VFC Program Basics

About the VFC program

The Vaccines for Children (VFC) Program provides vaccines to children whose parents or guardians may not be able to afford them. Serving as one of the nation's most important contributors to health equity, the program helps ensure that all children have a better chance of getting their recommended vaccinations on schedule and staying healthy.

The VFC program was created on August 10, 1993, when congress passed the Omnibus Budget Reconciliation Act. The VFC program was created in response to the measles epidemic in the United States during 1989–1991.

The goal of the VFC Program is to ensure that a VFC Program-eligible child does not contract a vaccine-preventable disease because of their parent or guardian's inability to pay for the vaccine.

VFC enrollment

If you are interested in becoming a VFC provider, please e-mail the program at vfc@wisconsin.gov. A general overview of the steps to become a provider are outlined below.

1. Get a WIR account: Before a provider can enroll in the VFC Program, they must have a Wisconsin Immunization Registry (WIR) account. WIR is an immunization database that tracks immunization records for children and adults. If you are not currently a WIR user, please contact the WIR Help Desk at 608-966-9691 to begin the process.
2. Complete VFC enrollment forms: Once you've become a WIR user e-mail the VFC program at vfc@wisconsin.gov to express your interest in becoming a provider and for enrollment forms and requirements.
3. Prepare: Review the VFC Resource Guides (under "Resources and forms") for requirements and begin implementation and complete the new coordinator training.
4. Enrollment site visit: During the enrollment visit, providers will receive an overview of all the VFC requirements and assess storage and handling equipment.
5. After the site visit, the provider will receive an e-mail confirming enrollment.

Key staff

Primary and back-up coordinator

At a minimum, the VFC program requires providers to have a fully trained primary and backup coordinator. The primary coordinator must be physically on-site during most clinic hours and is responsible for day-to-day operations of the VFC Program. The backup coordinator must be readily available to perform the same tasks

whenever the primary is not present. If any responsibility is delegated to another staff member (such as temperature monitoring, vaccine inventory) the primary coordinator must ensure adequate training occurs.

If there is a change in VFC staff at the clinic, these changes must be communicated to the program using the Change of Information Form. Once the form is submitted to the program, please make appropriate updates in WIR. VFC providers are required to ensure that all key staff are always trained on VFC program requirements.

Medical director

The VFC medical director takes responsibility for the practice's use of VFC vaccines and agrees that all staff will follow the outlined requirements. The medical director must be licensed to administer pediatric vaccines in Wisconsin.

If the VFC medical director changes, notification must be made to the program. Medical director changes can be communicated to the program using the Change of Information Form.

Annual re-enrollment

Each VFC site is required to complete the annual re-enrollment process in WIR. Through re-enrollment, providers agree to comply with VFC Program requirements, update practice information, and provide updated estimates of all VFC eligible and privately insured children who will be immunized in the coming year. The VFC Program then verifies that the practice is eligible for continued enrollment. Providers will be notified when re-enrollment begins.

Annual training

The primary and back-up coordinators must complete annual VFC training. In addition, any staff responsible for the viability of the vaccine must be trained, providers may use a train the trainer model or complete the annual training (staff responsible for temperature documentation). Providers will be notified of the annual training requirements once available.

Certificates of completion must be kept on file as proof of training. These documents may be requested during compliance visits. Please also document the completed training in the clinic's vaccine management plan.

Site visits

Providers enrolled in VFC agree to participate in required site visits:

- Compliance site visits – a scheduled visit conducted every two years to offer guidance and ensure you are meeting the VFC requirements.
- Unannounced site visits – an unscheduled visit that can happen at any time and serves as a spot check of proper storage and handling practices.

Records retention

All VFC documentation and records must be kept for a minimum of three years. The documents may be stored in a paper-based or electronic format. Examples of documents that should be kept include temperature logs, vaccine ordering records, training records, packing slips, borrowing forms, and re-enrollment documentation**.**

Suspension and termination

Suspension

A provider's ordering privileges might be suspended due to non-compliance with VFC Program requirements. Once the issue has been resolved, ordering privileges will be reinstated. Examples of reasons for suspension include not completing annual training or re-enrollment.

Termination

Providers may voluntarily terminate enrollment in the program. Providers must notify the program at vfc@wisconsin.gov and agree to program requirements of termination which involve vaccine accountability. This could mean returning vaccine or transferring to another VFC location.

The VFC Program also might remove a provider from the VFC Program for failure to comply with program requirements. Examples of reasons for termination include but are not limited to:

- Failure to comply or resolve compliance issue.
- Fraud or abuse involving VFC supplied vaccines.
- Inadequate vaccine storage equipment or practices.
- No VFC orders over a 12-month period.

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Responsibilities of a Vaccine Coordinator

At a minimum, the VFC program requires providers to have a fully trained primary and backup coordinator. The primary coordinator must be physically on-site during most clinic days and is responsible for day-to-day operations of the VFC Program. An individual is not allowed to be a primary coordinator for more than one VFC location. The backup coordinator must be readily available to perform the same tasks whenever the primary is not present. If any responsibilities are delegated to another staff member, the primary coordinator must ensure adequate training occurs. Providers must report when coordinators change using the Change of Information form. Once the form is submitted to the program, please make appropriate updates in WIR. New coordinators must complete the New Coordinator Training.

New coordinator checklist

☐ Complete the Change of Information form and email it to VFC@wisconsin.gov.
☐ Update the coordinator information in WIR.
☐ Complete the New Coordinator Training (PowerPoint slides).
☐ Review VFC Resource Guide for program requirements.

Vaccine coordinator checklist

☐ Have a Vaccine Management Plan. Update the plan annually or when a change occurs.
☐ Assess and document minimum and maximum temperatures daily along with date, time, and initials.
☐ Download and review temperature data, weekly is recommended, but at a minimum monthly.
☐ Ensure all digital data loggers have a current and valid certificate of calibration.
☐ Ensure the clinic has a back-up digital data logger (DDL) available.
☐ Respond immediately to temperature excursions.
☐ Maintain storage unit setup, ensuring separation of private and public vaccine stock.
☐ Manage vaccine inventory.
- Place vaccine orders in WIR.
- Accept vaccine orders in WIR upon arrival.
- Be present for vaccine deliveries.
- Maintain vaccine inventory in WIR.
- Rotate stock as needed.
- Maintain vaccine borrowing records
- Return expired vaccine.

☐ Report all issues with vaccine deliveries within one hour.
☐ Complete annual re-enrollment and training.
☐ Maintain all VFC records for a minimum of three years.
☐ Understand VFC eligibility and ensure proper screening and documentation.
☐ Understand the clinic's VFC billing practices.

For further questions, contact your Regional Rep/Site Monitor or the VFC program at VFC@wisconsin.gov

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WI VFC Program Contacts

General contact information

Email: VFC@wisconsin.gov

Website: https://www.dhs.wisconsin.gov/immunization/vfc-provider.htm

Fax: 608-267-9493

Regional staff

Northern Region

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Southeastern Region

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Jill Gasperic Jill.Gasperic@wi.gov

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Wisconsin Immunization Registry (WIR)

The Wisconsin Immunization Registry (WIR) was developed to record the immunization dates of Wisconsin's children and adults, as well as to forecast when upcoming immunizations are due. All VFC providers must have a WIR account to manage their VFC program.

VFC/WIR requirements

- ☐ Maintain accurate clinic information including name, address, and delivery windows.
- ☐ Maintain VFC primary and backup coordinator contact information.
- ☐ Enter all administered immunizations into WIR within three days.
- ☐ Provide doses administered data at the dose level (known in WIR as "Dose Level Eligibility").
- ☐ Order VFC vaccine (unless specific instructions are given).
- ☐ Pre-book influenza vaccine.
- ☐ Maintain accurate VFC inventory in WIR.
- ☐ Document all wasted/spoiled doses in WIR.
- ☐ Accept all vaccine transfers (for example, receipt of orders).
- ☐ Complete VFC annual re-enrollment.
- ☐ Manage WIR users, ensure everyone has their own login, and terminate access to individuals who leave the clinic (IR Administrator access only).

WIR resources and trainings

- Introduction to WIR (PDF)
- Accessing WIR (PDF)
- Managing access (PDF)
- WIR maintenance (PDF)
- Inventory management (PDF)
- Managing clients (PDF)
- Immunizations (PDF)
- Mass Vaccinations (PDF)
- Ad hoc reports (PDF)
- Benchmark reports (PDF)
- Reminder/Recall report (PDF)
- VFC reports (PDF)
- WIR acronyms and glossary (PDF)
- WIR provider FAQs (PDF)

See the WIR website under "Training Resources" for updated information.

WIR contact information

WIR Help Desk
Phone: 608-266-9691
Email: dhswirhelp@dhs.wisconsin.gov
Website: https://www.dhfswir.org/

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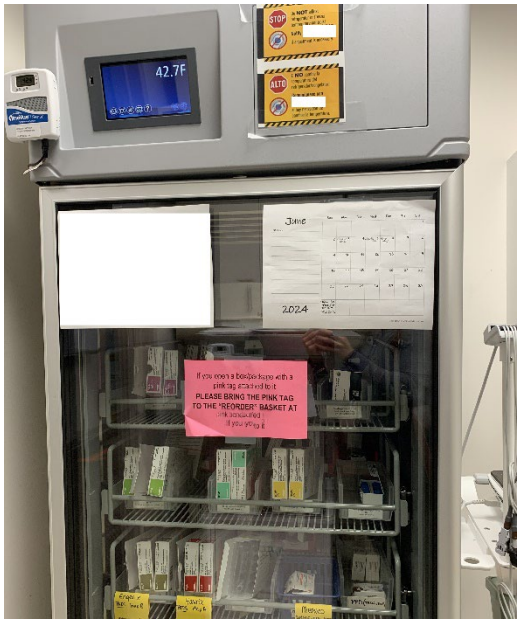
Vaccine Storage Unit and Setup

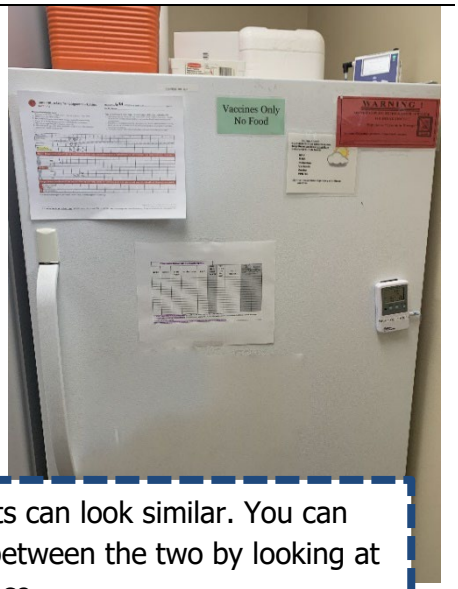
All VFC providers are required to properly store and handle vaccines. This starts by having the proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed.

Vaccine storage unit type

The VFC program recommends the following vaccine storage unit types (in order of preference): pharmaceutical grade/purpose-built units, commercial units, and household units. A dorm-style may never be used to store vaccine.

Pharmaceutical Grade	Commercial	Household
Best	*Good*	*Discouraged*
Designed for storage of biologics, including vaccines, they maintain temperatures more consistently.	Units not built for vaccine storage and instead intended for commercial food use.	Unit built for food storage with compressors less powerful than commercial units.





Commercial and household units can look similar. You can use the manual to distinguish between the two by looking at compressor size and performance.

Pharmaceutical grade units

- These units can be stand-alone or combination units. The units can vary in size from a compact, under-the-counter style to a large stand-alone unit.
- These units have good temperature recovery when the unit has been opened to get vaccines and nearly all the internal space in the unit can be used to store vaccines. Use water bottles in open space unless the manufacturer states not too.
- Pharmaceutical grade units do include vending or doorless style units. Please contact the VFC program to see if your unit meets VFC program requirements.

Commercial grade units

- These are acceptable but may not provide consistent temperatures as well as purpose-built units, and they are not built for vaccine storage.
- Vaccine cannot be stored in the doors, vegetables bins, or on the floor of these units and water bottles must be used for temperature maintenance.

Household units

- If you are using a combination household unit, only the refrigerator section can be used for vaccine storage. A separate, stand-alone freezer must be in use.
- Vaccine cannot be stored in the doors, vegetables bins, or on the floor of these units and water bottles must be used for temperature maintenance.
- If a temperature excursion occurs the program may request a provider obtain a new vaccine storage unit that is either a purpose-built or commercial unit.
- Household combination units are not acceptable for new VFC providers enrolling in the program after July 2024, new equipment must be purchased.

Dorm-style units

- Not an acceptable unit for vaccine storage at any time.
- A dorm-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Storage unit size

Storage units must have enough room to store the largest inventory a provider location might have at the busiest point in the year without crowding to promote good airflow. The unit should have enough room to store routine vaccine plus additional room for seasonal vaccines when applicable.

The following guidance can be used to estimate size needs:

Public (on-hand) + private (on-hand) = Current Inventory X1.25 = maximum doses

> 2,000 doses	May need two units
1000-2000 doses	40 cu ft
900-1000 doses	36 cu ft
801-900 doses	23 cu ft
701-800 doses	17-19.5 cu ft
400-700 doses	11-16.7 cu ft
100-399 doses	4.9-6.1 cu ft

Storage unit location

The storage units should be in a well-ventilated location where there is good air circulation. The ideal room temperature is between 68°F and 77°F.

Storage unit setup

Basic setup requirements

- All storage units must have a temperature monitoring device that is a digital data logger.
- Protect the power source for all storage equipment by using "Do Not Disconnect" warning labels at the electrical outlet and circuit breaker.
- Storage units must be plugged into an electrical outlet. Power strips are not allowed to be used.
- Never store food or beverages in the unit with vaccine.

Example of a labeled outlet

Temperature requirements

- Refrigerator: Store between 2°C to 8°C or 36°F to 46°F
- Freezer: Store between: -15°C to -50°C or 5°F to -58°F

Vaccine placement requirements

- Keep private and public vaccines clearly labeled and separated.
- Vaccine must be stored in the original packaging or amber colored bags with the following information: vaccine name, lot number, expiration date, and the NDC number from the box.
- Place vaccines with the earliest expiration date in front of those with a later date.

The picture on the right gives an example of what proper vaccine storage looks like in a pharmaceutical-grade unit.

☒ Vaccine is stored in the original packaging.

☒ Vaccine is separated by stock-type

- Private vaccine labeled yellow.
- Public vaccine labeled red.

☒ Vaccine is well organized.

☒ Vaccine is stored in bins that allow for airflow.

New storage unit setup and routine maintenance

New unit setup

It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday. Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

Recommended routine maintenance

Regular maintenance of vaccine storage units is recommended to ensure proper operation and to maintain temperatures suitable for vaccine storage. Suggested maintenance includes:

- Clean the inside of the storage unit.
- Check door seals and hinges.
- Clean coils or remove dust as needed according to manufacturer's recommendations.
- Prevent frost build-up, defrost freezer according to manufacturer's recommendations.
- Check drain pans, if applicable.
- Test back-up generator, if applicable.

Digital Data Loggers

It is required of all VFC providers to have a calibrated temperature monitoring device in each storage unit. The VFC program requires all temperature monitoring devices be digital data loggers (DDL).

Digital data loggers (DDL) requirements

To meet VFC requirements, the digital data logger must have the following features:

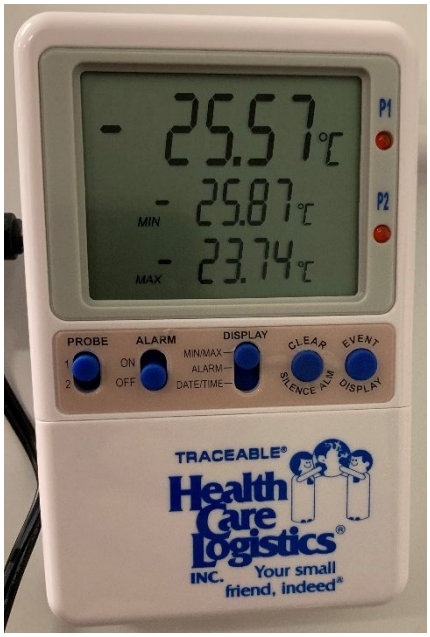
- An active display that can be read from outside the unit and display the minimum, maximum, and current temperature.
- The capacity for continuous monitoring and recording capabilities, where the data can be routinely downloaded and analyzed for review.
- A buffered probe that reflects vaccine temperature (see image on page 3 for examples)
- An alarm for out-of-range temperatures. The alarm can be audible or email, text, or call alerts.

Understanding your DDL

A wide range of digital data loggers are available that have different mechanisms for logging of the temperature data. The two groups available are manual downloads and automatic data downloads.

DDL with manual download

Temperature data usually stored in device's internal memory until downloaded by USB or docking station.



DDL with WiFi/cloud

Models usually send temperature data directly to the cloud or other online application.

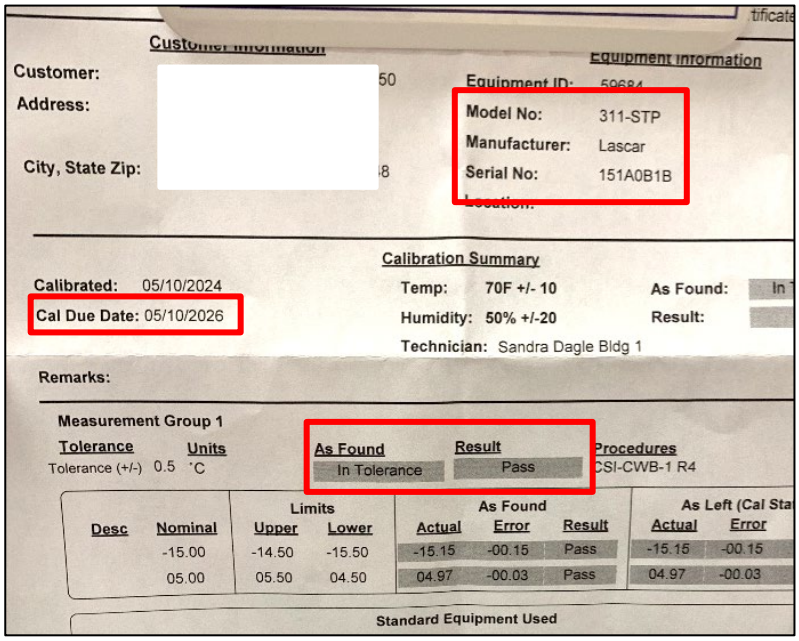
Regardless of the DDL you use, understanding how your device works is critical to temperature monitoring. When learning how to use your device focus on the following:

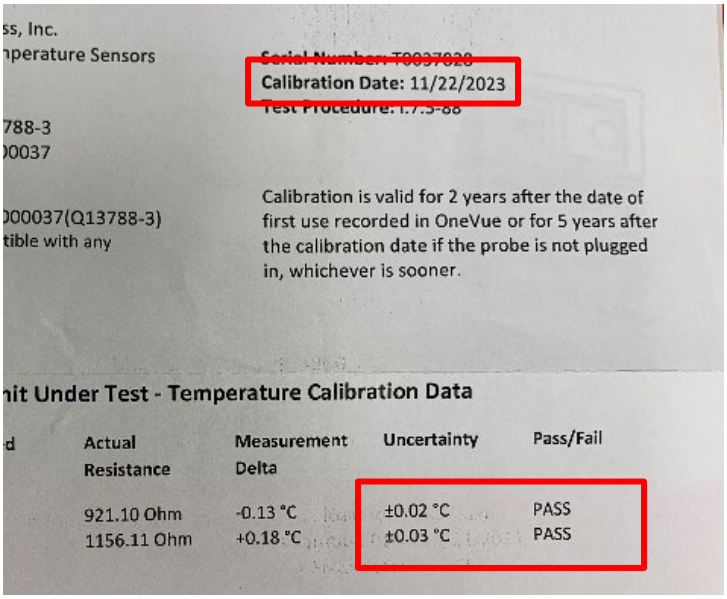
- Understand the digital display.
  - Locate the current, minimum, and maximum readings.
  - Understand what all buttons and icons on the display mean.
- Know how to retrieve and save the temperature data, for example manual download or accessing the cloud.
- Understand how to or when the device resets the minimum and maximum temperatures.
- Understand when your device needs to be recalibrated and how-to recalibrate it.
- Have manufacturer training materials or user guides available.

Certificate of calibration

All DDLs need to have a current and valid certificate of calibration. Calibration testing is required to assure the accuracy of a temperature monitoring device and should be done at least every three years or according to the manufacturer's suggested timeline. Certificates of Calibration must include the following:

- Model/device number and serial number.
- Date of calibration (report or issue date).
- Confirmation the instrument passed testing (or the instrument in tolerance).





Calibration date, due date, and first use date
Different devices may have different recommendations and language referring to when a DDL needs to be calibrated. All certificates will have a calibration date. This is the date the device was last calibrated. Some certificates will provide a due date (see above). This is the date the DDL must be calibrated by. If no date is provided, the DDL must be re-calibrated at a minimum every three years. Some DDLs base the re-calibration date on the date the probe is first installed, referred to the first use date. See the example to the left. The device must be re-calibrated two years after first use.

DDL use and placement

- All vaccine storage units must have a digital data logger.
- All VFC providers must have at least one back-up DDL. The back-up temperature monitoring device should be stored outside of the storage unit until needed and should have a different calibration date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time.
- Providers who transport vaccine must have a DDL that can be used during transport of vaccine.
- Ensure appropriate logging interval is setup. At a minimum the DDL must log temperatures at least every 30 minutes.
- Probe must be placed in the center of the storage unit; the only exception is for units with a built-in port that dictates probe placement.

DDL probe placed in dedicated probe location of a pharmaceutical grade unit.

DDL probe placed in the center of the storage unit.

Temperature Monitoring

1. Temperature ranges

Vaccines must be stored within these ranges:

- Refrigerator: Store between 2.0°C to 8.0°C or 36.0°F to 46.0°F.
- Freezer: Store between -15.0°C to -50.0°C or 5.0°F to -58.0°F.

Any temperature reading outside of the above ranges is a temperature excursion. Exposure to out-of-range temperatures can affect the vaccine and lead to vaccine losses and/or revaccination if administered. **All excursions require follow-up;** requirements are outlined in the temperature excursion section.

2. Temperature review and documentation

Daily temperature review

Daily temperature review of each storage unit is required. The VFC program requires reviewing and documenting the minimum and maximum temperature readings at the beginning of every clinic day. Providers are required to have protocols for reviewing and recording temperature readings in vaccine storage units daily. The process, at a minimum, should include:

- Checking temperatures at the beginning of the clinic day.
- Documenting the minimum and maximum temperatures and then resetting the unit if needed.
- Documenting the current date, time, and name (initials) of the person checking the temperatures.
- Acting if a temperature excursion is identified.

Daily temperature review can be paper-based or electronic. If your system can document the current date, time, and person who checked the temperatures along with the minimum and maximum temperature, electronic documentation is acceptable.

Temperatures should be documented to the tenth decimal place.

5.4°C or 39.3°F

Do not round temperatures to a whole number, especially to determine if an excursion occurred. Due to differences among manufacturer stability reports and rounding, do not apply general rounding rules.

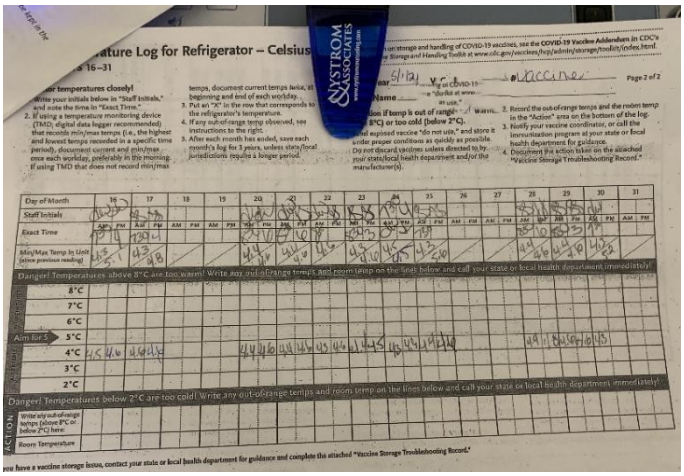
Monitoring the minimum and maximum temperature

This provides the highest and lowest temperature reached since the device was last checked and cleared. Some devices require you to physically reset the minimum and maximum temperatures— this should be done after each reading in the morning. **Not resetting the unit after each reading could cause inaccurate monitoring and leave the vaccine vulnerable to out-of-range temperatures.**

Some devices automatically reset the minimum and maximum temperature at a set time such as at midnight. **It is important that all providers understand the features of your device.**

This image shows an example of acceptable daily temperature monitoring.

For each clinic day, the provider documented the minimum and maximum temperature as well as their initials, date, and time.



Weekly or monthly temperature review

Temperature data from the DDL must be downloaded and reviewed weekly or monthly and when a temperature excursion is identified. It is recommended and best practice to download and review the data weekly; however, it must be downloaded and reviewed, at a minimum, monthly. The logs should be reviewed for temperature excursions that were missed or temperature trends that could indicate a storage unit performance issue. It is recommended to compare daily temperature checks with data downloads to ensure accurate and complete temperature monitoring. These logs should be kept for a minimum of three years, the same as the paper temperature logs.

Looking for temperature log templates?

- Refrigeration – Fahrenheit
- Refrigeration – Celsius
- Freezer – Fahrenheit
- Freezer – Celsius

Best practice for temperature monitoring is to set up the logging interval at 30 minutes. A longer interval time may increase the likelihood that a temperature excursion could be missed. All investigations regarding a possible excursion must be documented.

Example of data download

In the downloaded data you can see a reading is provided every 30 minutes in one and every 15 minutes in the other. Every system will look different, but for the system to meet VFC requirements it must have the ability to generate a similar report as seen in the examples.

P2	Time	Date
4.7 --.--	8:30	4/12/2024
4.72 --.--	8:15	4/12/2024
4.72 --.--	8:00	4/12/2024
4.71 --.--	7:45	4/12/2024
4.72 --.--	7:30	4/12/2024
4.71 --.--	7:15	4/12/2024
4.71 --.--	7:00	4/12/2024
4.75 --.--	6:45	4/12/2024
4.71 --.--	6:30	4/12/2024
4.72 --.--	6:15	4/12/2024
4.73 --.--	6:00	4/12/2024
4.71 --.--	5:45	4/12/2024
4.72 --.--	5:30	4/12/2024
4.73 --.--	5:15	4/12/2024
4.71 --.--	5:00	4/12/2024
4.74 --.--	4:45	4/12/2024
4.73 --.--	4:30	4/12/2024
4.73 --.--	4:15	4/12/2024
4.74 --.--	4:00	4/12/2024

	A	B	C	D
1	Log Time	Temperature(℃)	Temperature2(℃)	
2	2024-03-18 00:06:04	3.9	3.8	
3	2024-03-18 00:36:04	4.1	4.0	
4	2024-03-18 01:06:04	4.2	4.1	
5	2024-03-18 01:36:04	3.7	3.6	
6	2024-03-18 02:06:04	3.5	3.4	
7	2024-03-18 02:36:04	3.7	3.7	
8	2024-03-18 03:06:04	3.8	3.7	
9	2024-03-18 03:36:04	3.8	3.7	
10	2024-03-18 04:06:04	4.2	4.1	
11	2024-03-18 04:36:04	4.3	4.2	
12	2024-03-18 05:06:04	3.9	3.8	
13	2024-03-18 05:36:04	3.7	3.6	
14	2024-03-18 06:06:04	3.8	3.6	
15	2024-03-18 06:36:04	3.5	3.4	
16	2024-03-18 07:06:04	4.0	3.9	
17	2024-03-18 07:36:04	4.2	4.1	

3. Temperature excursions

What is a temperature excursion?

A temperature excursion refers to any storage temperature outside the recommended range for a vaccine.

	Low temperature	High temperature
Refrigerator	1.9°C or colder (35.9°F)	8.1°C or warmer (46.1°F)
Freezer	-50.1°C or colder (-58.1°F)	-14.9°C or warmer (5.1°F)

How to identify and respond to a temperature excursion?

Situations	Examples	Steps to Take
Situation 1: **The unit is currently out of range and the DDL alarm is on.**	*It is a busy clinic day and staff have been in and out of the refrigerator all morning. During the afternoon you start to complete your weekly physical vaccine inventory. Within 10 minutes of starting, the DDL alarm goes off and you record the temperature at 8.2°C.*	Begin to stabilize temperatures in the storage unit. Examples of actions to stabilize temperatures include closing the unit door and checking to ensure a tight seal, checking power supply to the unit, and checking DDL probe placement. Monitor for 30 minutes. If the unit does not return to recommended temperatures, move the vaccines to your back-up storage unit location and begin to follow the instructions to respond to and report a temperature excursion below. If the unit returns to recommended ranges within 30 minutes, document the incident and, if applicable, implement procedures to prevent an excursion in the future.
Situation 2: **The unit is currently in range but the minimum or maximum indicate an out-of-range temperature.**	*During the Monday morning temperature check, the unit's current temperature was 5.4°C but the maximum temperature reading was 10.2°C.*	Begin to follow the instructions to respond to and report a temperature excursion below.

Instructions to respond to and report a temperature excursion

1. Label the vaccine "do not use." This ensures vaccines are not administered while investigating a temperature excursion.
2. Notify the appropriate contacts about the temperature excursion.
3. Obtain and document the details of the excursion.
   a. Download and review the temperature data. Determine the highest and/or lowest temperature and the duration of the excursion.
   b. Collect the vaccine information of all vaccines in the unit (lot number, expiration dates).
   c. Obtain historical data about previous excursions, if appliable.
4. Contact the manufacturer and obtain determination reports. These reports state if the vaccine is still viable.
5. Next steps:
   a. ***If the vaccine is still viable***, remove the "do not use" sign and attempt to correct the issue to prevent future excursions. Label the vaccine noting the excursion, as this information will be needed if another excursion occurs. Complete the Wisconsin VFC program's temperature excursion report and send the report, with the determination reports, to the VFC program at vfc@wisconsin.gov.
   b. ***If the vaccine is not viable***, remove the non-viable vaccine from the unit to prevent accidental use. Complete the Wisconsin VFC program's temperature excursion report and send the report, with the determination reports, to the VFC program at vfc@wisconsin.gov.

Temperature excursion forms and resources

Temperature Excursion Incident Report, F-02257 (Word)
Vaccine Return - Request for Authorization to Return (wisconsin.gov)
Temperature Excursion Flow Chart
Vaccine Storage Troubleshooting Record
Emergency Response Worksheet

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Vaccine Management

Proper vaccine management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need.

Vaccine management plan

VFC providers are required to maintain a current and complete vaccine management plan that includes routine and emergency storage and handling processes. The plan must include:

- Current coordinators' names and contact information.
- Documentation of primary and back-up coordinator training along with key staff, if applicable.
- Proper storage and handling practices.
- Plan for receiving vaccines.
- Emergency planning.
- Vaccine ordering and inventory management practices.
- How to handle wastage or expired vaccines.
- Date it was updated and signed.

At a minimum, the plan must be updated annually; however, the plan should be updated anytime there are changes to coordinators or clinic procedures. It is recommended to keep the vaccine management plan in a location that is easily accessible by staff, ideally on or near the storage units.
VFC providers can use the WI VFC Vaccine Management Plan Template as a resource when creating a vaccine management plan.

Ordering and receiving

Vaccine ordering

All vaccine orders must be made in the Wisconsin Immunization Registry (WIR) unless otherwise specified. Before placing an order, perform a physical inventory of all vaccines in stock and update WIR accordingly. Not completing this step could lead to delays and denied orders. When ordering VFC vaccines, keep the following in mind:

- Order only the actual amount of vaccine needed.
- Avoid stockpiling or build-up of excess vaccine inventory.
- Do not exceed a five-week supply of vaccine inventory.

Ordering influenza vaccine:
Seasonal VFC flu vaccine is pre-booked during January or February. An email notice with instructions will be sent out to all VFC coordinators. The pre-book order is placed in WIR.

All VFC providers are expected to order VFC flu vaccine for VFC-eligible children 6 months and older as recommended by the Advisory Committee on Immunization Practices (ACIP).

Vaccine receiving

When receiving VFC vaccines, complete the following steps:

1. Inspect shipment and open package immediately.
2. Check the temperature monitor(s) included in the vaccine shipment. If any monitor indicates a temperature excursion, notify the VFC Program immediately.
3. Check the vaccine in the shipment against the packing slip. Compare lot numbers, doses, and funding source. If there are any discrepancies, notify the VFC program right away.
4. Store vaccines in the appropriate storage unit.
5. Accept the vaccine transfer in WIR upon receipt of each shipment.
6. Retain the vaccine-packing slip(s) for 3 years.

This image is an example of a packing slip you will see with your vaccine delivery. When verifying the contents of your delivery, it is important to pay attention to the Material Description Manufacturer, MFR Lot #, Expiration Date, and dose type (VFC Doses in the above example).

McKesson Specialty Care Dist.
8745 Forest Hill Irene, Suite 105
Olive Branch, MS 38654

Packing Slip

This is not an invoice

Page 1 of 2

Provider PIN:
Delivery Number: 227836872
Quality Check Date: 12/18/2023
Customer Contact:

Internal use only

227836872

Ship-to:

Awardee:
WISCONSIN STATE DIVISION OF PUBLIC
P.O. BOX 2659
MADISON, WI 53701
(608) 266-1506

NDC	Customer P.O.	Material Description Manufacturer	MFR Lot#	Exp. Date	VFC Doses	317 Doses	State Doses	CHIP Doses	Order Qty	Ship Qty	Unit Price	Extended Price
58160-0827-30 5015830	808543	MCV4; SDV;10-PACK GLAXO SMITHKLINE	BL3ES	12/31/2024	10	0	0	0	10	10	$105.60	$1,056.00
				Total					10	10		$1,056.00

This vaccine was purchased with public (state, local, and/or federal) funds and may be administered only to patients eligible to receive publically-funded vaccine.

If you have any questions about your order please contact your Immunization Program for assistance.

VFC shipping issues

If you receive a VFC vaccine delivery that is damaged or having temperature issues, store the vaccine appropriately, label it "do not use," and immediately contact the program at VFC@wisconsin.gov
When contacting the program, have available:

- A picture of the top of the box with the shipping label visible.
- The packing slip.
- A picture of the temperature monitor if the shipment was out of range.

Inventory

Inventory management is crucial to vaccine accountability and preventing missed opportunities. Clinics must have a process for inventory management that prevents vaccine wastage and borrowing. VFC vaccine inventory must be maintained in WIR. Providers can choose to manage their private vaccine inventory in WIR but is not a requirement of the VFC program.

Inventory management best practices:

- Ensure public and private vaccines are clearly labeled.
- Keep an organized storage unit. This will prevent confusion and make conducting inventory easier.
- Keep an adequate supply of public and private vaccine.

- Keep a four-week supply of vaccine on hand.
- Review stock weekly and place vaccines with the earliest expiration date in the front.
- Develop a system to ensure expired vaccines are removed immediately.
- Conduct a physical vaccine inventory once a month. Providers are required to conduct a physical inventory before ordering VFC vaccine.

Returns

All VFC vaccines (including influenza) that expire or are spoiled and intact (not opened) must be returned. Instructions are available on the Authorization to Return Vaccine form, page 2. Returns must be completed within six months of the expiration date or spoil date. Never store spoiled or expired vaccine in the storage unit. The vaccine should be removed immediately and stored outside the unit until the vaccine is returned.

IPOL (multi-dose vial) – IPOL may be used through the expiration date printed on the label as long as the vaccine is not contaminated. If the multi-dose vial is opened when the vaccine expires, it cannot be returned. Please dispose of the vial according to your clinic's policy and report the remaining doses to the program using the Vaccine Wastage Form.

All public vaccine, including VFA, VFC, and mass clinic can be documented and returned using the WI VFC Vaccine Return Form.

If you are returning vaccine because it is spoiled due to a temperature excursion or other similar situation, that vaccine will need to be documented on a separate WI VFC Vaccine Return Form from your expired vaccine. In this situation you will send in two vaccine return forms, one for expired vaccine and the second for spoiled vaccine. For spoiled vaccine, don't forget to adjust your inventory in WIR.

Borrowing

Vaccine borrowing is when you use a privately purchased vaccine to immunize a VFC-eligible child or use a VFC-funded vaccine to immunize a privately insured patient in rare unplanned situations or to prevent missed opportunities. Borrowing should not become a routine practice. Every time a dose is borrowed it must be documented using the WI Borrowing Form. The form captures all required information that needs to be documented when a dose is borrowed according the VFC requirements. The vaccine should be replaced as soon as possible (within 90 days is ideal). Proper inventory practices of both public and private vaccines should be implemented to prevent borrowing.

Borrowing is a tool to help prevent missed opportunities but should not be used to make up for poor inventory practices. It is recommended that providers review borrowing logs routinely to ensure doses being borrowed are paid back and review reasons for borrowing to identify areas for improvement.

Availability

The Advisory Council on Immunization Practices (ACIP) advises CDC on immunization policies. It is a VFC program requirement that you offer all the ACIP-recommended vaccines based on the clinic's patient population. All routine vaccines should be kept on-hand at the clinic.

Vaccines available in the VFC program

COVID-19	Hepatitis A	**Meningococcal B***	Rotavirus
DTaP	HPV	MMR	Nirserimab
Polio	Influenza	Varicella	**Maternal RSV***
Hepatitis B	Polio	Pneumococcal	**PPSV***
Hib	Meningococcal ACWY	Tdap/Td	**Dengue***

***Non-routine VFC Vaccines:** VFC Providers must ensure that VFC-eligible children have access to non-routine vaccines as needed. Non-routine vaccines may be ordered as needed.

Vaccine accountability

VFC providers agree to operate their VFC program in a manner intended to avoid fraud and abuse.

Fraud	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. It includes any act that constitutes fraud under applicable federal or state law.	Abuse occurs when provider practices are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Examples:

- Providing VFC vaccine to a non-VFC-eligible patient and not completing required documentation.
- Providing VFC vaccine to clinics or persons for which it is not intended or to individuals not enrolled in the VFC Program.
- Selling or otherwise misdirecting VFC vaccine.
- Billing a patient or third party for VFC vaccine.
- Charging more than the established maximum vaccine administration fee for an eligible child.

Vaccine Transport

General transport information

Vaccine must be shipped directly to your clinic. Moving vaccine from the delivery location is not recommended; however, there are a few circumstances when vaccine may be moved:

- **Emergency transport**: This includes necessary transport during power outages, natural disaster, or equipment failure.
- **Transport to another clinic to avoid wastage**: Transporting vaccines directly from provider to provider to prevent wastage or expiration of vaccines before use.
- **Transport to an off-site clinic:** Transporting vaccines to conduct immunization services outside of the clinic location (such as an influenza clinic).

Regardless of the reason for vaccine transport, the following guidelines must be followed:

- All transports require the use of a certified digital data logger that meets VFC requirements, no matter how short the transport.
- Temperatures must be monitored during vaccine transport. Documentation of temperatures before, during, and after transport are required.
- Never use gel packs or cold packs (such as the ones that come in the vaccine shipping containers). Use the phase change material (PCM) that came with the qualified container or conditioned water bottles if it is an emergency transport.
- Vaccines should not be in transport for longer than eight hours. If the vaccine is being transported to an off-site clinic with a proper storage unit that follows all VFC guidelines, then the time the vaccine is in the clinic storage unit does not count toward the eight hours of transport time.
- Multidose vials that have been opened should never be transported unless in emergency situations.
- Vaccine transport and packing protocols for both routine and emergency situations must be included in your clinic's storage and handling policies.
- Only trained individuals can transport vaccine.
- All vaccine being transported for the purpose of a vaccine transfer must be documented in WIR. See instructions for documentation can be found on page 42 of the Wisconsin Immunization Registry Inventory Management guide.

Planned transport

Planned vaccine transport requires either portable refrigerators/freezers or qualified containers and pack-outs. The conditioned water bottle method cannot be used for planned transport.

Portable vaccine storage unit	Qualified containers and pack-outs
Always the best option when transporting vaccine for any reason. Portable vaccine storage units require a power source and have built-in temperature controls. In addition, most units come with a cord that can be plugged into a vehicle's auxiliary power outlet.	These containers and supplies have been tested under laboratory conditions to maintain desired temperatures for short-term travel when a portable refrigerator is not available. These units do not have built-in temperature control but are able to maintain temperatures when paired with appropriate pack-out.

Emergency transport

To transport vaccine during an emergency, any transport unit, including the conditioned water bottle method, is acceptable. If using the conditioned water bottle method, follow the CDC's guidelines outlined in Packing for Emergency Transport.

Resources

- Wisconsin Vaccine Transport Requirements
- Packing Vaccines for Transport during Emergencies
- Vaccine Transport Temperature Log Template

WISCONSIN DEPARTMENT of HEALTH SERVICES

Division of Public Health

VFC Eligibility, Screening and Documentation

VFC providers must screen every patient under 19 years old for program eligibility at each immunization encounter and document their eligibility status. VFC vaccines can only be administered to children who meet the eligibility criteria.

VFC eligibility

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

American Indian/Alaska Native

For the purposes of the VFC program, AI/AN is defined by the Indian Health Care Improvement Act [25 U.S.C. 1603]. AI/AN children are VFC-eligible under any circumstance. However, because VFC is an entitlement program, participation is voluntary.

When an AI/AN child also fits a second VFC eligibility category, the provider should always choose the category that will cost less for the family.

Medicaid-enrolled/eligible

Children who are eligible for the Medicaid program are VFC eligible. For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably.

Medicaid as secondary insurance: Some children may have a private primary health insurance plan with Medicaid as their secondary insurance. These children are considered VFC-eligible because of their Medicaid enrollment.

Uninsured

Children not covered by any health insurance plan.

Underinsured

Underinsured means the child has health insurance, but the insurance policy either:

- Doesn't cover any ACIP-recommended vaccines.
- Doesn't cover all ACIP-recommended vaccines (underinsured for vaccines not covered).
- Does cover ACIP-recommended vaccines but has a fixed dollar limit or cap for payment.

Only available at Federally Qualified Health Centers (FQHC), or Rural Health Centers (RHC).

Insured (not eligible). Insured is defined as having health insurance that covers the cost of the vaccinations. This applies even for plans with a high deductible that has not yet been met along with copays, deductibles or other charges associated with the cost of vaccines.

VFC screening requirements

VFC providers must screen and document patient eligibility at each immunization visit.

- Document eligibility appropriately in the patient record which can be paper, EHR, or WIR.
- The provider must document by eligibility category such as Medicaid or Uninsured and not just "Yes" or "No."
- The documentation must be at the dose level, not patient level.
- Providers should select the eligibility requiring the least out-of-pocket expense to the family.

Vaccine administration documentation requirements

Providers must follow federal requirements for documenting vaccines administered. For every vaccine administered, provider must document:

- Name of vaccine administered, manufacturer, and lot number.
- Address of the clinic where the vaccine was administered.
- Date when the dose was administered.
- Name and title of the individual administering the vaccine.
- Date when vaccine information sheet (VIS) was given and VIS publication date.
- Vaccine eligibility status.

Providers are required to distribute the current VIS for every vaccine before vaccine administration. For vaccines without a VIS, providers are required to distribute an Emergency Use Authorizations (EUA)/Emergency Use Instructions (EUI) fact sheet. Additionally, VFC providers are required to report all clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

A note about nirsevimab – an Immunization Information Statement (IIS) must be provided prior to administration. Additionally, if nirsevimab is not co-administered with other vaccines, adverse reactions are to be reported to MedWatch**.**

Eligibility chart and special situations

Insurance Status	VFC Eligible	VFC Eligibility Category
Enrolled in Medicaid	Yes	Medicaid
Has private insurance and enrolled in Medicaid	Yes	Medicaid: Individuals are not required to participate in the VFC program, choose the option that is most cost-effective.
Enrolled in a Health Care Sharing Ministry	Yes	Uninsured; Health Care Sharing Ministries are not considered insurance coverage in WI.
Does not have any health insurance coverage	Yes	Uninsured
Enrolled in Medicaid and is AI/AN	Yes	AI/AN or Medicaid: Choose the option that is most cost-effective.
Has private insurance and is AI/AN	Depends	AI/AN or Insured: Individuals are not required to participate in the VFC program, choose the option that is most cost-effective.
Has private insurance	No	Insured
Has private insurance that covers vaccines but has not yet met deductible	No	Insured: This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has private insurance that covers vaccines but has not yet met deductible and enrolled in Medicaid	Yes	Medicaid
Has private insurance but does not cover all or some vaccines	Yes	Underinsured: Individuals can only receive vaccines not covered by the plan.
Has insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Depends	Insured until the fixed dollar limit is met. Underinsured after the fixed dollar limit is reached.
Incarcerated at a juvenile detention center or correctional facility and lost insurance or Medicaid coverage	Yes	Uninsured

WISCONSIN DEPARTMENT of HEALTH SERVICES

Division of Public Health

Vaccine Administration Fees and Billing

Cost of vaccine

VFC-supplied vaccines are provided at no cost to both the VFC provider and VFC-eligible children. Do not charge patients, Medicaid, or other third-party payer for the cost of VFC vaccines.

Administration fees

A provider may charge a "vaccine administration fee" when vaccinating VFC-eligible children.

- **For Medicaid-eligible patients**: Providers must accept the Medicaid reimbursement rate and cannot charge the patient.
- **For non-Medicaid VFC-eligible patients**: Provider can bill a vaccine administration fee that does not exceed the administration fee cap of $20.83 per vaccine in Wisconsin. The provider may only issue a single bill to the patient within 90 days of vaccine administration. If the vaccine administration fee remains unpaid, these charges may not be sent to collections. In addition, the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees or who are unable to pay the administration fee.

If a billing compliance issue is identified, providers may need to show proof of proper billing practices and may be required to provide billing statements for review.

Clarification for select situations:

Medicaid as secondary insurance: The provider should choose the option that is most cost-effective for the family. The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

- Some children may have a private primary health insurance plan with Medicaid as their secondary insurance. These children are considered VFC-eligible because of their Medicaid enrollment.
- If a child has Medicaid as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out of pocket for vaccines, the child should be considered VFC-eligible if the family has not yet reached its deductible.
- It is best practice for a clinic to have a policy in place to ensure the proper eligibility category is selected and billed appropriately.

American Indian or Alaskan Native with private insurance or Medicaid:

- If the patient has private insurance, the provider should choose the eligibility category that is most cost-effective for the child and family.
- If the patient has Medicaid, it should be used for the administration fee because Medicaid provides the least out-of-pocket expense for the family.

Health Care Sharing Programs or Health Sharing Ministries: A health cost sharing program is not considered health insurance in the state of Wisconsin. Therefore, age-eligible children would be considered uninsured and thus eligible for VFC vaccines.

Medicaid billing resources

For questions related to Medicaid billing, please contact ForwardHealth directly.

- ForwardHealth Vaccines - Topic #12457
- ForwardHealth Immunizations – Topic #503
- ForwardHealth Vaccine for Children Program – Topic #3545
- ForwardHealth Procedure Codes – Topic #2408
- ForwardHealth Telephone Hotlines
- Vaccine Billing for Local and Tribal Health Departments: Live Training
- Vaccine Billing for Local and Tribal Health Departments: Q/A Document

WISCONSIN DEPARTMENT of HEALTH SERVICES

Division of Public Health

Vaccine Administration

ACIP vaccine recommendations

VFC providers agree to comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP).

ACIP Immunization Schedules

- Child and Adolescent Recommended Immunization Schedule
- Adult Recommended Immunization Schedule

Vaccine administration best practices

It can be easy to make a vaccine administration error. Make sure vaccinators know and adhere to the "7 Rights" of vaccine administration:

- The right patient
- The right time
- The right vaccine
- The right dosage
- The right route, needle, and technique
- The right injection site
- The right documentation

In addition to the "7 Rights," other important vaccine administration practices include:

- Never administer expired vaccines or diluent. Always check expiration dates for vaccines and diluent prior to preparation.
- Only use the diluent provided by the manufacturer for that vaccine.
- Do not pre-draw doses.

Vaccine administration errors

If a vaccine administration error occurs:

- Notify patient and/or family about the error.
- Report the error to VAERS.
- Revaccinate or follow-up as needed (depending on which vaccine is affected).
- Review internal practices to prevent future errors.
- Document doses as given in WIR. WIR may report the doses as invalid, but that is what the person received so that is what should be recorded in the record.

See the Vaccine Administration Preventable Errors document for information on preventing vaccine administration errors.

Vaccine administration resources

- Vaccine Administration chapter in Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)
- CDC e-Learn: Vaccine Administration
- CDC Administering Vaccines
- CDC General Best Practice Guidelines.
- Giving All the Doses (Under 12 months)
- Giving all the Doses (Over 12 months)
- Giving All the Doses (Adolescents)

WISCONSIN DEPARTMENT of HEALTH SERVICES

Division of Public Health

VFC Requirements Checklist

This list is a quick review of the VFC program requirements. This checklist can be used to help prepare for an upcoming VFC site visit. For details about each requirement, please review the VFC Resource Guide or e-mail vfc@wi.gov

VFC Basics

	Ensure each provider has assigned a trained primary and backup coordinator
	Communicate all coordinator changes to the program
	Complete annual re-enrollment
	Complete annual training (both primary and back-up coordinator)
	Maintain all VFC documentation for 3 years
	Operate the VFC program in a manner intended to avoid fraud and abuse as defined by Medicaid regulations
	Participate in VFC program compliance site visits, unannounced visits, and other educational opportunities associated with VFC program requirements.

Storage and Handling

	Have a vaccine storage unit that meets VFC requirements and always maintains recommended temperatures
	Have a current and valid calibrated digital data logger (DDL) for every storage unit
	Have at least one calibrated backup DDL
	Check and document temperatures at least once a day
	Download (if needed) and review temperature data weekly or monthly
	Respond to and document all temperature excursions
	Have 'do not unplug' signs at the circuit breaker and outlets that supply power to the storage units
	Keep vaccines in their original packaging
	Keep public and private vaccines separated

Vaccine Management

	Offer all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for the population the clinic serves
	Maintain an adequate inventory of vaccines to prevent borrowing and wasted doses
	Order VFC vaccines through the Wisconsin Immunization Registry (WIR) unless otherwise noted
	Maintain VFC vaccine inventory in WIR
	Document and return all borrowed doses within 90 days
	Maintain a current vaccine management plan
	Return all spoiled or expired VFC vaccines to CDC's centralized vaccine distributor within six months

VFC Eligibility, Documentation, and Administration

	Know and understand all VFC eligibility criteria
	Screen and document eligibility status at each immunization encounter
	Document administrated doses in accordance with federal law
	Enter all immunizations into WIR within three days of administration
	Provide the vaccine information sheet (VIS) before vaccine administration
	Report all clinically significant adverse events after vaccination to the Vaccine Adverse Event Reporting System (VAERS)
	Comply with the immunization schedules, dosages, and contraindications that are established by ACIP

VFC Billing

	Never bill for the cost of a VFC vaccine
	Do not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of $20.83 per vaccine dose
	Do not send unpaid vaccine administration fees to collections
	Do not deny children vaccination based on inability to pay the administration fees

For details about each requirement, please review the VFC Resource Guide or e-mail vfc@wi.gov