

2027 MnVFC Policies and Procedures Manual

Replacement Method and Separate Stock Sites

MnVFC PIN: _____

Vaccine Coordinator: _____

Backup Vaccine Coordinator: _____

Update your information if the vaccine coordinator or backup change:



[MnVFC Contact Update Form](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY)

[\(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY)

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Checklist for required action steps

Every 24 months requirement

- ☐ Medical Director needs to complete and sign a *Minnesota Vaccines for Children (MnVFC) Program Provider Agreement* every 24 months in odd years, distributed by MnVFC program staff via online survey.
- ☐ Contact the MnVFC Program inbox at health.mnvfc@state.mn.us if your Medical Director changes as they will need to sign a new provider agreement.

Every 12 months requirements

Vaccine coordinator and backup vaccine coordinator need to do the following by Nov. 30, 2026:

- ☐ Complete the *MnVFC Annual Report of the Number of Immunized Pediatric Patients* (only parent sites need to submit an annual report).
- ☐ Complete the 2027 MnVFC Online Training (follow along in the manual as you listen to the training) and print the certificate. Keep it with your records.
- ☐ Replacement method sites complete and sign a *2027 Replacement Method of Vaccine Management Agreement*.
- ☐ Read the *2027 MnVFC Policies and Procedures Manual* and sign the **Signature Page**.
- ☐ Create a **Routine Vaccine Management Plan** for patients to receive any non-routine vaccines that this site may not stock (i.e., COVID-19, mpox, PPSV23, RSV maternal).

Create, review, or update your vaccine management plan and emergency plan.

There are two options:

- ☐ Use the *2027 MnVFC Policies and Procedures Manual* for your vaccine management plan and emergency plan.
 - Vaccine Coordinator to read the manual and sign the **Routine Vaccine Management Plan**.
 - Vaccine Coordinator to fill out the **Worksheet for Developing an Emergency Plan for Managing Vaccine** in this manual and sign it **or** use the fillable PDF on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).

Or

- ☐ Use your own institutional policy and procedure for vaccine management.
 - The policy should include all of the elements of the vaccine management and emergency plans found in this manual.
 - Vaccine Coordinator needs to review, date, and sign the policy each year.

Create, review, or update your Anaphylaxis Protocol.

- ☐ Medical provider needs to review, date, and sign every three years. Visit How to Manage the MnVFC Program for more details.

Required trainings and forms not found in the manual can be found at [Minnesota Vaccines for Children Program \(MnVFC\) \(www.health.state.mn.us/vfc\)](http://www.health.state.mn.us/vfc).

Minnesota Vaccines for Children (MnVFC) basics

What is MnVFC?

The Minnesota Vaccines for Children (MnVFC) program is Minnesota's version of the federal Vaccines for Children (VFC) program, which works to make vaccine accessible and affordable for all children from birth through age 18 years. MnVFC distributes more than \$72 million worth of vaccines to enrolled sites each year. It is managed by the Immunization Program at the Minnesota Department of Health (MDH).

Why enroll in MnVFC?

MnVFC provides vaccine at no cost for eligible children and increases patient satisfaction by providing your patients access to vaccine in their healthcare home. MnVFC participation also helps increase your immunization rates because you are able to provide vaccine to eligible patients who otherwise could not afford them.

By Minnesota law (Minnesota Statutes, section 256B.0625, subd. 39), all sites that provide immunizations to children must ensure equal access for children enrolled in a Minnesota Health Care Program (MHCP). We strongly encourage you to do this by enrolling and participating in the MnVFC program.

If a site is not enrolled in the MnVFC program and is providing vaccines to privately insured children, they must provide the same vaccines to MHCP-enrolled children free of charge. The site cannot charge the recipient for the cost of the vaccine or administration fee. Additionally, the site is not permitted to bill the MHCP for the cost of the vaccine or the vaccine administration fee if they are not enrolled in the MnVFC program.

How do you enroll in MnVFC?

1. Call or email the MnVFC program at 651-201-5522, or health.mnvfc@state.mn.us to start the enrollment process.
2. Enrollment information will be emailed to you. Follow instructions to complete required documents.
3. When your forms are complete, MnVFC staff will schedule an enrollment visit for your site. You must have a visit before you are allowed to order MnVFC vaccine.
4. Once you have met the requirements of the MnVFC program and your site has been assigned a Personal Identification Number (PIN), you will be able to order MnVFC vaccine.
5. Place your first order for MnVFC vaccine within 90 days from your initial site visit. If you wait longer, you may need to have another enrollment visit.



If your site is closing, moving, or changing ownership, contact the MnVFC program.

Introduction to MnVFC Policies and Procedures Manual

This manual lays out the policies established by the federal VFC program. It will help you navigate the requirements to provide access to viable vaccines for eligible individuals. To keep this manual manageable, we do not cover the full range of general immunization best practices and recommendations, but the “Contacts and Resources” section at the end gives you a number of great resources with additional information.

How to use your MnVFC Policies and Procedures Manual

- Have your vaccine coordinator and backup vaccine coordinator read this manual and sign the **Signature Page**, certifying that they have read the manual. This is required.
 - Consider having all staff whose work relates to immunizations read this manual and sign and date the **Signature Page** (e.g., the front desk staff who receives immunization shipments and staff giving immunizations).
- Use this manual to fulfill the requirement for having a routine vaccine management plan. To do this, the appropriate individual needs to certify that this manual is implemented as your site’s **Routine Vaccine Management Plan**.
 - Use of the manual to fulfill this requirement is optional. You can create your own routine vaccine management plan.
 - Create a **Routine Vaccine Management Plan** for patients to receive any non-routine vaccines that this site may not stock (i.e., COVID-19, mpox, PPSV23, RSV maternal).
- Use this manual to fulfill the requirement for an emergency vaccine management plan. Develop a plan using the documents in this manual and have the appropriate individual certify that it has been implemented if needed.
 - A fillable PDF version of the emergency vaccine management plan is available on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html).
 - Use of the manual to fulfill this requirement is optional. You can create your own emergency vaccine management plan.

Helpful definitions

- **Sites:** In this manual, all organizations that store and/or administer vaccine to MnVFC-eligible children will be referred to as sites.
- **Separate Stock:** This method involves keeping privately purchased vaccine and public vaccine separated. Staff must choose vaccine from the correct vaccine “stock” to administer to patients based on their eligibility. Sites using the separate stock method cannot switch to the replacement method at this time without MDH approval and are considered on an individual basis.
- **Replacement Method:** This method allows a site to use privately purchased vaccine to vaccinate MnVFC-eligible children and the MnVFC program replaces the private vaccine that was administered. The replacement method is currently only allowed at sites that have it already in place.

An online version of this manual is also available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).

Signature page

By signing below, I certify that I have read the 2027 MnVFC Policies and Procedures Manual and have completed the annual online training (print certificates of completion).

Name	Signature	Title	Date
Vaccine Coordinator*:			
Backup Vaccine Coordinator*:			
Others†:			

*Definitions of vaccine coordinator and backup vaccine coordinator can be found in the How to be Accountable in the MnVFC Program section.

Vaccine coordinator and backup vaccine coordinator are required to read the manual and view the annual online training.

†Optional: Staff whose work relates to immunizations (e.g., the front desk staff who receive immunization shipments and staff giving immunizations).

Routine vaccine management plan

As a MnVFC provider, you are required to have a routine vaccine management plan that includes the date of review and the reviewer's name, title, and signature. The plan must be reviewed annually or more often as changes occur (e.g., vaccine coordinator and/or backup vaccine coordinator in new role).

The routine vaccine management plan must include:

- Name and contact information of the current vaccine coordinator and backup vaccine coordinator.
- Documentation of staff completing annual online training including the staff member's name and date of training.
- Proper vaccine storage and handling practices (e.g., temperature monitoring and vaccine storage).
- Vaccine shipping and receiving procedures.
- Vaccine ordering procedures.
- Inventory control (e.g., stock rotation).
- Protocol for responding to and reporting vaccine loss.
- Documentation of staff training on elements of the plan.
- Name, signature, and title or role of the person responsible for reviewing and implementing the content.
- Recorded review date within the last 12 months.

NEW: Plan for patients to receive any non-routine vaccines this site may not stock (i.e., COVID-19, mpox, PPSV23, RSV maternal):

You can use this manual to fulfill the requirement for a routine vaccine management plan if:

- You have the appropriate individual certify that this manual will be implemented as your site's routine vaccine management plan.
- Your vaccine coordinator and backup vaccine coordinator sign and date the **Signature Page** certifying that they have read the manual.

This manual should be easily accessible, either printed or online.

By signing below, I certify that the 2027 MnVFC manual will be implemented as my site's routine vaccine management plan.

Vaccine coordinator

MnVFC PIN	
Site name	
Date reviewed	
Name (printed)	
Vaccine coordinator signature	

Emergency vaccine management plan

Whether you use our emergency plan template or your own, it is a requirement for sites to develop, post, and prepare to follow a plan for transporting and storing vaccine in an emergency situation. The plan must be reviewed, signed, and dated each year or more often if there are changes (e.g., reviewer changes or location of supplies has changed).

- If using this manual's emergency plan, remember to sign and date it.
- You may complete an online, fillable version of the [Worksheet for Developing an Emergency Plan for Managing Vaccine \(www.health.state.mn.us/people/immunize/hcp/mnvfc/emplanwrkst.pdf\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/emplanwrkst.pdf).
- Emergency plans must be printed and easily accessible to staff.

You must develop your own site-specific plan and store it in an easily accessible area near your storage unit(s) and/or emergency transport materials. Staff should routinely be trained on the emergency plan. They should know where supplies are located, how to pack vaccine for transport, and where to transport vaccine. We encourage you to regularly practice your plan to identify unforeseen problems.

Essential components for your emergency vaccine management plan

- Designated vaccine coordinator and the backup vaccine coordinator's name, title, contact information, and their responsibilities during an emergency.
- Emergency staff contact list in order of priority.
- Vaccine storage unit specifications for your site (type, location, brand, model, and serial number).
- Emergency procedures for situations such as equipment malfunctions, power failures, or natural disasters.
- Written instructions for how to enter your facility and access vaccine storage units if the building is closed or it's after hours (e.g., what to do if electronic access does not work).
 - Include building security after-hours access procedure; a floor diagram; and the locations of keys, locks, light switches, alarms (with instructions for use); and circuit breaker location(s).
 - Include location of flashlights, spare batteries, and appropriate packing materials to safely transport and/or temporarily store vaccine.
- Written instructions for vaccine packing to maintain the cold chain with appropriate supplies. Refer to:
 - [Packing Vaccines for Transport during Emergencies \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).
 - [CDC: Vaccine Storage and Handling \(www.cdc.gov/vaccines/hcp/storage-handling/\)](http://www.cdc.gov/vaccines/hcp/storage-handling/).
- Written instructions on location of backup continuous temperature monitoring device and instructions for its use.
- Alternate vaccine storage facility(s) needs to be a medical storage facility that is monitoring temperatures appropriately and preferably has a backup power supply.
 - Written information for:
 - How to contact the facility(s) during and after business hours.
 - Identifying vehicles and drivers for transporting vaccine to and from the alternate vaccine storage facility(s).
 - Appropriately storing vaccine at the alternate storage facility(s).
- Documentation of incident and actions.
- Emergency resources contact list.

Worksheet for Developing an Emergency Plan for Managing Vaccine

A fillable version of this and other forms can be found on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html). The emergency plan must be printed and easily accessible to clinic staff.

Name	Phone numbers (home, cell)
Vaccine Coordinator:	
Backup Vaccine Coordinator:	
System-Level MnVFC Contact (if applicable):	

Emergency Staff Contact List		
Name (in order of priority)	Emergency role (pack, transport, etc.)	Phone numbers (home, cell)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		

Vaccine Storage Unit Specifications				
Type of unit (refrigerator or freezer)	Location	Brand	Model number	Serial number

Written instructions for how to enter your facility and access vaccine storage units if the building is closed or it's after hours.

Materials			
	Location of item	Person responsible for material	Phone number
Flashlights			
Spare batteries			
Hard-sided coolers, Styrofoam vaccine shipping containers, or portable fridge/ freezer			
Insulating materials (bubble wrap, packing foam, or Styrofoam and corrugated cardboard)			
Frozen water bottles (conditioned to transport refrigerated vaccine)			
Backup continuous temperature monitoring device with a current and valid Certificate of Calibration and calibration expiration date.			

Written instructions for vaccine packing to maintain the cold chain with appropriate supplies, including continuous temperature monitoring devices.

Alternate Vaccine Storage Facility(s)	
Facility name:	
Address:	
Contact person:	
Phone number during business hours:	Phone number after business hours:
Storage capacity:	
Facility name:	
Address:	
Contact person:	
Phone number during business hours:	Phone number after business hours:
Storage capacity:	

Transportation to Alternate Vaccine Storage Facility(s)		
	Contact person	Phone numbers
Vehicle 1:		

Emergency Resources Contact List			
Emergency resources	Company name	Contact person	Phone numbers
Electric power company			
Generator repair company			
Generator fuel source			
Refrigerator repair company			
Local health department			
State health department	MnVFC program		651-201-5522

Remember to document the incident and your actions.

Date reviewed	
Reviewed by (print)	
Vaccine coordinator signature	

How to Administer the MnVFC Program

1. Screen patients for MnVFC eligibility

- Screen all patients age 18 years and younger before administering vaccines to determine if they are eligible for MnVFC vaccine.
- Document and keep the patient's eligibility status on paper or in the electronic health record for three years.

MnVFC eligibility criteria

- Any child who is age 18 years or younger and meets at least one of eligibility criteria below can receive MnVFC vaccine at MnVFC-enrolled sites:
 - Uninsured.
 - Enrolled in a Minnesota Health Care Program (MHCP): Medical Assistance (MA), MinnesotaCare, and Prepaid Medical Assistance Plan (PMAP). For more information visit [Minnesota Department of Human Services Resources for MHCP members who get care through a health plan \(https://mn.gov/dhs/people-we-serve/adults/health-care/health-care-programs/programs-and-services/resources-for-mhcp-members.jsp#3\)](https://mn.gov/dhs/people-we-serve/adults/health-care/health-care-programs/programs-and-services/resources-for-mhcp-members.jsp#3).
 - American Indian or Alaskan Native: All American Indian or Alaska Native children who are age 18 years or younger are eligible for MnVFC vaccine. But those with insurance may not bill insurance if MnVFC vaccine is used. Ensure billing staff are aware.
 - Underinsured:
 - The following two categories are considered underinsured and are only MnVFC-eligible at local public health (LPH), Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS), and tribal health clinics:
 - Has health insurance that does not cover one or more vaccines, as can be the case with newly licensed vaccines that are not yet covered (MnVFC-eligible for non-covered vaccines only), or does not provide first dollar coverage (which includes copays, coinsurance, or deductibles) for ACIP-recommended vaccines.
 - Has health insurance that caps vaccine coverage at a certain amount. Once that amount is reached, the person is MnVFC-eligible.

Healthcare sharing ministries

- Healthcare sharing ministries (HCSMs) are a form of health coverage whose members share a common belief system. Collectively, they “share” healthcare costs between its members.
- Although HCSMs, in general, are **not** recognized as insurance, their features strongly mimic traditional insurance plans.
 - If you are unsure if a HCSM is recognized as insurance, please call the plan directly.
- MnVFC-eligibility.
 - Children with a HCSM plan that is not recognized as insurance are considered uninsured and are MnVFC-eligible.
 - Use MnVFC vaccine and do not bill the patient for the cost of the vaccine. You may charge the patient up to \$21.22 for the administration fee per dose (not per antigen). Waive the administration fee if the patient is unable to pay it.
 - However, if a HCSM is not recognized as insurance but has 100% vaccine coverage, you must use private vaccine and bill the HCSM plan.

- Patients enrolled in HCSMs that are recognized as insurance are insured and are **not** MnVFC-eligible.

Screen all patients for eligibility

- Prior to immunizing each patient who is age 18 years and younger, you must inform the patient, parent, or legal representative of the MnVFC eligibility criteria and/or give them an eligibility screening form to complete. If a patient is eligible for more than one category, the provider must select the category that will require the least amount of out-of-pocket expense for the patient.
- Visit [Free or Low-Cost Shots for Children \(www.health.state.mn.us/people/immunize/basics/howpay.html\)](http://www.health.state.mn.us/people/immunize/basics/howpay.html) for a self-screening form parents can fill out. The form is available in multiple languages.
- MnVFC vaccine must only be used for MnVFC-eligible patients.

Document the patient's eligibility status

- Document eligibility screening at each visit in the patient's medical record even if the patient is not eligible for MnVFC. Documentation may be done electronically or by using a paper form.
- The MnVFC program provides screening record forms on [MnVFC Program Resources \(www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/resources.html). You do not have to use the MnVFC forms, but you do have to collect all the information that is on them.
- Separate stock sites are highly encouraged to submit your patients' MnVFC eligibility status to the Minnesota Immunization Information Connection (MIIC). The MnVFC program also refers to this information as dose-level eligibility.
 - Reporting dose-level eligibility to MIIC for all vaccines administered to patients age 18 years or younger is strongly encouraged for all sites participating in the MnVFC program.
 - For more information, including how to submit dose-level eligibility information to MIIC (either electronically or by manually entering data), refer to [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/managevax/index.html\)](http://www.health.state.mn.us/people/immunize/miic/managevax/index.html).
- Replacement method sites must submit your patients' MnVFC eligibility status to the Minnesota Immunization Information Connection (MIIC).
- Keep a record of the patient's eligibility for three years.

2. Give patients a VIS with each immunization

- Provide a current Vaccine Information Statement (VIS) every time a patient receives a vaccine.
- Document the publication date of the VIS and the date the VIS was given in the patient's medical record.
- You are required to give the current VIS (either paper or electronic) to the patient or their parent or legal representative before administering each dose of vaccine.
- It is acceptable to make a VIS available to be read before the immunization visit (e.g., giving the patient or parent a copy to take home during a prior visit or telling them how to download or view it on the web). We encourage this when possible. You must still offer a copy (which can be an electronic copy) of each appropriate VIS following the vaccination. However, the recipient may decline.
- An Immunization Information Statement (IIS) should be provided prior to administration of RSV monoclonal antibody products.
- Current VISs are available on [Immunize.org Vaccine Information Statements \(www.immunize.org/vis/\)](http://www.immunize.org/vis/) and [CDC: Vaccine Information Statements \(VIS\) \(www.cdc.gov/vaccines/hcp/current-vis/index.htm\)](http://www.cdc.gov/vaccines/hcp/current-vis/index.htm). Sign up to receive email updates when VISs change.

- When possible, provide the VIS in the person's native or preferred language. Translated VISs are available. You are encouraged to distribute the current English version at the same time as the translation.
- Let the patient, parent, or legal representative keep a paper copy of the VIS, or if they prefer to view the VIS on a tablet or mobile device, direct them to [CDC: Vaccine Information Statements \(VIS\) \(www.cdc.gov/vaccines/hcp/current-vis/index.htm\)](https://www.cdc.gov/vaccines/hcp/current-vis/index.htm) during the visit and make sure they have a chance to have their questions answered. Give them a phone number to call in case of any questions or unexpected symptoms after receiving a vaccine.
- You must document the publication date of the VIS (located on the bottom corner) in the patient's medical record and the date the patient was given the VIS to review.
- You do not need to have the patient, parent, or legal representative sign anything to verify they have received the VIS, unless your site requires this.

3. Administer vaccines in accordance with recommended immunization schedules

- Administer vaccines in accordance with the *General Recommendations on Immunization* and immunization schedules, dosage, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the MnVFC program unless:
 - In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate, or
 - The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Offer all ACIP-recommended vaccines for your patient population

- As a MnVFC-enrolled site, you must offer all ACIP-recommended vaccines for your patient population, including a plan for patients to access non-routine vaccines as appropriate. This plan must be documented in your **Routine Vaccine Management Plan**.
 - This includes RSV monoclonal antibody products, if appropriate for your population.
- Separate stock sites are not required to maintain a full stock of all ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance includes, but is not limited to, RSV monoclonal antibody products. *If a separate stock site VFC provider does not carry privately purchased stock, they are not permitted to use VFC stock on non-VFC-eligible patients.*
- The current ACIP-recommended schedules are available on [CDC: Vaccine Administration: Before Giving Vaccine \(www.cdc.gov/vaccines/hcp/administration/before.html\)](https://www.cdc.gov/vaccines/hcp/administration/before.html).
- Use [Immunize.org: Guide to Contraindications and Precautions to Commonly Used Vaccines for All Ages \(www.immunize.org/wp-content/uploads/catg.d/p3072a.pdf\)](https://www.immunize.org/wp-content/uploads/catg.d/p3072a.pdf).
- The state laws related to vaccination requirements and acceptable vaccine exemptions can be found at [Vaccines for Infants, Children, and Adolescents \(www.health.state.mn.us/people/immunize/basics/kids.html\)](https://www.health.state.mn.us/people/immunize/basics/kids.html).

Train staff on how to administer vaccines correctly

- Comprehensive, competency-based staff training and education, including the "rights of medication administration," patient care, vaccine preparation, and skill validation should occur for all personnel who administer vaccines based on their scope of practice. Sites may have their own internal training program. For those who do not, there are options available:

- Vaccine Administration chapter in [CDC: Chapter 6: Vaccine Administration \(www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html\)](http://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html).
 - CDC eLearn: [Vaccine Administration \(https://www2.cdc.gov/vaccines/ed/vaxadmin/vaccine.asp\)](https://www2.cdc.gov/vaccines/ed/vaxadmin/vaccine.asp).
- Vaccine Administration lessons from [California VFC Program EZIZ Training \(https://eziz.org/eziz-training/\)](https://eziz.org/eziz-training/).
- To ensure competency, staff training should occur when: new staff are hired, new or different vaccines are added to the site's usual inventory, new recommendations are published, and when old recommendations are revised. Annual updates and skill reviews are recommended for all staff.
- Encourage staff to ask questions about vaccine administration if they are unsure.

Immunization administration resources

- [Immunization Best Practices \(www.health.state.mn.us/people/immunize/hcp/bestpractices.html\)](http://www.health.state.mn.us/people/immunize/hcp/bestpractices.html).
- [Reliable Sources of Immunization Information \(www.health.state.mn.us/people/immunize/basics/imminfo.html\)](http://www.health.state.mn.us/people/immunize/basics/imminfo.html).
- [CDC: Preventing Unsafe Injection Practices \(www.cdc.gov/injection-safety/hcp/clinical-safety/\)](http://www.cdc.gov/injection-safety/hcp/clinical-safety/) for safe injection practices.
- Immunization education and training: “You Call the Shots” (www.cdc.gov/vaccines/ed/you-call-the-shots/) modules, the Vaccine Administration e-Learn, and Pink Book Webinar Series.
- [Immunize.org: Skills Checklist for Immunization \(www.immunize.org/catg.d/p7010.pdf\)](http://www.immunize.org/catg.d/p7010.pdf).
- [Immunize.org: Vaccination Tools for Administering Vaccines \(www.immunize.org/clinic/administering-vaccines.asp\)](http://www.immunize.org/clinic/administering-vaccines.asp).
- [Immunize.org: Vaccines with Diluents: How to use them \(www.immunize.org/catg.d/p3040.pdf\)](http://www.immunize.org/catg.d/p3040.pdf).

4. Document immunizations in the medical record

Document required information in each patient's medical record for all doses of vaccine administered in accordance with the National Childhood Vaccine Injury Act.

- A patient's medical record must include:
 - Site/facility address where the vaccine was administered.
 - Date vaccine was administered.
 - Vaccine type.
 - Vaccine manufacturer.
 - Vaccine lot number.
 - Signature and title of person(s) administering vaccine.
 - Publication date of VIS (located at the bottom of VIS).
 - Date VIS was given to the patient, parent, or legal representative (usually the same as the vaccine administration date but still needs to be documented).
- Best practice recommendations also include documenting the following information:
 - Dose.
 - Site and route of injection.
 - History of vaccine reaction, if the patient has experienced a clinically significant or unexpected event after an immunization (even if there is uncertainty that the vaccine caused the event).

- Contraindications and precautions that may apply to this patient.
- Serologic test results related to vaccine-preventable diseases.
- For combination vaccines, record the vaccine information in the spaces that correspond to each individual antigen in the combination product, indicating the combination type (for example, DTaP-IPV-HepB) and the name of the combination vaccine (for example, Pediarix).
- You should give patients/parents a record of each immunization.
- MIIC cannot serve as the permanent medical record.

5. Report vaccine administration to MIIC

- Providers are required to report doses administered data to Minnesota Immunization Information Connection (MIIC) within seven days of the vaccine administration date.
- Visit [Enroll in MIIC \(www.health.state.mn.us/people/immunize/miic/provider/enroll.html\)](http://www.health.state.mn.us/people/immunize/miic/provider/enroll.html) to determine the best way to submit data to MIIC for your organization. If you do not already submit this data, you may be able to do so with your current electronic health record (EHR) system or other electronic data submissions. We recommend discussing this with your technical staff and/or EHR vendor support.
- For detailed instructions on how to submit this dose-level eligibility data, refer to [Doses Administered by Eligibility Report \(www.health.state.mn.us/people/immunize/miic/train/dar.pdf\)](http://www.health.state.mn.us/people/immunize/miic/train/dar.pdf).

MDH has started designing a new version of MIIC. We expect the new system to be able to do what you do now and be easier to use.

- The new system will include updated vaccine ordering, inventory, and related functionality.
- A comprehensive training plan is being developed to ensure provider organizations have the sources they need to efficiently and effectively use MIIC.
- The best way to get updates about the MIIC modernization effort is to sign up for email updates at [MIIC Modernization \(https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_900\)](https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_900).
 - Updates specific to vaccine ordering may also be sent out via MnVFC Announcements. Sign up for email updates at [MnVFC Announcements \(www.health.state.mn.us/people/immunize/hcp/mnvfc/announcements.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/announcements.html).

Resources on [MIIC User Guidance and Training \(www.health.state.mn.us/people/immunize/miic/train/index.html\)](http://www.health.state.mn.us/people/immunize/miic/train/index.html) will assist you with all reporting aspects of MIIC.

- If you need help with data reporting, contact the MIIC Help Desk at health.miichelp@state.mn.us.

6. Charge only allowable fees for MnVFC

- Do not charge for the cost of vaccine if the patient is MnVFC-eligible.
- Charge only the allowable fees for administering MnVFC vaccine.
- Waive the administration fee if a patient is unable to pay.

Patient's status	MnVFC eligible?	Cost of the vaccine	Administration fee
Minnesota Health Care Program (MHCP)	Yes	Don't bill or charge for the cost of the vaccine.	- Bill the MHCP \$21.22 per dose. - Certain sites including FQHC, RHC, IHS* and tribal clinics may bill an encounter fee for the entire visit, and this is allowable.
Uninsured	Yes	Don't charge for the cost of the vaccine.	Charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
American Indian/Alaska Native	Yes	- Don't bill or charge for the cost of the vaccine. - However, if the patient is privately insured and prefers to use insurance, use private vaccine and bill the insurance.	- If covered by a MHCP, bill the MHCP \$21.22 per dose. - If un- or underinsured, charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it. - If privately insured and prefers to use insurance, bill the insurance for the fee.
Underinsured	Only at local public health (LPH), Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS), and tribal health clinics:		
	Yes	Don't charge for the cost of the vaccine.	Charge the patient \$21.22 or less per dose. Do not issue more than a single bill; waive the fee if the patient is unable to pay it.
	At a site that is not eligible to see underinsured children:		
	No	- Consider sending the patient to a site where they would be eligible for MnVFC. - If the patient stays at a private site, do not use MnVFC vaccine.	Consider sending the patient to a site where they would be eligible for MnVFC.
Insured	No	Bill the insurance.	Bill the usual and customary administration fee to the insurance.

*Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC), Indian Health Services (IHS).

Do not bill or charge for the cost of the vaccine

- You may not bill or charge for the cost of the vaccine for MnVFC-eligible patients.

Charge allowable office visit and administration fees

- You may bill or charge for the office visit.
- You may bill or charge an administration fee of up to \$21.22 per dose (not per antigen) for administering MnVFC vaccine.

- For patients who are not enrolled in an MHCP, **you can bill them only one time** (within 90 days of vaccine administration) for the administration fee. If the bill is not paid, the administration fee must be waived.
- To be reimbursed for the administration fee for pediatric patients enrolled in a Minnesota Health Care Program (MHCP), you must follow the billing procedures of each program. MHCPs include Medical Assistance (MA) and MinnesotaCare. For billing questions, call the health plan directly or call the Minnesota Department of Human Services (DHS) at 651-431-2700.
- If a provider administers MnVFC vaccines to a Medicaid VFC-eligible child from a neighboring state, the provider must be Medicaid-enrolled for the child's state of residency in order to receive administration fee reimbursement from that Medicaid program.

Waive the administration fee

- You may bill or charge patients an administration fee one time, but if they are unable to pay it, it must be removed from their bill. Having these bills go to collections is not acceptable.
- No MnVFC-eligible patient may be denied vaccine for inability or failure to pay an administration fee.

Remove vaccine charges from a MnVFC-eligible patient's bill

- Make sure your billing department is prepared to respond to questions related to MnVFC eligibility and to adjust bills as needed; review [Immunization Billing Guidance for MnVFC \(www.health.state.mn.us/people/immunize/hcp/mnvfc/billingtips.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/billingtips.html).

7. Report adverse events to the Vaccine Adverse Events Reporting System (VAERS)

Report adverse events following immunization to VAERS.

Vaccine Adverse Event Reporting System (VAERS)

- The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA). It collects information about adverse events that occur after the administration of vaccines licensed for use in the United States.
- VAERS provides a way for adverse events following immunization to be reported and analyzed.
- Adverse events are health effects that occur after immunization that may or may not be related to the vaccine. By reporting an event, you are not saying that the vaccine caused the event.

Reporting to VAERS

- The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report to VAERS:
 - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of vaccine.
 - Any event listed by the manufacturer in the [VAERS Table of Reportable Events Following Vaccination \(https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf\)](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified time period after vaccination.
- Healthcare providers are encouraged to report:
 - Any adverse event that occurs following the administration of a vaccine licensed in the U.S., whether or not it is clear that a vaccine caused the adverse event.
 - Vaccine administration errors.

- Anyone is able to file a VAERS report, including healthcare providers, manufacturers, vaccine recipients, or families.
- Submit the form as soon as possible after an adverse event following vaccination. Information about VAERS is on the back of every VIS. For more information or to report an event, visit the [Vaccine Adverse Event Reporting System \(VAERS\)](https://vaers.hhs.gov/) (<https://vaers.hhs.gov/>) or call 800-822-7967.

8. Keep MnVFC program records for three years

Keep all records related to the MnVFC program for at least three years, even in the case of provider retirement or provider closure (electronic or hard copies; you do not need to do both).

- The following MnVFC records must be kept for at least three years:
 - Routine and emergency vaccine management plans, including the Policies and Procedures Manual as appropriate.
 - MnVFC eligibility screening information (forms or documentation in the electronic medical record).
 - Storage unit temperature documentation. Provider locations must maintain all paper temperature logs or a backup system of electronic data for a minimum of three years, unless state statutes or rules require longer retention. This requirement applies even in the case of provider retirement or provider location closure.
 - Certificate of Calibration for each continuous temperature monitoring device used including your backup device.
 - All forms related to vaccine management:
 - *Temperature Excursion Incident Log.*
 - *Temperature Excursion Incident Checklist.*
 - *Minnesota Department of Health (MDH) Vaccine Transfer Record.*
 - *Minnesota Department of Health (MDH) Nonviable Vaccine Form.* (If you submit the nonviable form via MIIC, you do not need to keep paper copies.)
 - *Vaccine Borrowing Report* or other borrowing documentation.
 - Monthly ordering records.
 - Packing lists of vaccine shipments.
 - Monthly inventory log.
 - *MnVFC Program Annual Report of the Number of Immunized Pediatric Patients.*
 - *Minnesota Vaccines for Children (MnVFC) Program Provider Agreement.*
 - Certificate of completion of the annual MnVFC online training.
- Check your own site's policies about keeping records beyond three years.

How to Manage the MnVFC Program

9. Have appropriate storage equipment

- Have and maintain appropriate vaccine refrigerator/freezer(s) to store vaccine.
- Safeguard the power supply to storage units.
- Use a continuous temperature monitoring device that has a current and valid Certificate of Calibration to monitor temperatures in each storage unit.
- Place the temperature probe in the center of the storage unit with the vaccine.
- Have one backup continuous temperature monitoring device with a current and valid Certificate of Calibration readily available for each MnVFC site.

Vaccine storage units

- Storage units, in order of preference, are:
 1. Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units.
 2. Vaccine storage units that conform to National Sanitation Foundation (NSF)/ American National Standards Institute (ANSI) Standard 456 (which have been tested rigorously to be used for the storage of vaccines).
 3. Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.
 4. Household combination refrigerator/freezer unit, using only the refrigerator compartment to store vaccines. Store frozen vaccine in a stand-alone freezer. Household combination units will need to be replaced with option #1, #2, or #3 above in the following situations:
 - When purchasing new storage unit equipment (e.g., unit stops functioning, etc.).
 - Vaccine loss due to storage unit failure.
- Newly enrolled sites are required to store vaccine in a pharmaceutical unit (combo or stand-alone), stand-alone refrigerator or stand-alone freezer.
- Dormitory units (i.e., combination refrigerator/freezers with one exterior door) are not allowed for storing MnVFC vaccines. Vaccine stored in this type of unit are considered unusable due to a significant risk of freezing vaccine.

Features and use of vaccine storage units

- Must be able to maintain required vaccine storage temperatures:
 - Refrigerator between 36°F and 46°F (between 2°C and 8°C), aim for 40°F (5°C).
 - Freezer between -58°F and +5°F (between -50°C and -15°C), aim for 0°F (-18°C).
 - Ultra-cold freezer between -130°F and -76°F (between -90°C and -60°C).
- Must be large enough to hold the year's largest inventory, for example, the back-to-school rush or the flu season, based on how many doses of vaccines you order annually.
- Must have sufficient room to store water bottles in the refrigerator and frozen water bottles in the freezer to help stabilize the temperature.
 - **Note:** Water bottles are recommended for household-grade units and are not recommended for use with the majority of pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.
- Must have room for air to circulate so the proper temperature range is maintained.

- Should be used only for vaccines or other medical supplies. Storage of food and beverage is not recommended in vaccine storage units. A limited supply of Pedialyte or juice for patient use is acceptable, ideally on the top shelf or bottom of the unit.
- Sharing a storage unit with your lab is not recommended because of possible contamination of the vaccine and an increase in temperature fluctuations due to increased frequency of the door opening. If you must store vaccines in a unit that contains lab specimens, store the specimens on a shelf below the vaccines.
- Must be repaired or replaced immediately if there are mechanical problems.
- Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday. Once you have two consecutive days of temperature recorded within the recommended range, your unit is stable and ready for use:
 - Refrigerator units may require two to seven days to stabilize and maintain temperatures within the recommended range.
 - Freezer units may take two to three days to stabilize and maintain temperatures within the recommended range.

Safeguard the power supply

- Do not use ground fault interrupter (GFI) outlets, extension cords, or power strips.
 - Plug in only one storage unit per electrical outlet.
- Make sure the storage unit is plugged into an outlet where it cannot be accidentally unplugged. An outlet that has an electrical plug with a safety lock is ideal. If your building has auxiliary power, use the outlet supplied by that system.
- You must label storage unit and electrical outlets with “Do Not Unplug” stickers. Order stickers for free on [Order Printed Immunization Materials \(www.health.state.mn.us/people/immunize/ordermat.html\)](http://www.health.state.mn.us/people/immunize/ordermat.html).
- Fuse box and/or circuit breakers for vaccine storage units must be labeled with “WARNING” stickers to prevent any disruption of the power to vaccine storage units. Order stickers for free on [Order Printed Immunization Materials \(www.health.state.mn.us/people/immunize/ordermat.html\)](http://www.health.state.mn.us/people/immunize/ordermat.html).
- In larger sites, we encourage you to have a backup power system as a source of backup power in case of an emergency. You may also want to install an alert system to notify appropriate personnel of a power outage.
 - If you have a backup power system, it should be tested quarterly and receive annual maintenance.

Continuous temperature monitoring devices

- There are two categories of continuous temperature monitoring devices: data loggers and continuous temperature monitoring systems. Technology for these devices and systems is evolving.
 - **Data loggers:** A portable measurement instrument that can be programmed to record temperatures at preset intervals. They are capable of recording and storing thousands of temperature readings that can then be retrieved, viewed, and evaluated.
 - **Continuous temperature monitoring systems:** A system that provides information on temperatures for multiple vaccine storage units throughout a clinic or system, recorded at preset intervals. It transmits real-time data to a computer and has the ability to alert multiple people via text and/or email. There should be a written procedure to address who is notified when out-of-range temperatures occur and how the contact list is updated.

- Use a continuous temperature monitoring device with a current and valid Certificate of Calibration (in each storage unit).
 - Thermometers are not allowed for monitoring MnVFC vaccine.

Features of continuous temperature monitoring devices

- **Required features:**
 - A temperature probe placed in the center of the storage unit with the vaccine.
 - In a pharmaceutical unit, placement of the probe in other locations may be suitable because pharmaceutical units maintain more consistent temperatures throughout the unit.
 - Continuous monitoring and recording capabilities to track and record temperatures over time.
 - The capacity to routinely download/save temperature data to an electronic file or folder (recommended at least weekly).
 - Temperature (current, minimum, and maximum) display that is easily read from outside the unit, including on a computer monitor.
 - A probe in buffered material (e.g., biosafe glycol) is required.
- **Recommended features:**
 - Alarm for out-of-range temperatures.
 - Accuracy within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
 - Low battery indicator.
 - User programmable logging intervals (e.g., the user can set how often the device records the temperature) recommended at intervals of 15 minutes and no more than 30 minutes.

Backup continuous temperature monitoring device

- Each MnVFC site must have access to at least one readily available backup continuous temperature monitoring device that has a valid Certificate of Calibration and meets the above requirements. Backup DDLs are usually maintained on site.
 - Use this device in case your main continuous temperature monitoring device is not working properly, or current equipment requires calibration testing.
 - The Certificate of Calibration for the backup device should have a different calibration date than the main continuous temperature monitoring devices at the site unless you have onsite calibrations performed all on the same day.
 - Use the backup device if you need to transport vaccine.

Certificate of Calibration

- Calibration of continuous temperature monitoring devices must be performed at a minimum of every two to three years from the last calibration testing date or more frequently if recommended by the manufacturer. If no expiration date is listed on the certificate, the device must be recalibrated every two years. All continuous temperature monitoring devices will “drift” over time, and normal use can impact their accuracy. Therefore, all devices require recalibration. To be considered “valid,” a Certificate of Calibration must have the following required elements:
 - Model/device name or number.
 - Serial number.
 - Date of calibration.
 - Whether the instrument passed or failed testing (or instrument in tolerance).

- Recommended element:
 - Documented uncertainty (recommended uncertainty = $\pm 0.5^{\circ}\text{C}$ / $\pm 1.0^{\circ}\text{F}$). If the DDL is no longer accurate within these parameters, it must be replaced; adjusting the DDL is not recommended.
- To determine if a certificate of calibration testing was issued by an appropriate entity, check to see if the certificate indicates one or more of these items:
 - Conforms to ISO 17025.
 - Performed by an ILAC/MRA Signatory body accredited laboratory. You can review this list of the [ILAC MRA and Signatories \(http://ilac.org/ilac-mra-and-signatories/\)](http://ilac.org/ilac-mra-and-signatories/).
 - Traceable to the standards maintained by NIST.
 - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F ($\leq 0.5^{\circ}\text{C}$) or better.
 - Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.
- **Note:** CDC recommends that certifications be issued for the entire monitoring unit (detachable probe, data logger, etc.) and not individual certificates for each component.

10. Receive and store vaccine carefully

- Properly receive and store vaccine and diluents.
- On site staff record minimum and maximum temperatures for each storage unit at the start of each clinic day.
- Take immediate action on out-of-range temperatures.

Receive vaccine shipments

- Appropriate staff must be on site to receive vaccine shipments at least one day per week other than Monday.
- If you receive a shipment outside of your shipping window, call McKesson or Merck (depending on the vaccine) to report.
- You must check the condition of all vaccines and diluents immediately when they arrive.
 - Open vaccine packages immediately and store at appropriate temperatures.
 - Inspect the vaccine and packaging for damage.
 - Compare the vaccine received with the packing list. Report any discrepancies to the MnVFC program inbox at health.mnvfc@state.mn.us.
 - Check expiration dates and put vaccines and diluents with the earliest expiration date in front to be used first.
- Check that the vaccine has remained in the correct temperature range.
 - Check the cold chain monitor for any indication of a temperature excursion in refrigerated vaccine shipments from McKesson. If the vaccine shipment is compromised in any way, the provider must contact McKesson Specialty Customer Care immediately at **1-877-TEMP123 (1-877-836-7123)**. It is critical that McKesson Specialty Customer Care be contacted within two hours of the vaccine arrival.
 - For shipments from Merck, use the date on the packing list to determine how long the vaccine was in transit. Merck will send your vaccine in a small shipping container that is qualified for two days in transit, or a larger shipping container qualified for four days in transit. See the shipping container insert to confirm approved number of days. If vaccine has been in transit for longer than the approved number of days, or you have any concerns about the condition of the vaccine, call Merck immediately at **1-800-672-6372**.

- Document on your packing slips and/or inventory logs the date and time the shipment was received, packing material condition, and temperature indicator status. Keep this documentation for at least three years.
- If you receive vaccine with an expiration date of six months or less, call the MnVFC program for guidance.
- MMRV and varicella must be shipped directly to all sites.

Store vaccine

- **Vaccine packaging:**
 - Keep vaccine or diluent in their original packaging to:
 - Protect them from light.
 - Help prevent medication errors by making labels easier to read.
 - Provide additional protection in case of an out-of-range temperature, power outage, door left open, or mechanical failure.
 - Simplify managing your vaccine inventory.
- **Organizing storage unit:**
 - Store vaccine and diluents with enough space for cold air circulation.
 - Store vaccine and diluents in the middle of the compartment, two to three inches away from walls, ceiling, floor, door, and cold air vent. The temperature near the floor and walls of the unit differs from that in the middle of the compartment and the cold air vent can freeze refrigerated vaccines.
 - Use open trays and baskets to organize vaccines.
 - Clearly label each container with the vaccine type.
 - Separate stock sites must separate MnVFC vaccine and diluent from private vaccine and other public stock (if applicable).
 - Do not store “look-alike” and “sound-alike” vaccines and diluents next to each other (e.g., Tdap and DTaP, HepA and HepB and Hib).
 - Do not store vaccine or diluent in the door or drawers of the refrigerator or freezer.
 - Never store diluents in the freezer.
 - For vaccine or diluent stored in a household combination refrigerator/freezer:
 - You cannot store vaccine in the freezer section of a combination household unit.
 - For vaccine stored in the refrigerator section, do not use the top shelf for storing vaccine because the cold air vent blowing from the freezer may freeze vaccine located there. If you must use the top shelf of this type of unit, place water bottles underneath the cold air vent to prevent vaccine from being stored there.
 - Do not store food or beverages in the refrigerator or freezer because frequent opening of doors can lead to temperature variations that may affect vaccine viability. There is also a risk of contaminating vaccines.
- **Water bottles:**
 - Water bottles are especially important in household units. They are not recommended for use in all purpose-built or pharmaceutical-grade units (refer to manufacturer guidance).

- Store water bottles in the doors, on the floor, and near the cold air vent in the refrigerator and frozen water bottles in the freezer to help maintain a stable temperature if there is a power failure and when the door is opened frequently. Water bottles in the refrigerator help stabilize temperatures.
 - Add or subtract water bottles one at a time to prevent temperature fluctuations.
- Too many water bottles in the door can prevent the door from closing tightly.
- Mark water bottles “Do Not Drink.”

Monitor and document temperatures

- Temperature monitoring and documentation requirements.
 - Record for each storage unit **at the start of each workday that the clinic is open**:
 - Minimum (lowest) and maximum (highest) temperature to the first decimal point for the previous 24-hour period.
 - Date and time.
 - Name or initials of **on-site staff** reviewing and recording the min/max temperatures.
 - Temperatures can be recorded either electronically or on a paper temperature log. Record actual temperatures and do not record alarm settings.
 - Based on the type of continuous temperature monitoring device in use, the min/max may or may not need to be reset. Follow the manufacturer’s instructions specific to your device.
 - Review storage unit temperature readings **weekly** for out-of-range temperatures or changes in temperature trends that might require action (e.g., adjusting unit temperature or repairing/replacing storage or continuous temperature monitoring equipment).
- Temperature monitoring best practices.
 - Record current temperatures in each storage unit twice each day.
 - View temperatures throughout the day and take immediate action on out-of-range temperatures.
 - Document any actions taken on out-of-range temperatures.
 - Check that:
 - Probe is located in the center of the unit with the vaccine, unless manufacturer advises differently.
 - Vaccines are in their original boxes.
 - Vaccines are stored away from the walls, floor, or vents.
 - Vaccine is not stored in the door or in the drawers.
 - The door of the unit is tightly closed.
 - Paper logs note when site is closed and missed readings are left blank.
 - A copy of your temperature logs/reports may be requested by the MnVFC program to check temperature control or to assist in troubleshooting issues.

Move vaccine immediately for refrigerated vaccine that is less than 2 degrees Celsius (36 degrees Fahrenheit) and follow action steps for out-of-range temperatures. Vaccines exposed to freezing temperatures for even a brief time may become nonviable (unusable).

Take immediate action on out-of-range temperatures and excursions

When your continuous temperature monitoring device is reading a temperature that falls outside the recommended range, it is considered an excursion or out-of-range temperature. Vaccines exposed to out-of-range temperatures may become nonviable (unusable, especially if frozen).

Be aware that open multidose vials and refrigerated MMR vaccine are especially sensitive to out-of-range temperatures. Confirm viability with vaccine manufacturer(s) with every excursion even if the temperature stabilized within 30 minutes.

- Vaccine must be stored within the following temperature ranges:
 - Refrigerator between 36°F and 46°F (between 2°C and 8°C), aim for 40°F (5°C).
 - Freezer between -58°F and +5°F (between -50°C and -15°C), aim for 0°F (-18°C).
 - Ultra-cold freezer between -130°F and -76°F (between -90°C and -60°C).
- All the following incidents must be reported to the MnVFC program:
 - Refrigerated vaccine reached a temperature **less than 2°C (36°F)** for any amount of time.
 - The temperature of the fridge or freezer unit was too warm and did not stabilize in the correct range **within 30 minutes**.
 - Any out-of-range temperature that happened in any unit storing **open multi-dose vials (MDVs) or refrigerated MMR vaccines** for any amount of time.
 - Vaccine was stored improperly in a way that led to the vaccine sitting at an out-of-range temperature for 30 minutes or more.
- Report the temperature excursion to the MnVFC program by completing the [MnVFC and UUAV Temperature Excursion Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T\)](https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T), and our staff will follow-up with you on next steps.
- **If you find an out-of-range temperature, take immediate action:**
 - Determine the problem. Attempt to fix the cause, if possible. It might be easily corrected (e.g., door not shut, power outage, unit malfunction).
 - Adjust the storage unit's temperature, if necessary.
 - Report the excursion to the vaccine coordinator or backup vaccine coordinator, if available.
- Monitor the temperature. If the temperature is too warm and doesn't stabilize in the correct range within 30 minutes, follow these action steps:
 - Stop using the vaccine.
 - Mark the vaccine "Do Not Use" so no one administers it.
 - Move the vaccine to a storage unit that is maintaining the correct temperature.
 - Collect the lot numbers, expiration dates, storage unit temperatures, the room temperature, and the time the unit was out-of-range.
 - Evaluate the temperature log (download data or review CTM information) to determine the length of time the storage unit was out of range and how high/low the temperature got.
 - Determine if any of this vaccine was involved in a previous storage and handling mishap or temperature excursion incident.
 - Call the vaccine manufacturer(s) and ask to speak to a medical consultant or quality assurance staff. Manufacturer contact information is available on [Immunize.org: Vaccine Manufacturers \(www.immunize.org/clinical/external/manufacturers/\)](http://www.immunize.org/clinical/external/manufacturers/).

- Report the temperature excursion to the MnVFC program by completing the [MnVFC and UUAV Temperature Excursion Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T\)](https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T), and our staff will follow-up with you on next steps.
- Document your actions. You can use the *Temperature Excursion Incident Log*, the *Temperature Excursion Incident Checklist*, or your own site's form to document out-of-range temperatures and actions taken. Keep these logs for three years.
- Replacement method sites with a temperature excursion that results in a large amount of nonviable vaccine are asked to contact the MnVFC program for information on how to replace vaccine.
- When an out-of-range temperature incident occurs, the MnVFC program may hold your vaccine orders until all issues are resolved.
- Separate stock sites with MnVFC vaccine that is determined to be nonviable must report it to MDH.
- Vaccine that is expired or exposed to out-of-range temperatures and is in its original vial or pre-filled syringe can be returned to McKesson Specialty Distribution within six months of expiration. Open multi-dose vials determined to be nonviable should be discarded per your site's policy.
- Return or dispose of privately purchased nonviable vaccine per your site's policy.

More detailed information about receiving and storing vaccine

- [Vaccine Storage Guide \(www.health.state.mn.us/people/immunize/hcp/vaxhandling.html\)](http://www.health.state.mn.us/people/immunize/hcp/vaxhandling.html).
- [CDC: Vaccine Storage and Handling \(www.cdc.gov/vaccines/hcp/storage-handling/\)](http://www.cdc.gov/vaccines/hcp/storage-handling/).

11a. Manage MnVFC vaccine efficiently for Separate Stock sites

- Take monthly vaccine inventory, order only the amount of vaccine you need, rotate stock, and transfer vaccine that is nearing expiration to other sites to prevent wasting vaccine.
- Keep privately purchased vaccine separate from MnVFC vaccine.
- Avoid borrowing between your public and private vaccine stocks; however, if it is necessary, complete all of the fields on the borrowing report.
- Report all MnVFC vaccine that becomes nonviable or lost to MDH.
- Return all spoiled or expired vaccine in its original vial or pre-filled syringe to McKesson Distribution within six months of expiration.

Manage inventory

- Physical inventory of your MnVFC vaccine should be done weekly and must be done at least monthly and before placing a vaccine order.
 - Record the number of doses, lot numbers, and expiration dates.
- Rotate your vaccine stock so vaccine due to expire first is in front.
 - Vaccine must be rotated every week or when a new shipment comes in (whichever happens more frequently).
- Keep vaccine in the original packaging to make managing inventory easier.

Order the amount of vaccine you actually need

- Place an order when you have a four-week supply of vaccine remaining to ensure that you have enough vaccine to allow for any potential delays.
- Place smaller, more frequent orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit.

- It is an expectation that enrolled sites will order vaccine at least every 12 months.
 - If your site does not order vaccine in the twelve-month period, MnVFC staff may follow-up with you to discuss the reason behind the lack of ordering.
- Order vaccine online through the [Minnesota Immunization Information Connection \(MIIC\) \(www.health.state.mn.us/miic\)](http://www.health.state.mn.us/miic).
 - If your site is not set up for ordering in MIIC, contact the MIIC Help Desk at health.miichelp@state.mn.us.
- You must include current storage unit temperatures with each order.
- Provide doses on hand, lot number, and expiration date of all public vaccine in stock (MnVFC and UUAV, if applicable) with each MDH vaccine order.
 - You can print out the doses on hand page and bring it to your storage unit to collect your doses on hand information.

Track your MnVFC vaccine orders in MIIC

- In MIIC, select *View Vaccine Management* to track the shipment status of your MnVFC vaccine orders.
- Influenza vaccine product requests can also be tracked under *Manage Special Vaccine Event* in MIIC.
- Go to [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/train/managevax.html\)](http://www.health.state.mn.us/people/immunize/miic/train/managevax.html) for a detailed guide on how to create and view the shipping status of your MnVFC vaccine orders in MIIC.

Keep privately purchased vaccine separate from MnVFC vaccine

- MnVFC vaccine must only be used for MnVFC-eligible patients.
- Select the dose from the MnVFC supply when you see a patient who is eligible for MnVFC vaccine.
- Mark the MnVFC boxes or vials and/or keep them in a clearly marked open tray or basket.

Transferring vaccine

- Transferring vaccine occurs when a MnVFC site is unable to use vaccine before its expiration date and is transferred to another MnVFC-enrolled site to avoid wastage.
- You are responsible for transferring any vaccine you will be unable to use to another MnVFC site.
- Once a site has been identified, call them to make sure they can use the vaccine, have space to store it, and someone will be there to receive it.
- If you are unable to locate another MnVFC site that can take your vaccine, call the MnVFC program and we will help you find a home for it.
 - If you have frozen vaccines (MMRV and varicella) that will expire within three months that you cannot use, call the MnVFC program for guidance.
- Only full, sealed vials or unopened pre-filled syringes can be transferred.
- Report all MnVFC vaccine that is transferred to another site using the *Vaccine Transfer Record*.
- Keep one copy, enclose one copy with the vaccine, and send one copy to the MnVFC program.
 - Whether you are sending or receiving a vaccine transfer, you must keep your copy of the *Vaccine Transfer Record* for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range (between 36°F and 46°F or between 2°C and 8°C) during transport of vaccine.

- Guidance for packing and transporting vaccine is available in [Packing Vaccines for Transport during Emergencies \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf\)](https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).
- You must use a continuous temperature monitoring device with a valid Certificate of Calibration.

Borrowing vaccine

- Borrowing occurs when a provider borrows vaccine from MnVFC stock to administer to a patient not eligible for the program, or when a provider borrows vaccine from private stock to use on MnVFC-eligible patients.
- This should be a rare, unplanned occurrence.
- Borrowing is approved only in these instances:
 - Lack of vaccine stock due to delayed or spoiled shipments.
 - Vaccine expiring soon will be lost if not used. Providers with a small, privately insured patient population can use this option to administer short-dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
 - New staff calculated ordering intervals incorrectly, leading to a lack of either private or public vaccine stock.
 - VFC seasonal influenza vaccine stock is not yet available. Private seasonal influenza vaccine stock may be borrowed for VFC-eligible children and replaced when VFC vaccine becomes available. This one-directional borrowing is unique to seasonal influenza vaccine.
- Use the *Vaccine Borrowing Report* to document every time MnVFC vaccine is borrowed to administer to a non-eligible patient or when private stock is used for a MnVFC-eligible child.
 - Document the vaccine type borrowed, vaccine stock used, patient's name and date of birth, date the dose was administered, why the vaccine was borrowed, and the date the vaccine was replaced.
 - Keep a copy of the *Vaccine Borrowing Report* for three years.

Manage nonviable vaccine

- All nonviable MDH vaccine must be reported to MDH. We recommend you report wastage on a monthly basis. Vaccine that is expired or exposed to out-of-range temperatures and is in its original, unopened vial or pre-filled syringe should be returned to McKesson Specialty Distribution within six months of expiration.
- There are two categories of nonviable vaccine: Returned and wasted.
 - **Returned:** This is nonviable vaccine in its original, unopened vial or syringe. Examples of vaccine that should be reported for return include:
 - Expired vaccine. Note: Do not return vaccine as “expired vaccine” before its expiration date, including influenza vaccine, unless it was short dated by the manufacturer.
 - Vaccine that is recalled by the manufacturer.
 - Vaccine that is nonviable due to exposure to out-of-range temperatures.
 - **Wasted:** This is nonviable vaccine that should not be returned and should be properly disposed of according to your policy. Examples of vaccine that should be reported as wastage include:
 - Vaccine drawn into the syringe but not administered.
 - Vaccine in open vial but doses not administered.
 - Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial.
- How to report nonviable MDH vaccine:

- MIIC online [Reporting Nonviable MDH Vaccine to MIIC \(www.health.state.mn.us/people/immunize/miic/train/nonviable.pdf\)](http://www.health.state.mn.us/people/immunize/miic/train/nonviable.pdf).
- Keep nonviable vaccine documentation for three years (if you report nonviable vaccine via MIIC, you do not need to keep a paper copy).
- Once you have determined vaccine is nonviable, remove it from your storage unit and mark it “Do Not Use” to avoid unintentional use.
- For multiple dose vials, refer to the product’s package insert regarding the expiration and beyond-use date. Package inserts for vaccines can be found on IAC’s [Package Inserts & FDA Product Approvals page \(www.immunize.org/fda/\)](http://www.immunize.org/fda/).
- If you report vaccine for return, you will receive an email with shipping labels from “UPS Quantum View [pkginfo@ups.com].”

11b. Manage MnVFC vaccine efficiently for Replacement Method sites

Take monthly vaccine inventory, order only the amount of vaccine you need, rotate stock, and transfer vaccine that is nearing expiration to other sites to prevent wasting vaccine.

Manage inventory

- Rotate your vaccine stock so vaccine due to expire first is in front.
 - Vaccine must be rotated every week or when a new shipment comes in (whichever happens more frequently).
- Keep vaccine in the original packaging to make managing inventory easier.

Track and order MnVFC vaccine based on administration data

- Develop policies and procedures related to how your site operationalizes the replacement method of vaccine management.
- The vaccine coordinator or designee will run a monthly report that shows doses of private vaccine given to MnVFC-eligible children. Analyze the vaccine administration data to track doses and determine your MnVFC vaccine order. Every dose administered must be documented to determine the number of doses needed to order.
 - The preferred report to use is the [Doses Administered by Eligibility Report \(DAER\) \(www.health.state.mn.us/people/immunize/miic/train/dar.pdf\)](http://www.health.state.mn.us/people/immunize/miic/train/dar.pdf) in MIIC.
 - Another option is to run your own report (e.g., through electronic health record or billing data, etc.), but to use this option, you must periodically compare your data to make sure it aligns with the DAER.
- When providers have administered the minimum order amount of a given vaccine to MnVFC-eligible patients, they may place an order to replenish those privately purchased doses. MnVFC vaccine ordered must replace doses previously administered to MnVFC-eligible patients; vaccine ordered cannot exceed the number of doses given.
 - For example, you can only order polio after administering 10 doses of polio to MnVFC-eligible patients. If you have administered 12 doses of polio you can order 10 doses now and after you administer eight more doses you can order an additional 10 doses.
- Order the same vaccine type that was administered to MnVFC-eligible patients.
 - For example, if patients have received Infanrix vaccine, you can replace the doses with any of the DTaP vaccines regardless of presentation or brand. You are not able to replace those doses with a different vaccine like Hepatitis A or a combination vaccine like DTaP-HepB-IPV.
- It is an expectation that enrolled sites will order vaccine at least every 12 months.

- If your site does not order vaccine in a twelve-month period, MnVFC staff may follow-up with you to discuss the reason behind the lack of ordering.
- Order vaccine online through the [Minnesota Immunization Information Connection \(MIIC\) \(www.health.state.mn.us/miic\)](http://www.health.state.mn.us/miic).
 - If your site is not set up for ordering in MIIC, contact the MIIC Help Desk at health.miichelp@state.mn.us.
- You must include current storage unit temperatures with each order.

Track your MnVFC vaccine orders in MIIC

- In MIIC, select *View Vaccine Management* to track the shipment status of your MnVFC vaccine orders.
- Influenza vaccine product requests can also be tracked under *Manage Special Vaccine* event in MIIC.
- Visit [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/train/managevax.html\)](http://www.health.state.mn.us/people/immunize/miic/train/managevax.html) for a detailed guide on how to create and view the shipping status of your MnVFC vaccine orders in MIIC.

Transferring vaccine

- If you want to receive MnVFC vaccine from a site that is not within your system, you need to have administered at least as many doses of that type of vaccine to MnVFC-eligible children. These will count as doses from the MnVFC program in the same way as doses ordered from MDH.
- Only full, sealed vials or unopened pre-filled syringes can be transferred.
- If you want to send vaccine to another site, identify a site, call them to make sure they can use the vaccine, have space to store it, and someone will be there to receive it.
- Report all MnVFC vaccine that is transferred to another site using the *Vaccine Transfer Record*.
- Keep one copy, enclose one copy with the vaccine, and send one copy to the MnVFC program.
 - Whether you are sending or receiving a vaccine transfer, you must keep your copy of the *Vaccine Transfer Record* for three years.
- Follow CDC and manufacturer specifications for maintaining the recommended temperature range (between 36°F and 46°F or between 2°C and 8°C) during transport of vaccine.
 - Guidance for packing and transporting vaccine is available in [Packing Vaccines for Transport during Emergencies \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).
- You must use a continuous temperature monitoring device with a valid Certificate of Calibration.

Manage nonviable vaccine

- All nonviable MDH vaccine must be reported to MDH. We recommend you report wastage on a monthly basis. Vaccine that is expired or exposed to out-of-range temperatures and is in its original, unopened vial or pre-filled syringe can be returned to McKesson Specialty Distribution within six months of expiration.
- There are two categories of nonviable vaccine: Returned and wasted.
 - **Returned:** This is nonviable vaccine in its original, unopened vial or syringe. Examples of vaccine that should be reported for return include:
 - Expired vaccine.
 - **Note:** Do not return vaccine as “expired vaccine” before its expiration date, including influenza vaccine, unless it was short dated by the manufacturer.

- Vaccine that is recalled by the manufacturer.
- Vaccine that is nonviable due to exposure to out-of-range temperatures.
- **Wasted:** This is nonviable vaccine that should not be returned and should be properly disposed of according to your policy. Examples of vaccine that should be reported as wastage include:
 - Vaccine drawn into the syringe but not administered.
 - Vaccine in open vial but doses not administered.
 - Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial.
- How to report nonviable MDH vaccine:
 - MIIC online: [Reporting Nonviable MDH Vaccine to MIIC \(www.health.state.mn.us/people/immunize/miic/train/nonviable.pdf\)](http://www.health.state.mn.us/people/immunize/miic/train/nonviable.pdf).
 - If you report vaccine for return, you will receive an email with shipping labels from “UPS Quantum View [pkginfo@ups.com]”.
- Keep nonviable vaccine documentation for three years. (If you report non-viable vaccine via MIIC, you do not need to keep a paper copy).
- Once you have determined vaccine is nonviable, remove it from your storage unit and mark it “Do Not Use” to avoid unintentional use.
- For multiple dose vials, refer to the product’s package insert regarding the expiration and beyond-use date. Package inserts for vaccines can be found on IAC’s [Package Inserts & FDA Product Approvals page \(www.immunize.org/fda/\)](http://www.immunize.org/fda/).

12. Post an anaphylaxis protocol

- Develop and clearly post an anaphylaxis protocol.
 - Ensure staff are properly trained on your anaphylaxis protocol to respond to an emergency related to vaccine administration.
- An anaphylaxis protocol must be clearly posted in the area where vaccines are administered. For an example of a protocol, review *Medical Management of Vaccine Reactions in Children and Teens* and *Medical Management of Vaccine Reactions in Adult Patients* by the Immunize.org.
 - The protocol must be reviewed at least every three years and signed and dated by your medical provider.
 - All staff who administer vaccines should maintain current emergency response skills:
 - Know the signs of anaphylaxis and be currently certified in cardiopulmonary resuscitation (CPR).
 - Review the protocol with all staff that administer vaccine and care for patients who receive vaccine
 - both when they are hired and each year after that.
 - Emergency supplies must be readily available where vaccines are administered. On a monthly basis, assign staff to check that emergency supplies have not expired and to replenish supplies after an anaphylaxis event has occurred.
 - Provider should plan for the availability of at least three doses of epinephrine [CDC: Preventing and Managing Adverse Reactions \(www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html\)](http://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html).
 - Assign a staff member to submit a report to [Vaccine Adverse Event Reporting System \(VAERS\) \(https://vaers.hhs.gov\)](http://vaers.hhs.gov) in the event of an adverse reaction following vaccine administration.

How to be Accountable in the MnVFC Program

13. Assign a vaccine coordinator and backup vaccine coordinator

- Designate a vaccine coordinator and backup vaccine coordinator to oversee site administrative immunization activities, ordering and vaccine management activities.
- Notify us of all vaccine coordinator and backup vaccine coordinator changes by completing the [MnVFC Contact Update Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY).
- Have written immunization staff responsibilities. This manual can fulfill this requirement if staff read the entire manual and sign the **Signature Page**.
- The vaccine coordinator and backup vaccine coordinator must complete the MnVFC Online Training.

Assign a vaccine coordinator and backup vaccine coordinator

- Assign staff to the roles of vaccine coordinator and backup vaccine coordinator. Train them on the required activities listed below. Vaccine coordinator is responsible for all activities and can assign some activities to the backup vaccine coordinator (or other designee).
- Vaccine coordinator is the primary MnVFC/UUAV contact at each site. All sites are required to have a vaccine coordinator on-site. This person is ultimately responsible for the management of vaccine and ensuring their site complies with MnVFC program requirements. They receive MIIC vaccine order confirmation emails for MnVFC orders.
- Backup vaccine coordinator is the secondary MnVFC contact at each site. All sites are required to have a fully trained backup vaccine coordinator who is responsible when the primary vaccine coordinator is unavailable. They receive MIIC vaccine order confirmation emails for MnVFC orders.
- Notify us of all vaccine coordinator and backup vaccine coordinator changes by completing the [MnVFC Contact Update Form \(https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY\)](https://redcap.health.state.mn.us/redcap/surveys/?s=HTF4FJ7W734XKJWY).

Vaccine coordinator and backup vaccine coordinator responsibilities

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, (or backup vaccine coordinator if the vaccine coordinator is unavailable) including:

- Develop and maintain the Vaccine Management Plan.
- Monitor storage and handling and vaccine administration practices in the facility.
- Oversee vaccine ordering and transfer vaccine that is nearing expiration to another MnVFC-enrolled site to avoid wastage.
- Replacement method sites must run monthly vaccine reports and track data to inform MnVFC vaccine ordering.
- Ensure and document annual management training for designated staff, as well as train new staff upon hire.
- Participate in and document completion of annual training on VFC requirements.
- Store all required documentation for three years, or longer if required by state statutes or rules, even in the case of provider retirement or provider location closure.
- To effectively perform their duties, the vaccine coordinator and backup vaccine coordinator must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.

- Communicate with the MnVFC program. These people will receive regular communications from the MnVFC program by mail, phone, and email. They will need to share some of it with other staff.
 - Complete the MnVFC Online Training on [Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).
 - Sign up to receive [MnVFC Announcements \(www.health.state.mn.us/people/immunize/hcp/mnvfc/announcements.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/announcements.html) via email.
 - Sign up for [Got Your Shots? News \(www.health.state.mn.us/people/immunize/hcp/gys/index.html\)](http://www.health.state.mn.us/people/immunize/hcp/gys/index.html) and the [Immunize.org IZ Express \(www.immunize.org/subscribe/\)](http://www.immunize.org/subscribe/).
- Train other staff that have vaccine-related responsibilities (for example, the front desk staff who receives immunization shipments and providers giving immunizations) as well as new staff upon hire and keep a log to document attendance.
- Develop policies and procedures related to vaccine management. This manual can fulfill this requirement if your staff read the entire manual, sign the **Signature Page**, and complete the emergency plan and attach an anaphylaxis protocol to the manual (review Introduction to the MnVFC Policies and Procedures Manual for more information).
- Download and review temperature data weekly.
- Make sure all ACIP-recommended vaccines for your patient population are ordered, received, stored, and handled properly.
- Be aware of where vaccines are stored in all site clinics and be responsible for making sure they are meeting the requirements.
- Designate on-site staff to document the min/max temperature in each storage unit at the start of each day the site is open.
- Respond to temperature excursions (out-of-range temperatures).
- Conduct inventory of vaccines at least monthly and with each order.
- Check expiration dates and rotate stock weekly.
- Keep a file of vaccine inventory logs and packing slips.
- Keep a list of names and phone numbers of key contacts like the generator repair company and packing materials suppliers.

14. Follow up on feedback you receive from site visits

- Participate in a MnVFC site visit every one to two years to ensure that you are meeting MnVFC program requirements.
- Follow up on improvement or corrective plans you receive after a MnVFC site visit.
- Cooperate with MnVFC site reviewer staff performing an unscheduled storage and handling site visit if your site is selected to be visited.

MnVFC compliance site visits

- You will participate in a site visit by an MDH or local public health staff person, called a MnVFC site reviewer, every one to two years.
- You will need to have three months of temperature documentation data available at site visits for each vaccine storage unit for the site reviewer to review.
- Site visits take approximately two hours.
- They will offer you support and guidance and ensure you are meeting the federal and state MnVFC requirements.

- The MnVFC site reviewer will:
 - Contact you in advance of each visit.
 - Encourage you to invite other staff members who could contribute to the visit.
 - Share resource materials during the visit.
 - Provide you with a site visit summary.
- If your site is not meeting a specific program requirement, they will work with you to develop a corrective action plan that you will need to follow within a specified time frame, usually 30 days.
- You may also call on MnVFC site reviewers for in-service training, guidance in developing policies and procedures and troubleshooting vaccine-related concerns.

Unscheduled site visits

- The MnVFC program is required by CDC to perform unscheduled storage and handling visits to serve as “spot checks” for proper storage and handling practices.
- These visits ensure all MnVFC-eligible children are receiving properly managed, viable vaccines and provide education about requirements and best practices related to storage and handling.
- As part of your signed *MnVFC Provider Agreement*, your participation in unscheduled visits is required. We appreciate your cooperation when we arrive at your site unannounced.

15. Maintain your enrollment in the MnVFC program

- Sites must complete the following required reports and trainings to maintain their enrollment:
 - *MnVFC Program Provider Agreement*.
 - *MnVFC Annual Report of Immunized Pediatric Patients*.
 - MnVFC Online Training.
 - *Replacement method sites must also complete the Replacement Method of Vaccine Management Agreement.*

Maintain your enrollment in MnVFC

Each site that stores and/or administers MnVFC vaccine must enroll in the MnVFC program and have their own personal identification number (PIN). Sites are responsible for maintaining their enrollment in the program by completing the requirements below.

Every 24 months requirement

Submit the ***MnVFC Program Provider Agreement***

- All sites need to complete and have their medical director sign a *MnVFC Program Provider Agreement* every 24 months in odd years.
- A link to complete the *MnVFC Program Provider Agreement* will be emailed. More information is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).

Every 12 months requirements

Submit the ***MnVFC Annual Report of Immunized Pediatric Patients***

- Complete and submit the *Minnesota Vaccines for Children (MnVFC) Program Annual Report of the Number of Immunized Pediatric Patients* by Nov. 30. This report is an unduplicated count of all patients 0 through 18 years of age that received an immunization between Oct. 1 and Sept. 30.

- If you redistribute to satellite sites, submit one annual report that includes data from those sites.
- A link to complete the *MnVFC Annual Report of Immunized Pediatric Patients* will be emailed to your system-level contact (if you have one), or it will be emailed to your vaccine coordinator when it becomes available. More information is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).
- Sites that track immunizations with dose-level eligibility (DLE) information in MIIC can use the *Request MnVFC Reports in MIIC* to produce data for this report. For more information, see the MnVFC Reports in MIIC user guidance on [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/train/managevax.html\)](http://www.health.state.mn.us/people/immunize/miic/train/managevax.html).
- Ordering privileges may be suspended if the *MnVFC Annual Report of Immunized Pediatric Patients* is not submitted by Nov. 30.

Replacement method sites must submit the *MnVFC Replacement Method Agreement*

- Complete and sign a *Replacement Method of Vaccine Management Agreement* by Nov. 30 of each year. The Replacement Agreement is in addition to the Provider Agreement.
- Systems may sign one Replacement Method of Vaccine Management Agreement on behalf of all sites using the replacement method within the system. A list of the MnVFC PINs for all of the sites included in the agreement must be attached.
- If you don't submit the *Replacement Method of Vaccine Management Agreement* and/or meet the requirements of the agreement, you will be required to switch to the Separate Stock method of vaccine management.

Complete the MnVFC Online Training

- Your site's vaccine coordinator and backup vaccine coordinator must complete the MnVFC Online Training each year by Nov. 30 to meet the federal VFC education requirement.
- The MnVFC Online Training is available on [MnVFC Required Annual Reports and Trainings \(www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/required.html).
- After completing the training, print the completion certificate and keep it with your MnVFC documents for three years. You will be asked to show your certificate during your MnVFC site visit.

16. Avoid fraud and abuse

- Take responsibility for being aware of and following MnVFC requirements.
- Call the MnVFC program if you have questions about requirements, policies, and procedures.
- Cooperate with any investigation/inquiry related to potential fraud and/or abuse of the MnVFC program and any follow-up requirements, such as additional staff training.

Potential fraud and abuse

- Fraud 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 provider practices that are inconsistent with sound fiscal, business, or medical practices. It results 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 healthcare.
- Report fraud or abuse to the MnVFC program by calling 651-201-5522 or emailing health.mnvfc@state.mn.us.
- All instances of possible fraud or abuse will be investigated on a case-by-case basis.

- If you have not met MnVFC requirements or followed MnVFC procedures as outlined in this manual, but the MnVFC program finds no intentional deception, misrepresentation, or negligence on your part, you may be required to participate in training and/or to take other actions to rectify the situation.
- If the MnVFC program finds evidence of intentional deception, misrepresentation, or negligence on your part, the situation will be further investigated for potential enforcement of relevant laws including fraud and abuse, consumer protection, and professional licensure.
- Examples of potential fraud and/or abuse:
 - Providing MnVFC vaccine to non-eligible patients.
 - Selling or otherwise misdirecting MnVFC vaccine.
 - Billing a patient or third party for MnVFC vaccine.
 - Charging more than the maximum allowable fee for administration of a MnVFC vaccine.
 - Not providing MnVFC vaccine to an eligible patient because they are unable to pay the administration fee.
 - Failing to screen and document patients for MnVFC eligibility at every visit.
 - Failing to maintain MnVFC records for a minimum of three years.
 - Failing to fully account for MnVFC vaccine.
 - Failing to properly store and handle MnVFC vaccine, including not responding appropriately to temperature excursions.
 - Wasting MnVFC vaccine.
 - Over ordering MnVFC vaccine.
 - Failing to comply with any part of the provider agreement.
 - Replacement method sites: Not tracking private vaccine doses administered to MnVFC-eligible children.
 - Replacement method sites: Not ordering MnVFC vaccine doses to replace private doses administered.
 - Replacement method sites: Failing to comply with any part of the replacement agreement.

17. Separate stock method sites replace MnVFC vaccine wasted due to negligence

MnVFC vaccine that has been wasted due to negligence must be replaced on a dose-for-dose basis with privately purchased vaccine. If nonviable vaccine was administered, you may also be required to purchase vaccine to revaccinate patients.

Replace wasted MnVFC vaccine

- The MnVFC program will review all instances of spoiled or expired MnVFC vaccine on a case-by-case basis. This review will help determine whether negligence was involved. Negligent waste of vaccine may be considered fraud or abuse of the MnVFC program.
- If negligence is found and restitution is necessary, the MnVFC program will send you a letter informing you of the number of doses of each vaccine that must be replaced on a dose-for-dose basis with privately purchased vaccine.
- You must replace vaccine upon receipt of the letter. The MnVFC program will stop supplying you with vaccine until all of the nonviable vaccine is replaced.

- Providers must submit receipt of purchase of vaccine to the MnVFC program within 90 days demonstrating that all doses were replaced appropriately.
- You may file an appeal with the MnVFC program by mail if you believe you can offer proof that the waste of vaccine was not due to negligence.
 - Use the *Vaccine Restitution Appeal Form* on [Vaccine Management Forms \(www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html\)](http://www.health.state.mn.us/people/immunize/hcp/mnvfc/forms.html), or include the same information contained on the form.
 - The appeal must be signed by your medical director or by your local health director if you are a public health department.
- Examples of situations that may require restitution:
 - Failure to rotate or transfer vaccine that results in expired vaccine.
 - Drawing up vaccine before screening patients.
 - Not receiving or storing vaccine properly.
 - Leaving a refrigerator or freezer unplugged or an electrical breaker switched off.
 - Leaving a refrigerator or freezer door open or ajar.
 - Not repairing or replacing a broken refrigerator/freezer immediately.
- Examples of situations that do not require restitution because they are out of your control:
 - A shipment is not delivered to you on time or is damaged in transit.
 - You are unable to take action during a power outage.
 - A vial is accidentally dropped or broken.
 - Vaccine drawn after screening for contraindications and parental education but not administered due to parental refusal or a change in the physician orders.

Contacts and Resources

Phone/Email

CDC Immunization Information Contact Center, for general immunization and vaccine questions:

- Phone: 800-232-4636 (English and Spanish)
- Phone: 800-232-6348 (TTY)
- Contact CDC-INFO online form: <https://wwwn.cdc.gov/dcs/ContactUs/Form>

MnVFC Program

- Phone: 651-201-5522
- Email: health.mnvfc@state.mn.us

MDH Immunization Program, for Minnesota-specific questions, including MnVFC, Minnesota Immunization Information Connection (MIIC), Minnesota School Law, and to order immunization materials:

- Toll free phone: 800-657-3970
- Metro: 651-201-5503

Web

- [Minnesota Vaccines for Children Program \(MnVFC\) \(www.health.state.mn.us/vfc/\)](http://www.health.state.mn.us/vfc/)
Includes MnVFC overview, forms used by MnVFC providers, and an archive of update notices sent to MnVFC providers.
- [Vaccine Ordering and Management in MIIC \(www.health.state.mn.us/people/immunize/miic/train/managevax.html\)](http://www.health.state.mn.us/people/immunize/miic/train/managevax.html)
Includes user guides on how to create and view vaccine orders, report dose-level eligibility to MIIC, and how to use MnVFC reports in MIIC.
- [Immunization \(www.health.state.mn.us/immunize/\)](http://www.health.state.mn.us/immunize/)
Contains links to other pages listed below.
- [Immunization Best Practices \(www.health.state.mn.us/people/immunize/hcp/bestpractices.html\)](http://www.health.state.mn.us/people/immunize/hcp/bestpractices.html)
Information needed to make sure patients are properly immunized and vaccine is stored correctly.
- [Minnesota Immunization Information Connection \(MIIC\) \(www.health.state.mn.us/miic/\)](http://www.health.state.mn.us/miic/)
- [Immunize.org \(www.immunize.org\)](http://www.immunize.org/)
Immunize.org is a non-profit agency that provides CDC-approved materials, including Vaccine Information Statements (VISs) in 32 languages, screening questionnaires, anaphylaxis standing orders.
 - [Subscribe to IZ Express \(www.immunize.org/subscribe/\)](http://www.immunize.org/subscribe/)
A weekly email that includes the latest vaccine recommendations and licensures, new and updated VISs, and practical vaccination resources.
 - [Vaccine Manufacturers: Contact and Product Information \(www.immunize.org/clinical/external/manufacturers/\)](http://www.immunize.org/clinical/external/manufacturers/)
 - [Food and Drug Administration: Package Inserts & EUAs \(www.immunize.org/official-guidance/fda/pkg-inserts/\)](http://www.immunize.org/official-guidance/fda/pkg-inserts/)

- [Centers for Disease Control and Prevention \(CDC\) Vaccines & Immunizations \(www.cdc.gov/vaccines/\)](http://www.cdc.gov/vaccines/)
Includes links to VFC program, vaccine safety information, resource materials for parents and health professionals, and information on the National Childhood Vaccine Injury Act.
- [Vaccine Storage and Handling Resources \(www.cdc.gov/vaccines/hcp/storage-handling/resources.html\)](http://www.cdc.gov/vaccines/hcp/storage-handling/resources.html)
Online training videos and resource materials including checklists, logs, records, and posters.
- [VAERS \(https://vaers.hhs.gov/\)](https://vaers.hhs.gov/)
Report online or download the report form.
- [Preventing and Managing Adverse Reactions \(www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html\)](http://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html)
- Additional temperature monitoring guidance:
 - [Temperature Monitoring Best Practices for Refrigerated Vaccines–Celsius \(C\) \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/a-vax-temp-best-practices-fridge-c.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/a-vax-temp-best-practices-fridge-c.pdf)
 - [Temperature Monitoring Best Practices for Frozen Vaccines–Celsius \(C\) \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/b-vax-temp-best-practices-frozen-c.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/b-vax-temp-best-practices-frozen-c.pdf)
 - [Temperature Monitoring Best Practices for Refrigerated Vaccines–Fahrenheit \(F\) \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/temp-fridge.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temp-fridge.pdf)
 - [Temperature Monitoring Best Practices for Frozen Vaccines–Fahrenheit \(F\) \(www.cdc.gov/vaccines/hcp/admin/storage/downloads/temp-frozen.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temp-frozen.pdf)