

If fraud/abuse is suspected, follow the Fraud & Abuse Corrective Action Procedure [available here](#).

Documenting Fraud or Abuse Allegations

When possible, collect the following information regarding suspicion of VFC fraud or abuse:

- Name and contact information of the person reporting the fraud/abuse (assure them this information will be kept confidential)
- Name and contact information of the suspected provider
- Relationship between the reporting person and the provider
- Detailed information regarding the fraud/abuse (Dates, timeline, and examples)

All allegations are **confidential** and will be assessed in conformance with the requirements of *42 CFR 455.15*. If it is determined there was no intentional deception, misrepresentation or negligent deception or misrepresentation of the VFC Program by the provider or office staff, the situation may be appropriate for correction through educational training(s).

Investigation of Fraud or Abuse Allegations

Investigation of an allegation involving fraud begins with the LHD and/or the assigned MDHHS Immunization Field Representative contacting the provider and reviewing the allegation with the provider. All aspects of the review should be well documented.

1. The MDHHS VFC Program staff will immediately discuss the alleged fraud and abuse case with the Immunization Program Management staff.
2. The MDHHS VFC Program and the MDHHS Immunization Program will respond to any allegation of fraud and abuse within five working days of the allegation.
3. Where possible, an on-site visit shall be conducted within five business days of the allegation.
4. Attempts shall be made to educate providers and to provide them with an opportunity to change their policies/procedures to ensure future compliance with VFC guidelines. If a provider was unaware that their practices were fraudulent and intends to immediately rectify the situation, documentation of these facts shall be made and a copy of the investigation's findings and corrective action shall be given to the provider.
5. Follow up with the provider shall occur at 30 days and again at six months. If the provider continues to comply with VFC guidelines, the investigation may be closed. A copy of all documentation regarding the investigation shall be kept on file with the LHD and a copy shall be submitted to the MDHHS Immunization Program.

An investigation, in which a provider refuses to acknowledge wrongdoing and cannot/will not provide documentation to demonstrate compliance with VFC guidelines, will be referred to the appropriate State agency for further investigation.

1. If appropriate, the MDHHS VFC Program staff shall refer the allegation of fraud and/or abuse to the CDC and Centers for Medicaid and Medicare Services (CMS) Investigation Section-Medicaid Integrity Group via email within ten working days from assessment.
2. The CMS referral should be sent to the Medicaid Program Investigation Manager.
3. The referral document shall be submitted in a hard copy format, written on department letterhead and sent via inter-departmental mail. Supporting documentation shall be included.
4. In addition to the above, MDHHS VFC Program staff will provide any additional information requested by Medicaid or CDC. No HIPAA-sensitive material will be e-mailed.
5. If prosecuted, the provider remains in the VFC fraud file until medical license is reinstated.

Providers who have been removed from the program for intentional fraud and/or abuse, shall be required to re-apply for VFC Program participation and re-assessed for compliancy.

The following criteria will be utilized to determine if an incident is appropriate for correction through educational training(s):

- Amount of money lost by the VFC Program
- Any inadvertent financial gain of the provider
- How the incident was identified
- Length of time the situation occurred
- Provider's willingness to replace lost VFC vaccine with privately purchased vaccine
- Provider's willingness to participate in the educational referral and post-education follow-up
- Provider's willingness to revaccinate, if necessary

Should Vaccines be Removed from the Practice?

If an allegation of fraud or abuse has been substantiated and the matter has moved forward for investigation by the offices of Medicaid Integrity Group or the Michigan Attorney General's Office, all VFC vaccine in the provider's possession shall be collected and returned to the LHD. MDHHS may assist in removal of VFC vaccines, if necessary. The provider shall be prohibited from receiving future shipments of VFC vaccine and their VFC PIN number shall be inactivated in VTrckS and MCIR.

MDHHS Immunization Program Fraud and Abuse Contacts

MDHHS VFC Coordinator.....Fraud and Abuse Coordinator
Darcy Wildt, VFC Accountability Coordinator.....Back-up Person

Collaborating Agencies

- **Michigan Medicaid:** Identifies questionable provider practices and conducts preliminary investigations into complaints of Medicaid fraud and abuse. If there is sufficient information to conclude that fraud or abuse has occurred, a full investigation may be conducted and the case referred to the Medicaid Integrity Group or appropriate law enforcement agency.
- **Medical Fraud Control Unit (MFCU):** Investigates and prosecutes (or refers for prosecution) violations of State law pertaining to fraud in the administration of the Medicaid Program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan. The MFCU also works with State Medicaid agencies to develop methods and procedures to identify, detect, and investigate fraud and abuse. The MFCU is located in the Department of the Attorney General's office, which has statewide authority to prosecute individuals for violations of criminal laws involving the Medicaid Program.

Section 9: ADDITIONAL PUBLIC VACCINE PROVIDERS

In this section:

Local Health Departments
Michigan Adult Vaccine Program
Universal Hepatitis B Vaccine Provider
High-Risk Hepatitis A and B Vaccine Provider

★ For chart showing vaccines available in our public vaccine programs as well as Adult Medicaid and Medicare B and D, see this document [Vaccine Resources for Eligible Populations](#).

LOCAL HEALTH DEPARTMENTS AS VFC PROVIDERS

Local Health Departments implement additional requirements as a VFC Provider as well as provide support for VFC providers across the state. For guidance on oversight of non-LHD providers, see LHD Guidance for Oversight. As a VFC and MI-AVP Provider, LHDs must implement all requirements included in this manual, as well as the following additional expectations:

Alarm system

- A continuous temperature monitoring alarm notification system must be in place in each unit
- All monitoring devices and alarm systems must be calibrated weekly to ensure they function compatibly and accurately.
- Readings may not exactly match the DDL since the DDL may react differently to changes in temperature than the alarm system does, depending on types of probes (measuring air temperature vs. liquid-filled solutions). It is best to check the calibration of the alarm system after the unit has been closed for a period of time.
- An alarm system should be tested at least monthly to assure it is working correctly.

Weekly Calibration

Weekly calibration of temperature devices monitoring all units with VFC vaccine as follows:

- Calibrate temperature devices compared to continuous monitoring certified digital data logging device (gold standard calibration control). Indicate which device is the DDL.
- Documentation: Date of calibration, type of device, temperatures of devices
- Fahrenheit temperatures must be within 3 degrees of certified thermometer temperature; Celsius temperatures must be within 1.5 degrees.
- Document adjustments, if needed. Include which device was adjusted (e.g., Data-logger is certified thermometer, 6-17-19 DL= 40.1, S=46.2. Adjusted Sensaphone).

Miscellaneous

- Ensure that backup data logger is available on-site.
- Receive vaccine soon-to-expire under appropriate time frame and storage. See [Loss Policy](#).

Provider Oversight and Support

- Oversee VFC providers and their adherence to requirements, including processing enrollments, vaccine orders, ret/waste reports, performing site visits, etc.
- These are outlined in [Local Health Department Responsibilities](#)
- **LHDs Processing and Submitting Provider Orders to MDHHS**
 - Prior to placing a VFC provider's vaccine order, LHDs must review supporting documents, reviewing and approving for accuracy. This must be done before the order is approved in MCIR VIM and submitted to MDHHS for processing.
 - LHD staff should check MCIR for pending vaccine orders at a minimum of twice a day to ensure vaccine orders are reviewed and approved by MDHHS in a timely manner.

LHD VFC Site Visits

LHDs receive a yearly VFC Compliance Site Visit performed annually by MDHHS Field Reps. See VFC Site Visit Preparation Guide, located at www.michigan.gov/vfc. Additional assessments are made at LHD site visits, including:

- Be able to provide updated immunization materials such as:
 - [CDC Storage & Handling Toolkit](#) (via computer link or printed)
 - Review of print materials in LHD clinic such as MDHHS handouts, AIM materials, storage & handling charts on www.michigan.gov/vfc
- Emergency Protocol Review, including:
 - Alarm testing for out-of-range temperatures
 - Review of generator testing schedule, if applicable
- Updated Immunization Manual, standing orders, signed by Medical Director, reviewed yearly
- Updates to ACIP recommendations within 90 days of update
- Accreditation indicators applicable to immunizations

LHDs Submitting LHD Order to MDHHS:

LHDS	Submit with Order	Submission Frequency
Place order in MCIR via E-ordering	1. Doses Administered Report 2. Ending Inventory Report 3. Temperature/Calibration logs including satellites 4. Borrowing Logs 5. Data logger documentation (if temps are out of range)	LHDs should submit their MCIR vaccine order and supporting documentation to MDHHS at the same time. Do not send supporting documents unless placing an order. Supporting documents must be generated within 10 calendar days of order.

ADULT VACCINE PROGRAM (MI-AVP)

MI-AVP is a vaccine program for uninsured and underinsured adults; MI-AVP is available to the following provider types: Federally Qualified Health Centers (FQHCs), LHDs, Migrant Health Centers (MHCs), and Tribal Health Centers (THCs). Rural Health Centers (RHCs) and private providers cannot participate in this program. MI-AVP providers must implement all VFC requirements within this manual (storage, handling, and inventory management of vaccine). This section highlights those specific to MI-AVP providers.

Eligibility, Documentation & Billing

- **Eligibility:** Only the vaccines and indications listed below may be provided to **uninsured and underinsured adults 19 years** of age or older, who meet certain risk factors listed below.
 - Adults with vaccine insurance coverage or Medicaid **do not qualify**. For these patients, providers must use privately purchased vaccine. However, adults with Medicaid spend down are considered uninsured and eligible until the spend-down is met.
 - Adults with a complete documented vaccine series are considered up to date for that vaccine and **not eligible** for MI-AVP vaccine. Special considerations may be indicated such as when serologic testing is indicated and shows a patient needs additional doses of vaccine (e.g., PrEP serology testing for hepatitis B indicating additional doses of vaccine needed, despite having completed a 3-dose hepatitis B vaccine series previously). If the patient is AVP-eligible, MI-AVP vaccine can be used in such an instance.
- **Screen and Document:** Screening for eligibility must occur at each vaccination visit. See criteria listed below within “Vaccines Available & Criteria for Eligibility”.
 - Document AVP vaccination appropriately in MCIR as “MI-AVP” within the eligibility drop-down field for vaccine administration.
- **Billing:** A provider cannot charge for the vaccine itself. However, MI-AVP providers may charge an uninsured/underinsured patient for an administration fee if they wish, which **cannot exceed \$23.03** per vaccine (not per antigen in combination vaccines).
 - Providers who choose to bill for the vaccine administration fee of an **uninsured/underinsured AVP-eligible adult after the date of service** may issue **only ONE bill to the patient, and this one bill must be issued within 90 days** of vaccine administration. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible patient who has unpaid administration fees. The provider must establish a process to waive the fee if the patient remains unable to pay the vaccine administration fee. This does NOT apply to vaccine administration fees billed to Medicaid. This is effective as of January 1, 2020.

Vaccines Available & Criteria for Eligibility

The vaccines listed below are provided for **uninsured and underinsured adults 19 years or older**, who have risk factors listed below and are seen at LHDs, FQHCs, MHCs and THCs. For additional resources, see [“Helping Your Adult Client Pay for Vaccines.”](#)

MI-AVP Vaccines Available

The following MI-AVP vaccines are available with vaccine-specific detailed indications below:

Hepatitis A	MMR	PPSV23	Zoster
Hepatitis B	PCV15	Td	

For access to the CDC Adult Vaccine Schedule, visit [this website](#). For MDHHS Vaccine Quick Looks and other vaccine education resources, visit www.michigan.gov/vaccinequicklooks.

Hepatitis A

Persons who meet one of the following criteria:

- **Direct contact with a hepatitis A virus (HAV)-infected person**
- **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- **HIV infection**
- **Men who have sex with men**
- **Injection or non-injection drug use**
- **Persons experiencing homelessness**
- **Work with hepatitis A virus** (research lab or with nonhuman primates with hepA virus infection)
- **Travel in countries with high or intermediate endemic hepatitis A**
 - [CDC Yellow Book on Hepatitis A and travel](#)
- **Close, personal contact with international adoptee** (e.g., household, or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A
- **Pregnancy if at risk** for infection or severe outcome from infection during pregnancy
- **Settings for exposure**, including health care settings targeting services to injection or non-injection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)
- **Desire for protection against hepatitis A**

Hepatitis B

Persons 19 years of age and older are no longer required to have a risk factor to be eligible for MI-AVP hepatitis B vaccine.

- Heplisav-B and PreHevbrio are not currently recommended in pregnant persons due to lack of safety data.
- The safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis.

See CDC's [guidance here](#).

HPV

- **Adults aged 19 years through 26 years**, without history of completed series

MMR

- Adults **born on or after 1/1/57**, who do not have evidence of immunity
 - Evidence of immunity: Born before 1957 (health care personnel, see [Special Considerations](#)), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)
- An adult that previously had **only one dose of MMR** and qualifies for MI-AVP (may receive the second dose of MMR under this program)

PCV15, PCV20, PPSV23

Persons who meet one of the following criteria:

- **Adults 65 years of age and older**
- **Adults 19 through 64 years old with certain underlying medical conditions or other risk factors**
 - Alcoholism
 - Cerebrospinal fluid leak
 - Chronic heart/liver/lung disease (including congestive heart failure, cardiomyopathies, chronic obstructive pulmonary disease, emphysema, and asthma)
 - Chronic Renal Failure*
 - Cigarette smoking
 - Cochlear implant
 - Congenital or acquired asplenia*
 - Congenital or acquired immunodeficiencies (includes B-(humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)*)
 - Diabetes
 - Generalized malignancy*
 - HIV infection*
 - Hodgkin disease*
 - Iatrogenic immunosuppression (includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy)*
 - Leukemia, lymphoma, multiple myeloma*
 - Nephrotic syndrome*
 - Sickle cell disease or other hemoglobinopathies*
 - Solid organ transplants*

*Considered an immunocompromising condition

Resources: [Pneumococcal Vaccine Timing for Adults-April 1, 2022 \(cdc.gov\)](#); [ACIP Pneumococcal Vaccine Recommendations | CDC](#); and [PneumoRecs VaxAdvisor: Vaccine Provider App | CDC](#)

Td or Tdap

- **Previously did not receive Tdap at or after age 11:** 1 dose Tdap, then Td or Tdap every 10 years
- **Previously did not receive primary vaccination series for tetanus, diphtheria, or pertussis:** At least 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks after Tdap and another dose Td or Tdap 6–12 months after last Td or Tdap (Tdap can be substituted for any Td dose, but preferred as first dose); Td or Tdap every 10 years thereafter
- **Pregnancy:** 1 dose Tdap for each pregnancy, preferably in early part of gestational weeks 27–36
- **Persons with close contact to an infant less than age 12 months should receive one dose of Tdap, even if they have already received Td (no minimum interval required)**
- **Tetanus prophylaxis in wound management**
 - See [Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2019 | MMWR \(cdc.gov\)](#). Also available is [MDHHS Tetanus Prophylaxis Guidelines](#).

Resources: MDHHS “Quicklook at Td/Tdap Vaccine” [available here](#).

Zoster Vaccine: Shingrix (Recombinant Zoster Vaccine)

- **Adults aged 50 years and older**, regardless of prior receipt of varicella vaccine, ZVL, or herpes zoster episode, who have no insurance coverage for this vaccine (a high co-pay does not make them eligible for the vaccine) and are eligible for zoster vaccination
- **Adults aged 19 years and older**, who are or will be immunodeficient or immunosuppressed because of disease or therapy

Resources: ACIP recommendations for Shingrix are [available here](#).

UNIVERSAL HEPATITIS B VACCINE PROVIDER (BIRTHING HOSPITAL)

Birth hospitals are **highly encouraged** to participate in the Universal Hepatitis B Vaccination Program. The goal is to immunize **all newborns** with the birth dose of hepatitis B vaccine. The vaccine is available for all newborns *for the first dose, regardless of eligibility status*. There is no charge to the provider or to the parents of the newborn for this vaccine.

- Providers must implement all VFC Requirements including storage, handling, and inventory management. Below is an *overview* of these expectations, but details are found throughout this manual and at www.michigan.gov/vfc.

Enrollment & Annual Re-Enrollment

- Enrollment and re-enrollment are required, similarly to any other VFC provider
- To enroll as a Universal Hepatitis B provider, follow guidance for enrollment within [Section 2](#)

Training & Site Visits

- Designate a VFC Primary and Backup Vaccine Coordinator. They must complete VFC training annually and initial training on MCIR vaccine inventory module (VIM).
 - Refer to “Annual Training” details at www.michigan.gov/vfc
- Create a Vaccine Management Plan and an Emergency Response Plan, updating annually. Templates are available at www.michigan.gov/vfc
- A VFC compliance visit is performed by LHD staff at least every 24 months, but annually in many regions” See VFC Site Visit Preparation Guide, located at www.michigan.gov/vfc

Storage & Handling

- Temperatures must be assessed and documented twice daily, including min/max once daily in the morning. This must occur for ALL units housing public vaccine (OB unit, pharmacy, etc.).
- Notify the LHD immediately when an excursion occurs, as it is critical to assess any need for revaccination and ensure the Perinatal Hep B program is made aware.
- A management plan must be maintained and updated yearly or anytime there is a change in key staff who manage vaccine. A template is [available here](#).

Inventory, Documentation, and Balancing

- Hospitals are required to report hepatitis B vaccinations to MCIR. The easiest way is via electronic birth certificate (EBC). This may also be provided to MCIR by other methods.
- MCIR Guidance for Universal Hepatitis B Providers is [available here](#).
- **Monthly balancing** is required. Hospital administrations may not deduct from their VFC/Public inventory in MCIR. Therefore, after counting doses, manual entry may be needed as follows: Adjustment – Data Entry Correction – Inv Effect = SUBTRACT. Indicate # of doses administered to subtract. Add a comment such as “subtracting doses administered to newborns.”

Hepatitis B Resources: For comprehensive manuals and resource documents to support Hepatitis B vaccination as well as reporting Hepatitis B positive reports, visit www.michigan.gov/hepatitisb

Immunization Action Coalition Hepatitis B Birth Dose Honor Roll: Birthing facilities who have Hepatitis B policies in place and have provided Hepatitis B vaccine to more than 90% of their babies may be eligible to enroll in the Immunization Action Coalition (IAC) Hepatitis B Birth Dose Honor Roll.

- Enrollment allows statewide and national recognition! To enroll, [visit immunize.org](http://visitimmunize.org).
- For more information on the Hepatitis B Birth Dose Honor Roll or the Perinatal Hepatitis B Prevention Program, contact Pat Fineis at 517-242-8319 or fineisp@michigan.gov.

HIGH-RISK HEPATITIS A AND B VACCINE PROVIDER

The High-Risk Hepatitis A & B Program is designed to protect adolescents* and adults at increased risk for Hepatitis A or B infection, and whose age and/or dependency status may be a barrier to seeking care. High-Risk Hepatitis A and B Vaccine Providers must implement all VFC Requirements within this manual including storage, handling, and inventory management of vaccine.

Adolescents < 19 years old who qualify for the VFC Program should receive **VFC vaccine, not MI-AVP.*

Under this program, pediatric and adult Hepatitis A & B vaccines are available to **STD clinics, teen health centers, and family planning clinics** for patients regardless of insurance status who meet one of the high-risk criteria below. For additional resources on adult vaccination, see [“Helping Your Adult Client Pay for Vaccines.”](#)

- **Eligibility:** Hepatitis A & B vaccine may be provided to patients seen at an enrolled provider (STD clinic, teen health center, family planning clinic) **and who meet risk factors listed below.** Adolescents < 19 years who qualify for the VFC Program should receive **VFC** vaccine, not MI-AVP.
 - Adults with a complete documented vaccine series are considered up to date for that vaccine and **not eligible** for MI-AVP vaccine. Special considerations may be indicated such as when serologic testing is indicated and shows a patient needs additional doses of vaccine (e.g., PrEP serology testing for Hepatitis B indicating additional doses of vaccine needed, despite having completed a 3-dose Hepatitis B vaccine series previously). If the patient is AVP-eligible, MI-AVP vaccine can be used in such an instance.
- **Screen and Document:** Screening for eligibility must occur at each vaccination visit. See criteria listed below. Document in MCIR as “MI-AVP” within the eligibility drop-down field for vaccine administration.
- **Billing:** This program provides Hepatitis A & B vaccines but does not provide reimbursement for administration fees. Providers may be reimbursed for administration fees if Medicaid-eligible client. However, providers may charge an uninsured/underinsured patient for an administration fee if they wish, which **cannot exceed \$23.03** per vaccine (not per antigen in combination vaccines). A provider cannot charge for the vaccine itself.
 - Providers who choose to bill for the vaccine administration fee of an **uninsured/underinsured high-risk hepA/hepB-eligible adult after the date of service** may issue **only ONE bill to the patient, and this one bill must be issued within 90 days** of vaccine administration. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible patient who has unpaid administration fees. The provider must establish a process to waive the fee if the

patient remains unable to pay the vaccine administration fee. This does NOT apply to vaccine administration fees billed to Medicaid. This is effective as of January 1, 2020.

Hepatitis A

Persons who meet one of the following criteria:

- **Direct contact with a hepatitis A virus (HAV)-infected person**
- **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- **HIV infection**
- **Men who have sex with men**
- **Injection or non-injection drug use**
- **Persons experiencing homelessness**
- **Work with hepatitis A virus** (research lab or with nonhuman primates with hepA virus infection)
- **Travel in countries with high or intermediate endemic hepatitis A**
 - [CDC Yellow Book on Hepatitis A and travel](#)
- **Close, personal contact with international adoptee** (e.g., household, or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A
- **Pregnancy if at risk** for infection or severe outcome from infection during pregnancy
- **Settings for exposure**, including health care settings targeting services to injection or non-injection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)
- **Desire for protection against hepatitis A**

Hepatitis B

Adolescents and adults are no longer required to have a risk factor to be eligible for hepatitis B vaccine through the High-Risk Hepatitis A & B Program.

- Heplisav-B and PreHevbrio are not currently recommended in pregnant persons due to lack of safety data
- The safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis.

See CDC's [guidance here](#).