Wisconsin Vaccines for Children (VFC) Resource Guide

Wisconsin Department of Health Services
Division of Public Health
Bureau of Communicable Disease
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Wisconsin Vaccines for Children Program
Email: VFC@wisconsin.gov
www.dhs.wisconsin.gov/immunization/vfc
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<td><strong>Key Staff</strong></td>
<td>The VFC program requires providers to have a fully trained primary and backup coordinator, with the primary coordinator located at the clinic for most of the week. If a new coordinator is assigned, they must complete the New Coordinator Training upon hire. The primary and back-up coordinator must be knowledgeable of all the VFC requirements, regardless of assigned clinic responsibilities. The names and contact information of the clinic’s medical directors and coordinators must be reported to the VFC Program. 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.</td>
<td><strong>Change of Information Form</strong></td>
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<td><strong>Annual Training</strong></td>
<td>The primary and back-up coordinators must complete annual training. In addition, any staff responsible for the viability of the vaccine must complete the training as well (i.e., staff responsible for temperature documentation). 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. You will be notified when the new annual training becomes available via: Email The Wisconsin Department of Health Services website, VFC webpage In the Wisconsin Immunization Registry (WIR), under the announcement section</td>
<td><strong>WI VFC Program Website</strong></td>
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<tr>
<td><strong>Annual Reenrollment</strong></td>
<td>Each VFC site is required to complete the annual reenrollment process in WIR. You will be notified when reenrollment starts via: Email In the Wisconsin Immunization Registry (WIR), under the announcement section.</td>
<td><strong>VFC Reenrollment Instructions</strong></td>
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**Site Visits**

Providers enrolled in VFC agree to participate in two types of required programmatic site visits:

*Compliance Site Visits* – scheduled visit conducted every two years to offer guidance and ensure you are meeting the VFC requirements.

*Unannounced Site Visits* – unscheduled visit that can happen at any time and serves as a spot check of proper storage and handling practices.

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**Record 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 reenrollment documentation.

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**Annual Requirements Checklist**

The following is a list of items that each provider must complete on an annual basis. Announcements will be sent by email or posted on WIR when available, if applicable.

- [ ] Influenza Vaccine Pre-Book
- [ ] Annual Re-enrollment
- [ ] Annual VFC Training
- [ ] Update Vaccine Management Plan

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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, which will be set up during VFC registration. Along with recording patient immunization information in WIR, VFC providers use WIR to order and transfer vaccines, as well as manage their inventory. To learn more about WIR or schedule a WIR Training, please contact the WIR Help Desk.

- The WIR Help Desk hours are 7:30 a.m. to 4:30 p.m., Monday through Friday.
- Phone #: (608) 266-9691
- Email: dhswirhelp@wisconsin.gov

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**WIR Home Page**
Contact Information

Wisconsin VFC Contact Information
Vaccine Storage and Handling

- CDC Storage and Handling Toolkit
- Preventable Errors in Vaccine Storage and Handling

### Vaccine Storage Units

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<td><strong>Vaccine Storage Units</strong></td>
<td>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. The type of storage unit used can vary based on inventory size and budget. Below are the Wisconsin VFC program’s recommendations/requirements:</td>
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<td>• Preferred: Purpose-built or pharmaceutical-grade units</td>
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<td>• Other options: Household unit using only the refrigerated compartment with a separate stand-alone freezer unit required</td>
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<td>• Never: Dorm-style units</td>
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### Vaccine Storage Unit Set-up

- Basic storage unit set-up requirements:
  - Never store food or beverages in the unit with vaccine.
  - Use water bottles labeled “Do Not Drink” on the top and bottom shelves and in the door unless the unit is designated otherwise.
  - Storage units should be plugged into an electrical outlet. Power strips are not allowed to be used.
  - Post “Do Not Unplug” warning signs at the outlet (email your VFC site monitor if you need new signs).
  - Label the circuit breaker and fuse to identify the vaccine storage units.
  - Have adequate storage room for vaccines to prevent crowding and promote good airflow. The unit should have enough room to store vaccine, plus room for influenza vaccine when applicable.
  - The unit must have a digital data logger (DDL) temperature monitoring device located with each unit. The DDL screen should be placed in a way that allows temperatures to be read without opening the unit. Each unit only requires one DDL. The back-up DDL should not be stored in the unit.
  - The DDL probe should be is the middle of the unit.
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 and storage:
- 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.
- Do not store vaccine in the door, vegetable bins, under fans, or on the top or bottom shelves.

Vaccine with the earliest expiration date should be placed in front of those with a later date.

**Digital Data Loggers (DDL)**

All temperature monitoring devices are required to be a DDL with the following parameters:
- Active display, showing the current, minimum and maximum temperature readings that can be read from the outside of the unit
- External buffered probe
- The capacity for continuous monitoring and data download.

All digital data loggers need to have a current and valid certificate of calibration. The following items are required
- Model/device name or number
- Serial number
- Date of calibration testing
- Instrument passed testing

A back-up DDL is required and should be onsite or be able to be obtained by the next required temperature reading. The back-up DDL must have a different expiration date then the DDL in-use.

**Temperature Monitoring**

Monitoring storage unit temperatures is critical to maintain the viability of the vaccine. At a minimum, the following is required:
- Check temperatures once a day, preferably in the morning.
- Document the minimum and maximum temperatures and then reset the unit.*
- Document current date, time and name (initial) of the person checking the temperatures.

Refrigeration – Fahrenheit
Refrigeration – Celsius
Freezer – Fahrenheit
Freezer – Celsius
Logs can be found on the Immunize Action Coalition webpage.

*Once the minimum and maximum temperatures have been recorded, the unit should be reset
to capture the minimum and maximum temperatures for the next 24-hour period. Not resetting
the unit after each reading could cause inaccurate monitoring and leave the vaccine vulnerable
to out-of-range temperatures.

Data from the DDL must be downloaded and reviewed weekly or monthly or if a temperature
excursion is identified. The logs should be reviewed for temperature excursions that were
missed or temperature trends that could indicate a storage unit performance issue. These logs
should be kept electronically for a minimum of three years—the same as the paper temperature
logs.

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.

| VACCINE MANAGEMENT PLAN | Maintain a current and complete vaccine management plan that includes routine and
emergency storage and handling situations. The plan must include the following:

- Current coordinators and staff training
- Proper storage and handling practices
- Plan for when receiving vaccines
- Emergency planning
- Vaccine ordering and inventory management practices
- How to handle wastage or expired vaccines
- Date updated and signed

At a minimum, the plan must be updated annually.

Keep the vaccine management plan in a location that is easily accessible by staff, ideally near
the storage units.
**Temperature Excursion**

When the DDL is reading outside of the recommendation range or the minimum or maximum indicates the temperature was out of range at some point, this is considered a temperature excursion and action needs to be taken immediately.

1. Notify staff as needed and label the vaccine “do not use.”
2. Obtain and document the details of the excursion.
   - Download and review the temperature data. Determine the highest/lowest temperature and the duration of the excursion.
   - Collect the vaccine information of all vaccines in the unit (lot number, expiration dates).
3. Contact the manufacturer and obtain determination reports. These reports state if the vaccine is still viable.
4. Next steps:
   - If the vaccine is still viable, attempt to correct the issue to prevent future excursions and make sure to keep all documentation related to the excursion in your files.
   - 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@wi.gov.

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**Vaccine Transport**

Vaccine must be shipped directly to your clinic and transporting vaccine is not recommended, however there are a few specific circumstances when vaccine may be transferred.

- 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 (for local and tribal health departments only)—transporting vaccines to conduct immunization clinics outside of the clinic location (i.e., influenza clinic).

If you need to transport vaccine, please see the Wisconsin Vaccine Transport Requirement Handout for proper procedures.
Vaccine Management
Proper vaccine inventory management is essential to the VFC Program. Vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need.

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<td><strong>Vaccine Returns</strong></td>
<td>All VFC vaccines (including influenza) that expire or are spoiled must be returned. Instructions are available on the Authorization to Return Vaccine form. Returns must be completed within six months of the expiration date/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.</td>
<td>Vaccine Return-Request for Authorization to Return Wasted Vaccine Record Form</td>
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<tr>
<td><strong>Borrowing</strong></td>
<td>Vaccine borrowing is when you use a privately purchased vaccine to immunize a VFC-eligible child or use VFC-funded vaccine to immunize a privately insured patient to prevent missed opportunities. Borrowing should not become a routine practice. Proper inventory practices should be implemented to prevent borrowing. During influenza season, a clinic may receive their private influenza vaccine first. It would be acceptable to borrow until the VFC vaccine is received or vice versa.</td>
<td>Wisconsin Borrowing Form</td>
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<td><strong>Restitution</strong></td>
<td>Restitution is when vaccines become non-viable due to clinic negligence. If this occurs, your clinic must replace VFC vaccines with privately purchased vaccine dose for dose. To learn more, view Wisconsin’s restitution policy.</td>
<td>Vaccine Restitution Policy</td>
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<tr>
<td><strong>Fraud and Abuse</strong></td>
<td>Agree to operate within the VFC program in a manner intended to avoid 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. 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</td>
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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.

| VACCINE 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 to patients. All routine vaccines should be kept on-hand at the clinic. Non-routine vaccines, such as PPSV23 and MenB must be made available when indicated. The recommended vaccines can be found on the ACIP Immunization Schedules. |

Immunization Schedule for Children

Immunization Schedule for Adults

Immunization Catch-up Guidance
# Vaccine Administration and Documentation

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| **VFC Eligibility, Screening and Documentation** | Providers must screen every patient under 19 years old at each immunization encounter for VFC eligibility. VFC vaccine is available to children through the age of 18 who are in one of the following categories:  
- American Indian or Alaska Native  
- Enrolled in Medicaid  
- No health insurance  
- Underinsured (only available at Federally Qualified Health Centers (FQHC), Rural Health Centers (RHC) or Local Health Departments (LHD))  
VFC eligibility, including the eligibility category, must be documented at the dose-level at every encounter. If entering this information in the provider's electronic health record, dose-level eligibility must be sent to WIR via data exchange, or manually entered. Along with VFC eligibility, the provider is also required to document the following with every immunization given:  
- Name of the vaccine  
- Lot number and manufacturer  
- Date given  
- Name and title of person who administered the vaccine  
- VIS publication date and date the VIS was provided  
- The clinic’s address | |
### Vaccine Administration

Providers must comply with the recommendations established by the Advisory Committee on Immunization Practice (ACIP) and Wisconsin Council on Immunization Practices (WCIP) regarding immunization schedules, dosages, and contraindications.

Staff should be trained on how to administer vaccines correctly. Clinics may have their own internal trainings, but for those who don’t, or who are looking for supplemental training, the following trainings are available:

- [Vaccine Administration chapter in Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)](#)
- [CDC e-Learn: Vaccine Administration](#)

### Vaccine Information Statements (VIS) and Vaccine Adverse Event Reporting System (VAERS)

It is a requirement to distribute the current VIS for every vaccine before vaccine administration.

VFC providers are required to report all clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

### Vaccine Administration Fee and Billing

Providers are not allowed to bill for the VFC vaccine itself but may bill for a vaccine administration fee.

- Medicaid eligible children: Provider should bill Medicaid and accept the reimbursement for the vaccine administration fee set by the state Medicaid agency or the contracted Medicaid health plans.

- Non-Medicaid eligible children (uninsured, underinsured, or American Indian/Alaskan Native): Provider should bill a vaccine administration fee that does not exceed the administration fee cap of $20.83 per vaccine dose in Wisconsin. Effective 1/1/2020, the provider may only issue a single bill to the patient within 90 days of vaccine administration.

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[Guide to Contraindications and Precautions](#)
[CDC Administering Vaccines](#)
[Giving All the Doses (Under 12 months)](#)
[Giving all the Doses (Over 12 months)](#)
[Giving All the Doses (Adolescents)](#)
[Vaccine Administration Preventable Errors](#)
[VIS – It’s the Law](#)
[CDC – Current VIS](#)
[VAERS Fact Sheet](#)
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. These fees must be waived.

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.

- **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.

- **Healthcare 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.