
For VFC Providers

January 2014
Contents

Module 1: Overview of the VFC Program ............................................................................................................................... 4
  Vaccines for Children (VFC)................................................................................................................................................. 4
  VFC and I-CARE in Illinois .................................................................................................................................................... 4
Module 2: Eligibility ................................................................................................................................................................ 5
  VFC Eligibility Criteria .......................................................................................................................................................... 5
   Underinsured Children.................................................................................................................................................... 5
   Table 1: VFC Eligibility Scenario ...................................................................................................................................... 6
   VFC Eligible Decision Tree ............................................................................................................................................... 6
  VFC Eligibility Hierarchy ...................................................................................................................................................... 8
   VFC Eligibility Exceptions Occurring with Older Children ............................................................................................... 8
   Insured Children without Medicaid as a Secondary Insurance ....................................................................................... 8
   Fully Insured Children with Medicaid as Secondary Insurance ...................................................................................... 8
   AI/AN with Health Insurance that Covers Immunizations .............................................................................................. 9
   Minors at Family Planning Clinics ................................................................................................................................... 9
   Juveniles in Correctional Facilities .................................................................................................................................. 9
   State of Residency ........................................................................................................................................................... 9
  Provider Responsibility to Screen for VFC Eligibility ........................................................................................................... 9
Module 3: Provider Enrollment ............................................................................................................................................ 10
  Enrollment Terms .............................................................................................................................................................. 11
  VFC Enrollment Visits ........................................................................................................................................................ 13
  Education Requirement .................................................................................................................................................... 13
Module 4: Equipment Recommendations and Requirements ............................................................................................. 14
  Equipment Types .............................................................................................................................................................. 14
  Equipment Size .................................................................................................................................................................. 15
  Temperature Monitoring .................................................................................................................................................. 15
  Certified Calibrated Thermometers .................................................................................................................................. 17
  Vaccine Refrigerator Setup ............................................................................................................................................... 19
  Vaccine Freezer Setup ....................................................................................................................................................... 21
Module 5: Borrowing VFC Vaccines ...................................................................................................................................... 23
Module 6: Vaccine Loss and Replacement ........................................................................................................................... 24
  Definitions ......................................................................................................................................................................... 24
  Situations that Require Vaccine Replacement .................................................................................................................. 24
<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Situations that Do Not Require Vaccine Replacement</td>
<td>25</td>
</tr>
<tr>
<td>Procedures for Returning Nonviable Vaccine</td>
<td>26</td>
</tr>
<tr>
<td>Procedures for Vaccine Replacement</td>
<td>26</td>
</tr>
<tr>
<td>Provider-to-Provider Transfer of Vaccines</td>
<td>26</td>
</tr>
<tr>
<td>Module 7: Accountability</td>
<td>27</td>
</tr>
<tr>
<td>VFC Vaccine Orders</td>
<td>27</td>
</tr>
<tr>
<td>Provider Profiles</td>
<td>27</td>
</tr>
<tr>
<td>Vaccine Return and Waste</td>
<td>28</td>
</tr>
<tr>
<td>VFC Provider Withdrawal</td>
<td>28</td>
</tr>
<tr>
<td>Module 8: VFC Site Visits</td>
<td>29</td>
</tr>
<tr>
<td>VFC Compliance Visit</td>
<td>29</td>
</tr>
<tr>
<td>Storage and Handling Site Visit</td>
<td>29</td>
</tr>
<tr>
<td>Conducting the Site Visit</td>
<td>29</td>
</tr>
<tr>
<td>Following Up After the Site Visit</td>
<td>29</td>
</tr>
<tr>
<td>Module 9: Fraud and Abuse</td>
<td>30</td>
</tr>
<tr>
<td>Overview</td>
<td>30</td>
</tr>
<tr>
<td>Fraud and Abuse Policy</td>
<td>31</td>
</tr>
<tr>
<td>Allegations of Suspected Fraud and Abuse</td>
<td>31</td>
</tr>
<tr>
<td>Examples of Fraud and Abuse</td>
<td>31</td>
</tr>
<tr>
<td>Fraud and Abuse Contacts</td>
<td>33</td>
</tr>
<tr>
<td>Ongoing Provider Monitoring Procedures</td>
<td>33</td>
</tr>
<tr>
<td>Reporting VFC Provider Termination</td>
<td>33</td>
</tr>
<tr>
<td>Appendices</td>
<td>34</td>
</tr>
</tbody>
</table>
Module 1: Overview of the VFC Program

Vaccines for Children (VFC)
The Illinois Department of Public Health (the Department) administers the Vaccines for Children (VFC) program through federal funds from the Centers for Disease Control and Prevention (CDC) and provides immunizations for children under the age of 19 who are uninsured, Medicaid-eligible, American Indian or Alaskan Native. Underinsured children (children who have limited coverage or caps on the amount of vaccines allowed annually) can access VFC vaccines recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP) at participating federally qualified health centers and rural health clinics (FQHC/RHC), or local health departments (LHD) under an approved deputization agreement.

VFC vaccines should be administered to eligible children without requiring charges to the provider or the parent. VFC providers have contributed to increased immunization coverage level rates and reduced delays in immunizations and, subsequently, the risk of serious illness or death from vaccine-preventable diseases. To ensure providers enrolled in the VFC program adhere to the many program requirements, increased accountability processes are needed. VFC compliance site visits are conducted at clinics and public health offices throughout Illinois to ensure accountability.

This program manual is intended for providers currently enrolled in the Illinois VFC program.

Note: In Illinois, the state does not require parental or guardian consent for vaccination. Local administrators of clinics and/or health departments may require consent under local agency guidance. However, CDC and the Department view required consent as a possible barrier to vaccination. Provision of a vaccine information statement (VIS) must be routinely provided upon vaccination.

VFC and I-CARE in Illinois
Beginning January 1, 2013, the Illinois Immunization Section requires VFC providers to be enrolled and active users of the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). The Immunization Section has integrated many of its ordering and vaccine management functions into I-CARE. This integration allows for greater accountability and programmatic oversight.

In 2014, Illinois VFC providers must provide patient-level data on the administration of VFC vaccines, also referred to as Phase 2 in I-CARE. This patient-level data can either be manually entered into I-CARE or can be electronically transmitted to I-CARE from the provider’s electronic medical record (EMR) system via HL7 messaging. Illinois has established a schedule to transition providers to Phase 2. Providers will be notified when they need to begin to transition and will have 30 days to come into compliance. The transition plan will ensure providers are at Phase 2 no later than May 31, 2014. VFC providers not in compliance will not be able to continue participating in the VFC program.
Module 2: Eligibility

VFC Eligibility Criteria

Providers must screen for and document VFC eligibility with every visit. All provider forms are available at http://www.idph.state.il.us/about/immunizationvfc.htm. To be eligible to receive VFC vaccine, children (regardless of their state of residency) must be younger than 19 and meet at least one of the following criteria:

- **Medicaid-eligible**: a child who is eligible for the Medicaid program. [For the purposes of the VFC program, the terms “Medicaid-eligible” and “Medicaid-enrolled” are equivalent and refer to children who have health insurance covered by Medicaid, including All Kids.]
- **Uninsured**: a child who has no health insurance coverage.
- **American Indian or Alaskan Native (AI/AN)**: as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
- **Underinsured**: a child who has health insurance, but the coverage does not include vaccines or a child whose insurance covers only selected vaccines. Children who are underinsured for select vaccines are VFC-eligible for non-covered vaccines only.

Underinsured Children

Effective January 1, 2013, underinsured children are eligible to receive all ACIP recommended VFC vaccines ONLY through a FQHC, RHC, or LHD under an approved deputization agreement.

The following are common scenarios occurring among underinsured children and would qualify patients for access to VFC vaccine at a FQHC, RHC or a deputized LHD:

- **Underinsured** children include those children who have commercial (private) health insurance, but the coverage does not include vaccinations, making the child VFC-eligible for non-covered vaccines only. This child is then considered underinsured for the purposes of the VFC program and can acquire access to recommended VFC vaccines at a FQHC, RHC or a deputized LHD.
- **Underinsured** children whose coverage does not allow all recommended vaccines. Once the vaccines covered by the commercial insurance are administered, these children are considered underinsured. The child must be referred to a FQHC, RHC or a deputized LHD to access VFC vaccine for the ACIP recommended vaccines not covered by their commercial insurance.
- **Underinsured** children whose coverage caps the number of allowable provider visits. Once the child has exceeded the number of provider visits allowed and the insurance will not cover the cost of additional vaccines needed in the annual period, the child is then considered underinsured for the purposes of the VFC program and can access VFC vaccine at a FQHC, RHC or a deputized LHD.
- **Underinsured** children whose insurance caps vaccine coverage at a certain dollar amount. Once that coverage amount is reached, these children meet the criteria of being underinsured. To be eligible to access VFC vaccine once that insurance dollar amount has been met, these children must be referred to a FQHC, RHC or a deputized LHD for vaccinations.

Memorandum of Understanding (MOU) with a FQHC or RHC (when applicable)

LHDs who wish to qualify to vaccinate underinsured children using VFC vaccine must be established and recognized as a FQHC, RHC or an agency with FQHC delegate authority. A FQHC can use a memorandum of understanding (MOU) (request from VFC administrator) to delegate authority to certified LHDs who are not an FQHC with a Health Resources and Services Administration PHS Section 330 grant award notice or an RHC with a Department RHC status letter and participate in the Illinois VFC program to vaccinate underinsured children on their behalf. Providers should retain a copy
of their MOU and submit annually during VFC re-enrollment to continue to be able to administer VFC vaccine to underinsured patients.

**Table 1: VFC Eligibility Scenario**
Based on the Centers for Disease Control and Prevention’s VFC Operations Guide

<table>
<thead>
<tr>
<th>VFC eligibility scenario: Child is insured and...</th>
<th>Insurance Status</th>
<th>Is child VFC eligible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has not yet met plan’s deductible.</td>
<td>Insured</td>
<td>No, not VFC eligible</td>
</tr>
<tr>
<td>Plan covers all ACIP recommended vaccines but excludes certain products/combination vaccines.</td>
<td>Insured</td>
<td>No, not VFC eligible</td>
</tr>
<tr>
<td>Plan covers only a portion of the vaccine cost and does not have Medicaid as secondary insurance.</td>
<td>Insured</td>
<td>No, not VFC eligible</td>
</tr>
<tr>
<td>Seeking contraceptive or STD services at school-based clinic or facility whose main services are primary or acute care and wants to be immunized but does not want to access insurance.</td>
<td>Insured</td>
<td>No, not VFC eligible</td>
</tr>
<tr>
<td>Seeking contraceptive or STD services at family planning clinic or STD clinic and wants to be immunized, but does not want to access insurance or doesn’t know status.</td>
<td>Uninsured</td>
<td>Yes, VFC eligible</td>
</tr>
<tr>
<td>Has Medicaid as secondary insurance.</td>
<td>Medicaid eligible</td>
<td>Yes, VFC eligible</td>
</tr>
<tr>
<td>Plan covers only a portion of the vaccine cost and has Medicaid as secondary insurance.</td>
<td>Medicaid eligible</td>
<td>Yes, VFC eligible</td>
</tr>
<tr>
<td>Has not yet met plan’s deductible and has Medicaid as secondary insurance.</td>
<td>Medicaid eligible</td>
<td>Yes, VFC eligible</td>
</tr>
<tr>
<td>Cannot access health insurance due to being incarcerated.</td>
<td>Uninsured</td>
<td>Yes, VFC eligible</td>
</tr>
<tr>
<td>Has exceeded plan’s annually allowed number of provider visits.</td>
<td>Underinsured only through FQHC/RHC/Deputized LHD’s</td>
<td>Yes, VFC eligible but only through FQHC/RHC/Deputized LHD’s</td>
</tr>
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**VFC Eligible Decision Tree**
Please see the following VFC eligible decision tree.
**DETERMINING WHO TO VACCINATE WITH VFC VACCINE**

1. **START**
   - **Is patient insured?**
     - Yes
       - Does patient have private insurance that covers all vaccines?
         - Yes
           - **Patient has Medicaid**
             - **Is patient a child ≤18?**
               - Yes
                 - **Vaccinate with VFC vaccine**
               - No
                 - **No longer eligible for VFC vaccine**
             - **Is patient ≥19 yrs.**
               - Yes
                 - **Vaccinate with VFC vaccine**
               - No
                 - **Refer underinsured to FQHC, RHC or deputized LHD*** for VFC vaccine
     - No
       - **Patient is uninsured, Native American or Alaskan Native**
         - **Is patient a child ≤18?**
           - Yes
             - **Vaccinate with VFC vaccine**
           - No
             - **No longer eligible for VFC vaccine**
         - **Is patient ≥19 yrs.**
           - Yes
             - **Vaccinate with VFC vaccine**
           - No
             - **Refer underinsured to FQHC, RHC or deputized LHD*** for VFC vaccine
   - **Patient is underinsured**
     - **Are you a private provider?**
       - Yes
         - **Vaccinate with VFC vaccine**
       - No
         - **No longer eligible for VFC vaccine**
     - **Are you a FQHC, RHC or deputized LHD***?
       - Yes
         - **Vaccinate with VFC vaccine**
       - No
         - **No longer eligible for VFC vaccine**

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* It is the responsibility of providers to screen patients to ensure fully insured patients do not receive federally-supplied VFC vaccine. Providers should encourage patients to review insurance benefits when scheduling, have staff check benefits. If a patient arrives for an appointment and is still unsure of vaccine coverage, vaccination should be deferred until insurance coverage question(s) can be answered.

** Underinsured children include those children whose insurance coverage does not include any vaccinations, OR does not allow all recommended vaccines, OR has coverage caps on the number of allowable provider visits OR has caps at a certain dollar amount. Once those criteria are reached, the underinsured child can receive VFC vaccine only at an FQHC, RHC or LHD that has been deputized by a FQHC to serve the underinsured.

*** Federally qualified health center, rural health clinic or a local health department deputized by a FQHC to serve the underinsured

**Patients 18 years of age and younger with Medicaid, either as primary or secondary insurance, are eligible to receive VFC vaccines.

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VFC Eligibility Hierarchy
Providers must screen/review for and document VFC eligibility at every visit. Occasionally, children may be eligible for VFC vaccine in two different categories. Providers should always choose the option that requires the least amount of out-of-pocket expenses to the parent/guardian. Providers should always verify insurance coverage prior to administering vaccines.

As of January 1, 2014, the VFC program will no longer 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 for vaccination or reschedule the child.

VFC Eligibility Exceptions Occurring with Older Children
Minors under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or sexually transmitted infection treatment can be considered uninsured for the purposes of the VFC program. CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted infections. Note: VFC-enrolled providers whose main services are primary or acute care do not meet CDC’s definition of a family planning clinic and cannot use this VFC eligibility category.

A minor under 19 years of age who may be insured but is seeking vaccination against hepatitis B or HPV under confidential circumstances in a family planning clinic is considered uninsured for the purposes of the VFC program.

Note: In Illinois, the state does not require parental consent for adolescents who wish to be vaccinated against hepatitis B and/or human papillomavirus (HPV). Local clinic and/or health department administrators may require consent under local agency guidance. However, CDC and the Department view consent as a possible barrier to vaccination. A vaccine information statement (VIS) should routinely be provided upon vaccination.

Insured Children without Medicaid as a Secondary Insurance
Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible had not been met. Privately insured children, even those without a medical home, cannot be vaccinated with VFC vaccine by any VFC provider site – even an FQHC or RHC. These children must be vaccinated with privately acquired vaccine.

The following common scenarios do not qualify patients for access to VFC vaccine:

- Children whose insurance plans maintain high deductible rates that deny provider payment claims for the cost of the vaccine and its administration when the plan’s deductible (high deductible plan) have not been met.
- Children whose insurance plans cover all ACIP-recommended childhood vaccines, but exclude certain combination vaccines or certain products. A child with this type of coverage would be considered insured and not eligible for VFC because all recommended vaccines are covered.
- Children whose insurance plans cover a portion of the cost of the vaccine, even though it may be only a small portion of the cost of the vaccine. These children are considered insured and not eligible for VFC vaccine.

Fully Insured Children with Medicaid as Secondary Insurance
Situations can occur where children have private health insurance that includes full immunization benefits and Medicaid as a secondary insurance. These children are VFC-eligible as long as they are enrolled in Medicaid. VFC is an entitlement
program, and participation is not mandatory for an eligible child. **For children who have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost effective to child and his/her family.** Since January 1, 2014, the VFC no longer allows the borrowing of VFC vaccines. Providers cannot use private vaccine VFC patients and expect to pay back private stock with VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then paid back with private stock. **Providers should ensure private insurance private insurance will cover the vaccinations before vaccines are administered.**

### AI/AN with Health Insurance that Covers Immunizations
American Indian/Alaskan Native (AI/AN) children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. **For AI/AN children who have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost advantageous to the child and family.**

### Minors at Family Planning Clinics
Minors under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or sexually transmitted disease treatment can be considered uninsured for the purposes of the VFC program. CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. Any VFC-enrolled provider whose main services are primary or acute care does not meet CDC’s definition of a family planning clinic and cannot use this VFC eligibility category.

### Juveniles in Correctional Facilities
If a child under age 19 years loses access to their health insurance because of incarceration, the child is considered uninsured and VFC-eligible.

### State of Residency
At times, VFC-eligible children receive health care in a bordering state instead of their state of residency. Illinois providers enrolled in the VFC program may vaccinate children who are VFC-eligible, but reside in another state. Providers must be educated that if the provider administers VFC vaccine to a Medicaid VFC-eligible child from a neighboring state the provider must be a Medicaid enrolled provider for the state where the Medicaid VFC-eligible child resides in order to receive reimbursement for the administration fee from that state’s Medicaid program.

### Provider Responsibility to Screen for VFC Eligibility
**Screening to determine a child’s eligibility to receive vaccines through the VFC program must take place with each immunization visit.** The Patient Eligibility Screening Record developed by the Department provides a means of recording parent response to VFC eligibility questions. The parent, guardian or provider may complete the VFC eligibility portion of the form. Verification of parent/guardian responses is not required. If providers elect not to use the Department’s tool, a separate screening form must be used. Providers must correctly document VFC eligibility in I-CARE for each dose of vaccine administered.

Providers using electronic medical records (EMRs) to document* vaccinations must have the capability to enter VFC eligibility status, the criteria in which the patient qualifies and vaccine lot numbers on a per dose basis.

* VFC program related documentation, including eligibility screening, must be retained for three years.
Module 3: Provider Enrollment

Provider education must begin during the recruitment and enrollment process and continue with every provider contact. All providers enrolling in the VFC program must have an initial VFC enrollment site visit. The purpose of this visit is to ensure the provider and office staff are educated on the VFC program requirements and have the appropriate resources to implement those requirements. Education regarding the VFC program should be structured according to the requirements for provider enrollment.

VFC providers are required to register to use the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE), a tool used by health care providers, parents, public health agencies, and schools to record and promote immunization records. The VFC program utilizes the I-CARE program to record VFC vaccine use, inventory, and ordering completed online.

Annual enrollment for the VFC program is submitted through I-CARE. Enrollment forms are completed in I-CARE with an enrollment confirmation page to be signed and faxed or e-mailed to the Department.

Providers who are new to the VFC program will need to complete the I-CARE application first. Information and forms for enrollment in I-CARE are available at [http://www.idph.state.il.us/health/vaccine/icarefs.html](http://www.idph.state.il.us/health/vaccine/icarefs.html). Providers may contact the I-CARE team at DPH.ICARE@illinois.gov to check the status of their I-CARE enrollment.

Providers already enrolled in I-CARE should complete the VFC enrollment in I-CARE.

Providers not currently registered for I-CARE may find additional information at [http://www.idph.state.il.us/health/vaccine/icarefs.html](http://www.idph.state.il.us/health/vaccine/icarefs.html).

The following information must be documented in I-CARE for enrollment.

**Provider Profile**
This documents the number of VFC-eligible and non-VFC-eligible children seen in the practice. It is used to establish a projected provider-based need for vaccine, evaluate vaccine orders and ensure the amount of VFC-funded vaccine ordered is appropriate for the number of VFC-eligible children receiving care from that provider office.

**Facility information**
Providers must verify the facility information in I-CARE. If any information needs to be changed, providers need to contact the IPC by selecting the “contact us” link in I-CARE and selecting the category “VFC.”

Providers must enter the information for all VFC vaccine coordinators, indicating which individual is the primary VFC vaccine coordinator. Providers also will need to indicate if the VFC vaccine coordinators have completed the annual VFC training on storage and handling. Providers receiving a VFC compliance site visit will not need additional training. The Department reviews the providers listed in the enrollment form for their eligibility to participate. Persons on the Medicaid “List of Excluded Individuals/Entities” are excluded from participating in federally-funded health care programs, and are not eligible to participate in the VFC program. A VFC-enrolled provider site that is employing a person
on the excluded provider list must be terminated from the VFC program. Illinois Medicaid also is notified of the termination. Excluded providers cannot participate in the program indirectly, such as providing services under a non-excluded VFC provider. The Department also verifies professional license numbers and license status through the Illinois Department of Financial and Professional Regulation’s database. The Department will check for suspected fraud and abuse allegations or reports.

Providers must document vaccine storage unit(s) in I-CARE, under the temperature log page. Providers must document all VFC appliances used, the type of storage units, and details on each unit’s certified calibrated thermometers.

Providers must measure temperatures twice daily and record a month’s worth of temperatures prior to their first vaccine order approval. Storage unit temperatures are required to be read and documented twice each workday. The CDC recommends that minimum/maximum temperatures be checked and documented at the beginning of the workday. Providers also must enter temperatures in I-CARE at least three (3) days per week. VFC documentation must be retained for up to three years.

Providers must agree to replace vaccine wasted due to practice negligence or failure to correctly store, handle or transport vaccine. The Vaccine Loss and Replacement Policy is available in I-CARE or at http://www.idph.state.il.us/about/imunizationvfc.htm. The Vaccine Loss and Replacement policy defines the conditions in which wasted vaccines must be replaced with private purchase vaccines.

After completing the required information in I-CARE, providers must print a signature page and fax or e-mail it to the Department.

**Enrollment Terms**

All VFC providers must agree to the following enrollment terms.

> To receive publicly funded vaccines at no cost I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or practice administrator or equivalent:

1. *I will screen patients and document eligibility status at each immunization encounter for VFC eligibility and administer VFC-purchased vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:*
   a. are an American Indian or Alaska Native
   b. are enrolled in Medicaid
   c. have no health insurance
   d. 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.**

2. *I will 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;
b. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

3. I will maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and make these records available to public health officials, including the state or Department of Health and Human Services, (DHHS) upon request.

4. I will immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.

5. I will not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of $23.87 per vaccine dose. For Medicaid VFC-eligible children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

6. I will not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

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

8. I will comply with the requirements for vaccine ordering, vaccine accountability, and vaccine management. I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. I understand VFC providers may not store federally purchased vaccine in dormitory style refrigerators at any time. I will return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.

9. I will participate in VFC program compliance site visits, storage and handling unannounced visits, and other educational opportunities associated with VFC program requirements.

10. I-CARE Participation/Requirements
   a. I agree to 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. Data in the I-CARE registry may only be used to assure adequate immunization, avoid unnecessary immunizations, meet immunization requirements, and for other public health purposes as determine by the Department. Participation will include, but not be limited to, documenting patients receiving VFC vaccines, VFC vaccine inventory, temperatures of refrigerators and freezers storing or containing VFC vaccines and routine use of the VFC vaccine ordering system.
   b. When my staff, representative or I access I-CARE, I agree to be bound by the Department’s terms of use for interacting with the registry. I further agree to be bound by any applicable federal laws, regulations or guidelines related to accessing an IDPH system and ordering publicly funded vaccines.
   c. In advance of any I-CARE access by my staff, representative or myself, I will identify each member of my staff or representative who is authorized to order vaccines on my behalf. In addition, I will maintain a record of each staff member who is authorized to order vaccines on my behalf. If changes occur, I will inform the Department within 48 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.

11. For providers with a signed Memorandum of Understanding between a FQHC or RHC and the state/local immunization program to serve underinsured VFC-eligible children, I agree to:
a. Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;
b. Vaccinate "walk-in" VFC-eligible underinsured children and
c. Report required usage data

12. Dose for dose reimbursement for state-supplied vaccine will be requested if wastage was due to the
provider’s failure to properly store, handle or rotate vaccine inventory.

13. I understand this facility or the state/local immunization program may terminate this agreement at any time.
If I choose to terminate this agreement, I will properly return any unused VFC vaccine as directed by the
immunization program.

14. The term of this Agreement is from January 1, 2014-December 31, 2014 unless terminated earlier. If I want to
participate in the VFC Program after this Agreement expires, then I will be required to re-apply for enrollment
annually by completing a new Practice Profile Form and Provider Agreement. Re-enrollment is not
guaranteed and may be denied for any reason. Failure to re-apply for enrollment will mean suspension and
possible termination from the VFC program. I will comply with City’s/State’s Vaccine Loss and Replacement
Policy, Policy and Procedure for Medicaid Fraud and Abuse.

VFC Enrollment Visits
All providers enrolling in the VFC program must receive an enrollment visit prior to receiving any vaccine through the
VFC program. The enrollment visit must include the following content:

- Review and confirm provider and staff understand and are able to implement the requirements of the VFC
  program.
- Confirm that the provider has the proper equipment to maintain VFC vaccine and staff understand how to
  properly store, handle and monitor VFC vaccine, and know who to contact if problems arise.

Department staff performing the enrollment visit must document the visit in the CDC’s reporting system. A VFC storage
and handling site visit may be scheduled approximately three months after the provider begins receiving VFC vaccine.

Education Requirement
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 educational visits, regional
VFC trainings offered through the Department partners (ICAAP or EverThrive) or through CDC online training, “You Call
The Shots – Module 10 – Storage and Handling,” available at
http://www2a.cdc.gov/nip/isd/yccts/mod1/courses/sh/ce.asp. Additional online training will be available soon through
the Illinois Chapter of American Academy of Pediatrics at http://illinoisaap.org/. A VFC Training Log is available in the
Vaccine Management Plan for providers to document their training.
Module 4: Equipment Recommendations and Requirements

Equipment Types

Vaccine must be stored in one of the following equipment types:

- Stand-alone refrigerator
- Stand-alone freezer
- Combination refrigerator/freezer- using only the refrigerator compartment for vaccine storage
- Pharmaceutical/medical/laboratory grade refrigerator
- Pharmaceutical/medical/laboratory grade freezer
- Compact (under counter) refrigerator
- Compact (under counter) freezer

CDC recommends that providers store vaccines in separate, stand-alone refrigerator or freezer units. However, if a combination unit is used, it should have separate controls for the refrigerator and freezer sections. Providers may want to consider planning and budgeting for the replacement of equipment to meet CDC recommendations.

VFC vaccines cannot be stored in dormitory-style refrigerators at any time.

As of January 1, 2013, the CDC mandated that dormitory-style refrigerators are not allowable to store VFC vaccine at any time. Dormitory-style refrigerators do not maintain proper temperatures and pose a high risk of freezing vaccine. Any VFC vaccines found to be in dormitory-style refrigerators will be wasted and providers will be expected to replace the wasted VFC vaccine with privately purchased vaccine. See the CDC Storage and Handling Toolkit at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf for additional information.

CDC does not recommend storage of any vaccine in a dormitory-style (or bar-style) combined refrigerator/freezer unit under any circumstances. A dormitory-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. Some dormitory-style units may be sold as medical grade units, but may still be classified as dormitory-style due to having one exterior door with a freezer compartment located inside the refrigerator section.

The 2009 NIST research concluded that “the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance.” In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This type of unit exhibited severe temperature control and stability issues. Large spatial temperature gradients confirmed there is no “good” vaccine storage area in this style unit. Dormitory-style (or bar-style) units pose a significant risk of freezing vaccine even when used for temporary storage. Note that the use of dormitory-style units for storage of VFC vaccines or other vaccines purchased with public funds is prohibited. Compact, purpose-built storage units for biologics are available that are not considered to be dormitory-style or bar-style.
The following examples are considered dormitory-style refrigerators and are NOT allowable to store VFC vaccines at any time.

Equipment Size
Any refrigerator or freezer unit used for vaccine storage must be able to maintain vaccine storage temperatures year-round, be large enough to hold the year’s largest inventory, be dedicated only to the storage of vaccines, and must have a certified calibrated thermometer inside each compartment used for storing vaccine.

VFC providers receive vaccine at no cost to them. However, the vaccines are purchased with millions of taxpayer dollars. To reduce waste and spoilage of expensive vaccines, the VFC program has guidelines for vaccine storage units.

### Equipment Size Recommendations

<table>
<thead>
<tr>
<th>Office Size</th>
<th>Required Equipment</th>
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<tbody>
<tr>
<td>Very High Volume 10,000 doses/year</td>
<td>Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units</td>
</tr>
<tr>
<td>High Volume 2,000-10,000 doses/year</td>
<td>Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units</td>
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<tr>
<td>Medium Volume 500-2,000 doses/year</td>
<td>Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units OR</td>
</tr>
<tr>
<td>Low Volume Less than 500 doses/year</td>
<td>Pharmacy-grade or biologic-grade under the counter units.</td>
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Temperature Monitoring
Refrigerator temperatures must be between 35 F to 46 F (2 to 8 C). Ideally, the temperatures should be maintained around 40 F (5 C). Freezer temperatures must be less than 5 F (-15 C).
## Acceptable Temperatures for Vaccines

<table>
<thead>
<tr>
<th>FAHRENHEIT</th>
<th>CELSIUS</th>
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<tbody>
<tr>
<td>Refrigerator</td>
<td>Freezer</td>
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<tr>
<td>55°F</td>
<td>10°F</td>
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<tr>
<td>54°F</td>
<td>9°F</td>
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<tr>
<td>53°F</td>
<td>8°F</td>
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<td>52°F</td>
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<td>51°F</td>
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<td>47°F</td>
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<td>46°F</td>
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<tr>
<td>45°F</td>
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<tr>
<td>44°F</td>
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<tr>
<td>43°F</td>
<td>-2°F</td>
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<tr>
<td>42°F</td>
<td>-3°F</td>
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<tr>
<td>41°F</td>
<td>-4°F</td>
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<td>40°F</td>
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<td>36°F</td>
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<td>35°F</td>
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<td>34°F</td>
<td>-11°F</td>
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<td>33°F</td>
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<td>7°F</td>
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<td>6°F</td>
<td>-39°F</td>
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<tr>
<td>5°F</td>
<td>-40°F and colder</td>
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Certified Calibrated Thermometers

The recommended method to ensure a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day each workday, and no fewer than three times a week. The office must adhere to the following guidance:

- Each refrigerator and freezer must have a calibrated working thermometer certified in accordance with the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST, placed in a central area inside each compartment used for storing vaccine.
- CDC recommends providers also have a certified calibrated back-up thermometer in place.
- Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued).

Providers should have a thermometer in each unit, with a back-up thermometer available. CDC recommends 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)

Providers are responsible for maintaining current Certificates of Traceability and Calibration Testing. Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued). Provider must keep the certificate of calibration for each thermometer and back-up thermometer, and make them available for inspection during site visits.

As of April 2013, CDC will allow calibration testing and traceability to be performed by a laboratory accredited by an ILAC MRA signatory body OR, as an alternative, by a laboratory or manufacturer that provides documentation that demonstrates calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability. **Between the two options, CDC recommends testing be performed by ILAC accredited laboratories.** An ILAC MRA accredited laboratory is the easiest way to identify the instrument has been tested correctly according to international standards.

A Certificate of Traceability and Calibration Testing (also known as a Report of Calibration) must include key pieces of information. Information required on the certificate depends on whether the laboratory performing calibration testing is an accredited or non-accredited laboratory. Before sending your thermometer(s) for calibration, check with the calibration company to verify required information will be included on your certificate.

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1 Certificate of Traceability and Calibration Testing (also known as Report of Calibration) is a certificate that informs the user of a thermometer’s level of accuracy compared to a recognized standard based on testing by the National Institute of Standards and Technology (NIST).
Calibration testing performed by an ILAC accredited laboratory

- ILAC accredited laboratories are (logos are shown below):
  - The American Association for Laboratory Accreditation (A2LA).
  - Laboratory Accreditation Bureau (L-A-B).
  - ANSI-ASQ National Accreditation Board (AClass).
  - International Accreditation Service (IAS).
  - Perry Johnson Laboratory Accreditation, Inc. (PJLA).

### ILAC/MRA Signatory body accredited Laboratory

The Following Table lists the accredited laboratories

<table>
<thead>
<tr>
<th>A2LA</th>
<th>L-A-B</th>
<th>AClass</th>
<th>IAS</th>
<th>PJLA</th>
<th>NVLAP</th>
</tr>
</thead>
</table>

- The certificate of calibration must have these items:
  - Name of device (optional)
  - Model number
  - Serial number
  - Date of calibration (report or issue date)
  - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F or 0.5 C)

Calibration testing not performed by an accredited laboratory:

- These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:
  - Name of device (optional)
  - Model number
  - Serial number
  - Date of calibration (report or issue date)
  - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F or 0.5 C)
  - Measurement results for the device
  - Statement that calibration testing conforms to ISO 17025

Storage temperatures are manually recorded:

- Twice a day
- Three months of temperature logs available
- Recorded in I-CARE at least weekly
Vaccine Refrigerator Setup
Please see the following diagram for VFC vaccine refrigerator setup.

1. Remove all drawers and bins. Vaccines should not be stored in refrigerator doors, drawers, or bins.

2. Put a few water bottles in areas where vaccines will not be stored.

3. Use a calibrated thermometer to ensure accurate temperatures. The thermometer must have a glycol-encased probe. The digital monitor must display CURRENT, MIN, and MAX temperatures. Place the probe in the center of the refrigerator near the vaccines.

4. Attach the monitor to the outside of the refrigerator, either on the door or on the side.


6. Set the refrigerator temperature. If the refrigerator has a thermostat, set it for 40°F. If it has a dial with a range of numbers, set it to slightly warmer than the middle of its range. The next morning, check the temperature and adjust it until it stabilizes at approximately 40°F.

7. Once the temperature has stabilized, record it on the temperature log. Record CURRENT, MIN, and MAX temperatures twice a day. Do not store vaccines in the refrigerator until the temperature is stable at around 40°F for 3–5 days.
Refrigerator-only Unit

Almost all of the space is usable (inside dashed lines).

- Always keep vaccine in its original box. Do not open the box until you are ready to use the vaccine.
- Place vaccine boxes in breathable plastic mesh baskets or directly on shelves. Label baskets or shelves by type of vaccine.
- Group vaccines by pediatric, adolescent, and adult types.
- Separate VFC vaccine from privately purchased vaccine and label them clearly.
- Keep baskets 2-3 inches from walls and other baskets.
- Store only vaccine and other medication in vaccine storage units.
- Keep vaccines with shorter expiration dates to front of shelf.
  If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.
- Keep temperatures between 35°F to 46°F.
  - Below 35°F is too cold! Call VFC.
  - Above 46°F is too warm! Call VFC.

- No vaccine in doors.
- No vaccine in solid plastic trays or containers.
- No food in refrigerator.
- No vaccine in drawers or on floor of refrigerator.
Vaccine Freezer Setup

Please see the following diagram for VFC vaccine freezer setup.

1. Put a few cold packs in areas where vaccines cannot be stored, like the door and the top shelf.

   - Stand-alone freezer
   - Chest freezer

2. Use a calibrated thermometer to ensure accurate temperatures. The thermometer must have a glycol-encased probe. Place the probe in the center of the freezer, near the vaccines.

3. Temperature monitors must display CURRENT, MIN, and MAX temperatures. Attach the display of the primary thermometer to the outside of the freezer.


5. Set the freezer temperature. If the freezer has a thermostat, set it at -5°F or below. If it has a dial with a range of numbers, set it in the middle. The next morning, check the temperature and adjust it until it stabilizes below 0°F.

6. Once the temperature has stabilized, start recording temperatures on the temperature log twice a day. Do not store vaccines in the freezer until the temperature stays below 0°F for 3-5 days.
Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

Separate the VFC vaccine supply from privately purchased vaccine.

Keep vaccines with shorter expiration dates to front of shelf. If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.

Keep temperatures 5°F or colder. Aim for 0°F and below. Above 5°F is too warm! Call VFC.
Module 5: Borrowing VFC Vaccines

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.

As of January 1, 2014, the VFC program will no longer 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 or FQHC or reschedule the child.
Module 6: Vaccine Loss and Replacement

Current state and federal vaccine contracts stipulate that spoiled or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by the Department’s program budget. Since the VFC program is so important to people’s health and well-being, it is essential that we ensure every dose of vaccine is used to provide protection against preventable diseases. Providers must continually monitor vaccine storage and handling practices. Providers may notify the Illinois VFC program if they would like to receive an educational visit regarding vaccine storage and handling. VFC providers are required to report all wasted, expired, spoiled or lost vaccine to the Illinois VFC program.

The Vaccine Loss and Replacement Policy describes the procedure for the management of incidents that result in loss of state-supplied vaccine. Dose-for-dose reimbursement of state-supplied vaccine will be requested if waste was due to the provider’s failure to properly store, handle or rotate vaccine inventory. Provider’s ordering privileges may be suspended until replacement is made.

Definitions

Wasted: Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the vaccine manufacturer and Illinois VFC program before determining that the vaccine is spoiled or non-viable.

Lost: Commercial carrier (FedEx or UPS) or U.S. Postal Service (USPS) does not deliver the vaccine or does not deliver in a timely manner.

Situations Requiring Vaccine Replacement

Expired Vaccine

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine.
- Provider orders of vaccines that exceed the provider profile on file, which results in excessive expired inventory.

Spoiled Vaccine

- Pre-drawn vaccine that is not used. Note the Illinois VFC program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine left out of the refrigerator or freezer and becomes non-viable. Call the vaccine manufacturer first to help determine the stability/viability of vaccine left out of the refrigerator/freezer.
- Vaccine stored in dorm style refrigerators.
- Freezing vaccine supposed to be refrigerated.
- Refrigerating vaccine supposed to be frozen.
- Refrigerator/freezer left unplugged.
- Refrigerator/freezer door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the Illinois VFC program within 30 days from the date you became aware of the situation.
• Power outages in which the provider fails to follow the facility’s Vaccine Storage and Emergency Response Plan.
• Vaccine considered spoiled due to the provider not checking, reviewing and recording refrigerator and freezer temperatures twice daily.
• Vaccine considered spoiled due to the provider failing to use currently certified calibrated thermometers in each VFC storage unit to check temperatures twice daily.
• Vaccine that is spoiled and must be wasted because a provider did not take immediate or appropriate action on out-of-range temperatures to prevent vaccine from becoming spoiled.
• Provider not available to receive a delivery of vaccines during provider’s posted hours on file with the order and vaccine was exposed to temperature excursions during return to McKesson Specialty.
• Replacement vaccine: health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for replacement of the vaccine needed to re-vaccinate.
• Depending on the outcome of any suspected fraud investigation by the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office and/or the appropriate state Medicaid agency, providers may be required to, among other things, return all VFC vaccine, reimburse the state for the cost of used vaccines, and/or potentially be terminated from the VFC Program. The Department of Public Health reserves any and all rights with respect to any future action.

Wasted Vaccine

• State-provided vaccine given to children or adults who are not eligible to receive it based on the most recent VFC eligibility criteria and Illinois immunization guidelines.
• Discarding vaccine before the manufacturer’s expiration date (includes multi-dose vials discarded after 30 days).

Situations Not Requiring Vaccine Replacement

Below is a list of situations NOT considered “provider negligence.” This list is not exhaustive. In these situations, the provider is deemed not to be at fault. Providers may be required to produce a letter from the alarm/alert company or the power company.

• A commercial carrier or USPS does not deliver to the provider in a timely manner and the provider was available to receive the vaccine during provider’s posted hours. Before making the determination the vaccine is non-viable, first call the vaccine manufacturer.
• A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider.
• A provider moves vaccine to a nearby hospital due to anticipated inclement weather, the hospital experiences a power failure, and the Illinois VFC program later deems the vaccine not viable.
• Power was interrupted or discontinued due to a storm, provider is able to confirm the facility’s Vaccine Storage and Emergency Response Plan was followed, and after consultation with the vaccine manufacturer(s) and the Illinois VFC program, it is determined that vaccine is not viable.
• A vial accidentally dropped or broken.
• Vaccine drawn at the time of the visit, but not administered due to parental refusal or a change in physician orders.
• Expired vaccine not due to provider negligence (including seasonal influenza vaccine).
- Extraordinary situations not listed above that are deemed by Illinois VFC program to be beyond the provider’s control.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Illinois VFC program within 30 days from the date you became aware of the situation.

Procedures for Returning Nonviable Vaccine
- Complete the vaccine incident report to determine if the suspected vaccine is viable or not and fax or e-mail the Vaccine Incident report, along with the vaccine manufacturer(s) report to the Illinois VFC program. The vaccine incident report is available in I-CARE under “reports.”
- Failure to report wasted vaccine to the Illinois VFC program may result in your facility no longer being able to receive state-supplied vaccine.
- Return all unopened vials and manufacturer’s pre-filled syringes of spoiled or expired vaccine with a completed Vaccine Waste Packing List for Excise Tax Credit and Disposal to McKesson Specialty regardless of any financial restitution status applied to the vaccine. Vaccine provided by the Illinois VFC program should never be discarded. The only exception is open vials or syringes, including multi-dose vials, from which some doses have already been withdrawn. These can no longer be sent back to McKesson Specialty. A wastage form must still be filled out and sent to the Illinois VFC Program, and the open vials and syringes should then be discarded per your facility’s policy. Providers must record the vaccine as waste in I-CARE then print the completed waste form. The waste form must then be e-mailed to DPH.Vaccines@illinois.gov or faxed to 217-786-7506.

Procedures for Vaccine Replacement
This updated policy applies to any vaccine received as wasted by the Illinois VFC program on or after January 1, 2014.
- The provider will receive a notice from the Illinois VFC program requesting proof of replacement of vaccine reported as wasted to the Illinois VFC Program.
- Acceptable proof is a packing list or paid invoice showing type, amount, lot number and expiration date of privately purchased vaccine that will then be marked and used as VFC vaccine.
- The provider must enter the privately purchased vaccine in I-CARE and record it as payback to VFC. The provider must first add the privately purchased vaccine lots to their inventory in I-CARE and then add a transaction to payback VFC.
- Replacement of the vaccine is due within 30 days of receiving the Illinois VFC program notice.
- The Illinois VFC program will not supply vaccine to the negligent provider until restitution has been made. Enrollment or re-enrollment in the VFC program will not be accepted until full restitution is made.

Provider-to-Provider Transfer of Vaccines
Providers who have excess vaccine on hand that will not be used before expiration are encouraged to transfer this vaccine to other Illinois VFC providers to utilize, and thus avoid being charged for wasted vaccine. Providers should begin this process within three to six months of the vaccine expiring. It is the provider’s responsibility to find another provider willing to accept the vaccine, and also to properly pack and ship the vaccine to that provider following standard cold-chain procedures. CDC requires the provider obtain pre-approval from the Department before any transfers. The transfer pre-approval request form, with transportation guidelines, is available at http://www.idph.state.il.us/about/immunizationvfc.htm.
Module 7: Accountability

VFC Vaccine Orders

Providers should order vaccine in accordance with actual vaccine need and avoid stockpiling or build-up of more than a three-month supply. Providers should maintain enough vaccine inventory to last five weeks, but no more than three months. Orders may take two to four weeks from submission of order to vaccine delivery.

All vaccine orders are submitted through I-CARE. As of June 1, 2013, faxed or e-mailed orders are no longer accepted. Providers must enter the following information to submit an order in I-CARE:

- Vaccine accountability.
- Temperature logs for all storage units being used to store state-supplied vaccine.
- All temperature excursions must have a Vaccine Incident Report on file.
- Vaccine inventory and accountability for all state supplied vaccine must be up to date.
- Clinic must be open at least three days a week with sufficient hours to be able to receive a delivery.

In 2014, Illinois VFC providers must provide patient-level data on the administration of VFC vaccines, also referred to as Phase 2 of I-CARE VFC use. This patient-level data can either be manually entered directly into I-CARE or can be electronically transmitted to I-CARE from the provider’s electronic medical record (EMR) system via HL7 messaging. Illinois has established a schedule to transition providers to Phase 2. Providers will be notified when they need to begin to transition and will have 30 days to come into compliance. VFC providers must be at Phase 2 (patient-level data in I-CARE) no later than May 31, 2014. VFC providers not in compliance will not be able to continue participating in the VFC program.

Providers must also notify the Department when there has been a change in the VFC coordinator or storage units either by calling 217-786-7500 or sending an e-mail to dph.vaccines@illinois.gov.

The Department will review submitted documentation within 10 working days of receipt from the provider. If the documentation shows significant wasted/lost or unaccounted for vaccine, temperature excursions without appropriate follow-up documentation, or a change in VFC coordinator or storage units used, the Department must follow up with the provider. If a provider does not submit the required documentation, orders will be held until the required documentation is submitted and reviewed.

Additional information on ordering through I-CARE is available in I-CARE under “About I-CARE” and going to “How To.”

Provider Profiles

Provider profiles will be used by the VFC administrator and appropriate staff to monitor provider orders. The VFC coordinator and appropriate staff must consult the provider profile when reviewing orders to ensure providers are ordering adequate amounts of VFC vaccine for their VFC population. Providers ordering more vaccine than should be needed for their VFC population will be contacted. If orders for excess amounts of vaccine are placed on a regular basis, the provider will be contacted. The issue also will be forwarded to the VFC administrator for follow-up at a VFC compliance site visit. Providers may order enough vaccine for a three-month supply if storage space allows.
**Vaccine Return and Waste**

The vaccine must be documented in I-CARE as waste or expired vaccine. Returns must be completed within six months after the product expiration or waste date.

1. Record the vaccine as waste or expired in I-CARE. NOTE: McKesson Specialty no longer requires a minimum of doses to be returned, but does require doses be submitted within six months after the product expiration date.
2. Indicate the reason why the vaccine was wasted in the area provided.
3. Print the completed Vaccine Waste Packing List for Excise Tax Credit and Disposal form.
4. Fax a copy of the Vaccine Waste Packing List for Excise Tax Credit and Disposal form to the Illinois VFC Immunization Promotional Center (IPC) at 217-786-7506 or e-mail to DPH.Vaccines@illinois.gov.

The Illinois VFC program will arrange to have McKesson Specialty mail a return label to be to you, so that your office can ship the expired/wasted vaccines back to McKesson Specialty in the vaccine shipping box you maintain.

**VFC Provider Withdrawal**

Unfortunately, some circumstances may occur that necessitate VFC providers withdrawing from their role as an approved provider. The cause for these circumstances may vary, but timely and appropriate notification by the provider is desired and expected. The following steps should occur:

- The clinic would complete the VFC Provider Withdrawal Form available at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm) and fax or e-mail to the Illinois VFC program.

- If the clinic is able to provide documentation of the cold chain being maintained, the clinic must find another VFC provider to transfer their remaining vaccines.

- The Department will contact the provider to follow up on the withdrawal.
Module 8: VFC Site Visits

VFC Compliance Visit
The Department is mandated by CDC to conduct a compliance site visit to each enrolled and active VFC provider office at least once every other year to ensure compliance with VFC program standards. The VFC compliance visit requires availability of key staff that can accurately provide a realistic picture of how your clinic is implementing the VFC program on a daily basis. The VFC compliance site visit includes staff guidance and education on “best practices” to store and manage VFC vaccines, ensure all VFC-eligible children are receiving properly maintained vaccines, and address practice-based questions about VFC program initiatives.

Storage and Handling Site Visit
The vaccine storage and handling visit serves as a “spot check” for proper practices on storage and handling of VFC vaccine. The goal of these visits is to provide guidance and education, to protect the vaccine, and to ensure VFC-eligible children are receiving properly managed vaccines.

The current vaccine storage and handling toolkit was updated November 2012 and is available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf. The toolkit outlines best practice strategies and recommendations on the following:

- Equipment considerations for storage units and thermometers
- Maintaining the cold chain
- Routine storage and handling practices
- Inventory management
- Emergency procedures for protecting vaccine inventories

Please be advised that checks to monitor vaccine storage unit temperatures by pharmaceutical representatives or other entities do not satisfy the CDC mandate for storage and handling visit requirements.

Conducting the Site Visit
The VFC site visits are conducted either by the Department’s immunization staff or by local health departments trained by the Department to act as delegates to perform compliance visits.

Following Up After the Site Visit
During or at the end of the VFC compliance site visit, VFC staff shall provide education to the provider staff when non-compliant behaviors or practices are observed or encountered in order to correct the situations. If the provider is found to be non-compliant, a provider follow-up plan will be completed and reviewed with the provider office.
Module 9: Fraud and Abuse

Overview
As childhood vaccines become more expensive and immunization programs more complex, the VFC program becomes vulnerable to fraud and abuse. A working understanding of what constitutes fraud and abuse is critical for all persons working in the VFC program. Consistent with “fraud” and “abuse” as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of this guide, the following definitions will be used:

Fraud: 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: provider practices 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 Department’s Immunization Program, a health insurance company or patient] or in reimbursement for services not medically necessary or fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Oversight: Illinois specifies any suspected case of fraud and abuse should immediately be reported to the Department’s VFC administrator, immunization assistant section chief, or immunization section chief. Within five working days, the Department’s Immunization Program will contact the provider in question or the person reporting the suspected fraud and abuse to perform an in-depth interview, with documentation recorded on the Department’s fraud and abuse form. A file will be established for each provider suspected of fraud and abuse with a copy of all verbal and written correspondence maintained, as well as maintaining a fraud and abuse referral database. The Department’s Immunization Program will follow-up with the external agency within ten working days, or sooner.

Enforcement: If the VFC program determines from the assessment of information available that the situation requires referral for further investigation by an outside agency, the VFC program will make these referrals within ten working days from assessment. All suspected cases of fraud and abuse that require further investigation must be referred first to the immunization section chief or equivalent for referral to the Medicaid Integrity Group (MIG) and the CDC, with notification of the referral also sent to Department’s legal counsel and auditor.

Termination: The Department’s Immunization Program has the right to exclude or terminate providers from the VFC program that are not following any other Illinois VFC program or I-CARE requirements. Vaccine will be removed from the provider’s possession and the provider will be prohibited from receiving future shipments until the exclusion is lifted. The terminated provider or entity may be eligible to re-apply for the VFC and I-CARE Programs after the exclusion is lifted. The Illinois VFC program will terminate providers from participating in the VFC program if the provider is found to be in non-payment status under Medicare, Medicaid, and other federal health care programs. Termination of providers may also occur due to Office of Inspector General (OIG) sanction, failure to renew license or certification registration, revocation of professional license or certification, or termination by the Illinois Medicaid Agency. Providers that are terminated from the VFC program (both voluntarily and involuntarily) will be removed from active status in the VFC program, removed from VFC Health Alert Notification (HAN) lists and excluded on reports to the Illinois Medicaid agency requesting data on active VFC providers.

All cases of suspected fraud and abuse will be handled according to this policy and the CDC Non-Compliance with VFC Requirements Protocol.
**Fraud and Abuse Policy**

The Fraud and Abuse Policy is a comprehensive written policy that addresses prevention, detection, investigation, and resolution of fraud and abuse allegations. VFC staff must be familiar with this policy and be able to prevent, to identify and to follow-up on situations that involve suspected fraud or abuse of the VFC program.

When providers enroll in the VFC program, they agree to comply with all the requirements of the program. Lack of adherence to the VFC program requirements by an enrolled provider could lead to fraud and abuse of the VFC program by that provider. Non-compliance with program requirements may occur due to an unintentional lack of understanding of the VFC program requirements, or the behavior may be intentional. **If the non-compliance appears intentional and the provider has received financial benefits from the behavior, the situation would require immediate referral to an outside agency for investigation of suspected VFC fraud and abuse.**

**Allegations of Suspected Fraud and Abuse**

The Department will investigate all allegations of suspected fraud and abuse and will determine if the situation is intentional fraud and abuse or unintentional abuse or error due to an excusable lack of knowledge of the VFC program with no purposeful intent to misrepresent or defraud the VFC program. If the situation is found to be unintentional, an educational intervention will be made, and arrangements will be established to replace any vaccine used inappropriately.

The Department’s Immunization Program staff will provide in-depth education to the provider’s key staff about the VFC program and Illinois VFC enrollment and accountability requirements. The provider will be required to complete and return a corrective action plan detailing the steps that will be taken to prevent further incidents. This signed plan must be returned to the Department’s Immunization Program within one month. The provider also will be required to sign an acknowledgment they received additional education, and that any recurrence of suspected fraud and abuse may result in termination from the VFC program and referral to an external agency for investigation.

If the investigation determines the situation is intentional, the situation will be reported to an external agency for investigation. All suspected cases of fraud and abuse that require further investigation will first be referred first to the Immunization Section chief or equivalent for review by the Office of Health Protection and the Department legal counsel and auditor. Suspected cases of fraud and abuse will then be referred to the Medicaid Integrity Group (MIG) and the CDC.

Suspected cases of fraud and abuse will be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office for further investigation. CMS/MIG may refer the suspected case to the appropriate state Medicaid agency for further investigation. VFC ordering privileges may be suspended when a referral is made to CMS/MIG. Depending on the outcome of any investigation by CMS/MIG and/or the appropriate state Medicaid agency, providers may be required to, among other things, return all VFC vaccine, reimburse the state for the cost of used vaccines, and/or potentially be terminated from the VFC Program. The Department reserves any and all rights with respect to any future action.

**Examples of Fraud and Abuse**

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the VFC program to prevent or detect than others, depending on how the VFC program is implemented. The VFC program will use provider profiles, ordering patterns, VFC site visits, temperature logs and doses administered reports to monitor provider compliance with VFC program requirements. Some examples of potential fraud are:
• Providing VFC vaccine to non-VFC-eligible children
• Selling or otherwise misdirecting VFC vaccine
• Billing a patient or third party for VFC vaccine
• Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to an eligible child
• Denying VFC-eligible children VFC-funded vaccine because of parents’ inability to pay administration fee
• Failing to implement provider enrollment requirements of the VFC program (see Module 3)
• Failing to screen patients for VFC eligibility at every visit
• Failing to maintain VFC records and comply with other requirements of the VFC program
• Failing to fully account for VFC-funded vaccine
• Failing to properly store and handle VFC vaccine
• Administering expired or compromised VFC vaccine to patients
• Ordering VFC vaccine in quantities or patterns that do not match the provider’s profile or otherwise over-ordering of VFC vaccine
• Waste of VFC vaccine
**Fraud and Abuse Contacts**

Suspected VFC fraud or abuse may be reported to any of the following Department staff.

- **Linda Kasebier, VFC administrator**, is designated as the primary contact.
  
  Linda.Kasebier@illinois.gov

- **Carol Finley, assistant chief, Immunization Section**, is designated as first back-up.
  
  Carol.Finley@illinois.gov

- **William Moran, chief, Immunization Section**, is designated as second back-up.
  
  William.Moran@illinois.gov

Each of these individuals may be contacted at:

- 525 W. Jefferson Street, 1st Floor
- Springfield, IL 62761
- 217-785-1455 or 800-526-4372

**Ongoing Provider Monitoring Procedures**

The Illinois VFC program will exclude providers from participating in the VFC program if the provider is found to be in non-payment status under Medicare, Medicaid, and other Federal health care programs. Exclusion of providers also may occur due to Office of Inspector General (OIG) sanction, failure to renew license or certification registration, revocation of professional license or certification, or termination by the state Medicaid agency. The Illinois Immunization Program will monitor OIG exclusions by checking the List of Excluded Individuals and Entities on the OIG website upon provider enrollment at [oig.hhs.gov/fraud/exclusions.asp](http://oig.hhs.gov/fraud/exclusions.asp). This list will be checked monthly thereafter and compared to currently enrolled providers. Claims are not processed by Medicaid for providers on the OIG list. **Providers are strongly encouraged to check the OIG website list of excluded individuals/entities prior to hiring or contracting with any individuals or entities.** Enrolled providers who employ a person (including, but not limited to, physicians, mid-level practitioners, nurses or nursing aides) from the excluded provider list will be terminated from the program and the state Medicaid and MIG agencies will be notified.

The Department’s Immunization Program also has the right to exclude providers not following any other Illinois VFC program or I-CARE requirements. Vaccine will be removed from the provider’s possession and the provider will be prohibited from receiving future shipments until the exclusion is lifted. The excluded provider or entity will be required to re-apply for the VFC and I-CARE Programs after the exclusion is lifted. The Illinois Immunization Program, state attorney’s office, and the Medicaid Fraud and Abuse Unit to share any information regarding allegations and exclusions due to fraud and abuse.

**Reporting VFC Provider Terminations**

Providers terminated from the VFC program (both voluntarily and involuntarily) will be removed from active status in the VFC program, removed from VFC Health Alert Notification (HAN) lists and excluded on reports to the state Medicaid agency requesting data on active VFC providers.
Appendices
The following documents are located in the appendix.

- VFC Tip Sheet – Manual Defrost Storage Units
- VFC Tip Sheet – Products with Multiple NDCs
- VFC Tip Sheet – Vaccine Storage Unit Checklist
Manual Defrost Storage Units

The Centers for Disease Control and Prevention (CDC) currently recommends stand-alone refrigerators and stand-alone freezers for vaccine storage. The CDC recommends auto defrost (self-defrosting) units, but if a provider has a unit with a manual defrost, he/she should have another storage unit for temporary storage capable of maintaining correct temperatures to place the vaccine in while defrosting the main unit.

The following is a suggested procedure for defrosting a manual defrost unit:

1. Check the inside walls of the freezer weekly
   a. When frost has accumulated to a thickness of approximately one cm, the unit requires defrosting.
   b. The more the unit is opened and closed, frost will build quicker.
   c. Follow the manufacturer’s specific recommendations for defrosting a freezer.
2. Remove all vaccine (from both compartments if using a combination refrigerator/freezer).
3. Place all vaccine in an alternate storage unit(s) that will maintain correct temperatures.
4. Turn off the power to the unit you are defrosting and unplug the unit.
5. Remove all frozen packs (keep frozen if possible).
6. Keep the freezer door open to allow the frost to melt.
7. Remove loose ice by hand to speed the process, but do not use sharp tools.
8. Defrosting time can be reduced by placing a container of warm water (not boiling hot) inside the compartment.
9. Once the frost is melted completely, clean the freezer compartment thoroughly and wipe dry.
10. Clean refrigerator compartment as well.
11. Connect the power, ensure that the thermostat is turned on and set correctly.
12. Wait for temperature to stabilize at the proper range before returning vaccine to defrosted unit. This may take hours or a day depending on the unit, so monitor with a calibrated temperature monitoring device.
13. Monitor and record the temperature frequently (every hour for several hours).
14. Re-stock the unit with vaccine once the temperature is stabilized.
15. Continue to monitor the temperature after the vaccine is returned to the unit.

For more information on vaccine storage and handling, refer to the CDC Vaccine Storage and Handling Toolkit at [http://www.cdc.gov/vaccines/recs/storage/toolkit/](http://www.cdc.gov/vaccines/recs/storage/toolkit/)
An important issue regarding any vaccine product with multiple national drug codes (NDCs) for different pieces or components is the only NDC that can be used to order, to report inventory, or to submit vaccine returns is the one listed on the CDC contract. Following is an example product with multiple NDCs.

**GSK – Rotarix**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>NDC</th>
<th>Lot:</th>
<th>Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Main Box</td>
<td>58160-0805-11</td>
<td>A41CA734A</td>
<td>05/09/2010</td>
</tr>
<tr>
<td>2</td>
<td>Lyophilized Vaccine Box</td>
<td>58160-0805-10</td>
<td>A41FA734A</td>
<td>05/09/2010</td>
</tr>
<tr>
<td>3</td>
<td>Diluent Syringes Pack</td>
<td>58160-0805-02</td>
<td>A41DA734A</td>
<td>06/14/2011</td>
</tr>
</tbody>
</table>

The only NDC that can be used to order, to report inventory, or to submit vaccine returns is the one listed on the CDC contract. Using the example above, NDC 58160-0805-11 appears on the outside of the main box (1) of Rotarix and this is the number listed on the CDC contract. The lyophilized vaccine vials box (2) is NDC 58160-0805-10 and the packet of diluent syringes (3) is NDC 58160-0805-02. **The number used when placing vaccine orders, reporting inventory and submitting vaccine returns is NDC 58160-0805-11, which is listed on the outside of the main box (1).**
Proper vaccine storage equipment is an insurance policy to protect patients' health, to safeguard providers against costly vaccine replacement, to avoid inadvertent administration of compromised vaccine, and to eliminate other potential consequences (e.g., the costs of revaccination and loss of patient confidence in your practice). Reliable, properly maintained equipment is critical to the vaccine cold chain. The Illinois Department of Public Health (IDPH) and the Centers for Disease Control (CDC) and Prevention do not recommend specific brands of vaccine storage units, but the CDC does provide guidance on types of storage units that offer greater assurance of proper temperatures for vaccine storage based on equipment testing by the National Institute of Standards and Technology (NIST).

**General Vaccine Storage Unit Recommendations**

- Maintain required vaccine storage temperatures.
  - Refrigerator: between 35F and 46F (2C and 8C)
  - Freezer: between -58F and +5F (-50C and -15C)
- Be frost-free or preferably have an automatic defrost cycle.
  - If a manual defrost is used, the provider should be diligent in periodic defrosting according to manufacturer recommendations or if there is a two-inch or greater ice build-up in the freezer. Ice build-up in the freezer will diminish the equipment's capability to maintain correct storage temperatures. Even manual defrost combination refrigerator/freezers cycle and, as mentioned above, cycling can affect storage unit temperatures.
- Have enough room to store the year's largest inventory without crowding.
  - It is recommended providers maintain vaccine inventory to last five weeks, but no more than three months.
- Have enough room to store water bottles (in the refrigerator) and frozen coolant packs (in the freezer) to stabilize the temperatures and minimize temperature excursions that can impact vaccine potency
  - In the National Institute of Standards and Technology (NIST) 2009 study on stand-alone refrigerators, the typical volume of water bottles used in testing was equal to 3 percent to 5 percent of the total refrigerator capacity. In the NIST 2010 study on dual zone combination style refrigerators and pharmaceutical grade refrigerators, the volume of water bottles used was equal to 4 percent of the total refrigerator capacity.
- Have a certified calibrated thermometer inside each storage unit.
- Reliably maintain the appropriate vaccine storage temperatures year-round.
- Be dedicated to the storage of vaccines. Food and beverages should NOT be stored in a vaccine storage unit
- The vaccine storage unit door must fit securely and tightly against the unit. There should be no gaps between the seal and the body of the unit when the door is closed.

**Disclaimer:** This tip sheet provides guidance on vaccine storage equipment to protect vaccines against equipment failure. Should temperature excursions or equipment failure occur, refer to the Vaccine Incident Report for additional guidance.

For more information on vaccine storage equipment, refer to the CDC Vaccine Storage and Handling Toolkit at [http://www.cdc.gov/vaccines/recs/storage/toolkit/](http://www.cdc.gov/vaccines/recs/storage/toolkit/)