The Vaccines For Children (VFC) program utilizes the Immunization Information System known as Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE) to record patient immunization records on VFC vaccine administration, inventory management, vaccine storage and handling, and ordering. Each provider must enroll in I-CARE first, which is currently taking about 4 to 6 weeks to complete the process.

The following link will guide you in enrolling in the I-CARE Program: [http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare](http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare)

To complete the I-CARE enrollment, providers must complete:
- Provider Agreement
- Individual Agreement for each person using I-CARE
- Web Portal Registration

All VFC providers must report patient immunization records in I-CARE on the administration of VFC vaccines. The patient-level data may either be directly entered into I-CARE or providers may work with their EMR vendor to have data electronically transferred. If you have an EMR that you will be using to transmit patient data, please review the information at the above website for “Submitting and Exchanging Data.” Also make sure you participate in meaningful use when you enroll in I-CARE.

If you have already submitted an enrollment for I-CARE but do not have access yet, please contact the I-CARE team at DPH.ICARE@illinois.gov to check the status of your I-CARE enrollment.

Once you have enrolled in I-CARE and have a Login ID and password or if you already have access to I-CARE, you will login to I-CARE to enroll in the VFC program on the Clinic page in I-CARE. Please make sure when you print out the VFC Enrollment Agreement sign-off page to have the medical director indicated in the enrollment sign the form. One the enrollment agreement sign-off page, write in “New Provider” where it asks for VFC PIN. After your enrollment is completed and approved by IDPH, you will be assigned a new VFC PIN.

If you have already submitted an enrollment for I-CARE but do not have access yet, please contact the I-CARE team at DPH.ICARE@illinois.gov to check the status of your I-CARE enrollment.

All VFC providers are required to submit an annual enrollment to continue in the VFC program. Annual enrollment must be submitted and approved by January 1st of the year or the provider’s ordering privileges will be suspended. Enrollment documentation is available in and submitted through I-CARE.

Providers will need to read and agree to the following policies, which are available in I-CARE and updated annually:
- VFC Enrollment Agreement Terms
- VFC Provider Enrollment Policy
- VFC Loss and Replacement Policy

Provider agreement forms must be signed annually by the medical director or the equivalent in a group practice. The health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law. The practitioner will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the Provider Enrollment Agreement.

All licensed health care providers in the enrolled practice – and their corresponding professional license numbers – must be listed on the provider agreement form.
According to Section 1928 (c) (1) (A) of the Social Security Act (42 U.S.C. 1396s (c) (1) (A) the following providers qualify to be VFC program-registered providers:

Health care providers “licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs” (subject to section 333 (e) of the Public Health Service Act, which authorizes members of the Commissioned Corps to practice).

The CDC Provider Agreement form represents the provider’s agreement to comply with all the conditions of the VFC program, as well as ensuring that the practice/clinic/facility and all providers listed on the agreement will adhere to the requirements of the program.

Please refer to I-CARE for detailed instructions on the enrollment procedure.

The VFC Program Manual provides additional information and is available at [http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program](http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program)

If you need additional information, please feel free to contact us at DPH.Vaccines@illinois.gov or 217-786-7500.
## PROGRAM PARTICIPATION OVERVIEW

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>DESCRIPTION</th>
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<tr>
<td><strong>I-CARE</strong></td>
<td>All VFC providers must participate in the Immunization Information System known as Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). I-CARE is administered by the Illinois Department of Public Health as authorized by the Immunization Data Registry Act, 410 ILCS 527. Participation will include, but not be limited to, documenting patient records with VFC eligibility criteria and administration data for all VFC shots provided, VFC vaccine inventory, temperatures of refrigerators and freezers storing or containing VFC vaccines, primary and back-up thermometer certificate of calibration information, and routine use of the VFC vaccine ordering system.</td>
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**E-mail**

All VFC providers must have an e-mail address that does not require e-mail verification or IDPH registration.

**Designation of key clinical staff**

VFC providers must designate a vaccine coordinator and at least one backup vaccine coordinator(s) who will both be fully trained to oversee and manage the clinic’s vaccine supply. The VFC program prefers to have an office manager, RN, NP, PA, or MD as the primary vaccine coordinator. The contact name and information for each vaccine coordinator must be current in the clinic’s profile in I-CARE. **Any personnel changes in this role must be immediately reported to the VFC Program through the “contact us” link in I-CARE.**

**Completion of VFC educational requirements**

Each VFC vaccine coordinator is required to complete and maintain documentation of receiving annual VFC education on vaccine storage and handling. Education is available through VFC compliance site visits, VFC trainings, or through CDC online training. “You Call The Shots – Module 10 – Storage and Handling,” available at [http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp](http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp). You will need to register for continuing education credits to receive a certificate of completion. Training should also be documented in the Vaccine Management Plan on the training log.

**VFC Eligibility Screening & Documentation**

Screening for VFC eligibility must occur with all clinic patients 0 through 18 years of age, prior to vaccine administration and must have VFC eligibility screening documented in the patient’s permanent medical record (paper-based or electronic medical record) **at each immunization encounter.** Eligibility documentation must be kept in the patient’s medical record for three years. Documentation of eligibility screening must include the following elements:

- Date of screening
- Whether the patient is VFC eligible or not VFC eligible
- If VFC eligible, the eligibility criteria the patient met

The VFC Eligibility Screening Form is available in I-CARE on the home page under “Immunization Links.” VFC vaccines may only be administered to children through 18 years who meet one or more of the following eligibility categories.

1. Are an American Indian or Alaska Native;
2. Are enrolled in Medicaid;
3. Have no health insurance;
4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). **Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.**

The location of the child’s residence is not a factor in eligibility.

**Children who are 18 years of age and younger with Medicaid, either as primary or secondary insurance, are eligible to receive VFC vaccines.** In addition to traditional Medicaid coverage, Medicaid also has managed care option plans (MCO) and All Kids, which is the state’s Child Health Insurance Program (CHIP). Children with any Medicaid coverage are VFC eligible. Children with All Kids coverage should have their eligibility documented as V06 VFC eligible - State specific eligibility. If the type of Medicaid coverage is not able to be determined, Medicaid eligibility may be documented as V02 VFC eligible-Medicaid/ Medicaid Managed Care. Providers should contact Medicaid for questions about Medicaid plans and coverage:

- Healthcare and Family Services 217-782-5565
- Provider Help Line 800-804-3833
- All Kids 217-524-7156 or 866-255-5437
- E-Mail: hfs.webmaster@illinois.gov
- Internet: [http://www.hfs.illinois.gov](http://www.hfs.illinois.gov)

**Vaccines**

Providers must agree to comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
A. In the provider’s medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;  
B. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Providers must offer all VFC vaccines for the patient population served within their clinic.

| Vaccine Information Statements (VIS) | VFC providers must distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain patient records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).  

To be considered compliant with the NCVIA, each patient record must contain ALL of the elements listed below:

- Address of clinic where vaccine was administered  
- Name of vaccine administered  
- Date vaccine was administered  
- Date VIS was given  
- Publication date of VIS  
- Name of vaccine manufacturer  
- Lot number  
- Name and title of person who administered the vaccine |

| VFC Vaccine Administration Fees | VFC providers may charge VFC-eligible children not covered by Medicaid a vaccine administration fee up to $23.87 per dose (not antigen) of vaccine. VFC providers may not exceed the federal maximum administration fee nor may they charge non-Medicaid VFC-eligible children for the cost of the vaccine. VFC vaccine administration should not be denied because the child’s parent/guardian/individual of records is unable to pay the administration fee. |

| Vaccine Ordering and Accountability | Adequate vaccine supply must be maintained in accordance with practice patient population. Providers should maintain enough VFC inventory for at least one (1) month; however, inventory should not exceed three (3) months. VFC vaccine supply and private vaccines should be kept separate and clearly labeled to allow easy identification and to prevent misuse of VFC vaccines on ineligible patients. All VFC documentation, including temperature logs, are required to be kept for a period of at least three (3) years.  

All VFC providers must report patient immunization records in I-CARE on the administration of VFC vaccines. The patient-level data may either be directly entered into I-CARE or providers may work with their EMR vendor to have data electronically transferred. If you need assistance with your electronic transmission, click on “Contact Us” in I-CARE and select “HL7” as the category or e-mail DPH.HL7ICARE@illinois.gov. |

| Storage Equipment | Vaccine must be stored in one of the following equipment types:  
A. Stand-alone refrigerator  
B. Stand-alone freezer  
C. Combination refrigerator/freezer- using only the refrigerator compartment for vaccine storage  
   *Household combination units will not be allowed as of January 1, 2017.*  
D. Pharmaceutical/medical/laboratory grade refrigerator  
E. Pharmaceutical/medical/laboratory grade freezer  
F. Compact (under counter) refrigerator  
G. Compact (under counter) freezer  

The VFC program recommends the use of stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.  

Dormitory-style refrigerators are not allowable to store VFC vaccine at any time, even for temporary storage. Dormitory-style refrigerators do not maintain proper temperatures and pose a high risk of freezing vaccine. A dormitory-style refrigerator is defined as a combination refrigerator/freezer unit that is outfitted with one exterior door that upon opening will expose a freezer compartment within the refrigerator. A dormitory-style unit may be a small unit that sits on top of or under the counter. A dormitory-style unit may also be an older household-size refrigerator with one outside door and the freezer door located within the refrigerator.  

As of January 1, 2017, household combination refrigerator/freezers will no longer be allowable for the storage of VFC vaccines. Purchasing new vaccine storage equipment may require planning to accomplish before January 1, 2017. If VFC providers need to replace equipment now, we strongly recommend considering the 2017 requirements in purchasing decisions. |
| Thermometers | Providers are required to have a thermometer in each unit, with at least one back-up thermometer available on-site. CDC recommendation is for the use of a digital data logger thermometer with a detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities. The temperature should be easily readable from the outside of the unit. Additional recommended features include:  
  - Alarm for out-of-range temperatures  
  - Current, minimum and maximum temperatures  
  - Reset button  
  - Low battery indicator  
  - Accuracy of +/- 1°F (0.5°C)  
  - Memory stores at least 4,000 readings; device will not write over old data – stops recording when memory is full  
  - User programmable logging interval (or reading rate) |
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<td><strong>As of January 1, 2017, all VFC providers must have certified calibrated digital data loggers for continuous temperature monitoring for each VFC storage unit and back-up thermometer.</strong> Purchasing new certified calibrated digital data logger thermometers may require planning to accomplish before January 1, 2017. If VFC providers need to replace thermometers now, we strongly recommend considering the 2017 requirements in purchasing decisions. Providers will continue to be required to physically assess and record temperatures twice a day and document the temperatures in I-CARE.</td>
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| Thermometer Calibration & Certification | Primary and back-up thermometers must have a certification of calibration that is current (no more than two years since last calibration testing or based on the manufacturer's recommended re-testing timeline). A valid certification of calibration must be kept on file and be readily available for review during VFC visits. Calibration should be conducted by an ILAC/MRA accredited laboratory.  
  - **Calibration certificates from an ILAC/MRA accredited laboratory must include:**  
    - Model number  
    - Serial number  
    - Date of calibration (report or issue date)  
    - Measurement results indicate unit passed testing: This may be listed under “Pass/Fail,” “In Tolerance,” or “In Tol.”  
    - The documented uncertainty is listed and within suitable limits (recommended uncertainty is +/- 1°F or 0.5°C). This may be listed under “Uncertainty,” “±U,” or “+/-.”  
  - **Calibration certificates from non-accredited laboratories must include:**  
    - Name and address of laboratory conducting testing  
    - Model number  
    - Serial number  
    - Date of calibration (report or issue date)  
    - Measurement results indicate unit passed testing: This may be listed under “Pass/Fail,” “In Tolerance,” or “In Tol.”  
    - The documented uncertainty is listed and within suitable limits (recommended uncertainty is +/- 1°F or 0.5°C). This may be listed under “Uncertainty,” “±U,” or “+/-.”  
    - Statement of conformance with ISO/IE17020 calibration procedure standards |
| **Thermometers that are no longer accurate within +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced. The VFC program recommends back-up thermometers have a different date of calibration so that providers do not have all of their thermometers certificates of calibration expiring at the same time.** |
| Temperature Monitoring | Temperatures for each unit must be read and documented twice each workday, at least three days a week, at the beginning of the day and prior to closing. Additionally, minimum and maximum temperatures are recommended to be read and documented at the beginning of each workday. Temperature logs are required to be maintained for three years. Temperatures should be recorded in I-CARE on a weekly basis. The VFC program strongly recommends clinics that are routinely closed for more than 2 consecutive days and do not have staff that assess and record temperatures twice a day on days when the office is closed, use a continuous monitoring and recording digital data logger with downloadable capabilities and the characteristics listed above. |
| Borrowing | VFC-enrolled providers are expected to maintain adequate inventories of vaccine for their privately insured and VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately- |
purchased vaccine inventory. The provider must ensure their VFC vaccine supply is adequate to meet the needs of the provider’s VFC-eligible patients.

The VFC program does not allow the borrowing of VFC vaccine. The VFC program cannot support a policy that permits borrowing of VFC vaccine for use in non-eligible children. Private vaccine used on VFC patients cannot be paid back using VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then paid back with private stock. If VFC vaccine is unavailable, the provider should refer the VFC eligible child to a local health department, FQHC, or reschedule the child.

Vaccine Transfers & Returns

Transfers

Ordered vaccines must be shipped and stored at the facility indicated on the clinic profile on the enrollment forms and in I-CARE. VFC vaccines may be transferred in limited situations and only to other VFC-enrolled providers. It is the provider’s responsibility to find another VFC provider willing to accept the vaccine. VFC providers must receive pre-approval for transfers. The transfer approval request form is available in I-CARE on the home page under “Immunization Links.” Please allow 10 business days for your request to be reviewed and receive approval. Transfer of vaccines should only occur for the following reasons:

- Vaccine is six months or less from expiration date and unable to be used by provider prior to expiration date.
- An area outbreak has resulted in unexpected surge of walk-in patients.
- Clinic closure requiring redistributing vaccines to other VFC providers.
- Seasonal clinic needing to transfer vaccine to other VFC providers at end of time facility will be open.

Providers may not transfer influenza vaccine.

IDPH will evaluate requests to transfer frozen vaccines on a case-by-case basis to ensure providers have the appropriate equipment.

Expired (Returned to McKesson) and Wasted (Not Returned to McKesson) Vaccines

VFC providers must record all expired and wasted vaccine doses in I-CARE so that expired vaccines may be returned to the vaccine distributor for excise tax credit. Expired vaccines must be return within six months of the expiration/spoilage date. Provider may not use the wasted (not returned to McKesson) transaction to balance their inventory. Providers reporting excessive expired or wasted vaccines may be responsible for replacing those vaccines according to the Vaccine Loss and Replacement Policy.

Site Visits

Actively enrolled VFC providers agree to VFC program site visits, which may include compliance visits, unannounced storage and handling visits, or educational site visits. Unannounced storage and handling visits serve as spot checks to ensure VFC supplied vaccines administered to VFC-eligible children are managed and stored according to program requirements. Any active VFC provider may be chosen to receive an unannounced storage and handling visit.

Vaccine Management Plan

All VFC providers are required to have a Vaccine Management Plan and to review it annually or more often if staff changes. The Vaccine Management Plan template is available in I-CARE on the home page under “Immunization Links.”