IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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VACCINES FOR CHILDREN PROGRAM MANUAL

FOR ILLINOIS VFC PROVIDERS

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PROTECTING HEALTH, IMPROVING LIVES
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1. OVERVIEW OF THE VFC PROGRAM

VACCINES FOR CHILDREN (VFC)

The Vaccines for Children (VFC) program is a federally-funded program from the Centers for Disease Control and Prevention (CDC) that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. The benefits of the VFC program include:

- Reducing referrals of children from private providers to state health departments for vaccination.
- Saving VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminating or reducing vaccine cost as a barrier to immunizing eligible children.

VFC providers contribute to increased immunization coverage level rates and reduced delays in immunizations and, subsequently, the risk of serious illness or death from vaccine-preventable diseases.

The Illinois Department of Public Health (the Department) administers the VFC program to provide immunizations for children through the age of 18 who are uninsured ("self-pay"), Medicaid Title XIX (19)-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 (FQHC) and rural health clinics (RHC), or local health departments (LHD) under an approved deputization agreement. All VFC providers must offer all ACIP-recommended vaccines for the populations they serve.

Children with Title XXI (21) or State-funded coverage (as shown in the Illinois Department of Healthcare and Family Services MEDI system in the "Special Information" section) have Children's Health Insurance Program (CHIP) coverage are not eligible for VFC vaccines and must receive CHIP vaccines. As of September 1, 2019, CHIP vaccines will be provided through the VFC program.

This program manual is intended for providers currently enrolled in the Illinois VFC program. Providers located within the City of Chicago should contact the Chicago Department of Public Health via e-mail at ChicagoVFC@cityofchicago.org.

The CDC Vaccine Storage and Handling Toolkit provides guidance and best practices for all health care providers (including VFC-enrolled providers) and is the source for information sited in this manual. The CDC Vaccine Storage and Handling Toolkit is available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP unique legal authority to determine recommendations for the routine administration of vaccines to children and adults in the civilian population. The ACIP is the only entity in the federal government that makes such recommendations.

These recommendations include:

- Age for vaccine administration
- Number of doses and dosing interval
- Precautions and contraindications

Major functions of the ACIP are as follows:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines to be provided through the VFC program.
- Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

VFC AND I-CARE IN ILLINOIS

The Illinois Immunization Section requires VFC providers to be enrolled and active users of the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). Additional information and forms for I-CARE are available at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare. The Immunization Section has integrated its VFC enrollment and vaccine management functions into I-CARE. This integration allows for greater accountability and programmatic oversight.

All Illinois VFC providers must provide individual patient immunization records on how each VFC vaccine was administered. The individual patient immunization records 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. VFC providers not in compliance will not be able to continue participating in the VFC program.

FEE CAPS ON VACCINE ADMINISTRATION

Illinois VFC providers may charge a vaccine administration fee for non-Medicaid VFC-eligible children only. Providers are not allowed to bill VFC-eligible children for the cost of the VFC vaccine. As of January 1, 2013, the vaccine administration fee may not exceed the administration fee cap of $23.87 per vaccine dose. VFC providers may not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

Effective January 1, 2020, VFC providers may issue a single bill for the administration fee for non-Medicaid VFC-eligible children within 90 days of vaccine administration.

Unpaid VFC vaccine administration fees may not be sent to collections and VFC providers may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

2. PROVIDER ENROLLMENT

All VFC providers must complete the enrollment annually to recertify their participation in the VFC program. Annual enrollment for the VFC program is submitted through I-CARE and supporting documentation faxed or emailed 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.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare. Providers may contact the I-CARE team at DPH.ICARE@illinois.gov to check the status of an I-CARE enrollment application.

VFC PROGRAM REQUIREMENTS SUMMARY

REQUIREMENT	COMPONENT
VFC Provider Requirements	VFC providers must: • Be licensed in Illinois to administer vaccines to children aged 18 and younger. • Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities. • Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines. • Be open at least 4 consecutive hours for three days a week to receive VFC vaccines.
Provider Agreement	• Providers must complete and sign CDC's Provider Agreement. • The medical director in a group practice must be authorized to administer pediatric vaccines under state law. • The provider signing the Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity. • All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed in the VFC Enrollment Form. • Providers must submit a Provider Population Profile at initial program enrollment and updated at least annually or when order patterns indicate a change.
Patient Eligibility Screening	• Providers must screen and document patient eligibility screening in the patient's permanent medical record (paper-based or electronic medical record) using the VFC Patient Eligibility Screening Record or document the required elements in the electronic medical record.
Vaccine Management	VFC providers must comply with vaccine management guidelines in the CDC's Vaccine Storage and Handling Toolkit, including: • Correct storage units; • Digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration; • Receiving and documenting vaccines; • Daily monitoring and recording of unit temperatures, including responding to any temperature excursion; • Managing expired, spoiled, or wasted vaccine; • Vaccine handling and preparation; and • Procedures for emergency situations.

REQUIREMENT	COMPONENT
Vaccine Management Plan	VFC providers must have standard operating procedures for routine and emergency vaccine management: • Contact information for current primary and backup vaccine coordinators; • Provider staff roles and responsibilities; • Documented training related to vaccine management; • Proper storage and handling practices, including how to handle a temperature excursion; • Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste; • Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster; and • Plans must be updated annually or more frequently as needed.
Immunization Schedule	VFC providers must comply with: • Current ACIP recommendations and VFC resolutions; • Making available the vaccines identified in the Provider Profile based on the provider type and population served, including non-routine vaccines, if applicable; • Understanding state laws related to vaccination requirements and acceptable vaccine exemptions; and • Using ACIP recommendations and vaccine package inserts to understand contraindications for each vaccine type available through the VFC program.
National Childhood Vaccine Injury Act (NCVIA)	VFC providers must comply with: • Obtaining and distributing the most current vaccine information statements for all vaccines included in the National Vaccine Injury Compensation Program; • Following the record-keeping requirements for the NCVIA; and • Reporting adverse reactions to VAERS.
Fraud and Abuse	• VFC providers must operate in a manner intended to avoid fraud and abuse.
Vaccine Restitution	• VFC providers agree to replace vaccines purchased with state and federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis with privately purchased vaccines.
VFC Visits	• VFC providers agree to VFC program site visits, which may include compliance visits, unannounced storage and handling visits, or educational site visits.

RECERTIFICATION OF ANNUAL ENROLLMENT

All VFC providers are required to submit an annual enrollment to recertify their participation in the VFC program. Enrollment documentation is available in and submitted through I-CARE with supporting documentation faxed or emailed to the Department.

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.

Providers re-enrolling after an absence must complete the annual enrollment. Re-enrolling providers may be required to resolve any inventory issues or outstanding vaccine replacements before a new enrollment may be approved.

VFC ENROLLMENT VISITS

All providers newly enrolling or re-enrolling after an absence in the VFC program must have an enrollment site visit before being approved to order VFC vaccines. The purpose of this visit is to:

- Educate providers about VFC program requirements.
- Educate providers on proper vaccine storage and handling.
- Certify providers have the appropriate resources to implement requirements.
- Confirm providers know whom to contact if problems arise, especially with storage and handling issues.
- Complete a Vaccine Management Plan.

A VFC storage and handling visit may be conducted approximately within three to six months after the enrollment visit and a compliance site visit within six to 12 months after the enrollment visit.

By the end of the enrollment visit, the provider and staff will understand:

- The eligibility requirements for the VFC program.
- Where to refer underinsured children for VFC vaccine if the child is not eligible in that practice – federally qualified health center (FQHC), rural health clinic (RHC) or a deputized local health department (LHD).
- How and when to screen and document VFC eligibility appropriately.
- How to screen and document VFC eligibility in special populations.
- How to identify CHIP-covered patients and the vaccine stock for use with CHIP-covered patients.

EDUCATION REQUIREMENT

All VFC vaccine coordinators are required to complete annual VFC education on vaccine storage and handling. Documentation of training must be retained and submitted with annual enrollment, as well as reviewed during site visits. Education is available through VFC compliance site visits, VFC educational visits, or through the CDC online training, "You Call The Shots – Module 10 – Storage and Handling," available at https://www.cdc.gov/vaccines/ed/youcalltheshots.html. Trainings offered by other states or projects (such as the Chicago VFC program or the Pink Book trainings) do NOT meet the Illinois VFC training requirement. A VFC training log is available in the Vaccine Management Plan for providers to document training received. Copies of training certificates must be attached to the training log.

MEMORANDUM OF UNDERSTANDING (MOU) WITH A FQHC OR RHC

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 with a Health Resources and Services Administration PHS Section 330 grant award notice or an RHC with a Department RHC status letter must use the CDC's memorandum of understanding (MOU) request to delegate authority to vaccinate underinsured children on their behalf. Providers should retain a copy of their MOU and submit it annually during VFC enrollment recertification to continue to be able to administer VFC vaccine to underinsured patients. Completed MOUs will be reviewed annually and updated as needed. For more information on deputization agreements, please contact the VFC program at DPH.Vaccines@illinois.gov.

TERMINATION OF ENROLLMENT AGREEMENT

The Illinois VFC program or the provider may terminate this agreement at any time or if there is failure to comply with these requirements. If the agreement is terminated, the provider agrees to properly return any unused VFC vaccines within 30 days of the termination date. VFC vaccines may not be used after the unenrollment or termination date.

Unfortunately, some circumstances may occur that necessitate VFC providers unenrolling 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 should complete the VFC provider unenrollment form available in I-CARE and fax or e-mail to the Illinois VFC program. Be sure to include the handwritten temperature logs for the previous three months and the current physical VFC inventory you have in stock.
- If the enrollment agreement is terminated, the provider agrees to properly return any unused VFC vaccine within 30 days of the termination date. The provider may not continue to administer VFC vaccines after the termination date.

- If the clinic can provide documentation of the cold chain being maintained, the clinic must find another VFC provider to transfer their remaining vaccines. The Illinois VFC program will review documentation of the cold chain and advise the provider of next steps.
- The Illinois VFC program will contact the provider to follow up on the unenrollment notification.

3. ELIGIBILITY

VFC ELIGIBILITY CRITERIA

Providers must screen, document, and verify VFC eligibility with every immunization visit before administering vaccines. Providers must check the eligibility status in the MEDI system (http://www.illinois.gov/hfs/MedicalProviders/EDI/medi/Pages/default.aspx) or an equivalent system receiving the HFS 270/271 electronic transaction data.

To be eligible to receive VFC vaccine, children (regardless of their state of residency) through the age of 18 (until the day of their 19th birthday) must meet at least one of the following criteria:

VFC ELIGIBILITY CRITERIA	DEFINITION
American Indian or Alaska Native (AI/AN)	This population is defined by the Indian Health Care Improvement Act (25 U.S.C. 1603). (AI/AN children are VFC-eligible under any circumstance.)
Medicaid-eligible	Children who are eligible for the Medicaid program Title XIX (19). For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably.
Uninsured	Children not covered by any health insurance plan
Underinsured	Underinsured means the child has health insurance, but the insurance policy: • Does not include any vaccines; • Does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP); or • Has a fixed dollar limit or cap for vaccines. Underinsured children are only eligible to receive VFC vaccines at a FQHC, RHC, or a deputized provider.

Any patient 19 years of age or older is NOT eligible for VFC vaccines, regardless of insurance status.

Occasionally, children may be VFC-eligible for more than one eligibility category. A provider must select and document the VFC eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations. ***VFC is an entitlement program and participation in VFC is not mandatory for an eligible child.***

Children with Title XXI (21) or State-funded coverage have CHIP coverage are not eligible for VFC vaccines and must receive CHIP vaccines. **See section 4 for information on vaccines for children with CHIP coverage.**

AMERICAN INDIAN OR ALASKA NATIVE (AI/AN)

The American Indian or Alaska Native (AI/AN) population, for the purposes of the VFC program, is defined by the Indian Health Care Improvement Act [25 U.S.C. 1603]. AI/AN children are VFC-eligible under any circumstance. However, because VFC is an entitlement program, participation is voluntary.

When an AI/AN child also fits a second VFC eligibility category, the provider should always choose the category that will cost less for the family. Depending on the facility where an AI/AN parent chooses to have their child vaccinated, the parent may be responsible for the vaccine administration fee if the vaccines are delivered through the VFC program. Therefore, if the child has private insurance (non-grandfathered plan under the Affordable Care Act (ACA) of 2010) or is enrolled in the CHIP program, it

may result in fewer out-of-pocket costs for the child to receive vaccinations through these programs than through VFC, as there would be no cost-sharing. Likewise, if the AI/AN child is also Medicaid-eligible, Medicaid should be used for the administration fee because it will provide the least out-of-pocket expense.

VFC ELIGIBILITY AND INSURANCE SITUATIONS

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in Medicaid Title XIX (19)	Yes	Medicaid (V02)
Has private health insurance plan with Medicaid Title XIX (19) as secondary insurance	Yes	Medicaid (V02)
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured (V01). This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit **and** has Medicaid Title XIX (19) as secondary insurance	Yes	Medicaid (V02)
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Yes	Insured (V01) until the fixed dollar limit is met. Underinsured (V05[1]) after the fixed dollar limit is reached.
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured (V05[1]). Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured (V05[1]). With implementation of ACA, this situation should be rare.
Enrolled in CHIP – Title XXI (21) or State-Funded	Not eligible for VFC, but is eligible for CHIP vaccines	Insured (V22 CHIP). The VFC program distributes vaccines for CHIP-covered children. *See section 4 for more information on CHIP.*
Has no health insurance coverage	Yes	Uninsured (V03)
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN (V04). However, the provider should choose the eligibility category most cost-effective for the child and family.
Has Medicaid Title XIX (19) and is AI/AN	Yes	Medicaid (V02) or AI/AN (V04). Providers should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.

[1] VFC vaccines for the underinsured may only be administered by a federally qualified health center (FQHC), rural health clinic (RHC), or a deputized local health department.

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in a Health Care Sharing Ministry	Uninsured-Yes Insured-No Underinsured-Yes[1]	Depends if the plan is recognized as an insurance plan and if the insurance plan covers vaccines: • If the plan is NOT recognized by the state insurance department as insurance, then the child is uninsured (V03), regardless of vaccine coverage provided by the plan, and eligible for VFC. • If the plan is recognized by the state insurance department and the plan covers vaccines, the child is insured (V01) and not eligible for VFC vaccines. • If the plan is recognized by the state insurance department but the plan does not cover all ACIP-recommended vaccines, the child is underinsured (V05) for the vaccines not covered by the insurance[1].

The chart below summarizes the type of vaccines to be used on patients with Medicaid Title XIX (19) coverage.

THE PATIENT'S AGE IS:	VFC VACCINES Eligible for VFC vaccines. Bill HFS for Admin Fee.	PRIVATELY PURCHASED VACCINES Administer privately purchased vaccines. Bill HFS or plan for vaccine(s).
18 years or younger	Yes	No
19 years or older	No	Yes

INSURED CHILDREN WITH MEDICAID TITLE XIX (19) AS SECONDARY INSURANCE

Some children may have a private primary health insurance plan with Medicaid Title XIX (19) as their secondary insurance. These children are considered VFC-eligible because of their Medicaid Title XIX (19) enrollment. However, their parents are not required to participate in the VFC program.

Billing options exist for the parent and provider in this situation. The provider should choose the option that is most cost-effective for the family. The parent of a child with Medicaid Title XIX (19) as secondary insurance should never be billed for a vaccine or an administration fee.

Options include:

- Option 1: The provider can administer VFC vaccines and bill Medicaid for the administration fee. Considerations regarding this option:
  - Easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee
  - No out-of-pocket costs to the parent for the vaccine or the administration fee
- Option 2: The provider can administer private stock vaccines and bill the primary insurance carrier for both the cost of the vaccine and the administration fee. Considerations regarding this option:

- The provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.

MEDICAID AS SECONDARY INSURANCE AND HIGH-DEDUCTIBLE INSURANCE PLANS

If a child has Medicaid Title XIX (19) as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out of pocket for vaccines, the child should be considered VFC-eligible (V02) if the family has not yet reached its deductible.

VFC vaccines should be administered, and the administration fee should be billed to Medicaid until the deductible is reached.

If a child does not have Medicaid Title XIX (19) as secondary insurance, the child is considered insured (V01) and not VFC-eligible even if a child's family has a high-deductible plan.

UNDERINSURED

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

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

The child is considered underinsured once the fixed dollar amount is reached.

Before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccines. If the provider cannot verify vaccination coverage, for the purposes of the VFC program, the child is considered insured (V01) and not eligible to receive VFC vaccines at that immunization encounter. VFC vaccines for the underinsured may only be administered by a federally qualified health center (FQHC), rural health clinic (RHC), or a deputized local health department.

HEALTH CARE SHARING MINISTRIES

Health Care Sharing Ministries (HCSMs) are nonprofit alternatives to purchasing health insurance from private, for-profit insurers. Generally, HCSMs are organizations whose members share a common belief system and collectively "share" the cost of their members' medical care and are usually not considered as an insurance plan. See the VFC Eligibility Scenario chart below for more information.

For the VFC program, "insurance" is defined as a plan that is:

- Regulated by a State's Insurance Commissioner and/or
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA), a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.

The Illinois Department of Insurance regulates insurance plans in Illinois and may assist in determining if a plan is insurance or a health cost-sharing plan. Contact information is available at http://insurance.illinois.gov/main/contactUs.html.

VFC ELIGIBILITY IN SPECIAL CIRCUMSTANCES

Special Circumstance	Vaccination Service Location	Child's Insurance Status	VFC-Eligible?	VFC Eligibility
Seeking contraceptive or STD services and wants to be vaccinated	School-located clinic or any VFC-enrolled provider whose main services are primary or urgent care	For confidentiality reasons, does not want to use insurance	No	Insured (V01)
Seeking contraceptive or STD services and wants to be vaccinated	Family planning clinic or STD clinic	For confidentiality reasons, does not want to use insurance or insurance status is unknown	VFC-eligible; however, eligibility must comply with the state's medical consent laws for minors	Uninsured (V03)
Incarcerated	Juvenile detention center that does not purchase vaccines	Lost access to health insurance due to incarceration	Yes	Uninsured (V03)

STATE OF RESIDENCY

At times, VFC-eligible children receive health care in a bordering state instead of their state of residency. VFC eligibility is not dependent upon state of residency for the child. Illinois providers enrolled in the VFC program may vaccinate children through age 18 who are VFC-eligible residing in another state. Providers must be aware if VFC vaccines are administered to a Medicaid Title XIX (19) VFC-eligible child from a neighboring state, the provider must be a Medicaid-enrolled provider for the state where the Medicaid Title XIX (19) VFC-eligible child resides to receive reimbursement for the administration fee from that state's Medicaid program.

PROVIDER RESPONSIBILITY TO SCREEN FOR VFC ELIGIBILITY

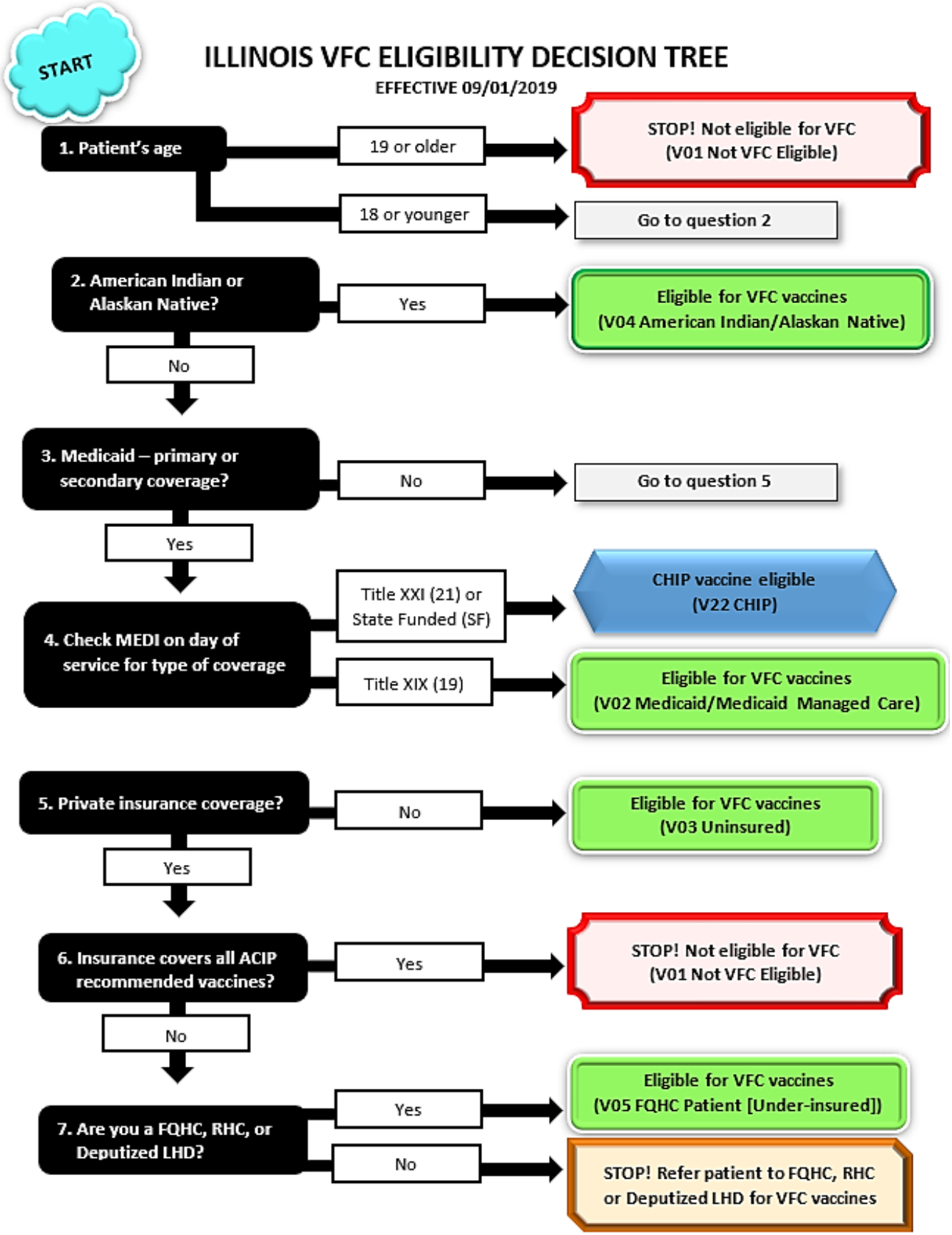
Screening to determine a child's eligibility to receive vaccines through the VFC program must take place with each immunization visit. The Patient Eligibility Screening Form developed by the Department provides a means of recording parent response to VFC eligibility questions. The provider, parent, or guardian may complete the VFC eligibility portion of the form. Verification of parent/guardian responses is not required. 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 and include all criteria from the Patient Eligibility Screening Record.

Before administering vaccines at each immunization encounter, providers must check eligibility status and type of Medicaid coverage in the MEDI system (http://www.illinois.gov/hfs/MedicalProviders/EDI/medi/Pages/default.aspx) or an equivalent system receiving HFS 270/271 electronic transaction data.

VFC ELIGIBILITY DECISION TREE AND SCENARIO CHART

The following eligibility decision tree will assist in determining if a patient is eligible to receive VFC or CHIP vaccines.


START
ILLINOIS VFC ELIGIBILITY DECISION TREE
EFFECTIVE 09/01/2019
1. Patient's age
19 or older
STOP! Not eligible for VFC (V01 Not VFC Eligible)
18 or younger
Go to question 2
2. American Indian or Alaskan Native?
Yes
Eligible for VFC vaccines (V04 American Indian/Alaskan Native)
No
3. Medicaid – primary or secondary coverage?
No
Go to question 5
Yes
4. Check MEDI on day of service for type of coverage
Title XXI (21) or State Funded (SF)
CHIP vaccine eligible (V22 CHIP)
Title XIX (19)
Eligible for VFC vaccines (V02 Medicaid/Medicaid Managed Care)
5. Private insurance coverage?
No
Eligible for VFC vaccines (V03 Uninsured)
Yes
6. Insurance covers all ACIP recommended vaccines?
Yes
STOP! Not eligible for VFC (V01 Not VFC Eligible)
No
7. Are you a FQHC, RHC, or Deputized LHD?
Yes
Eligible for VFC vaccines (V05 FQHC Patient [Under-insured])
No
STOP! Refer patient to FQHC, RHC or Deputized LHD for VFC vaccines

4. CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

As of September 1, 2019, the Illinois VFC program started providing vaccines purchased by HFS for use with children under the age of 19 with the CHIP coverage. CHIP coverage includes Title XXI [21] or State-funded coverage and hereafter will be referred to as "CHIP."

Children who have Medicaid "Title XXI [21]" or "State-funded" coverage (as shown in MEDI in the "Special Information" section) are not eligible for VFC vaccines and must receive CHIP vaccines. These children have CHIP coverage and are considered fully insured.

The chart below summarizes the type of vaccines to be used on patients with CHIP coverage.

THE PATIENT'S AGE IS:	CHIP VACCINES Eligible for CHIP vaccines through VFC. Bill HFS for Admin Fee.	PRIVATELY PURCHASED VACCINES Administer privately purchased vaccines. Bill HFS or plan for vaccine(s).
18 years or younger	Yes	No
19 years or older	No	Yes

More information on the CHIP program and MEDI is available on the HFS website at https://www.illinois.gov/hfs/MedicalProviders/NonInstitutional/Pages/default.aspx.

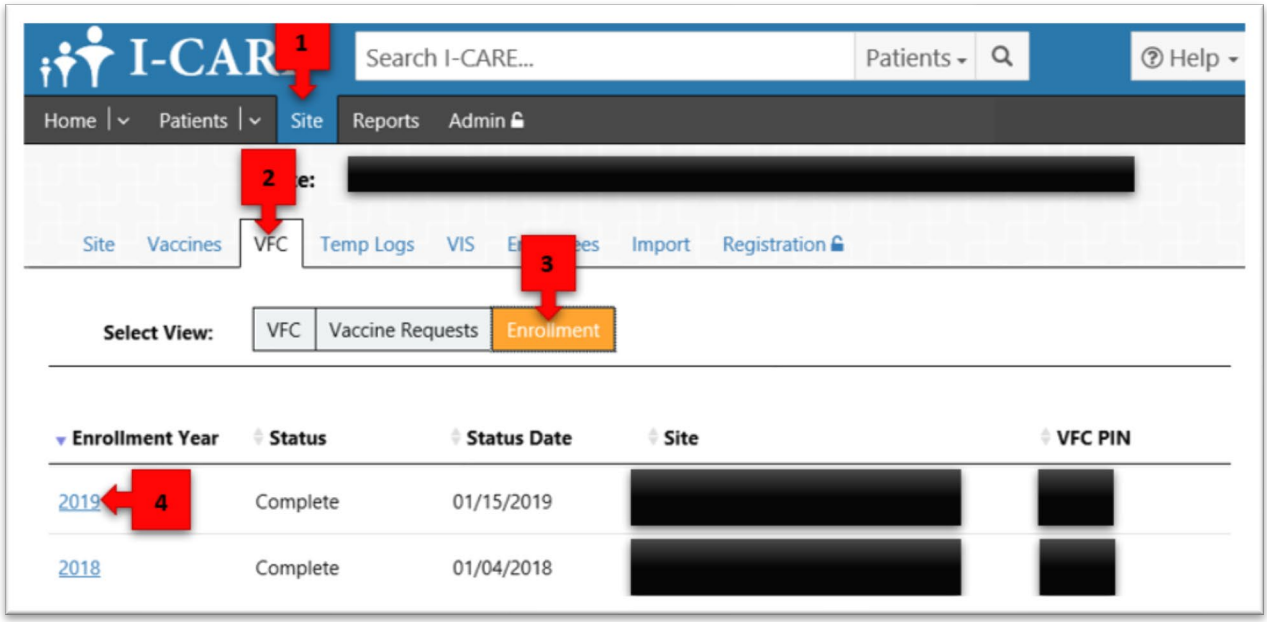
For questions regarding Medicaid or CHIP billing, please contact the Illinois Department of Healthcare and Family Services, Bureau of Professional and Ancillary Services at 877-782-5565.

The CDC requires that all VFC programs determine individual provider populations served and associated vaccine need by fund type. Illinois is required to establish a process for collecting and validating provider populations to ensure publicly purchased vaccines are distributed in amounts representing the provider population served and to adjustments if the population served changes.

VFC providers place orders to receive vaccines for CHIP-eligible children through the Illinois VFC program. The number of vaccines a clinic will receive for their CHIP-eligible children will be dependent on the patient population indicated in the VFC enrollment form in I-CARE.

VFC clinics are required to update their patient population at minimum annually or more often as needed. VFC clinics may submit their CHIP population or updates to their CHIP population through the online survey available at https://app.smartsheet.com/b/form/58f0005616e84e0cacf5a07821d22695.

The VFC clinic's patient population may be viewed in the current VFC enrollment form. In I-CARE, click on the site tab and then go to VFC. Click on the enrollment button and select the current year's enrollment form. See the screen shot on the following page.



Scroll down until you get to the patient population section.

Patient Population: Current VFC provider's patient population data will be automatically populated from patient immunization records in I-CARE. If your patient population data does not appear accurate, click on "Contact Us" and select "VFC Illinois" to request assistance.

	< 1 Year Old	1-6 Years	7-18 Years	TOTAL
Enrolled in Medicaid:	200	1400	1000	**2600**
No Health Insurance:	35	90	100	**225**
American Indian/Alaskan Native:	0	2	1	**3**
Underinsured (FQHC/RHC)(Disabled for non-FQHC/RHC Facility Type):	0	0	0	**0**
TOTAL VFC:	**235**	**1492**	**1101**	**2828**
Insured (private pay/health insurance covers vaccines):	0	0	0	**0**
Other Underinsured:	0	0	0	**0**
Children's Health Insurance Program (CHIP):	20	130	120	**270**
TOTAL NON-VFC:	**20**	**130**	**120**	**270**
TOTAL PATIENTS:	**255**	**1622**	**1221**	**3098**

The percentage of CHIP vaccines the VFC clinic will receive is based upon the clinic's patient population and applies the same to all vaccines. For this sample clinic shown on the previous page, their largest

population is the group 1 to 6 years of age, with 1,492 VFC eligible children and 130 CHIP children between 1 to 6 years of age.

For example, this clinic determined they need 10 doses of rotavirus vaccines for their next 1 to 3 months of appointments. In their order of 10 doses, they will receive 9 doses of VFC and 1 doses of CHIP. The clinic estimates 120 children will need measles, mumps, rubella vaccine in the next 1 to 3 months. In their order of 120 doses, they will receive 108 doses of VFC and 12 doses of CHIP.

All vaccines will be split according to the clinic's patient population, with the following exceptions.

- Single-dose packages of Bexsero, Pneumovax 23, and TD will default to VFC funding type. If a VFC clinic needs one of these vaccines for CHIP, please enter a note in the "Status Comments" box in the vaccine order form stating the name of the vaccine and specify the funding type needed.
- ProQuad and Varivax vaccines are shipped frozen directly from the manufacturer, Merck. Merck is unable to split funding sources on an order for ProQuad or Varivax and only one funding type for frozen vaccines may be specified per order. **Orders for ProQuad and Varivax will default to VFC funding.** If VFC clinics need CHIP-funded ProQuad or Varivax, the VFC clinic should enter a note in the "Status Comments" box specifying either CHIP ProQuad or CHIP Varivax is needed.

  If both VFC and CHIP doses are needed for ProQuad or Varivax, the VFC and CHIP orders must be placed separately. The clinic should enter the separate order for either CHIP Varivax or ProQuad and add a note to indicate the frozen vaccine order is needed for CHIP. The orders may be placed only in multiples of 10.

All other vaccines are available only in the package sizes listed in I-CARE. Any order would be split according to the VFC clinic's patient population profile.

See section 9 for information on ordering and receiving vaccines and section 10 for information on storing vaccines.

5. VACCINE STAFF AND TRAINING

VACCINE COORDINATORS

During the enrollment process, VFC providers are required to designate a primary vaccine coordinator and at least one backup vaccine coordinator for each facility. The primary vaccine coordinator will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert in the clinic's storage and handling standard operating procedures (SOPs).

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Management Plan
- Monitoring storage and handling and vaccine administration practices in the facility
- Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire
- Participating in and documenting completion of annual training on VFC requirements
- Storing all required documentation for three years, or longer if required by state statutes or rules

The vaccine coordinator responsibilities include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording the current temperatures at the start and end of each workday
- Checking and recording minimum/maximum temperatures at the start of each workday
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs:
    - Tracking inclement weather conditions
    - Ensuring appropriate handling of vaccines during a disaster or power outage

Coordinator responsibilities may be completed by the primary coordinator or backup coordinator delegated. The primary vaccine coordinator must ensure the backup coordinator(s) are trained and maintain documentation of competency for the specific task(s) assigned.

To effectively perform their duties, the vaccine coordinator and backup coordinator(s) must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.

VFC providers are required to notify the Illinois VFC program anytime there is a change in vaccine coordinator staff or the medical director.

STAFF TRAINING

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with your clinic's storage and handling SOPs.

6. VACCINE STORAGE AND TEMPERATURE MONITORING EQUIPMENT

Vaccine management is a broad term intended to describe the storage and handling practices that should be followed by all VFC providers. While the vaccine management practices here specifically apply to vaccines provided through the VFC program, we recommend providers consider the VFC vaccine management as a best practice for their private vaccine inventory as well.

The CDC Vaccine Storage and Handling Toolkit provides guidance and best practices for all health care providers (including VFC-enrolled providers) and is available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

VACCINE COLD CHAIN

All VFC vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Too much exposure to heat, cold, or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced even further. With loss of potency, vaccines become useless and are unable to provide immunity for the vaccinated individual.

Assuring vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers.

An effective cold chain relies on three main elements:

- A well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Results of a cold chain failure can be costly. ACIP's General Best Practice Guidelines for Immunization states, "vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."[2]

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases.

CDC's Vaccine Storage and Handling Toolkit provides guidance on safe and effective vaccine management practices for all health care providers. Though VFC providers are required by the VFC program to implement the recommendations and best practice guidance in the CDC Vaccine Storage and Handling Toolkit, the Illinois VFC program has additional requirements providers must adopt. The requirements are described below. Following these requirements, recommendations, and best practice guidance in the toolkit can minimize financial burden for providers due to vaccine loss and prevent the need for revaccination. The result is maximum vaccine effectiveness and patient protection.

[2] Centers for Disease Control and Prevention. ACIP's General Best Practice Guidelines for Immunization, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines—even when exposed to freezing temperatures—may not appear frozen, giving no indication of reduced or lost potency.

By following and implementing CDC-recommended storage and handling practices, providers can ensure patients receive high-quality vaccine that has not been compromised.

REFRIGERATOR AND FREEZER UNITS

Storage units must have enough room to store the largest inventory a provider might have at the busiest point in the year without crowding.

EQUIPMENT TYPES

CDC recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the- counter style to a large, stand-alone, pharmaceutical- grade storage unit

The Illinois VFC program does not allow combination household refrigerator/freezer units for the storage of vaccines obtained through the VFC program.

The use of dormitory or bar-style refrigerator/freezers is prohibited at all times for VFC program providers. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. The following examples are dormitory-style or bar-style units and are **NOT** allowable to store VFC vaccines at any time.

The following refrigerators are the size of a household refrigerator, but they are still classified as a dorm-style refrigerator because they have the one exterior refrigerator door with the freezer compartment located within the refrigerator sections. These are not allowable units for the storage of vaccines obtained through the VFC program.

PURPOSE-BUILT VACCINE STORAGE UNITS

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These purpose-built for vaccine storage can take many physical forms. Some look like traditional standalone units, while others can take the form of dispensing or vending units either with or without doors. Although these units may be similar to pharmaceutical grade or medical grade units, they are unique in that they are designed and tested to keep vaccines at their appropriate storage conditions.

Purpose-built vaccine storage units must meet the same requirements as other VFC storage units.

- Temperature Monitoring
  - Many purpose-built units have multiple temperature probes or sensors. It is important that these probes or sensors have current Certificates of Calibration.
  - Many of the purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
  - Digital Data Logger – Many purpose-built units will have built-in data loggers with electronic interfaces that will allow continuous temperature tracking and/or provide min/max temperatures. Providers should ensure the purpose-built unit will meet the same temperature monitoring device requirements as defined for other VFC storage units.
  - VFC providers are required to monitor, assess and document temperatures on a paper log with two current temperature readings per day, at least three days per week, at the beginning of the day and prior to closing, and the minimum and maximum temperatures documented at the beginning of each workday.
  - All temperature documentation must contain the time and date of each reading and the name (or initials) of the person who assessed and recorded the readings.
  - Data logger temperatures must be downloaded and reviewed at least on a weekly basis. Data logger files must be stored for at least three years.
- Vaccine Storage
  - Many purpose-built units have undergone testing and temperature mapping to have the probe placed in the most appropriate location.

    - Although purpose-built units can have multiple temperature probes, a backup temperature monitoring device is still needed for transport to a backup facility in an emergency.
    - Many purpose-built units do not need water bottles to serve as thermal ballast.
- Vaccine Management
    - Purpose-built units must have the ability to separate public and private vaccine stock either physically or electronically.
    - If stock is separated electronically, an inventory printout must be accessible upon request.
    - If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccines inaccessible.
    - The only NDC and lot number that can be used to order, report inventory, report administered vaccines in I-CARE, or to submit vaccine returns is the NDC and lot number on the outside box.
    - In situations of a temperature excursion or power outage, the provider must ensure they are able to remove and relocate the vaccines, if necessary, to an emergency response location on their emergency response plan.
- Reporting Requirements
    - VFC providers using the purpose-built dispensing units must ensure their unit is able to produce reports listing inventory by funding type and data logger reports during annual enrollment, during VFC site visits, or upon request.
    - If vaccine stock is separated electronically, an inventory printout must list the public and privately purchased stock by brand name, NDC, lot number and expiration date.
    - If providers are unable to physically remove expired vaccine from a purpose-built unit immediately after expiration, the unit must be able to make expired vaccine inaccessible. An inventory printout must list the expired vaccines that are inaccessible.

STORAGE UNIT PLACEMENT

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

STORAGE UNIT DOORS

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

STABILIZING TEMPERATURES IN NEW, MOVED, AND REPAIRED UNITS

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

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures and the current temperatures two times a day on each workday for two to seven days. Once two

consecutive days of temperatures are recorded within the recommended range, the unit is stable and ready for use.

TEMPERATURE RANGES

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F). Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). The Illinois VFC program recommends setting temperatures in Celsius and recording temperatures to one decimal place (i.e. 4.2 C). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

DIGITAL DATA LOGGERS

VFC providers must use digital data loggers (DDLs) with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing public vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and off-site clinics. The VFC program recommends having a backup data logger for each emergency transport unit.

To meet VFC program requirements, the DDL must be equipped with:

- A temperature probe or sensor (a buffered probe is recommended);
- An active temperature display outside the unit that can be easily read without opening the storage unit's door; and
- Continuous temperature monitoring and recording capabilities and the capacity to routinely download data.

Additional recommended DDL features include:

- Alarm for out-of-range temperatures
- Temperature display showing current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User-programmable logging interval (or reading rate) recommended at a maximum time interval of no less frequently than every 30 minutes

Certificates of Calibration Testing must include:

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

The certificate of calibration testing must be issued by an appropriate entity**.** The certificate must indicate at least one of the following items below about calibration testing.

- Conforms to ISO 17025
- Testing was performed by an ILAC/MRS Signatory body accredited laboratory.
- Is traceable to the standards maintained by NIST

- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (0.5 °C) or better

If a VFC provider's certificate(s) of calibration does not have all the required items, contact the manufacturer of the data logger (or whoever did the calibration testing) to see if they will reissue the certificates. Several manufacturers have indicated they are willing to reissue certificates to include the missing items.

If a VFC provider needs to purchase new data logger, we recommend contacting the company and to obtain a sample of their certificate of calibration to ensure all the required items are listed before purchasing the data logger. If you would like for the Illinois VFC program to review a sample certificate of calibration, please email it to DPH.Vaccines@illinois.gov. Please be sure to include your VFC PIN on all communication.

A backup DDL must be readily available in case a DDL fails or calibration testing is required. The back-up DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time. If the backup DDL has the same calibration retesting date, providers must have the unit retested prior to expiration ensuring that a valid DDL is available for required temperature monitoring. Each VFC provider must have a backup DDLs on site. Backup DDLs should not be stored in the storage unit. This can result in conflicting temperature readings between the backup and main DDLs, which can lead to potential confusion.

VFC providers must adhere to the following guidance:

- All data loggers must have a certificate of calibration that is current (up to two years since last calibration testing or based on the manufacturer's recommended re-testing timeline as indicated on the certificate of calibration).
- Download and review data logger data files on a weekly basis.

Certain types of temperature monitoring devices have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are checked, may fail to detect temperatures outside the recommended range.

CDC and the Illinois VFC program do not recommend the following temperature monitoring devices:

- Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- Bimetal stem temperature monitoring devices
- Temperature monitoring devices used for food
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that do not have a current and valid Certificate of Calibration Testing

Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

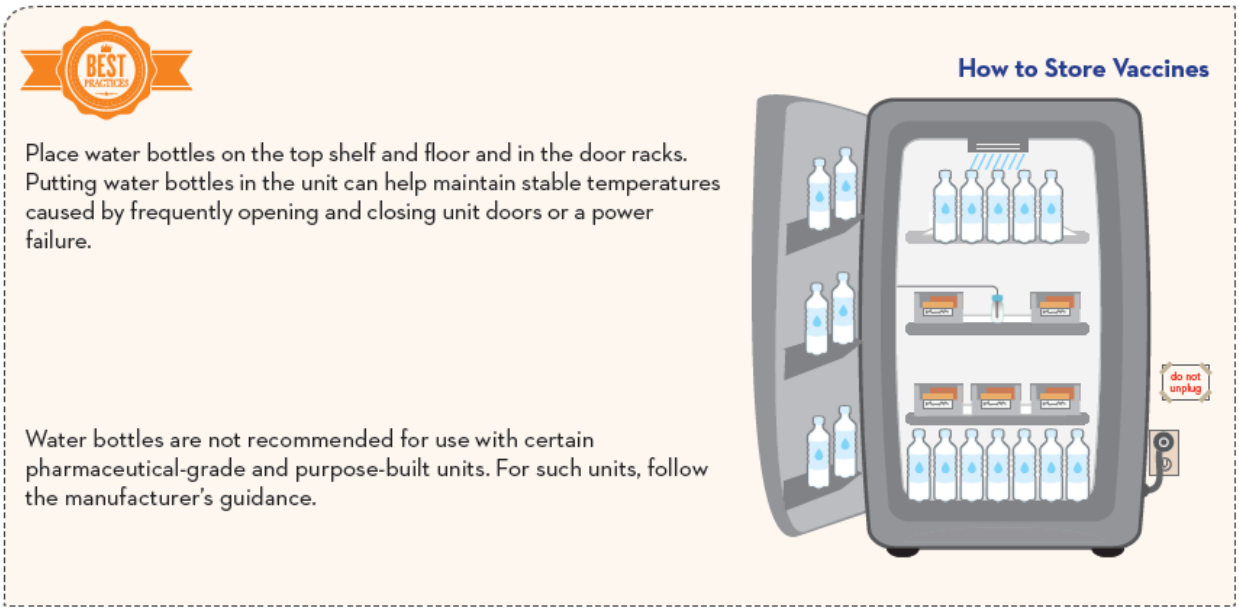
POWER SUPPLY

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply.

- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post “DO NOT UNPLUG” warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.
- Label fuses and circuit breakers to alert people not to turn off power to a storage unit.
- Use caution when using power outlets that can be tripped or switched off and avoid using:
  - Built-in circuit switches (may have reset buttons)
  - Outlets that can be activated by a wall switch
  - Multioutlet power strips

VACCINE UNIT SETUP

The diagrams below shows how the vaccine storage unit should be setup.



7. MOBILE VACCINE CLINICS

Vaccine storage in mobile vaccine clinics must meet the same VFC storage unit requirements: pharmaceutical/medical grade or stand-alone refrigerators and freezers permanently installed within the mobile clinic. These units may be either under-the-counter or upright units depending on the need. The mobile clinic should be plugged into the home site location to either generators or another power source when the mobile clinic is not being used. The mobile clinic vaccine storage units are continuously monitored by a data logger with temperatures manually checked two times a day and logged into I-CARE. The mobile vaccine clinic is treated as another exam room within the VFC provider site that happens to have wheels and a motor. The mobile vaccine clinic must be inspected as part of the VFC compliance site visit. Illinois VFC provider's mobile vaccine clinics may not transport Illinois VFC vaccines to the city of Chicago or outside of the state of Illinois. Although the Illinois VFC program does not have a residency requirement for VFC-eligible children, the VFC vaccines may only be administered by providers within the Illinois VFC project area, which does not include the city of Chicago or other states.

The vaccines must be delivered to the VFC provider's "brick and mortar" site, as with all the other VFC vaccines. If vaccines are to be permanently stored in the mobile vaccine clinic, the mobile unit must have a permanent source of power, either a generator or other permanent power source.

The following pictures shows an example of a mobile medical van.

8. OFF-SITE VACCINE CLINICS

VFC-enrolled providers may conduct temporary, off-site clinics. The transportation, storage and handling of VFC-program vaccines must meet the guidelines in the program manual and in the CDC Vaccine Storage and Handling Toolkit.

Current VFC policy specifies that VFC vaccines are to be delivered directly to VFC clinic location on file in the current enrollment. The VFC vaccines may only be administered by providers within the Illinois VFC project area, which does not include the city of Chicago or other states.

The VFC program and CDC does not recommend routine transport of vaccine due to the risk to the cold chain and vaccine viability. However, because most temporary mass clinics typically require vaccine transport on the day of the clinic, the VFC program and CDC has determined that these temporary off-site clinics (e.g., school located clinic) require enhanced storage and handling practices.

The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).[3] Only the amount of vaccines that are needed for the workday should be transported to each scheduled clinic. See section 9 for details on storing vaccines and section 10 for details on transporting vaccines and transport system recommendations.

If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F)[4]. Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F). Any stand-alone freezer that maintains these temperatures is acceptable.

Temporary off-site clinic vaccine storage must meet VFC program requirements to maintain appropriate temperatures throughout the clinic day and temperatures monitored with a digital data logger during transport and during storage at the off-site clinic. See section 10 for more information on storing vaccines.

At the end of the temporary off-site clinic, the vaccines must be transported back to the VFC provider's permanent location in the approved transport method. Providers must review the data logger data file to verify the vaccines were stored and transported within proper temperature ranges before returning the vaccines to the clinic's permanent inventory to prevent administration of vaccines that may have been compromised. Vaccines exposed to temperature excursions must be labeled "do not use" until further information can be gathered from the manufacturer(s) and verified by IDPH on the usability of the vaccine. See section 10 for more information on temperature excursions.

VFC-enrolled providers must submit an off-site vaccine clinic notification form in I-CARE at minimum 48 hours prior to the event. Only one event may be submitted per notification form.

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[3] CDC Vaccine Storage and Handling Toolkit pages 21-22. http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

[4] CDC Vaccine Storage and Handling Toolkit pages 23. http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

VFC-enrolled providers must provide the following information in the off-site vaccine clinic notification form.

- The VFC provider submitting notification of the event.
- The VFC coordinator name and contact information who is submitting the notification.
- List any partners involved in the off-site clinic, including other VFC-enrolled providers and non-VFC providers.
- All non-VFC providers must sign the VFC Provider Agreement to be uploaded with the notification form.
- The VFC provider submitting the event notification must submit a written description detailing the responsibilities for each non-VFC party involved.
- List the date, location, target population, and vaccines to be provided at the off-site clinic.

The VFC coordinator will submit the off-site clinic notification by checking a box indicating agreement with the Vaccines for Children storage and handling requirements as listed in the Illinois Vaccines for Children Program Manual and the CDC Storage and Handling Toolkit and understanding the medical director is accountable for compliance with these requirements.

The VFC provider should maintain a copy of the off-site clinic notification form in their records.

9. ORDERING AND RECEIVING VACCINES

PLACING VACCINE ORDERS

Providers should order vaccine in accordance with actual vaccine need for one month and avoid stockpiling or build-up of more than a three-month supply. **Providers should maintain enough vaccine inventory to last one month; however, inventory should never exceed three months.** Orders may take two to three weeks from submission of order to vaccine delivery. Vaccines provided through the VFC program must be distributed directly to the location at which the provider will administer the vaccines.[5]

CDC recommends smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Storing a larger volume of vaccines that a VFC provider needs can increase the risk of wasting vaccines if they expire before they can be used or compromised in some way (e.g., due to mechanical failure of a storage unit).

All vaccine orders are submitted through I-CARE. Providers must ensure the following information is completed or updated prior to submitting an order in I-CARE:

- Patient immunization records showing how each dose of VFC vaccine was administered.
- Temperature logs for all appliances are up-to-date as of the date the order is requested.
- All data logger certificates of calibration are valid and not expired.
- All temperature excursions must have a vaccine incident report on file.
- No expired vaccines are showing in the clinic's inventory.
- The clinic's inventory in I-CARE matches the physical inventory.
- The clinic's inventory in I-CARE is not showing any negative balances.
- Clinic must be open at least three days a week with at least four consecutive hours a day to be able to receive a delivery. Delivery hours must be entered and updated in I-CARE, including specifying if the clinic is closed during lunch or other hours, when placing orders through I-CARE.
- The vaccine order is enough for at least one month's inventory but does not exceed three months.

VFC providers should consider their clinic's delivery hours for the next two to three weeks to ensure a VFC vaccine coordinator will be on site to accept the delivery before placing an order.

The "Status Comment" field in the I-CARE order form should not be used to convey any of the following:

- Open/closed days
- Open/closed hours
- Critical delivery information

All Illinois VFC providers must provide individual patient immunization records on how each VFC vaccine was administered. The individual patient immunization records can either be directly entered into I-CARE or can be electronically transmitted to I-CARE from the provider's electronic medical record (EMR) system. VFC providers not in compliance will not be able to continue participating in the VFC program.

Providers interested in setting up their EMR to transmit data to I-CARE should contact the I-CARE team at DPH.HL7ICARE@Illinois.gov.

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[5] Centers for Disease Control and Prevention. *NCIRD Policy Regarding Grantee-supported Vaccine Depots*

Providers must notify the VFC program when there has been a change in the VFC coordinator, medical director, or storage units either by sending an e-mail to dph.vaccines@illinois.gov or use the "Contact Us" button in I-CARE and select "VFC Illinois" under the category for additional assistance.

PATIENT POPULATION PROFILES

The provider patient population profiles will be used by the Illinois VFC program to monitor provider orders. The patient population profile is automatically populated in I-CARE based on the patient immunization records entered by the clinic in I-CARE or has transmitted from the provider's EMR. Providers ordering more vaccine than should be needed for their VFC population will be contacted. If orders for excessive amounts of vaccine are placed on a regular basis, the provider will be contacted. The provider may be required to replace wasted vaccines due to excessive ordering.

TRACKING VACCINE ORDERS

Providers may track the status of the order in I-CARE.

#	Vaccine	Used (3-mo)	Used (12-mo)	Waste (12-mo)	On Hand	Line Status	Doses Ordered	Detail
1	Pediarix; SKB; SYR; 10-pack	0	32	0	26	Complete	40	NDC: 58160-0811-52 • Packaging: 10 • Fund: SPLIT/STATE Split/State: 7 Split/CHIP: 3 • Requested: 40 Approved: 40 • Tracking: FedEx 787073330990 • Lot: 74FN7 (VFC: 28, CHIP: 12)

- The vaccine line status will state the current status of the vaccine order.
  - Requested: The order has been submitted to the Illinois VFC program.
  - Approved: The Illinois VFC program has approved the vaccine requested.
  - Transmitted: The order has been transmitted to CDC for processing.
  - Shipped: The vaccine order has been shipped by either McKesson or Merck (frozen vaccines).
  - Completed: The vaccine order is complete.
- Once an order has shipped, VFC providers may go into the order and click on the symbol next to the NDC number to expand the details row. The shipment tracking number will be listed. Providers may click on this tracking number to go to the shipper's website and get more information, including signing up for delivery alert messages.

BORROWING VACCINES

VFC-enrolled clinics are expected to maintain adequate inventories of vaccine for their privately insured, CHIP and VFC-eligible patients. Vaccines provided through the Illinois VFC program cannot be used to replace a clinic's privately-purchased vaccine inventory. The clinic must ensure their vaccine supply is adequate to meet the needs of the VFC-eligible or CHIP-eligible patients.

VFC clinics may not swap doses between VFC inventory and CHIP inventory.

The VFC program does not allow the borrowing of VFC or CHIP vaccines. Private vaccines used on VFC patients cannot be paid back using VFC vaccine. VFC and CHIP vaccines cannot be used in non-eligible children and then paid back with private vaccine stock.

If a VFC clinic finds they need couple of doses of CHIP vaccines in between vaccine orders, VFC clinics may check with other nearby VFC clinics to see if they could transfer the needed CHIP doses. Be sure to fill out and submit the transfer request form, which is available in I-CARE.

If a VFC clinic runs out of vaccines during a clinic (whether it is VFC or CHIP) and is unable to find a clinic to transfer the needed doses immediately, the clinic would need to reschedule any children until a vaccine order can be placed and received. The VFC program does not allow the borrowing or swapping of vaccines between VFC and CHIP.

RECEIVING AND UNPACKING VACCINE SHIPMENTS

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit because the cool packs shipped with the vaccine may make the packaged vaccine too cold if placed inside the storage unit.

Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
- Check the order received against the order placed in I-CARE to ensure all vaccines ordered were received.
- The frozen vaccine packing list will show the maximum time vaccines can be in transit based on shipment date.
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
- Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Immediately check the cold chain monitor (CCM), a device used to monitor vaccine temperatures during transport, if one was included, for any indication of a temperature excursion during transit.

WITHIN TWO HOURS OF VACCINE DELIVERY: If any problem is noted with the delivery such as damage, excessive shipping time, cold chain breach has occurred, or a delivery shortage is noted, VFC providers must **IMMEDIATELY** call the Illinois VFC Program Services Staff at 217-785-1455.

- If the provider does not call the Illinois VFC program within two (2) hours of the vaccine delivery to report discrepancies and/or cold chain issues, this constitutes provider negligence in accordance with the Vaccine Loss and Replacement Protocol due to handling and storage mishaps by provider staff. Shipments that result in vaccine loss negatively impact the Illinois VFC vaccine budget.
- Providers should never refuse a shipment. Providers should receive the package and IMMEDIATELY report any concerns to the Illinois VFC program. Shipments refused at the provider site are not able to be returned and evaluated in a timeframe that is possible to save the vaccines. Providers will be responsible for replacing any vaccines wasted due to refusal to accept a shipment.
- When calling the Illinois VFC program about a vaccine delivery, staff will have to report on temperature indicators if anything is wrong (cold chain breach indicated). CDC or McKesson may ask for pictures of the vaccines received, including the shipping box. A questionnaire will be completed with the Illinois VFC program, CDC, and/or the vaccine manufacturer to determine viability. Provider staff should store the vaccine appropriately, mark the vaccines as "DO NOT USE" until advised by the Illinois VFC program, and maintain the shipment packing list. Ensure that temperature logs are maintained for the vaccine in question. IDPH, CDC, and/or McKesson Specialty MAY ask for this paper work.

MERCK FROZEN SHIPMENTS

Shown below are examples of Merck frozen shipping containers.

Frozen vaccines are shipped directly from Merck and will contain a shipper insert in the box to let the provider know how long the product is good for based on the shipment date shown on the packing list. Shown below are examples of the one, two, and four-day shipper inserts. With frozen vaccine shipments, the diluent is located in the lid compartment of the shipping box.

IDENTIFYING THE VACCINES BY FUNDING TYPE

When the vaccine shipment is received, VFC providers will need to identify the VFC, State, CHIP, and 317 doses within the shipment.

The VFC program has four different funding sources for vaccines.

- VFC: Vaccines for use with VFC-eligible children only.
- VFC/State: State purchased vaccines for use with VFC-eligible children only.
- CHIP: Vaccines for use with CHIP covered children only.
- 317: Vaccines available for local health departments for use with 317-eligible adults or for approved outbreak response.

VFC clinics have two ways to determine the number of doses by funding type.

The first way is to check the order in I-CARE. Go to the order in I-CARE. In the "Detail" column, click on the symbol next to the NDC number to expand the details row.

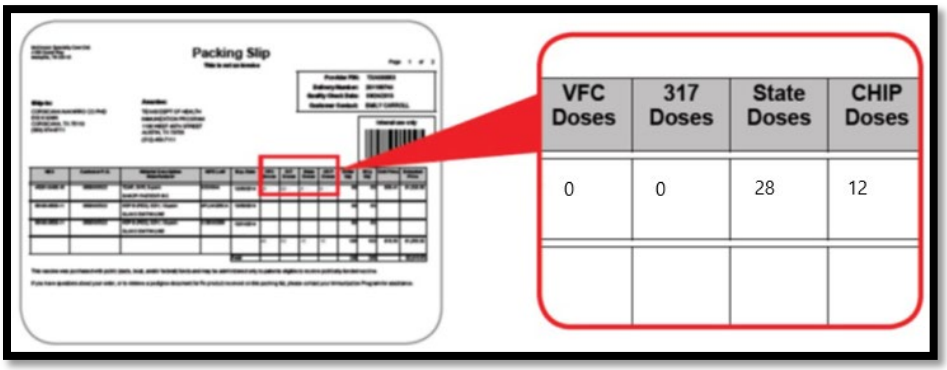
#	Vaccine	Used (3-mo)	Used (12-mo)	Waste (12-mo)	On Hand	Line Status	Doses Ordered	Detail
1	ActHib; PMC; SDV; 5-pack	19	84	3	19	Complete	10	NDC: 49281-0545-03
2	Adacel; PMC; SYR; 5-pack	0	0	0	30	Complete	10	NDC: 49281-0400-20

When the details row is expanded, the split by funding type will be listed. This provider's split is 7 doses VFC/State and 3 doses CHIP. The State-purchased vaccines are part of the VFC inventory and to be used with VFC eligible children.

In this order, the provider received 28 doses of VFC/State and 12 doses of CHIP of Pediarix.

#	Vaccine	Used (3-mo)	Used (12-mo)	Waste (12-mo)	On Hand	Line Status	Doses Ordered	Detail
1	Pediarix; SKB; SYR; 10-pack	0	32	0	26	Complete	40	NDC: 58160-0811-52 • Packaging: 10 • Fund: SPLIT/STATE Split/State: 7 Split/CHIP: 3 • Requested: 40 Approved: 40 • Tracking: FedEx 787073330990 • Lot: 74FN7 (VFC: 28, CHIP: 12)

The second way is to check the packing slip when the vaccine order is received. The packing slip shows how the vaccine order was split between funding sources.



For this VFC clinic's vaccine shipment, the packing slip shows 28 doses are State and 12 doses are CHIP. The state doses are for VFC-eligible children and these vaccines would be combined with the VFC inventory. In I-CARE, these are listed as VFC/State.

IDENTIFYING THE SPLIT DOSES

Vaccines must be stored in their original packaging with lids closed until ready for administration. Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. Removing doses from their original box may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines.

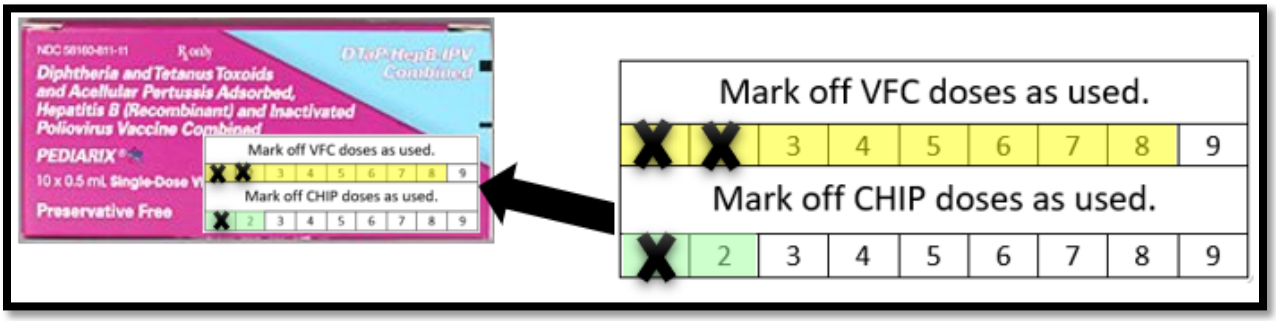
When more than one fund type is in a box, the VFC clinic must label the box to indicate the number of doses by funding type. Sample labels are available for printing and may be found on the home page of I-CARE under News and Announcements.

Using the previous order as an example, the provider received 40 doses or 4 boxes of vaccines: 28 doses are VFC/State and 12 doses are CHIP.

Of the 28 doses VFC/State, 20 doses are from 2 full boxes. These should be marked as VFC. 8 VFC/State doses will need to come out of another box.

Of the 12 doses CHIP, 10 of these are from 1 full box. This box should be marked as VFC. 2 CHIP doses will need to come out of another box.

In the final box, you will have 8 doses of VFC/State and 2 doses CHIP. Using a label, highlight the number of doses by funding type and apply the label to the box. As doses are administered, cross off the doses on the label.



Here are additional tips on storing split fund boxes.

- When storing split fund boxes, it is helpful to:
  - Store these vaccines in a separate bin
  - Identify the bin as “split” so staff will know the vaccine is split between different funding sources
- To keep track of your use:
  - Label the box of single-dose or multi-dose vaccines
  - Highlight the # of doses from each funding type
  - Mark off vaccines administered by funding type as it is used
- Some other important tips to note:
  - Do not cover important information such as vaccine name and lot# with your labels
  - Always keep vaccines in their original packaging
  - Ensure the short-dated vaccines are being used first before beginning another box

10. INVENTORY MANAGEMENT

STORING VACCINES

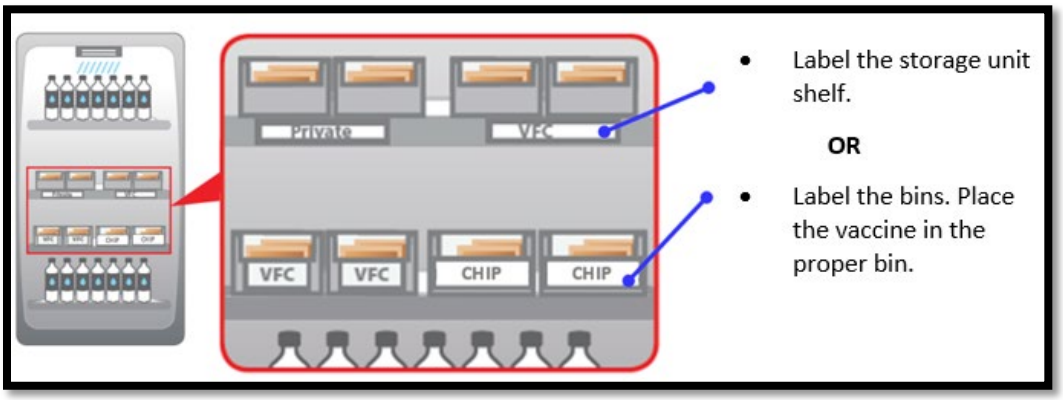
VFC clinics must develop a method for maintaining storing the vaccines to ensure VFC and VFC/State doses are only used for VFC eligible children and CHIP doses are only used for CHIP-eligible children. Clinics may decide to use separate storage units or maintain inventory in one unit. A separate refrigerator is not a requirement.

If a VFC clinic uses separate units for CHIP vaccines, only full boxes of vaccines may be stored separately. Any boxes with doses split for VFC, VFC/State, and CHIP must remain in the original box.

Here are two visual examples on how to store vaccines when you have full boxes with only one fund type and boxes with split fund types.

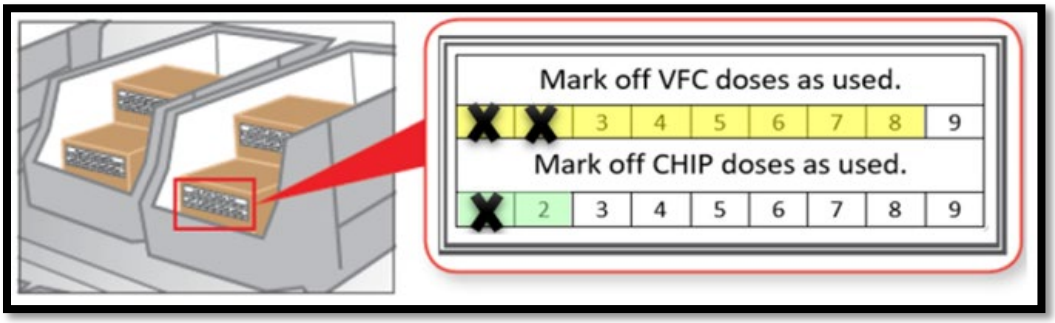
VACCINE STORAGE WITH ONLY ONE FUND TYPE IN A BOX

Organize your storage unit so vaccines are separated by VFC and VFC/State, CHIP (also referred to by CDC as "Other Public"), and private vaccines.



VACCINE STORAGE WITH MORE THAN ONE FUND TYPE IN A BOX

Vaccines must be kept in the original box.



When storing split fund boxes:

- store these vaccines in a separate bin
- Identify the bin as "split" so staff will know the vaccine is split between different funding sources
- Always keep vaccines in their original packaging
- Ensure the short-dated vaccines are being used first before beginning another box

VACCINE MANAGEMENT

DAILY TASKS

- When the clinic opens and before the clinic closes, read and record the current temperature for each refrigerator and freezer storing VFC vaccines—even when using a continuous temperature monitoring device/data logger.
- When the clinic opens, read and record the minimum and maximum temperature for each refrigerator and freezer storing VFC vaccines, even when using a continuous temperature monitoring device/data logger.
- Document temperatures on VFC temperature logs.
- The temperature logs must contain the time and date of each reading and the name or initials of the person who assessed and recorded the reading.
- If out of range temperatures are noted, immediately quarantine the vaccines, download the temperature data files from your data logger, and follow the guidance on the VFC Vaccine Incident Report (available in I-CARE).

WEEKLY TASKS

- Ensure temperatures were recorded twice daily, staff printed names and initials, and corrective actions were taken on any out of range temperatures.
- Download and analyze the data logger data files weekly to look for temperature trends that might indicate performance issues or any out of range temperatures with vaccine storage units and follow up on any out of range temperatures.

  Note: All VFC program related documentation, including eligibility screening, data logger data files, and vaccine order documentation, must be retained for three years.

- Enter the current, minimum, and maximum temperatures into I-CARE.

MONTHLY TASKS (OR MORE OFTEN AS NEEDED)

- Conduct a careful and accurate physical vaccine inventory and compare the physical inventory to the inventory in I-CARE.
- Check vaccine expiration dates and rotate stock to place vaccines that will expire soonest in front of those with later expiration dates.
- Transfer vaccines that will expire within six months to other providers (refer to the VFC Vaccine Transfer Approval Request Form in I-CARE for information and guidance on obtaining IDPH pre-approval).
- Remove any expired vaccines from the storage unit and enter the expired vaccine transaction into I-CARE to receive a mailing label to return the vaccines to McKesson.

ANNUAL TASKS (OR MORE OFTEN AS NEEDED)

- Check the expiration dates on the certificates of calibration for all data loggers and backup data loggers. See the data logger tracking form in the appendix to record the dates of calibration.
- Before the expiration date, arrange to have the data loggers recalibrated or purchase new data loggers. The VFC program will allow two years from the calibration date or longer based on the manufacturer's recommended re-testing timeline as indicated on the certificate of calibration.

  Note: If choosing to have your loggers recalibrated, backup data loggers will need to be placed in each unit storing VFC vaccines while the primary data loggers are being recalibrated. The VFC program recommends have the primary and backup data loggers calibrated on different schedules.

- File certificates of calibration in a readily accessible area, keep them for three years, and present them to VFC program staff for review upon request.
- Review with key practice staff the vaccine management plan's section on preparing for and responding to vaccine-related emergencies.

ROUTINE MAINTENANCE

- Establish a regular routine for cleaning vaccine storage units. Regular maintenance is recommended to ensure proper operation, to maintain required temperatures, and to extend the useful life of the appliance.
- Maintenance of the refrigeration unit and freezer includes:
  - Check the storage unit door seals regularly for signs of wear and tear. Seals should not be torn or brittle and there should be no gaps between the seals and the body of the unit when the door is closed. If seals need to be replaced, contact a repair technician immediately.
  - Check door hinges and adjust so that the door opens and closes smoothly and fits squarely against the body of the unit.
  - Clean unit coils and motor. Dust and dirt buildup can affect transfer of heat from the coils and prevent the unit from working efficiently.
  - Clean inside of units to discourage bacterial and fungal growth. Cleaning must be done quickly to minimize the risk of the temperature going out of range.
  - Defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. Follow the manufacturer's instructions. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.
- Keep a logbook (see the vaccine management plan) to indicate the date(s) of routine maintenance tasks, date(s) of any repairs or servicing, and the name of the person and/or company performing each of these tasks.
- Replace batteries in data loggers every six months, if batteries are accessible.
- If applicable, test backup generators quarterly and service backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
- If your facility has a backup battery power source, it should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).

BEST PRACTICES

The following are recommended practices for providers handling vaccines:

- Store vaccines in their original packaging
- Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
- Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under or near cooling vents.
- Do not store food or drink in vaccine storage units.
- Place water bottles throughout the refrigerator and frozen water bottles in the freezer storage units to:
  - Stabilize or extend temperatures during a power outage,
  - Help to mitigate the effects of frequent open/closing door during busy clinic days, and
  - Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions.

- Rotate vaccines every week or when a new shipment comes in so newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front and administered first.
- Open only one vial or box of a vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC strongly recommends NOT pre-drawing doses before they are needed.

TEMPERATURE EXCURSIONS

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable.

Any staff member who hears an alarm, notices a temperature excursion, or vaccine storage and handling issue potentially affecting the viability of the vaccines must notify the primary or backup vaccine coordinator immediately. Take immediate action as soon as temperature excursions are identified with vaccines provided through the VFC program. Vaccine that is considered spoiled because a provider did not take immediate or appropriate action on out-of-range temperatures may require the provider to replace the wasted VFC vaccine dose-for-dose with private purchase vaccines according to the VFC Vaccine Loss and Replacement Policy.

The Vaccine Incident Report is available in I-CARE and serves as a record of the incident, the steps taken to determine vaccine viability, and the disposition of the affected vaccine. Keep a copy of this report in your records.

If there is any question about whether vaccines may have been exposed to out-of-range temperatures for any reason, CDC recommends the following steps:

1. Do not use or discard the affected vaccines until the vaccine viability has been determined by the manufacturers and you have contacted the Illinois VFC program.
2. Label exposed vaccines, "DO NOT USE," marking the boxes with an "X," and isolate them from other vaccines in the storage unit at the proper storage temperature.
3. The primary or backup vaccine coordinator, supervisor, or, if necessary, the person reporting the problem should document the event on the Vaccine Incident Report and submit it to the Illinois VFC program.

FREEZER DEFROST CYCLES AND TEMPERATURE EXCURSIONS

Freezers with automatic defrost may produce temperature excursions when going through defrost cycles. Any time a vaccine storage unit has temperature excursions, a vaccine incident report must be completed to follow up on the out of range temperatures, including temperature excursions from

defrost cycles. Merck has stated providers should contact them each time they have a temperature excursion with frozen vaccines – even when it is due to defrost cycles. Merck explained the stability information they provide is based upon the specific set of conditions the provider reports and should not be applied generally across the board.

The CDC Storage and Handling Toolkit provides storage best practices that may help prevent temperature excursions in freezers with the automatic defrost cycles:

- The vaccines and the data logger probe should be placed in the center of unit, 2 to 3 inches away from walls, ceiling, floor, and door to allow the cold air to circulate. A data logger probe placed near the walls, floor, vent, ceiling, or door may indicate temperatures that are warmer during defrost cycles than the actual vaccine temperature.
- Frozen water bottles in the unit will help stabilize or extend temperatures in the freezer. Place frozen water bottles against the walls, in the back, on the floor, and in the door racks. Putting frozen water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors, power failures, or even the automatic defrost cycles. It can also prevent vaccines from being stored in areas where there is a greater risk of out-of-range temperatures (such as the floor and door).

For manual defrost freezers: While manually defrosting the freezer, providers should move their frozen vaccines to another freezer that is being monitor with a DDL and temperatures documented. This second freezer cannot be a household/commercial "combination" unit; it must be a stand-alone freezer or pharmaceutical grade freezer. When the original freezer is once again maintaining stable temperatures, the vaccines can be returned to the original unit.

PROVIDER-TO-PROVIDER TRANSFER OF VACCINES

CDC and the VFC program discourage regular transport of vaccines. The VFC program prefers that vaccines remain at the original location where they were initially delivered to avoid a possible break in the cold chain rendering the vaccine non-viable.

Where practical, and as long as the cold chain is maintained, transfer of short-dated vaccine can occur between VFC providers to avoid wasting vaccine.

- The Illinois VFC program must review and approve all requests to transfer vaccines BEFORE the transfer occurs.
- The Illinois VFC program requires the use of a data logger with continuous monitoring and recording capabilities during transport of vaccines.
- All data loggers should have a current and valid certificate of calibration.
- The VFC program does not recommend or find acceptable the use of alternative, one-time use temperature indicators since they do not provide adequate data on excursions that may occur during transport.

TRANSPORT OR SHIPPING

The terms "transport" and "shipping" have different meanings although often used interchangeably.

- Transport involves the movement of vaccine over a short time and distance between providers.
- Transport is typically performed by providers using private vehicles or courier services.
- The expected length of transport is less than eight (8) hours or regular business day.
- The VFC program's expectation is that transporting vaccines should be an extremely rare occurrence.

- Shipping, as compared to transport, typically involves further distance and time to move vaccine between locations.
- Often, vaccine is moved using a large, shipping management service and requires adherence to shipping standards that go beyond CDC guidance for the transport of vaccine.
- The VFC program does not allow providers to ship vaccines due to the potential risks to the cold chain and ultimately the viability of the vaccine.

TRANSFER PROCEDURE

Providers who have excess vaccine on hand that will not be used in three to six months 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 approximately six months of the vaccine expiring and until the vaccine expired**.** It is the provider's responsibility to find another provider willing to accept the vaccine, and to properly pack and transport the vaccines following standard cold-chain procedures. **VFC providers are not required to accept a transfer from another VFC provider.** Providers must allow up to 10 business days for transfer approval requests to be reviewed. See the VFC Vaccine Transfer Approval Request Form in I-CARE for more information.

Transfers should only occur for the following reasons:

- Vaccine is six months or less from outdate, and unable to be used by provider.
- Area outbreak resulting 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 the end of time facility will be open.

The following transfer requests will be reviewed on a case-by-case basis with appropriate explanation provided for the transfer request:

- Vaccines are more than six months from the expiration date.
- The provider has an immediate need for a couple of doses of vaccine before an order could be received.

Providers may not transfer influenza vaccine. If a provider needs a vaccine, they may order the vaccine as vaccine orders are usually shipped sooner than the 10 business days it could take to approve a transfer of vaccines. Transfers should be done on a rare basis and only for the reasons stated above. Vaccines should remain with the original location it was delivered to if possible, to avoid a possible break in the cold chain rendering the vaccine non-viable.

Providers must obtain pre-approval from IDPH before any transfers. All transfer requests must be submitted by and received by one of the VFC vaccine coordinators on file in the provider's enrollment. Transporting vaccines due to an emergency response and in accordance with your emergency response plan is not a transfer and does not require pre-approval. These vaccines are temporarily being stored at the emergency response location until the vaccines can be moved back to the original provider. If the vaccines will not return to the original provider after the emergency response, the provider must submit a transfer request.

The VFC provider requesting to transfer vaccines MUST advise the receiving VFC provider of all temperature excursions affecting the vaccines and provide the receiving VFC provider with a copy of the vaccine incident report with the manufacturer stability statements.

If a provider cannot be located to accept transferred vaccine, document attempted contacts on the vaccine transfer contact log available in I-CARE on the home page under "Immunization Links." If the

vaccines must be wasted, email or fax the completed vaccine transfer contact log to IDPH for review and consideration in the vaccine replacement decision. It is not required to document all contacts about transferring vaccines. However, if vaccines must be reported as expired, we will consider attempts to transfer the vaccines in the vaccine replacement decision.

VACCINE TRANSPORTATION GUIDELINES

Vaccine Transportation Recommendations

- CDC discourages regular transport of vaccines. The VFC program prefers that vaccines remain at the original location where they were initially delivered to avoid a possible break in the cold chain rendering the vaccine non-viable.
- The shipment of vaccines by a provider through a commercial carrier is not allowed due to the potential risks to the cold chain.
- Providers must maintain the vaccine cold chain at all times to protect the vaccine potency.
- If you cannot ensure the vaccine has been **stored** under proper conditions to maintain the cold chain, then DO NOT transport the vaccines.
- If you cannot ensure vaccines are **transported** under proper conditions to maintain the cold chain, then DO NOT transport the vaccines.

Vaccine Transportation Standard Operating Procedures

1. Vaccines are attended at all times during transport.
2. Vaccines are never placed in the trunk of a vehicle.
3. Vaccines are delivered directly to the facility.
4. Receiving facility promptly unpacks and appropriately stores vaccines.
5. Use a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.

Varicella-Containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMRV, VAR). If these vaccines must be transported, CDC recommends the following transportation guidelines.

- Transport only in a portable freezer unit that maintains the temperature between -50°C and -15°C (-58°F and +5°F).

  Use of dry ice is not recommended for temporary storage or emergency transport. Dry ice may subject varicella-containing vaccines to temperatures colder than -50°C (-58°F).

- The Illinois VFC program will review requests to transport varicella on a case-by-case basis to ensure transportation guidelines are followed.

Packing Vaccines for Transport

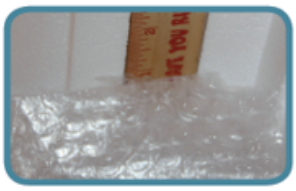
1. Gather the supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

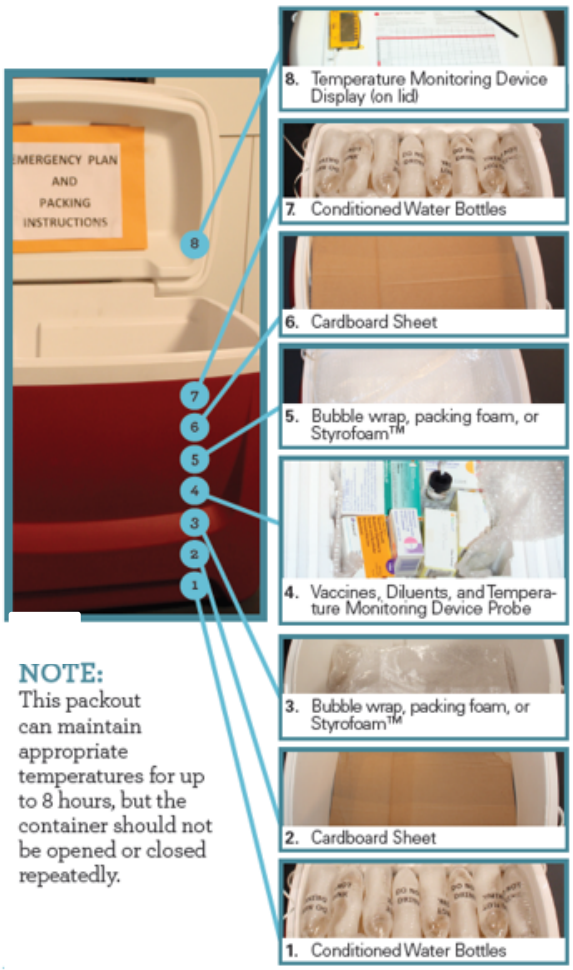
Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

2. Pack for transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3. Arrive at destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

TRANSPORT SYSTEM RECOMMENDATIONS

Type of Transport System	Emergency Transport/ Vaccine Transfer	Transport for Off-Site Clinic
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Coolant materials such as phase change materials (PCMs) may be purchased to maintain vaccines at proper temperatures of 4° C–5° C (39° F–41° F). Follow the manufacturer's instructions for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in emergency situations.

MOVING TO A NEW LOCATION

VFC providers planning to move their clinic to a new location must notify the immunization program before the clinic moves so the equipment and plan to transport the VFC vaccines may be reviewed and approved. Contact the Illinois VFC program at DPH.Vaccines@illinois.gov or by telephone at 217-785-1455.

The Illinois VFC Program needs to know the steps planned to ensure that vaccine cold chain is maintained before, during, and after the move, including the following information.

- The date of the move;
- Current address;
- New address (including suite or room numbers and zip code);
- Any changes to the clinic/organization name;
- Any change to the medical provider who signed the VFC enrollment agreement;
- Any change to the vaccine coordinators – primary and backup(s);
- Vaccine storage equipment – new equipment or moving existing equipment;
- Vaccine storage plans during the move;
- Vaccine storage plans until the storage equiment temperatures are stabilized; and
- Plans for transporting the vaccines, including frozen vaccines.

VFC ordering privileges will be suspended before the move to ensure a vaccine shipment is not compromised. Depending upon the circumstances surrounding a move, the Illinois VFC program may also require a site visit to be conducted before reinstating VFC ordering privileges.

Moving or installing a new refrigerator and freezer will take time to stabilize the temperatures within the unit. It may take two to seven days to stabilize the temperature between 2 C and 8 C (36 F and 46 F) in a newly installed or repaired refrigerator. Likewise, it may take two to three days to stabilize the temperature between -50 C and -15 C (-58 F and +5 F) in a newly installed or repaired freezer.

VFC providers must record refrigerator and freezer temperatures a minimum of two times each workday, including minimum/maximum temperatures one time each morning to make sure

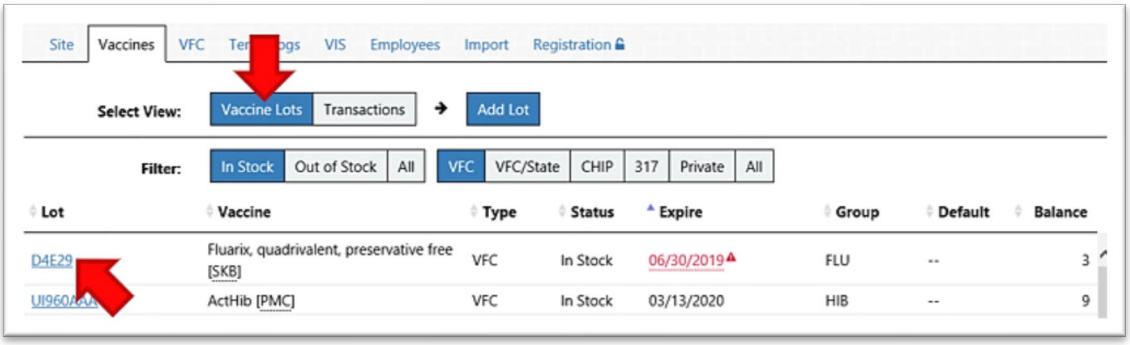
temperatures are within appropriate ranges for at least two days before using units to store vaccines. (Source: *CDC Storage and Handling Toolkit*).

EXPIRED, SPOILED, OR WASTED VACCINES

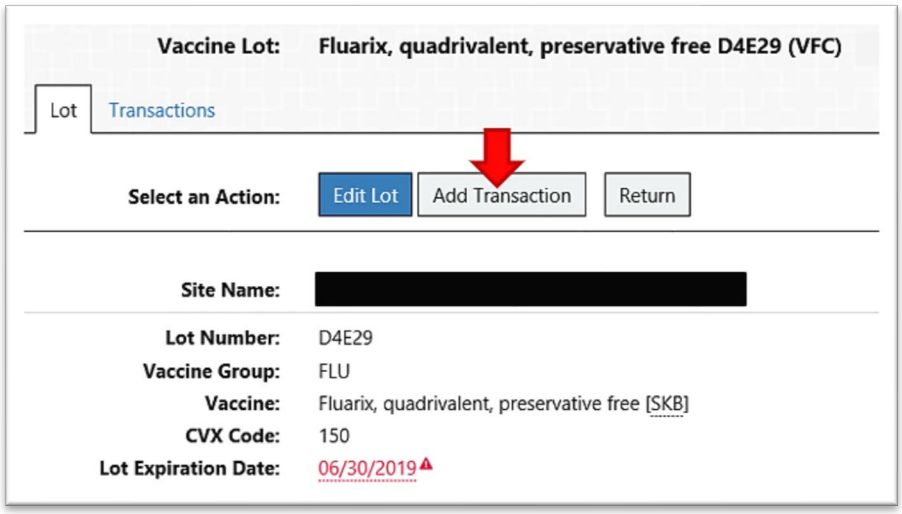
Vaccines that are expired/spoiled or wasted must be reported in I-CARE within one (1) week of the expiration date of the vaccine. All unopened vials and manufacturer's pre-filled syringes of spoiled or expired vaccine received from the VFC program must be returned within six (6) months of the expiration date for Excise Tax Credit and disposal to McKesson Specialty. Failure to report wasted vaccine to the Illinois VFC program may result in your facility no longer being able to receive state-supplied vaccine. VFC providers may be required to replace any excessive amounts of wasted vaccines or frequent reports of wasted vaccines with privately-purchased vaccines.

If the vaccine(s) were exposed to temperature excursions, complete the vaccine incident report BEFORE wasting the vaccines to determine if the suspected vaccine is viable or not.

To enter expired or wasted vaccines in I-CARE, go to the "Vaccines" page and click on "Vaccine Lots."



- Click on the lot number to be reported as expired, spoiled, or wasted.



- Click on the "Add Transaction" button.

Transaction Add

Site:	[redacted]
Vaccine Group:	FLU
Vaccine Name:	Fluarix, quadrivalent, preservative free
Lot Number:	D4E29 (VFC)
Lot Status:	In Stock
Expire Date:	06/30/2019
NDC Number:	58160-0898-52 Fluarix Quadrivalent, p-free; SKB; SYR; 10-pack (Quad)
Current Lot Balance:	3
Transaction Type:	*
Quantity:	*
Transaction Date:	*
Note/Comment:	

* = Required Field

Select an Action: Save Cancel

- Enter the required information to complete the transaction.
- Select the appropriate transaction type: Expired/Spoiled (vaccines to be returned to McKesson) or Waste (vaccines cannot be returned to McKesson).
- Select the appropriate waste code to describe why the vaccines can no longer be administered.
- The transaction screen in I-CARE will provide guidance if additional action needs to be taken before the vaccine may be reported as expired or wasted.
- When replacement is required, your privately purchased vaccines will replace the wasted/expired VFC vaccines and will be entered in during the waste transaction to be added to your VFC inventory.

The following vaccines should be returned to McKesson:

- Spoiled or expired product in its original vial or manufacturer pre-filled syringe.
- Unused manufacturer pre-filled syringes with an NDC printed on them.

The following vaccines should **NOT** be returned to McKesson:

- Used syringes, with or without needles
- Broken vials
- Syringe that was drawn up but not used (the VFC program discourages the use of pre-drawing any vaccine)
- Any multi-dose vial from which some doses have been withdrawn
- IG, HBIG, or PPD
- Diluent (expired or not expired)
- Private purchased vaccine.

The vaccines not returned to McKesson must be disposed of according to usual medical biosafety procedures, and according to your agency procedures. Federal excise tax (FET) credits can only be

processed for unopened vials and for unopened manufacturer prefilled syringes. Returns of products other than these are not eligible for FET credit.

Providers reporting expired/spoiled vaccines will receive an e-mail when the report has been received by CDC and should expect a return label via US mail within seven to 14 days of the e-mail date.

RETURN MAILING LABELS

A return UPS mailing label will be sent to the provider via USPS mail. The envelope containing the return mailing label is approximately 6.75" x 4.5" and has the wording "Return Label for Expired Vaccines" printed in red font (see the sample on the following page). The return mailing label may be addressed generically as "Attn: VFC Vaccine Contact." Providers may want to advise their mail room of the identity of their primary or backup VFC vaccine contact so the mailing label may be forwarded to the correct person.

Return mailing labels are only valid for 30 days. If the return label has not been used within 30 days, please contact us by clicking on "Contact Us" in I-CARE and select "VFC Illinois" as the category.

MULTIDOSE VIALS

Opened IPOL multidose vials can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised. The IPOL package insert (available at https://www.vaccineshoppe.com/image.cfm?doc_id=5984&image_type=product_pdf) does not require the use of a beyond use date (BUD).

The Joint Commission has specifically addressed the issue of discarding open multi-dose vaccines in the Joint Commission Standards Frequently Asked Questions (available at https://www.jointcommission.org/):

> *Question: Do vaccines need to follow the 28-day rule?*
>
> *Answer: "Currently, vaccines are exempted from this requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to assure integrity of the vaccine."*

The Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book: Course Textbook - 13th Edition (2015) (available at http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html) states, "A multidose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information."

Sanofi Pasteur has confirmed that multi-dose vials of IPOL can be used until the expiration date on the vial unless the vaccine in contaminated or compromised. Sanofi Pasteur also states only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses have been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached. CDC advises to never use partial doses from two or more vials to obtain a dose of vaccine. The letter from Sanofi Pasteur is shown on the following pages.

March 29, 2019

Dear Healthcare Provider :

This is in response to your request for information regarding IPOL®, Poliovirus Vaccine Inactivated and the following topic(s):

Storage and Use of Punctured MDV

Indications and Usage

IPOL vaccine is indicated for active immunization of infants (as young as 6 weeks of age), children, and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3. The enclosed materials are being provided in response to your unsolicited request and are for your information only. Sanofi does not recommend or intend for any of its products to be used in a manner which may be inconsistent with approved product labeling. To the extent the enclosed materials reference uses not in the approved product labeling, the safety and efficacy of such uses have not been established and are not approved by the Food and Drug Administration (FDA). Please refer to the enclosed package insert for full prescribing information.

To the extent you prescribe the product referenced in the enclosed materials for a use not in the approved product labeling, you make that decision based on your own medical judgment and discretion. As you may be aware, any prescriptions for uses not in the approved product labeling may not be eligible for reimbursement by federal health care programs.

Storage and use of Multidose Vials (MDVs)

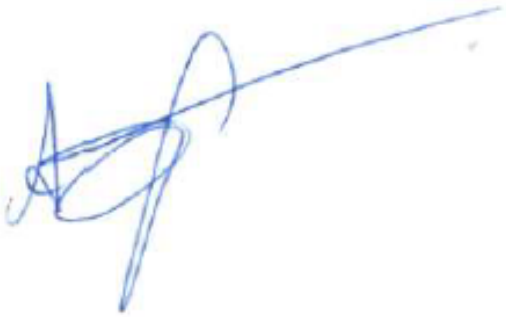
Multidose vials of IPOL (Poliovirus Vaccine Inactivated) are to be stored at 2°C to 8°C before opened and after used (punctured).[1]
Sanofi Pasteur does not endorse the storage and/or use of IPOL in a manner outside the recommendations of the prescribing information.
The following information regarding vaccine storage and handling is provided by the Centers for Disease Control and Prevention (CDC).[2]

• MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a BUD [beyond use date] noted in the package insert.
• Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses have been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached.

The United States Pharmacopoeia recommends that if any multidose vial has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened or accessed vial.[3] However, The Joint Commission has exempted this 28 day rule for all vaccines and suggest discarding the vaccine per the manufacturer's expiration date, with the understanding that the vaccines should be stored and handled appropriately (correct temperature maintained, frequency of temperature checks, etc.).[4]

Thank you for your interest in Sanofi Pasteur products. If we may be of any further assistance, please contact us by telephone at 1-800-VACCINE (822–2463) or visit the Sanofi Medical Information website at www.sanofiusmedicalinformation.com
MIS 1-1687320650

Please help us to improve our service by completing a brief survey:
https://www.surveymonkey.com/s/SBGR5Y



Anja Glaetzer, MD,PhD,PGDip Health Economics
Head Global Medical Information Content, Pasteur

Enclosure List:
• IPOL [package insert]. Swiftwater, PA: Sanofi Pasteur Inc.; August 2015.

Reference List:

1. IPOL [package insert]. Swiftwater, PA: Sanofi Pasteur Inc.; 2015.
2. CDC Vaccine Storage and Handling Toolkit 2019
3. *United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations.* United States Pharmacopeia (USP) 797. 2nd. The United States Pharmacopeial Convention; 2008.
4. CDC. Multi Dose Vials - Vaccine 28 Day Rule. Available at: https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=1079&&StandardsFAQChapterId=54&&ProgramId=0&&

11. VACCINE MANAGEMENT PLAN

STANDARD OPERATING PROCEDURES

VFC providers must develop, maintain, and implement a Vaccine Management Plan with detailed and up-to-date standard operating procedures for routine and emergency vaccine management.

The Illinois VFC program has created a vaccine management plan template, which is available in I-CARE on the home page under "Immunization Links." The responsibilities listed in the vaccine management plan are those of the primary and backup vaccine coordinators.

A copy of the Vaccine Storage and Emergency Response Plan must be posted on all refrigerators/freezers used to store VFC vaccines.

Office staff handling or administering vaccines should be familiar with the vaccine management plan, which includes the vaccine storage and emergency response plan, and ensuring vaccines are maintained within the required temperature range.

The VFC program recommends that providers use the vaccine management plan template developed by the Illinois VFC program as it covers all required elements. Providers may create their own vaccine management plan, but it must include all the following items.

- Name of the current primary vaccine coordinator and at least one backup coordinator
- Signature, name, and title of the person completing the plan
- Date the plan was completed
- Contact information for individuals with 24-hour access to the building
- General operations for the following vaccine storage and handling practices:
  - Proper vaccine storage and handling practices
  - Temperature monitoring
  - Vaccine storage (e.g., equipment, placement)
  - Vaccine shipping and receiving procedures
  - Vaccine ordering procedures
  - Inventory control (e.g., stock rotation)
  - Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
  - Protocols for vaccine storage equipment maintenance
  - Protocols for the correct placement of vaccines within storage units
  - Protocols for responding to vaccine storage and handling problems
- Staffing
  - Descriptions of the roles and responsibilities of the primary and alternate (backup) vaccine coordinators
  - Policy on education and training for facility staff
  - Staff training and documentation of training on VFC requirements, including proper vaccine storage and handling
- Emergency response plan:
  - The emergency response plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failure to vaccine storage units, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions.
  - Contact information for emergency storage locations.
  - Contact information for refrigerator and freezer maintenance and repair companies.

- Contact information for the vaccine storage unit alarm company (if applicable).
- Sources for packing materials, calibrated temperature monitoring devices, and portable refrigerator/freezer units or qualified containers.
- In addition, the plan must include policies and protocols for maintaining the vaccine cold chain during transport to and while stored in emergency storage locations.

EMERGENCY RESPONSE

- An on-site generator can prevent having to transport vaccines to an alternative storage facility during a power outage. A backup battery power source can also be used in lieu of a generator.
- Backup generators or battery power sources should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).

(Source: *CDC Storage and Handling Toolkit*).

12. VFC SITE VISITS

To ensure the quality of VFC vaccine and the integrity of the VFC program, the Illinois VFC program conducts the following type of provider site visits.

- Enrollment
- Compliance
- Storage and handling
- Educational

VFC visits help determine compliance with VFC program requirements. This includes identifying potential issues with VFC vaccine accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

The review and evaluation of VFC provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

The goals of these visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify the educational needs of VFC providers to support meeting program requirements.
- Ensure that VFC-eligible children receive properly managed and viable vaccine.

Additionally, site visits are critical opportunities to engage provider staff and develop and strengthen ongoing relationships.

As defined in the VFC enrollment agreement, VFC providers agree to participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.

VFC compliance staff finding or observing storage and handling practices that compromise the safety and efficacy of the VFC vaccines have the authority to act on behalf of the Illinois VFC program to retrieve and remove the VFC vaccines from the provider. Replacement may be required under the VFC Vaccine Loss and Replacement policy.

VFC COMPLIANCE VISIT

All enrolled and active VFC providers must receive a VFC compliance site visit every 24 months, at minimum, to ensure compliance with VFC program standards.

- Enrolled and active providers are providers that are enrolled in the VFC program and have ordered vaccine within the past 12 months.
- Conducting a VFC compliance site visit with providers every 24 months is a minimum-level requirement. Providers may receive a VFC compliance site visit on a more frequent basis.
- A new provider must be enrolled and active in the VFC program at least three to six months before receiving a VFC compliance site visit.

The VFC compliance visit requires availability of key staff that can accurately provide a realistic picture of how the 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.

VFC providers may be prioritized for an unannounced storage and handling visit based on the following:

- The provider's previous history with storage and handling compliance issues;
- Time since the last site visit;
- A newly enrolled provider; or
- Providers having excessive or habitual waste in the previous 12 months. Excessive waste is defined as wasted vaccine amounts that either exceeds $1,500 in value or three (3) percent of the total amount of vaccines received in the previous 12 months.

The CDC Vaccine Storage and Handling Toolkit outlines is available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. The toolkit outlines best practice strategies and recommendations on the following:

- Vaccine cold chain
- Storage and handling plans
- Staff
- Vaccine storage equipment
- Temperature monitoring equipment
- Vaccine storage and handling best practices
- Storage unit temperature monitoring
- Troubleshooting
- Vaccine inventory management
- Vaccine deliveries
- Vaccine transport
- Vaccine preparation
- Vaccine disposal

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 Illinois Department of Public Health's immunization staff or by local health departments trained by the Illinois VFC program 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 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.

13. VACCINE LOSS AND REPLACEMENT

Vaccine accountability is a cornerstone of the VFC program and one of the program's highest priorities. Vaccine losses are absorbed directly by the VFC program's budget. Since the Illinois VFC program is so important to the health and well-being of the children in Illinois, it is essential that every dose of vaccine is used to provide protection against preventable diseases. All VFC providers should continually monitor vaccine storage and handling practices. Providers may contact the Illinois VFC program to request an educational visit regarding vaccine storage and handling.

The Vaccine Loss and Replacement policy serves as the Illinois VFC program's policy for management of incidents that result in loss of vaccines provided through the VFC program, including VFC, 317, CHIP, or other state purchased vaccine (hereafter referred to as "VFC program vaccines"). VFC providers are required to report all wasted, expired, spoiled or lost vaccine to the Illinois VFC program.

Dose-for-dose replacement with privately purchased vaccine for VFC program vaccine may be required and provider's ordering privileges may be suspended until replacement is made. Providers having excessive or habitual waste in the previous 12 months may also receive a storage and handling visit. Excessive waste is defined as wasted vaccine amounts that either exceeds $1,500 in value or three (3) percent of the total amount of vaccines received in the previous 12 months.

DEFINITIONS

Wasted: Any vaccine that cannot be used.

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: Vaccines that a commercial carrier (FedEx or UPS) does not deliver or does not deliver in a timely manner. This includes VFC vaccines the provider cannot locate, account for, thrown away, or disposed of against VFC policies.

SITUATIONS REQUIRING VACCINE REPLACEMENT

Below is a list of situations that require dose-for-dose replacement with privately-purchased vaccines.

EXPIRED VACCINE

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine. VFC providers should document transfer attempts on the "VFC Vaccine Transfer Contact Log".
- 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. The Illinois VFC program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine that is left out of the refrigerator or freezer and becomes non-viable. Call the vaccine manufacturer first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer and complete the VFC Vaccine Incident Report.
- Vaccine stored in dorm style refrigerators or household combination refrigerator/freezer unit.

- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is 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 that is considered spoiled due to the provider not checking, reviewing, and documenting refrigerator and freezer temperatures twice daily for a minimum of three days a week.
- Vaccine that is considered spoiled due to the provider failing to use currently certified calibrated data loggers (as primary and backup data loggers) 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.

WASTED VACCINE

- VFC program vaccines given to children or adults who are not eligible to receive it based on the most recent VFC eligibility criteria and Illinois immunization guidelines.
- VFC program vaccines administered to children or adults with the State's Children Health Insurance Program (CHIP) coverage (Medicaid Title XXI [21] or State-funded).
- Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials discarded after 30 days).
- Excessive waste that either exceeds $1,500 in value or three (3) percent of the total amount of vaccines received in the previous 12 months.

LOST VACCINES

- VFC vaccines the provider cannot locate, account for, may have been thrown away, or disposed of against VFC policies.

OTHER

- Failure to call the VFC program within two (2) hours of receiving a VFC delivery when the delivered vaccines do not match the packing list or I-CARE inventory.
- Failure to call the VFC program within two (2) hours to report damaged or compromised VFC vaccine delivery.
- Transferring or transporting VFC vaccines, either refrigerated or frozen vaccines, to another VFC provider without IDPH pre-approval.
- Transferring or transporting varicella-containing vaccines to another VFC provider without IDPH approval on the transportation unit.
- Transferring or distributing VFC program vaccines to any non-VFC provider (also referred to as "depoting" vaccines).

SITUATIONS NOT REQUIRING VACCINE REPLACEMENT

Below is a list of situations that are NOT considered "provider negligence." This list is not exhaustive. In these situations, the provider is deemed not to be at fault. You 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 that 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 or act of nature, and the provider can confirm that 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 that is accidentally dropped or broken by a provider.
- Vaccine that is drawn after physician orders and parental agreement during the visit, but not administered due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
- Extraordinary situations not listed above which 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 VACCINE REPLACEMENT

This updated policy applies to any VFC vaccine documented as wasted.

- The provider will receive a notice from the Illinois VFC program or will be instructed via I-CARE that replacement of VFC vaccines with privately purchased vaccines is required.
- If proof of replacement is required, acceptable proof is 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. Guidance will be provided on how to enter the transactions in I-CARE.
- 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.
- If vaccine replacement is required, the VFC provider will be notified by the IDPH VFC program staff.

ADDITIONAL INFORMATION

- 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. The Illinois VFC program may inform the clinic's vaccine coordinator of patients that need revaccination discussed with their medical director. If revaccination is decided upon by the VFC provider's medical director, the Illinois VFC program may require a copy of the letter sent out to the patients advising of the revaccination recommendation.

- Depending on the outcome of any suspected fraud investigation by 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 program vaccine, reimburse the state for the cost of used vaccines, and/or potentially be terminated from the VFC program. The Illinois Department of Public Health reserves any and all rights with respect to any future action.

PROCEDURE TO APPEAL A VACCINE REPLACEMENT

Providers may appeal the decision for replacement of wasted VFC vaccines by submitting the request **in writing** either via e-mail to the Illinois Department of Public Health at DPH.Vaccines@illinois.gov.

Providers must include all documentation, including the vaccine incident report, any communication, and any other documentation supporting an appeal. **Providers must include their VFC PIN on all communication.**

Possible outcomes of an appeal may include the following.

1. A partial reduction in the amount of the required vaccine replacement.
2. Granting a substitution in the vaccine replacement (e.g. a multi-vaccine in place of a single component vaccine).
3. Extension up to 90 days for vaccine replacement.
4. Waive vaccine replacement. Factors to be considered include:
    a. Prior history of vaccine incidents and/or vaccine waste;
    b. Provider actions to prevent vaccine incidents from occurring again;
    c. Actions at the time of incident;
    d. Documentation of provider actions to transfer vaccines to other providers;
    e. Change in management, medical director, and providers within clinic; or
    f. Extenuating circumstances.
5. If the provider is unable to use the replacement vaccines, the replacement vaccines may be shipped to a local health department or other approved provider.

All appeal requests will be reviewed, and the provider notified of all decisions within 30 days.

14. 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 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

The following are additional definitions used in the VFC program.

Oversight: Illinois specifies any suspected case of fraud and abuse should immediately be reported to the Department's VFC administrator, coverage level administrator, 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 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 State of Illinois Rapid Electronic Notification (SIREN) 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.

Failure to comply with VFC requirements is defined as:

- Any VFC-enrolled provider who is identified as not maintaining any of the federal requirements for the VFC program as defined in the enrollment agreement.

Failure to comply may be identified by:

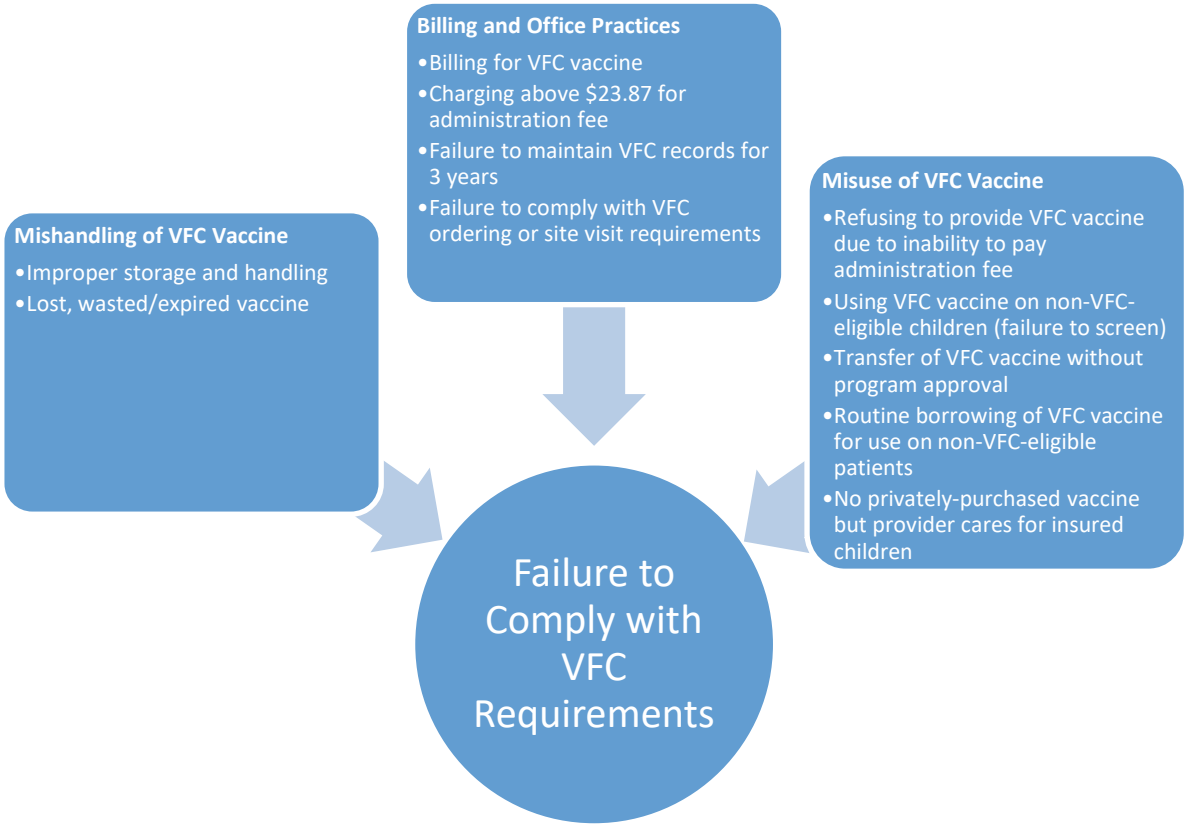
- VFC program staff
- The enrolled provider's staff, or
- A third party

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.**

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-funded vaccine
- Charging more than the established maximum regional charge ($23.87) for administration of a VFC funded vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen for and document eligibility status 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
- Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering VFC doses of vaccine
- Waste of VFC vaccine



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 an acknowledgement of receipt of the follow-up plan detailing the steps that will be taken to prevent further incidents. This signed plan must be returned within one month. The provider will be advised 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 to the immunization section chief or equivalent for review by the Office of Health Protection and the Department's 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.

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
- Karen Pendergrass, Immunization Coverage Level Administrator, is designated as first backup. Karen.Pendergrass@illinois.gov
- Gina Lathan, Immunization Section Chief, is designated as second backup. Gina.Lathan@illiniois.gov

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 (at https://oig.hhs.gov/exclusions/index.asp) upon provider enrollment and on a regular basis thereafter.

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 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 may share information with the state attorney's office, and the Medicaid Fraud and Abuse Unit 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 State of Illinois Rapid Electronic Notification System (SIREN) lists and excluded on reports to the state Medicaid agency requesting data on active VFC providers.

APPENDICES

The following documents are in the appendix.

- VFC Eligibility Status Codes
- VFC Tip Sheets
- Glossary of Important VFC Terms

VFC ELIGIBILITY STATUS CODES

The Centers for Disease Control and Prevention has updated the VFC eligibility codes. The complete list of codes is shown in the following table.

Code	Label	Definition
V01	Not VFC eligible	Client does not qualify for VFC because they do not have one of the statuses below. (V02-V05)
V02	VFC eligible – Medicaid/Medicaid Managed Care	All the following are true: • Client is currently eligible for Medicaid or Medicaid managed care Title XIX (19) • Client is < 19 years old • The type of vaccine administered is eligible for VFC funding
V03	VFC eligible – Uninsured	All the following are true: • Client does not have health insurance • Client is < 19 years old • The type of vaccine administered is eligible for VFC funding
V04	VFC eligible – American Indian/Alaska Native	All the following are true: • Client is a member of a federally recognized tribe • Client is < 19 years old • The type of vaccine administered is eligible for VFC funding
V05	VFC eligible – underinsured at FQHC/RHC/deputized provider	All the following are true: • Client has insurance, but insurance does not cover vaccines, limits the vaccines covered or caps vaccine coverage at a certain amount • Client is receiving care at an FQHC, RHC or deputized provider • Client is < 19 years old • The type of vaccine administered is eligible for VFC funding
V22	CHIP	Client is eligible for the CHIP program (Medicaid Title XXI [21] or State-funded), a separate state health insurance that is NOT a Medicaid expansion program. ***The patient must receive CHIP vaccines.***
V23	317	Client is eligible to receive vaccines under the state/program immunization policy and the vaccine administered is eligible for 317 funding. ***This should only be used upon direction by IDPH.***
V24	Medicare	Client is enrolled in Medicare. ***The patient is not eligible for VFC or 317 funded vaccines.***
V25	State program eligibility	Client is eligible for a state vaccine program. ***The patient is not eligible for VFC or 317 funded vaccines.***

VFC TIP SHEETS

The Illinois VFC program has created tip sheets to assist providers with specific tasks. The following are some of the tip sheets available in I-CARE on the home page under the "Immunization Links" tab.

- **Data loggers:** A tip sheet that provides a description of a data logger, explains how to identify if your unit is a data logger, and how to review and interpret the data logger's data and reports.
- **Moving to a new location:** A tip sheet for moving a VFC provider clinic to a new location.
- **VIS documentation:** A tip sheet detailing the Vaccine Information Statement documentation requirements.

GLOSSARY OF IMPORTANT VFC TERMS

Abuse (related to Fraud)

Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (also includes actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. Also includes program recipient practices that result in unnecessary cost to the Medicaid program.

Advisory Committee on Immunization Practices (ACIP)

The ACIP consists of 15 medical and public health experts selected by the Department of Health and Human Services Secretary to provide advice and guidance to the Secretary, Assistant Secretary for Health, and CDC on the control of vaccine-preventable diseases. The committee develops recommendations for the routine administration of vaccines to children and adults in the civilian population, including guidance on age for vaccine administration, number of doses and dosing intervals, and precautions and contraindications. See ***VFC-ACIP resolutions***.

Affordable Care Act

The comprehensive health care reform law enacted in March 2010 (sometimes known as ACA, PPACA, or "Obamacare").

The law has three primary goals:

1. Make affordable health insurance available to more people. The law provides consumers with subsidies ("premium tax credits") that lower costs for households with incomes between 100% and 400% of the federal poverty level.
2. Expand the Medicaid program to cover all adults with income below 138% of the federal poverty level. (Not all states have expanded their Medicaid programs.)
3. Support innovative medical care delivery methods designed to lower the costs of health care generally.

American Indian or Alaska Native (AI/AN)

As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603):

- "Indians" or "Indian," unless otherwise designated, means any person who is a member of an Indian tribe, as defined in subsection (d) of this section, except that, for the purpose of sections 1612 and 1613 of this title, such terms shall mean any individual who (1) irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.
- (d) "Indian tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 et seq.], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Deputization Agreement

A formal agreement through a Memorandum of Understanding (MOU), whereby Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs) delegate their VFC authority for vaccinating underinsured children to local health departments (LHDs), who then vaccinate underinsured children as agents of the FQHC/RHC. For more information on deputization agreements, please contact the Illinois VFC program at DPH.Vaccines@illinois.gov or 217-785-1455.

Department of Health and Human Services, Office of Inspector General (OIG)

Office mandated to protect the integrity of Department of Health and Human Services (HHS) programs and their beneficiaries. It is generally responsible for identifying, communicating and correcting activities of waste, fraud or abuse within DHHS programs. The OIG maintains the List of Excluded Individuals and Entities (LEIE).

Expiration Date

The last date on which the vaccine may be used; expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Fraud (related to Abuse)

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.

Health Care Sharing Ministries (HCSMs)

Nonprofit alternatives to purchasing health insurance from private, for-profit insurers. Generally, HCSMs are organizations whose members share a common belief system and collectively "share" the cost of their members' medical care.

Insurance

For the purpose of the VFC program, "insurance" is defined as a plan that is:

- Regulated by a State's Insurance Commissioner and/or
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA). ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.

List of Excluded Individuals and Entities (LEIE)

Providers on the LEIE are excluded from participating in federally funded health care programs because of issues that include program-related fraud, patient abuse, licensing board actions, and default on Health Education Assistance Loans. This list is maintained by the OIG of DHHS.

Office of Management & Budget (OMB)

Office that assists the President in overseeing the preparation of the federal budget and supervising its administration in Executive Branch agencies. OMB evaluates the effectiveness of agency programs, policies, and procedures.

Rural Health Clinic (RHC)

An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

Vaccine Administration Fee

The amount a VFC-enrolled provider can charge a non-Medicaid VFC-eligible child for each vaccine administered (also known as the administration fee or "admin fee"). State Medicaid agencies have the authority to reimburse at a lower level than the set vaccine administration fee. The Centers for Medicare and Medicaid Services (CMS) set and adjust these maximum regional charges.

VFC-ACIP Resolutions

The Advisory Committee on Immunization Practices (ACIP) has unique legal authority from Congress to provide recommendations for the VFC program. When recommending a new vaccine or a change in vaccine use, ACIP votes on a resolution to include the vaccine change in the VFC program. VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

Vaccines procured through the VFC program must be administered according to the guidelines outlined by ACIP in VFC resolutions. (VFC vaccines may also be administered in accordance with state school attendance laws.) CDC establishes contracts for VFC vaccines only after a VFC resolution is in place.

VFC-Program Eligibility Categories

- **VFC-eligible child**
  A child who is 18 years of age or younger and meets one or more of the following criteria:
  - American Indian (AI) or Alaska Native (AN)
  - Medicaid-eligible/enrolled (Title XIX [19] only)
  - Uninsured
  - Underinsured (has health insurance, but the coverage does not include any ACIP-recommended vaccines or includes only selected ACIP-recommended vaccines)
- **Uninsured**
  A child who has no health insurance coverage.
- **Underinsured**
  A child who has health insurance, but whose coverage does not include any ACIP-recommended vaccines or only includes selected ACIP-recommended vaccines. An underinsured child is VFC-eligible only for the vaccines that are not covered. A child whose insurance covers vaccines but has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount is reached, a child is then eligible. Underinsured children are eligible to receive VFC vaccine only through a federally qualified health center (FQHC), a rural health clinic (RHC), or under an approved deputization agreement.
- **Fully insured (not eligible)**
  A child with insurance that covers the cost of vaccine, even if the insurance plan has a high deductible or copay, or if 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 has not been met. This child is not eligible for the VFC program.