

2020-2021

VFC Provider Handbook

Tennessee Vaccine-Preventable Diseases and
Immunization Program
Vaccines for Children (VFC) Program



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Introduction

The Tennessee Vaccine-Preventable-Diseases and Immunization Program (TVPDIP) is within the Tennessee Department of Health's (TDH), Division of Communicable and Environmental Diseases and Emergency Preparedness (CEDEP).

Our Mission:

To protect people of all ages in Tennessee from vaccine-preventable diseases.

Our Vision:

A Tennessee free of vaccine-preventable diseases.

Core Values:

Credibility – Honest and accurate in all we do.

Innovation – Creative and responsive in changing times.

Accountability – Serve customers with integrity and compassion.

The Vaccines for Children Program (VFC) is a federally-funded program that provides vaccines at no cost to children who might not otherwise be vaccinated due to inability to pay. TVPDIP provides federally-purchased vaccine to eligible healthcare providers enrolled in the VFC Program. Children who are eligible for the VFC program are entitled to receive vaccines that are routinely or permissively recommended by the Advisory Committee on Immunization Practices (ACIP), as published in the Centers for Disease Control and Prevention's (CDC) "Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger" (<https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>).

VFC Program Benefits:

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using CDC's contracts, and eliminates state-to-state differences in price.
- Reduces referrals of children from private providers to local health departments (LHDs) for vaccination.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to immunizing eligible children.

Acronyms

ACIP	Advisory Committee on Immunization Practices
AS	Agreement Signatory (Certifying Provider, Provider of Record)
CDC	Centers for Disease Control and Prevention
DDL	Digital Data Logger
DHHS	Department of Health and Human Services
FQHC	Federally Qualified Health Center
EHR	Electronic Health Record
ETP	Electronic Trading Partner
HL7	Health-Level 7 (standards for electronic transmission of health data)
HRSA	Health Resources and Services Administration
IQIP	Immunization Quality Improvement for Providers
LHD	Local Health Department
MU	Meaningful Use
PA	Provider Agreement
PIN	Provider Identification Number
QA	Quality Assurance
REVMP	Routine and Emergency Vaccine Management Plan
RHC	Rural Health Center
RIR	Regional Immunization Representative (Field Representative)
TDH	Tennessee Department of Health
TE	Temperature Excursion
TennIIS	Tennessee Immunization Information System (Immunization Registry)
TVPDIP	Tennessee Vaccine-Preventable-Diseases and Immunization Program
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System (module within TennIIS)

TVPDIP Contact Information

VFC Enrollment and Operations	
Contact for general VFC enrollment questions, to report a facility change, or update the Primary and Back-up VFC Contacts	Phone: (800) 404-3006
	Fax: (615) 401-6831
	Email: VFC.Enrollment@TN.gov
	Available: Monday – Friday, 7:30am – 4:00pm CT
VFC Quality Assurance Team	
Contact for VFC vaccine storage and handling issues, temperature excursions, VFC compliance questions or concerns, VFC Report Card, and training webinars.	Phone: (800) 404-3006
	Fax: (615) 401-6829
	Email: VFC.Help@TN.gov (VFC Questions) TIP.Quality@TN.gov (Report Card Questions) Temperature.Health@TN.gov (TEs)
	Available: Monday – Friday 7:30am to 4:00pm CT
Vaccine Ordering Management System (VOMS)	
Contact for vaccine ordering, inventory, reconciliation, returns, supply issues, VOMS training and VOMS user permissions.	Phone: (615) 532-8511 (Public Health Departments) (800) 404-3006 (All other VFC Providers)
	Email: TennIIS.VOMS@TN.gov
	Available: Monday – Friday 8:00am to 4:30pm CT
TennIIS Help Desk	
Contact for general TennIIS assistance.	Phone: (844) 206-9927
	Email: TennIIS.Help@TN.gov
	Available: Monday – Friday 7:00am to 6:00pm CT
TennIIS Facility Registration and User Management	
Contact to register a facility in TennIIS, to add or inactivate users, or to apply TennIIS user permissions.	Phone: (615) 741-7207
	Email: TennIIS.Registration@TN.gov
	Website: https://www.tennesseeiis.gov
	Available: Monday – Friday 8:00am to 4:30pm CT
TennIIS Training	
Contact for information and training opportunities for TennIIS patient management, clinical and immunization questions.	Phone: (844) 206-9927
	Email: TennIIS.Training@TN.gov
	Available: Monday – Friday 8:00am to 4:30pm CT
TennIIS Electronic Exchange and Meaningful Use	
Contact about establishing an interface between your Electronic Health Record (EHR) and TennIIS.	Phone: (615) 253-1360
	Email: TennIIS.MU@TN.gov
	Available: Monday – Friday 7:30am to 4:00pm CT

VFC Fraud and Abuse Prevention	
Contact TVPDIP to report concerns about misuse or mishandling of VFC vaccines. Reports may be anonymous; all are confidential.	Phone: (800) 404-3006
	Fax: (615) 253-3279
	Email: VFC-Fraud.Health@TN.gov
	Website: https://www.tn.gov/health/cedep/immunization-program/ip/vfc/fraud-prevention.html
	Online Reporting: https://redcap.health.tn.gov/redcap/surveys/?s=JEC8P44CKR
Available: Monday – Friday 7:30am to 4:00pm CT	

VFC Program Resources for VFC Providers

TDH TVPDIP website	Documents and forms referenced in the VFC Provider Handbook can be found under <i>VFC Guidance & Toolkits</i> on the TVPDIP website at: http://www.tn.gov/health/cedep/immunization-program.html .
TennIIS Document Center	Important VFC communications are sent to all VFC contacts and are posted in the Document Center, accessible once user is logged into TennIIS.
TennIIS Homepage	The TennIIS homepage has links to TennIIS training guides, videos, webinars, and other helpful resources: https://www.tennesseeiis.gov .
Immunization Resources	Appendix A

Vaccines for Children

Protecting America's children every day

The Vaccines for Children (VFC) program helps ensure that all children have a better chance of getting their recommended vaccines. VFC has helped prevent disease and save lives.



CDC estimates that vaccination of children born between 1994 and 2018 will:

- prevent **419 million** illnesses
(26.8 million hospitalizations)

➔



more than the current population of the entire U.S.A.
- help avoid **936,000** deaths

➔



greater than the population of Seattle, WA
- save nearly **\$1.9 trillion** in total societal costs
(that includes \$406 billion in direct costs)

➔



more than \$5,000 for each American

Updated 2018 analysis using methods from "Benefits from Immunization during the Decade for Children Program (Epi—United States, 1994-2017)"



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/features/vfcprogram

K040102-0000018

1. VFC Program

1.1. Who May Enroll

To participate in the Tennessee VFC Program, a healthcare provider must have an active, unencumbered medical or advanced nursing practice license in the state of Tennessee. In addition to providing practice information, Advance Nurse Practitioners and Physician Assistants must also submit their supervising physician's full name, medical license number, and NPI number on the online Provider Agreement in TennIIS.



1.2. Initial Enrollment Process

A facility may join the VFC Program at any time but is encouraged to initiate enrollment during their county's Phased Enrollment Schedule ([Appendix B](#)). All VFC training and enrollment activities take place within [TennIIS](#); therefore, first-time enrollees not already registered in TennIIS must first register their facility and staff with TennIIS and request a TennIIS user account before requesting a Starter Kit from the VFC Program. Once logged into TennIIS, click on the Document Center link and refer to the Enrollment Walkthrough Guide for detailed instructions on completing the enrollment process.

Initial Enrollment Process ([Appendix C](#)):

1. Confirm or establish (1) a TennIIS facility registration and (2) an active TennIIS user account.
 - To register a new facility in TennIIS, complete the TennIIS Facility Registration application on the public TennIIS homepage at <https://www.tennesseeiis.gov>.
 - If the facility is already registered in TennIIS, but the provider does not have a TennIIS user account, contact the TennIIS Registration team at TennIIS.Registration@tn.gov to request one.
2. Email the VFC Enrollment team at VFC.Enrollment@tn.gov with your facility information and your intent to enroll in the VFC Program.

3. **Training** requirements for all new VFC clinics:
 - **TennIIS** – Information is available on the TennIIS homepage under the TennIIS Training and Education tab. All staff who will be using TennIIS should review the online training materials.
 - **Vaccine Ordering Management Training (VOMS)** – Link under VFC Training>>>Training Videos. This video shows how to order VFC vaccine and manage your VFC vaccine inventory. Intended for at least two people at each location responsible for VFC vaccine ordering (usually the Primary and Back-up Vaccine Coordinators).
 - **CDC's *You Call the Shots*** – The Agreement Signatory and Primary and Back-up VFC Contacts must complete two CDC *You Call the Shots* training modules annually: [Vaccine Storage and Handling](#) and [Vaccines for Children](#). A Certificate of Completion must be submitted to TVPDIP as proof. The modules can be accessed at: <https://www.cdc.gov/vaccines/ed/youcalltheshots.html>
4. Complete a [Routine and Emergency Vaccine Management Plan \(REVMP\)](#).
5. Complete the online Provider Agreement in TennIIS.
 - **Contact Details** – TVPDIP relies on email communications with VFC Program participants. Therefore, all facilities are required to list individual emails on the Provider Agreement under “Contact Details” for the following four contacts: Agreement Signatory (Certifying Provider), Primary Vaccine Coordinator, Back-up Coordinator, and a Facility Contact.
 - **Provider Profile** – TVPDIP uses the numbers of VFC and non-VFC children in the practice to evaluate the appropriateness of VFC vaccine orders. Therefore, Provider Profile numbers are required to be reviewed and updated at least annually. A new practice that has not yet established a patient base may submit a “zero” patient count when enrolling in VFC, but they must update their Provider Profile numbers by their annual re-enrollment period. In this instance, the practice will only receive one box of each ACIP-recommended vaccine until their Provider Profile is updated to reflect their patient population. The practice may need to update more frequently if the patient base and vaccine demand changes.

6. **Submit required documentation** – Scan/email to VFC.Enrollment@tn.gov or fax to (615) 401-6831.

1. CDC *You Call the Shots* training certificates of completion for the Agreement Signatory and Primary and Back-up Vaccine Coordinators
2. Print and sign two-page Provider Agreement Signature Page
3. Routine and Emergency Vaccine Management Plan (REVMP)
 - Submit **two** days of DDL temperature readings for each vaccine storage unit to Temperature.Health@tn.gov for review and approval.
4. Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit current Notice of Award from the U.S. Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates

7. The Primary Vaccine Coordinator will be notified by email and an alert message in TennIIS when there is a change in the status of the Provider Agreement. For further instructions, review the comment box located at the top of page one of the Provider Agreement.
8. Once all required enrollment documentation has been approved, all VFC contacts will receive an acceptance letter via email. The Regional Immunization Representative (RIR) will contact the practice to schedule an Enrollment Site Visit. Final approval into the VFC Program is dependent upon passing this visit.
9. After successfully passing the Enrollment Site Visit, the practice will be able to place its first VFC vaccine order in TennIIS.
 - New practices submitting zero patients on their Provider Profile will be authorized to order only one box of each vaccine until updated patient population information is submitted.

1.3. Provider Identification Number (PIN)

During the enrollment process, the VFC Program will issue the practice a unique six-digit Provider Identification Number (PIN). To expedite processing, please reference this number in **ALL** communications and correspondence with TVPDIP.

1.4. Provider Profile

The Provider/Practice Profile is a section within the Provider Agreement in TennIS. This section of the Agreement defines the number of VFC-eligible children and non-VFC-eligible children by age group served by a VFC provider. This information represents the population served by the practice or facility during the past 12 months.

If a practice is completing an annual re-enrollment, the Population Profile numbers will auto-populate with data submitted from the previous year. **Providers are required to review and update their patient population numbers annually.** To determine the patient population, a provider may use patient records and/or vaccine administration data submitted to TennIS. It is essential to be accurate when describing patient population in the Provider/Practice Profile section; this information determines the amount of vaccine each provider will need in the year ahead.

1.5. Record Retention

Providers are required to maintain all records related to the VFC Program for a minimum of **three years** and make these records available for review upon request. These records include:

- Enrollment documentation
- VFC patient screening and eligibility documentation
- Billing records
- Medical records of immunizations
- Vaccine ordering records
- Vaccine purchase and accountability records (such as VFC Borrowing Forms and invoices for replacement of borrowed vaccine)



*Practices are **required to maintain a private vaccine inventory** that is sufficient to serve their non-VFC eligible patient population, as reported on the Provider Profile in the Provider Agreement. The CDC generally considers a “sufficient” supply to be a four week inventory, based on the size of the practice’s stated non-VFC patient population.*



1.6. Changes in Staff/Facility Status

Providers are required to contact the VFC Program by email (VFC.Enrollment@TN.gov) or fax (615-401-6831) within the timeframe listed below for any change to the following:

1. Agreement Signatory (Certifying Provider that signed Provider Agreement)
 - Changes must be **reported immediately** and a new Provider Agreement must be received by TVPDIP **within 48 business hours**. A valid Provider Agreement is required in order to continue participation in the VFC Program; non-compliance will result in VFC vaccine retrieval.
 - Must complete the CDC *You Call the Shots* training modules ([Vaccine Storage and Handling](#) and [Vaccines for Children](#)) within 30 days of the departure of the former Agreement Signatory.
2. Primary and/or Back-up Vaccine Coordinator
 - Changes to a Vaccine Coordinator must be reported **within 10 days**.
 - Must complete the CDC *You Call the Shots* training modules ([Vaccine Storage and Handling](#) and [Vaccines for Children](#)) within 30 days of the departure of the former Vaccine Coordinator.
 - If the Primary Vaccine Coordinator is new, an educational visit with the RIR is required within 30 days of the departure of the former Coordinator.
3. Listed medical providers, report **within 10 days**
4. Mailing/shipping address, report **within 10 days**
5. Vaccine delivery hours, report **within 10 days**
6. Facility status (e.g., closure, merge, moving)
 - Changes to the facility status must be reported **at least 10 business days** before moving VFC vaccine to a new geographical site.
 - Any time a provider moves locations, the RIR will need to conduct a relocation visit **prior** to VFC vaccine being moved to new location.
 - Once vaccine storage units are moved to a new location, **two** days of in-range temperatures will need to be submitted to TVPDIP for review and approval **prior** to vaccine being placed in these units.

1.7. Annual Re-Enrollment

Annual re-enrollment in the VFC Program is required for all providers, in accordance with the Phased Enrollment Schedule. This schedule is based upon the county where a facility is located.

Providers must complete re-enrollment **within 60 days prior** to the expiration of their current Provider Agreement. The Phased Enrollment Schedule is located in the Document Center in TennIS and [Appendix B](#).

1. The Primary Vaccine Coordinator will receive an annual re-enrollment reminder email and alert message in TennIS 60 days prior to expiration of the current agreement.
2. If a Provider Agreement expires without renewal, the facility will be considered to have voluntarily withdrawn from the VFC Program. The provider will not be able to order VFC vaccine and will be contacted by the RIR so that any remaining VFC vaccine may be collected. In order to re-join the VFC Program, the facility must complete the full initial enrollment process, including an Enrollment Site Visit, if more than 14 days has elapsed between enrollments.

Steps to complete Annual Re-enrollment:

Re-enrollment is similar to the initial enrollment process with minor exceptions.

1. Add and complete a new online Provider Agreement in TennIS. This feature is located under the Orders/Transfers tab.
2. Both Primary and Back-Up Vaccine Coordinators must complete annual training. To meet this requirement, complete one of the following within the past 12 months:
 - Participate in a VFC Compliance or Education Site Visit, **OR**
 - Complete both CDC *You Call the Shots* training modules ([Vaccine Storage and Handling](#) and [Vaccines for Children](#)) for the current calendar year. The modules can be accessed at: <https://www.cdc.gov/vaccines/ed/youcalltheshots.html>
3. Complete and sign pages 2 and 14 of the REVMP.

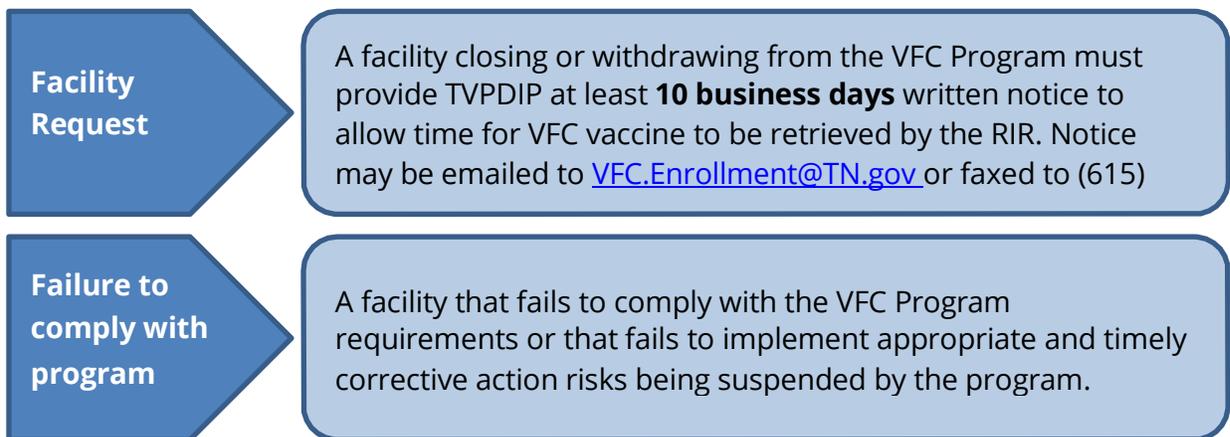
4. Submit required documentation: Scan/email to VFC.Enrollment@tn.gov or fax to (615) 401-6831.

1. Training records for the Primary and Back-Up VFC Coordinators (either Certificates of Completion for CDC *You Call the Shots* training modules or verification of participation in a VFC Compliance Visit, Education Visit, or Annual Review in the past 12 months).
2. Print and sign two-page Provider Agreement Signature Page
3. REVMP
4. Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit the current Notice of Award from the U.S. Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates designation.

5. The Primary Vaccine Coordinator will be notified by email and via an alert message in TennIIS when there is a change in the status of the online Provider Agreement. For further instructions, review the comment box located at the top of page one of the Provider Agreement.

1.8. Voluntary Withdrawal or Termination from the VFC Program

Either TVPDIP or the provider may terminate the VFC Provider Agreement at any time.



Failure to complete annual re-enrollment

A facility who allows their current Provider Agreement to expire without being renewed will be removed from the program and required to re-apply.

Vaccine ordering

A facility that has not placed a vaccine order in the past 12 months will be removed from the program and required to re-apply.

TVPDIP will contact providers that have been removed from the program to provide instructions on the transfer or return process for all VFC vaccines on hand. The provider is responsible for maintaining proper storage, temperature monitoring, and temperature logs until vaccine is retrieved by the RIR.

2. Fraud and Abuse

Federal fraud and abuse laws apply to the VFC Program; good stewardship of federal entitlement program taxpayer dollars is a top priority. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC Program. The following definitions are consistent with “fraud” and “abuse” as defined in Medicaid regulations 42 CFR § 455.2:

1. **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.
2. **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Well-organized and correctly administered VFC accountability programs are the cornerstones for preventing potential fraud and abuse incidents. Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier for the VFC Program to prevent or detect than others.

Fraud and Abuse Examples*

- Failing to comply with any part of the Provider Agreement
- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional fee for administration of VFC vaccine
- Over-ordering VFC vaccine (e.g., quantities or patterns do not match the provider’s profile)
- Waste of VFC vaccine
- Denying VFC-eligible children VFC-funded vaccine because of parents’ inability to pay the administration fee
- Failing to screen for and document eligibility status at each visit
- Failing to maintain VFC records for a minimum of three years
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine

**This list provides examples only, and should not be considered comprehensive.*

Any person may contact the TVPDIP to report concerns or questions about possible fraud or mishandling of VFC vaccines. Reports may be anonymous, and all are confidential.

1. **Written report** – Print and complete the [VFC Provider Fraud Report form \(PH-4130\)](#). Submit the completed form (PH-4130) to the Tennessee Immunization Program by fax, e-mail, or mail.
 - Fax: (615) 253-3279
 - E-mail: VFC-Fraud.Health@tn.gov
 - Mail: Tennessee Immunization Program (Attn: VFC Program Manager), 710 James Robertson Parkway, AJT 3rd Floor, Nashville, TN 37243
2. **Telephone report** – Call the Communicable and Environmental Diseases and Emergency Preparedness (CEDEP) toll free number (800) 404-3006 or (615) 741-7247 and request to speak to the Immunization Program Manager.
3. **Online report** – Go to the online reporting tool at <https://redcap.health.tn.gov/redcap/surveys/?s=JEC8P44CKR> to complete and submit the survey.

Additional resources may also be found on the Federal DHHS [Office of the Inspector General \(OIG\) Exclusions Program webpage](#).

3. Vaccine Eligibility and Documentation

In order for children to receive vaccines through the VFC Program, **eligibility screening and documentation must take place at each immunization visit**, up to 24 hours prior to vaccination. The only factors considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the VFC criteria described below.

3.1. VFC Eligibility Categories

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

1. **Medicaid-eligible** – For the purposes of the VFC Program, the terms “Medicaid-eligible” and “Medicaid-enrolled” are used interchangeably and refer to children who have or are eligible for health insurance through the TennCare program. Children covered by private insurance who have TennCare as a secondary insurer **ARE** eligible for VFC vaccine (see Insured Exceptions table on page 19).

NOTE: A child is VFC-eligible in Tennessee if they are insured by Medicaid in any state.

2. **Uninsured** – A child who has no health insurance coverage. Self-reported status is accepted.
 - A child covered by a Health Care Sharing Ministries (Medi-Share) is considered “uninsured” in Tennessee. These plans are nonprofit alternatives to purchasing health insurance and are not recognized as insurance by the Tennessee Department of Commerce and Insurance.
3. **American Indian or Alaska Native (AI/AN)** – As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
4. **Underinsured*** –
 - A child who has health insurance, but the coverage does not include vaccines.
 - A child whose insurance does not cover all ACIP-recommended vaccines. The child is eligible to receive from VFC only those vaccines not covered by the insurance.
 - A child whose insurance caps its payment for vaccine coverage. The child is eligible to receive VFC vaccine after the insurance cap has been

reached. If the cap is expected to be reached as a result of the cost of all of the services provided at the visit, VFC vaccine may be used.

NOTE: *Underinsured children may receive VFC vaccine only at an FQHC, RHC, or LHD.*

LHDs, FQHCs, and RHCs that serve underinsured children are REQUIRED to verify a child’s underinsurance status. Please refer to our Insurance “Cheat Sheet” in [Appendix L](#).

*Underinsurance, limited coverage, and “caps” are increasingly uncommon coverage options and may only occur in insurance plans not compliant with the Affordable Care Act (ACA). ACA-compliant plans are required to provide all ACIP-recommended immunizations with no deductible or co-pay when administered by an in-network provider).

Children who are ineligible for VFC vaccines include:

1. **Privately insured** – Children whose health insurance covers vaccinations as a benefit are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible has not been met.
2. **CoverKids** – The state child health insurance plan is not part of Medicaid, so children enrolled in CoverKids are ineligible for VFC vaccine.

Insured exceptions include ([Appendix D](#)):

<p>American Indian/Alaska Native with health insurance that covers immunizations</p>	<p>AI/AN children are always VFC-eligible. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC Program should be made based on what is most cost-beneficial to the child and family.</p>
<p>Insured, with Medicaid as secondary insurance</p>	<p>A child may have private health insurance and Medicaid as secondary insurance. The child is VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC Program. There are two options:</p> <ol style="list-style-type: none"> 1. Administer VFC vaccine and bill Medicaid for the administration fee 2. Administer private stock vaccine and bill primary insurance for both the cost of vaccine and the administration fee.

3.2. Documentation of Eligibility Screening

VFC eligibility screening and documentation of eligibility status must take place with each immunization visit, up to 24 hours in advance. Documentation of the eligibility status of all children under 19 years who are immunized in the practice must be retained and accessible in the health care provider's office for three years from the date of service. If the eligibility cannot be documented in the EHR, eligibility may be recorded on the [Patient Eligibility Screening Record \(Appendix E\)](#), and scanned into the EHR or maintained in a paper chart. The record may be completed by the parent, guardian, individual of record, or by the health care provider. Eligibility status documentation (paper or electronic) must include each of the following:

1. Child's first and last name and middle initial
2. Child's date of birth
3. Parent/Guardian/Individual of Record's first and last name and middle initial;
4. Primary provider's name
5. Date of each immunization visit
6. One of the following eligibility statuses:
 - Medicaid eligible/enrolled
 - Uninsured
 - American Indian/Alaska Native
 - Underinsured (served at FQHC, RHC, or LHD)
 - Insured (Private stock vaccine)

New Requirement for Manual Entry Providers:

Accurate VFC Eligibility documentation in TennIS is directly tied a process called manual decrementing. This process associates an administered dose directly to a vaccine lot number in a provider's inventory. When adding VFC-eligible administered vaccinations in TennIS manually, VFC Providers must associate a VFC lot number from their inventory for VFC eligibility to be recorded correctly in TennIS. At the time of entering the administered vaccination into TennIS, an additional step must be taken to add manufacturer information on the Vaccination Detail Add screen. This extra step will fill out manufacturer, lot number, and funding source for this vaccination. This will also automatically adjust inventory numbers for a more accurate, real-time reflection of VFC inventory. It is **highly encouraged** that manual entry VFC Providers begin to

decrement each administered vaccine in TennIIS. Starting July 1, 2020, VPDIP will run a monthly report of all VFC Providers who do not manually decrement their inventory to require mandatory training and ensure understanding of this process. **This will be a requirement for all Manual Entry Providers beginning July 2021.** Refer to [Appendix F](#) for a Manual Entry Decrementing for VFC Providers Quick Reference Guide.

3.3. Fee Policies for Vaccines

A provider receiving federal vaccine must comply with the following fee policies:

1. VFC vaccine is provided to eligible children at no cost to the patient or health plan (i.e., payer) for the vaccine itself.
2. A provider may charge a non-TennCare VFC-eligible child a vaccine administration fee of up to **\$20** per vaccine dose. Payment for vaccine administration to TennCare VFC-eligible children is set by the contracted TennCare health plans.
3. A provider must not deny administration of VFC vaccine to an established VFC-eligible patient whose parent/guardian/individual of record is unable to pay the administration fee. The administration fee must be waived. **It cannot be billed at a later date.**
4. Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service **may issue only a single bill to the patient within 90 days of vaccine administration.** This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.
5. Providers may charge an office visit fee, in addition to the administration fee.

3.4. Vaccine Administration Documentation

In accordance with 42 U.S.C. § 300aa-25, all VFC providers must maintain immunization records that include **ALL** of the following elements:

1. Name of vaccine administered
2. Date vaccine was administered
3. Date VIS was given
4. Publication date of VIS
5. Name of vaccine manufacturer
6. Lot number
7. Name and title of person who administer the vaccine
8. Address of clinic where vaccine was administered



Important
Message

VFC providers are **required** to record in TennIIS, every vaccine administered to all patients <19 years of age, regardless of VFC status, within two weeks of administration date.

3.5. Vaccine Information Statement (VIS), Vaccine Adverse Events

The National Vaccine Childhood Injury Act (NCVIA) requires all immunization providers to give the appropriate VIS to the patient (or parent or legal representative). The appropriate VIS must be given **prior** to vaccination and prior to **each dose** of a multi-dose series. It must be given **regardless of the age** of the recipient.

Ways to give a VIS:

In the past, healthcare providers and public health entities interpreted federal law as a requirement that a paper copy of each VIS is handed to the recipient prior to vaccination, and that the recipient must take this copy away with him or her following the vaccination.

The evolution of electronic media has resulted in broadening this interpretation.

For example, now:

1. A practice may produce permanent, laminated, office copies of each VIS, which may be read by recipients prior to vaccination.
2. VISs may be reviewed on a computer monitor (or any video display).
3. VISs may be downloaded by the recipient to a smartphone or other electronic device to read at his or her convenience. (VISs have been specially formatted for this purpose.)
4. VISs may be made available to be read before the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet). These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.
5. Providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take away following the vaccination. However, the recipient may decline.

It is recommended that you sign up for email updates to receive notification when a VIS has been updated. To sign up, go to <https://www.cdc.gov/vaccines/hcp/vis>.

Providers must maintain records in accordance with the NCVIA, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) by mail or online at <http://www.vaers.hhs.gov>. Deaths or severe reactions possibly associated with immunization should also be reported to TVPDIP by phone.

4. Vaccine Order and Accountability

4.1. Ordering Vaccine

All VFC vaccine requests must be placed through the TennIIS Vaccine Ordering and Management System (VOMS). Training materials consisting of short videos and/or PDF instructions about VOMS are available on the [TennIIS homepage](#) under the TennIIS Training tab. A [Create, Submit and Receive Vaccine Orders](#) Quick Reference Guide is also available to assist in the process. Questions regarding this process may be sent to the VOMS team at TennIIS.VOMS@TN.gov.

4.2. Vaccine Inventory

VFC providers must offer all ACIP-recommended vaccines for the population they serve and are responsible for proper maintenance of vaccine inventory. Providers must reconcile their VFC vaccine inventory every 30 days in VOMS. Reconciliation is required by CDC and is an accounting of vaccine doses administered, wasted, expired, lost (unaccounted for), and vaccine doses currently in inventory. TVPDIP recommends providers maintain a four to six week supply of vaccine to allow for any potential shipping delays.

1. Providers are required to have two separate vaccine inventories: one for publicly purchased vaccines and one for privately purchased vaccines. Vaccine inventories do **not** have to be stored in separate units.
2. Providers are required to reconcile their VFC inventory by the first Friday of every month, **even if a vaccine order is not placed.**
3. Any Provider who repeatedly fails to reconcile their VFC inventory in a timely and accurate manner will be required to complete mandatory VOMS training, and further noncompliance may result in suspension from the VFC Program.
4. Vaccine orders cannot be processed unless reconciliation reports are up-to-date in TennIIS.
5. Providers should review the [Inventory Reconciliation](#) Quick Reference Guide.
6. VOMS is only for ordering and inventory reporting of federal vaccine. Private vaccine stock should never be manually entered into VOMS.

4.3. Receiving VFC Vaccine

Providers must have procedures in place for immediate receipt and storage of

vaccine due to its temperature sensitivity. All staff must be trained to recognize a vaccine shipment and the procedures to follow once received. The following steps should occur upon receipt of a vaccine shipment:

1. Open vaccine packages immediately
2. Inspect the vaccine and packaging for damage
3. Compare the vaccine received with the products on the packing list
4. Check the temperature monitor readings in the shipping package (if available)
5. Immediately store at appropriate temperatures
6. For frozen vaccine only, verify the length of time that the vaccine was in transit. Check the shipping insert supplied in the box; this insert defines the acceptable transit time based on the shipment date on the packing list.
7. If the vaccine shipment is compromised, the order is incorrect (not the vaccine or the quantity ordered), or there is a problem with the temperature monitors, **contact TVPDIP immediately (within 2 hours)** at (615) 532-8509 or (800) 404-3006. It is critical that TVPDIP contact McKesson the same day the vaccine arrived at the provider in order to hold the supplier accountable for replacing a damaged or improper shipment.
8. Login to TennIIS/VOMS and electronically indicate receipt of the order in the Orders/Transfer page.
9. VPDIP checks pending orders in VOMS on a monthly basis for any orders that were not correctly received into provider inventory. Any provider who has failed to accept an order into their inventory will be contacted by VPDIP and asked to do so. Repeated failure to accept orders into inventory will result in mandatory VOMS training and risk of suspension from the VFC Program.

4.4. VFC Vaccine Returns

All VFC vaccine that has expired or has been spoiled or wasted must be reported in VOMS so that it may be returned to the supplier. The return process must be completed in VOMS in order to generate a shipping label to send the vaccine back to the supplier. Expired vaccine must be returned within 60 days. To review the steps for this process, reference the [Returning Vaccines](#) Quick Reference Guide available on the TennIIS homepage.

Influenza vaccine ordering (pre-booking) and return procedures are NOT managed within VOMS. Please refer to specific instructions provided by the Vaccine Manager for return of expired influenza vaccine each year.

4.5. Vaccine Borrowing

VFC-enrolled providers are expected to maintain a minimum of four weeks' inventory of vaccine to administer to privately insured and VFC-eligible children. Borrowing of vaccine between VFC and private vaccine inventories **is not permitted**, unless specifically authorized in advance by TVPDIP and due to extraordinary circumstances. For situations where borrowing is needed, contact TVPDIP at (615) 532-8509 or (800) 404-3006 to request approval.

If approved, borrowing must be documented "dose-by-dose" for each patient on the [Vaccine Borrowing Form \(Appendix G\)](#). Doses borrowed from VFC inventory must be replaced within 30 days. Replacement must be documented on the borrowing form and submitted to TVPDIP.

Please note: At the beginning of each influenza vaccine season there are differences in the arrival times of influenza vaccines for VFC and non-VFC patients. Borrowing between inventories of influenza vaccines is prohibited unless otherwise specified by TVPDIP.

4.6. Vaccine Transfers

It is important to report to TVPDIP any VFC vaccine with short expiration dates (vaccines expiring within three months) that are unlikely to be used before they expire. This allows TVPDIP the opportunity to transfer vaccines to another VFC provider. The RIR should be contacted to determine if there are other VFC providers in the area who could use the expiring vaccine. Vaccine transfers may only occur with the approval and direct guidance of TVPDIP.

4.7. Vaccine Schedules

VFC providers are required to comply with the immunization schedules, dosages, and contraindications recommended by the ACIP, unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, such compliance is medically inappropriate for the child.
2. State law, including laws pertaining to religious and other exemptions, applies.

Immunization schedules are available on the CDC website at: <https://www.cdc.gov/vaccines/index.html>. The CDC Vaccine Schedule app is available on iOS and Android devices.

5. Vaccine Storage and Handling

5.1. Storage and Handling

Vaccine loss is both costly and preventable. Just 10 doses of each routinely recommended child/adolescent vaccine is valued at more than \$10,000; most practices have far larger inventories. Vaccines must be stored appropriately in order to maintain efficacy. Failure to store and handle vaccines properly reduces vaccine potency, resulting in inadequate immune response and poor protection against disease. The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the **vaccine cold chain**. An effective cold chain relies on three main elements:

1. Effectively trained personnel
2. Reliable storage and temperature monitoring equipment
3. Accurate vaccine inventory management

A well-trained staff, familiar with key storage and handling principles, is critical to safeguarding the vaccine supply and the safety of vaccinated patients.

5.2. Vaccine Storage Units

Refrigerators and freezers are available in different grades (household and purpose-built), size, and types (stand-alone and combination refrigerator/freezer). Purpose-built units are sometimes referred to as “pharmaceutical grade” and are designed specifically for storage of biologics. It is important that the storage unit has enough space to store the largest inventory at the busiest point in the year (e.g., flu season) without crowding. The following storage units are acceptable for storing VFC vaccine:

1. A purpose-built unit for vaccine storage designed to either refrigerate or freeze (can be compact, under-the-counter-style or large units).
2. A stand-alone household frost-free refrigerator (a self-contained unit that only refrigerates).
3. A stand-alone automatic defrost freezer.
4. A stand-alone manual defrost freezer MAY be used, however, a back-up

freezer must be available that is approved to store vaccine when the main freezer unit is being defrosted and the provider must:

- Document a defrost plan in the REVMP
- Defrost the unit when ice has accumulated to a thickness of approximately 1 cm
- Guidance on defrosting a manual freezer is available [here](#)

TVPDIP consultation is strongly recommended prior to purchasing a new vaccine storage unit to ensure it meets VFC Program requirements. When a provider purchases a new vaccine storage unit, **two** days of digital data logger temperature readings must be sent to TVPDIP for review and approval **prior to vaccine being placed in the unit(s)**.

Unacceptable vaccine storage units:

1. Combination refrigerator/freezer units,
2. Dormitory or bar-style refrigerators
 - Small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the “freezer” within the refrigerator. Such refrigerators place vaccine at a high risk of freezing.

Storage Unit Placement

Air circulation around the outside of the storage unit is important for vaccine temperature stability. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and walls. Nothing should block the cover of the motor compartment. The unit should be stable and level, with the bottom of the unit raised above the floor. The unit door should open and close smoothly and fit squarely against the body of the unit. If not secured properly, unit doors pose a risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find that 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.

It is important to protect the unit’s power source with clear warning labels on both the plug and circuit breaker for each storage unit. Avoid using the same power

outlet for both storage units. Avoid using power outlets that may be tripped or switched off including:

1. Built-in circuit switches (may have reset buttons)
2. Outlets that may be controlled by a wall switch
3. Multi-outlet power strips
4. Electrical cords



5.3. Temperature Monitoring Devices

VFC providers are required to use a digital data logger (DDL) 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 VFC vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and mass vaccination clinics.

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

1. A detachable, buffered probe (or digitally buffered device that mimics a buffered probe)
2. Alarm (audible or visual) for out-of-range temperatures – alarm parameters should be set as follows:
 - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°C
 - Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes above 8.0°C
 - Freezer high alarm (too warm) set to trigger after 60 consecutive minutes above -15°C
3. Display indicating current, minimum, and maximum temperatures
4. An active display outside the unit so that temperatures may be monitored without opening the unit door
5. Low battery indicator
6. Ability to accurately report temperatures to +/-0.5°C
7. Memory storage of at least 4,000 readings
8. User programmable logging interval (or reading rate) – **It is recommended that this interval be set for 15 minutes**

9. Ability to easily download data for review
10. Ability to report temperatures in Celsius to fully account for the acceptable vaccine storage temperature range. Due to rounding of numbers when converting from °C to °F, the FDA-licensed acceptable temperature range for vaccine storage is smaller if using °F measurements, so temperature excursions are more likely to be reported by °F devices.

* Providers may have purpose-built or pharmaceutical-grade equipment (e.g., doorless or dispensing units) with temperature monitoring capabilities that may be as reliable as a DDL in monitoring vaccine temperature. Contact TVPDIP to determine if such a unit is capable of meeting VFC temperature monitoring device requirements.

In addition, VFC providers **must have at least one back-up DDL** with a valid and current Certificate of Calibration **on-site** to ensure that temperature assessment and recordings may be performed twice each day. A back-up DDL must be readily available in case a DDL in use is no longer working or calibration testing of the current DDL is required. CDC recommends that the back-up DDL be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion. The back-up DDL should have a different calibration retesting date than the primary so one may be used while the other is being replaced or sent out for re-calibration. Reference [Appendix H](#) for a guide for selecting a DDL.

5.4. Certificate of Calibration Testing

Valid and current Certificates of Calibration Testing (or Reports of Calibration Testing) must be maintained on all DDLs used in vaccine storage units. Calibration testing and traceability must be performed by:

1. A laboratory accredited by an ILAC MRA signatory body (recommended by CDC). Certificate must include the following elements:
 - ILAC/MRA signatory body-accredited laboratory
 - a. Laboratory accreditation should be clearly identifiable (to search ILAC-accredited laboratories, see box below)
 - b. An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards

- c. The certificate may have an Accrediting Body Symbol, which is the logo, and a unique laboratory code or certificate number included on the certificate
 - Name of Device (optional)
 - Model/Device Number
 - Serial Number
 - Date of Calibration Testing (report or issue date)
 - Confirmation the instrument passed testing (or instrument in tolerance)
2. An entity that provides documentation demonstrating the calibration testing performed meets ISO/ IEC 17025 international standards for calibration testing and traceability. Certificate must include the following elements:
 - Name of Device (optional)
 - Model/Device Number
 - Serial Number
 - Date of Calibration Testing (report or issue date)
 - Confirmation the instrument passed testing (or instrument in tolerance)
 - Statement that calibration testing conforms to ISO 17025

Contact TVPDIP or the RIR for help if uncertain if a certificate meets the above requirements.

5.5. Temperature Probe Placement

The DDL probe should be placed in the central/middle area of the storage unit **with** the vaccines. Do not place the temperature probe in the doors, near or against the walls, close to vents, or on the floor of the vaccine storage unit. Temperatures in these locations may differ significantly from the temperature in the zone where vaccine is actually stored. It is recommended that the probe be anchored in the center of the unit to prevent it from being moved.

5.6. Temperature Monitoring

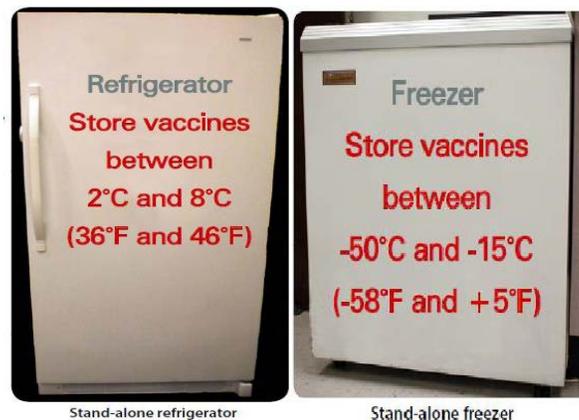
Temperature monitoring is the primary responsibility of the Primary and/or Back-up Vaccine Coordinators. It is required that temperatures are reviewed for each vaccine storage unit **twice each day** (morning and afternoon) and that the

minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should any actions that are taken if the temperatures readings are out of acceptable range.

If a DDL has the ability to record twice daily readings (e.g., Fridge Tag and Log Tag), the provider is required to use this function and document daily readings on the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) so that the identity of the person checking the temperature is recorded. If the DDL report is able to document the initials of the person completing the twice a day readings, the sign-off sheet does not need to be completed. If the DDL does not have the ability to document the twice a day readings on the DDL report, provider should document daily readings on the TVPDIP Temperature Logs for [Refrigerators](#) and [Freezers](#).

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Refrigerators should maintain temperatures between 2°C and 8°C at all times. The average daily temperature target for a refrigerator is 5°C. Freezers should maintain temperatures between negative (-) 50°C and negative (-) 15°C, with a suggested target of negative (-) 20°C or colder. Most freezers may safely be set on the coldest setting as freezers do not reach -50°C unless specifically designed to do so.



5.7 What is a Temperature Excursion (TE)?

A TE occurs any time the temperature in a refrigerator is outside the 2°C – 8 °C range or the temperature in a freezer is above -15°C **and** one of the below criteria are met:

1. Refrigerator temperature is below 2°C for ≥ 15 consecutive minutes.
 - Temperatures below 0°C quickly damages vaccine. Quick action may save vaccine.
2. Refrigerator above 8°C for ≥ 60 consecutive minutes.
3. Freezer above -15°C for ≥ 60 consecutive minutes.
 - Frost-free freezer defrost cycles may go above -15°C for short periods. Vaccine stability data supports these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. There is concern about a TE even though it doesn't meet above criteria.

Power Outage:

If experiencing a power outage, contact the utility company. If restoration is expected within **four** hours, **do not move vaccine**. Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If a power outage is expected to last more than four hours, follow the emergency procedures detailed in your REVMP. Notify TVPDIP for any planned or unplanned power outages as soon as possible.

Review the [Temperature Monitoring and Excursion Guide](#) on the TVPDIP website for more details on vaccine storage units and temperature monitoring.

5.8 Reporting a Temperature Excursion (TE)

When a TE is identified, TVPDIP must be notified as quickly as possible during business hours or the next business morning (Monday – Friday 8:00am – 4:30pm CT) and before any vaccine is administered.

Temperature is currently out-of-range	<ol style="list-style-type: none"> 1. Attempt to return vaccine to proper storage conditions: <ul style="list-style-type: none"> • Check to see if the storage unit is unplugged • Check to see if the storage unit door is open and is sealed adequately • Check the thermostat setting • Check location of the DDL probe; should be in the middle of the unit with the vaccine and properly attached to the DDL • Check coils and vents for excess dust 2. Quarantine vaccine; label "Do Not Use until Notified by TVPDIP" <ul style="list-style-type: none"> • Do not administer vaccine until approved by TVPDIP! 3. Immediately call TVPDIP (if during business hours) 4. If instructed by TVPDIP, or if after hours, follow the emergency procedures detailed in your REVMP, posted on or beside the storage unit. If the storage unit is not back in-range, transfer vaccine to the designated back-up location. For packing instructions, see Appendix I. 5. Download temperature log from digital data logger or document current temperature reading on temperature log 6. Note how long the temperature was out of range 7. Note the minimum/ maximum temperatures 8. Fax data logger report or temperature log to (615) 401-6829 or email to Temperature.Health@tn.gov (include the VFC PIN and name of contact)
Temperature is back in-range	<ol style="list-style-type: none"> 1. Troubleshoot – can you identify why it went out of range? 2. Quarantine vaccine; label "Do Not Use until Notified by TVPDIP" 3. Do not use any vaccine until approved by TVPDIP! 4. Immediately call TVPDIP, if during business hours 5. Download temperature log from digital data logger or document current temperature reading on temperature log 6. Note how long the temperature was out of range 7. Note the maximum and minimum temperatures 8. Fax data logger report or temperature log to (615) 401-6829 or email to Temperature.Health@tn.gov

1. If unit is out-of-range and it cannot be returned to proper temperature, transfer the vaccine to the designated back-up location listed in your REVMP.
 - For packing instructions, see [Appendix I](#). A DDL must be with the vaccine at all times during transport and at the back-up location and checked every hour that vaccine remains in the transport cooler.
2. If the unit is back in-range:
 - Quarantine vaccine; label “Do Not Use until Notified by TVPDIP”
3. Contact TVPDIP the next business morning to report TE.
 - If vaccines need to be used *before* the next business day do one of the following (still required to call TVPDIP the next business morning):
 - a. Contact vaccine manufacturer’s customer service lines directly to report the problem to obtain guidance.
 - b. Call (800) 404-3006, at the end of the message you will receive the phone number for the on-call epidemiologist for CEDEP. This person will provide a basic consultation but will not provide advice on the viability of the vaccine.

5.9 Unreported Temperature Excursions:

If the TE is not reported within the next business day, the provider will be placed on a six-month probation that includes the following actions:

1. Provider will need to submit weekly temperature logs to their RIR for four weeks and then monthly for the next five months.
2. RIR will conduct an Education Visit for the Certifying Provider and Primary and Back-up Vaccine Coordinators.
3. Provider may be required to service or purchase a new unit within six weeks. If so, vaccine orders will be placed on hold. The invoice and **two** days of temperatures will need to be sent to TVPDIP before approval is given to store VFC vaccine in unit.
4. If there was vaccine loss, the provider will receive an Unannounced Storage and Handling Visit during the six month period.
5. At the successful conclusion of the six month probation, the provider will resume routine monitoring.
 - If unable to maintain compliance with VFC vaccine storage and handling requirements during this period, the provider will be suspended from the VFC Program for up to a year. The RIR will pick up VFC vaccine and TVPDIP will notify TennCare.

6. Vaccine Management

6.1. Vaccine Coordinator (aka VFC Contact)

The Primary Vaccine Coordinator at each site is responsible for ensuring all vaccines are stored and handled correctly. Each site is also required to designate a second staff member to serve as back-up in the absence of the Primary VFC Contact. The Certifying Provider listed on the Provider Agreement should not be designated as the Primary or Back-up VFC Contact because the provider normally does not carry out VFC Contact responsibilities. An exception to this may be in circumstances where a more appropriate alternative cannot be identified within the practice and where the Certifying Provider is prepared to comply with all VFC Contact responsibilities. A VFC Contact may not be assigned to more than one site; **the assigned Primary and Back-up VFC Contacts must be predominantly on-site at their designated location.** Both VFC Contacts should be fully trained in routine and emergency policies and procedures.

VFC Contact responsibilities include:

1. Ordering vaccines
2. Overseeing proper receipt and storage of vaccine deliveries
3. Documenting vaccine inventory information
4. Organizing vaccines within storage units
5. Setting up temperature monitoring devices
6. Reading and recording storage unit temperatures a minimum of two times (morning and afternoon) each workday
7. Reading and recording minimum/maximum temperatures from a digital data logger at start of each workday, preferably each morning
8. Printing a **weekly digital data logger report** for each vaccine storage unit
9. Reviewing and analyzing the DDL report each week to detect any concerning temperature trends and/or unreported temperature excursions, and signing and dating the report once completed
10. Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
11. Removing expired vaccine from storage units
12. Responding to out-of-range temperatures (temperature excursion, "TE")

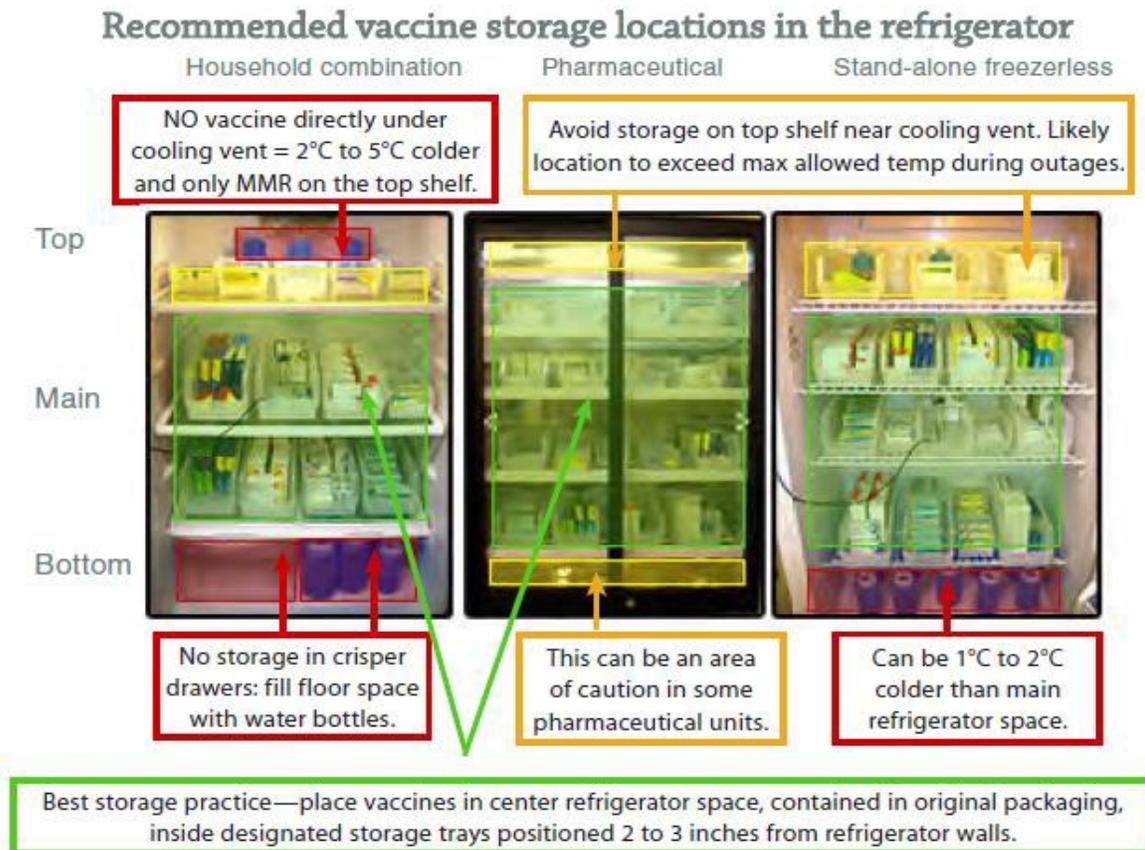
13. Maintaining all documentation, such as inventory and temperature logs
14. Ensuring staff is properly trained
15. Monitoring operation of storage equipment and systems
16. Overseeing proper vaccine transport (if necessary)
17. Overseeing emergency preparations
18. Primary VFC Contact is responsible for providing training to the Back-up Contact

6.2. Vaccine Storage and Handling Plan

VFC providers are required to develop, maintain and implement a vaccine storage and handling plan. The plan must be updated annually and include a review date and the signature of the individual responsible for the content. The minimum required components of the plan include the following:

1. Name of the current Primary VFC Contact and at least one Back-up VFC Contact
2. General operations for proper vaccine storage and handling practices:
Temperature monitoring
 - Vaccine storage (e.g., equipment, placement)
 - Vaccine shipment receiving procedures
3. Vaccine ordering procedures
4. Inventory control (e.g., stock rotation)
5. Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
6. Manual Defrost Plan for providers that don't have an automatic defrost freezer
7. For providers that do not have the non-routine ACIP recommended vaccines (i.e., PPV23 and MENB) in their inventory, a referral plan needs to be added for patients who require these vaccines
8. For providers that do not serve privately-insured patients, a referral plan needs to be added in case a patient's insurance status changes.
 - Private vaccine will need to be purchased and maintained if a provider begins accepting privately-insured patients.
9. Documentation of staff training on all plan elements
10. Recorded review date within the last 12 months

11. Signature of the individual responsible for the content



6.3. Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability. The following are best practices for day-to-day vaccine management:

1. Store vaccines in their original packaging (including UV protective bags used by CDC's centralized distributor for repackaged vaccines only).
2. Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
3. Do not store vaccines in the doors, vegetable bins, or on the floor of the unit, or under or near cooling vents.
4. Do not store food or drink in vaccine storage units.
5. Place water bottles throughout refrigerator and freezer storage units and frozen coolant packs in order to:
 - Stabilize or extend temperatures during a power outage,
 - Dampen the effects of frequent opening/closing of door, and

- Serve as physical barriers preventing the placement of vaccines in areas of the unit that are at higher risk for TEs.
6. Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front. Immediately remove any expired vaccine from storage units. Bag and label all expired vaccine as “DO NOT USE.”
 7. Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. For multi-dose vials, indicate on the label the date and time that the vial reconstituted or first opened.
 8. Store vaccine products with similar packaging in different locations in the storage unit to avoid confusion and medication errors.
 9. Limit access to the vaccine supply to authorized personnel only.
 10. Install locks on refrigerators and, if possible, the electrical plugs. Label the plugs “Do Not Disconnect.”
 11. Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
 12. In larger clinics, we recommend a source of back-up power (generator) and a security system to alert personnel in the event of a power outage.
 13. If applicable, test back-up generators quarterly and service back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules). **Document the quarterly tests and annual servicing on page 12 of the REVMP.**
 14. Vaccines should be prepared immediately prior to administration. CDC and TVPDIP strongly recommend against pre-drawing doses before they are needed.
 - Manufacturer pre-filled syringes are a good option in mass vaccination clinics. Although not recommended, in the event of a mass vaccination clinic, a provider may pre-draw up to 10 doses of vaccine from a multi-dose vial and administer them. All doses should be administered by the person who drew them up.

6.4 Emergency Vaccine Storage and Handling Plan

VFC providers are required to have an emergency vaccine storage and handling plan. The plan must include guidance on what to do in the event of:

1. Refrigerator or freezer malfunctions
2. Power failure to vaccine storage units
3. Natural disasters or other emergencies that might compromise vaccine storage conditions

The plan must include policies and protocols for maintaining the vaccine cold chain during transport to, and storage in, emergency storage locations. Plans should include the use of a commercial vaccine transport box qualified to maintain a temperature of 5°C, for refrigerated vaccines, for a specified number of hours or the use of the [CDC emergency transport vaccine qualified pack-out \(Appendix I\)](#). A DDL must remain with the vaccine at all times, including during transport. The vaccine storage units and DDLs used at the emergency location site must be in compliance with VFC requirements. Contacts at alternate or back-up storage locations must be contacted annually and agree to accept vaccines during an emergency. A Routine and Emergency Vaccine Management Plan template may be found here:

<https://www.tn.gov/content/dam/tn/health/documents/immunizationrequirements/vfc/REVMP.pdf>.

7. Quality Assurance Visits

Federal and state requirements mandate that TVPDIP conduct Quality Assurance (QA) visits, assessments, and education with each VFC provider.

7.1. Enrollment Visits

Enrollment Visits are required for newly enrolling providers or former VFC providers that have had a lapse of 14 days or greater between enrollments. The purpose of this visit is to provide education on VFC Program requirements and verify the facility has the appropriate resources to implement program requirements.

7.2. Compliance Visits

A Compliance Visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves administration of a questionnaire, evaluating compliance with requirements, and providing education. During the visit, there will be a formal review of vaccine management practices, as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring.

7.3. Unannounced Storage and Handling Visits

The VFC Program requires Unannounced Storage and Handling Visits be conducted to serve as “spot checks” for facility vaccine management practices.

The RIR will meet with the provider and staff after any VFC compliance or unannounced storage and handling visit is completed to review findings. Education will be provided for any issues identified and a corrective action plan will be completed.

7.4. Annual Education Requirement

The Primary and Back-up VFC Contacts are required to complete an annual educational session. This requirement may be met by participating in a VFC Compliance or Education Visit with both Contacts in attendance in the previous 12 months, or by completing the current version of the CDC's online *You Call the Shots* training modules annually: [Vaccine Storage and](#)

[Handling](#) and [Vaccines for Children](#) (updated in January of each year).

7.5. VFC Contact

“VFC Contacts” are communications delivered in person, by phone, or in writing that are directly related to communicating VFC Program requirements. Clarifying vaccine orders, formal educational opportunities in order to meet the annual training requirement, and follow-up for VFC Compliance or Unannounced Storage and Handling visits are **not** classified as “VFC Contacts.”

A provider may request additional education and training by contacting their RIR.

7.6. Immunization Quality Improvement for Providers (IQIP)

IQIP is CDC’s national quality improvement program for VFC providers. The purpose of IQIP is to promote and support the implementation of provider-level immunization quality improvement strategies designed to increase vaccine uptake among children and adolescents, in adherence to the routine schedule recommended by the Advisory Committee on Immunization Practices (ACIP).

RIRs conduct IQIP visits with a select number of VFC providers in their region annually. Providers are prioritized based upon criteria determined by VPDIP. This year, providers selected to participate in IQIP were prioritized by coverage rate assessments for both the childhood series and HPV completion.

The goals of IQIP visits are to ensure providers are:

1. Aware of and knowledgeable about their immunization rates,
2. Motivated to incorporate changes into their current practices,
3. Ready to try new immunization service strategies, and
4. Capable of sustaining improvements to their vaccination delivery services

The IQIP process begins with assessments conducted on 24-35 month old children and 13-17 year old adolescents, using immunization data from the provider’s active

patients in TennIS. Children are assessed based on their completeness of the 4:3:1:3:3:1:4 series¹, and adolescents are assessed based on their completeness of meningococcal, Tdap, and HPV (based on their age) vaccines.

Coverage rates are shared with the provider and staff during the initial IQIP site visit. The RIR and provider then discuss three core strategies to improve immunization services and raise coverage rates for children and adolescents. These three core strategies include:

1. Scheduling the next immunization visit before the patient leaves the office
2. Leveraging TennIS functionality to support immunization practice
3. Giving a strong vaccine recommendation (with an emphasis on HPV vaccination for providers serving adolescent patients)

During this initial visit, the RIR and provider will develop a strategy implementation plan. The RIR will provide technical assistance to the provider in implementing at least two of the core QI strategies.

Two months and **six months** after the initial IQIP visit, the RIR will conduct check-ins via telephone to review the provider's progress in implementing their chosen QI strategies. The RIR will provide additional technical assistance, if needed, and update the strategy implementation plan. **Twelve months** after the initial IQIP visit, the RIR will conduct a follow-up with the provider via telephone or in person. During this follow-up, the RIR and provider will review the provider's progress toward strategy implementation and any changes to the provider's coverage rates.

Only immunizations recorded in TennIS are assessed during the IQIP process. For the most accurate coverage rate assessments, practices are strongly encouraged to add missing historical vaccine doses when updating a patient's record. They are also encouraged to remove inactive patients from their facility patient list in TennIS. A Manage Patient Population Quick Reference Guide is available in the Document Center of TennIS and provides step-by-step guidance on how to inactivate patients in bulk. Practices with an electronic connection to TennIS may

¹ 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 Hep B, 1 Varicella, 4 PCV

upload historical immunizations from their EHR. Email the TennIIS team at TennIIS.MU@tn.gov with a subject line of “VFC Backloading” for details.

7.7. VFC Report Card

Each quarter, every active VFC Provider receives an individualized VFC Report Card and an accompanying Interpretation Document. The primary purpose of the report card is to allow providers and TVPDIP to work together to improve the quality of immunization services provided to VFC and non-VFC children in Tennessee. The report card tracks progress in compliance with reporting all vaccinations administered to patients <19 years, regardless of VFC status, within two weeks of administration. It also tracks key data quality measures, such as completeness of vaccination submission information and VOMS reconciled doses.

Following distribution of the VFC Report Card, the RIR contacts the VFC Primary Contact via telephone if opportunities for data quality improvement have been identified. TVPDIP Central Office contacts providers who do not submit vaccinations to TennIIS and providers who do not submit vaccinations within two weeks of administration. Recurring issues in submission may result in the provider being asked to fill out a Corrective Action Plan. Continued non-compliance may result in probation or suspension from the VFC program.

All staff listed on the Provider Agreement will receive the quarterly report card. Providers are encouraged to review the data quality measures and the vaccination coverage rates (Flu, HPV, 4th DTaP) reported on the card. Although providers are not able to generate their own report cards, quick reference guides in the TennIIS Document Center provide guidance on ways they can view their facility’s data submission in between report cards.

Through reliable, comprehensive immunization records that are available to all healthcare providers and provide lifelong patient immunization records, TennIIS may achieve its goal to simplify, expedite and improve immunization services, including coverage rates and compliance with childcare, school and college immunization requirements.

8. Mobile Immunization Clinics

Under conditions outlined below, VFC providers may incorporate a mobile immunization clinic into their practice. A mobile immunization clinic allows providers to vaccinate children at non-traditional locations (e.g., schools and health fairs) while maintaining a clinic setting and without a break in the vaccine cold chain.

The mobile immunization clinic is an extension of the provider's practice and will use the same unique VFC provider identification number (PIN) already assigned to the provider. The mobile immunization clinic must comply with all VFC Program requirements listed in the Provide Agreement. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The provider must be enrolled in the VFC Program and in good standing.
2. The VFC provider must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including protocols for establishing vaccine needs (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC stock are transported on each clinic day.
3. The mobile immunization clinic must pass the storage and handling site-visit; this is an *initial* and *annual* requirement.
 - Any staff participating in the mobile immunization clinics must receive VFC training either by the Primary or Back-up Vaccine Coordinator.
 - Any staff participating in the mobile immunization clinics must complete the same annual VFC training required of the Primary and Back-up Vaccine Coordinators.
4. Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement. Vaccines are only be transferred to the mobile unit on the day of the clinic.
5. Mobile Immunization Clinics may only be **conducted** within the state of Tennessee; VFC-eligible children are **not** required to be TN residents.
6. The provider must complete the [Mobile Immunization Clinic Log \(Appendix J\)](#) that lists the clinic dates, locations and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each mobile clinic.
7. Vaccine storage and handling equipment must meet CDC requirements:

- A stand-alone refrigerator
 - A separate, stand-alone freezer
 - VFC-compliant DDL(s) for temperature monitoring in each storage unit
 - Prior to transferring the vaccine to the mobile immunization clinic, the storage units must be operational and temperatures in-range (refrigerator temperature steady between 2°C – 8°C, hovering around 5°C; freezer temperature consistently colder than minus (-)15°C).
 - DDLs that are routinely stored outside a refrigerator or freezer should be placed in a functioning storage unit at least six hours, or the night before the clinic, to allow time for them to acclimate and register any issue.
 - The vaccine should be transferred to the mobile immunization clinic inside a cooler; transfer should not take longer than 15 minutes. If the transfer will take longer than 15 minutes, use the “Packing Vaccines for Transport during Emergencies” guidance or a commercial transport box qualified to maintain proper temperatures during transfer.
8. Only staff that have completed VFC training may transfer vaccines between the provider’s practice and the mobile unit.
 9. Only amounts of VFC vaccines that are appropriate, based on VFC need, should be transported to each scheduled clinic.
 10. Upon arrival at the clinic site, the mobile clinic staff must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:
 - Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic using a DDL.
 - Temperatures during transport (if >15 minutes) and mobile immunization clinic hours must be documented hourly on the Hourly Vaccine Temperature Log ([Appendix K](#)).
 11. At the end of each clinic day, the mobile immunization clinic staff must:
 - Print the temperature data logger report at the end of the clinic day and attach it to the mobile clinic temperature log. The Primary or Back-up Vaccine Coordinator needs to review the temperature logs and sign the Hourly Vaccine Temperature Log prior to the vaccine being returned to the primary clinic’s storage units.

- Vaccines exposed to temperature excursions (TEs) must be labeled “Do Not Use”, placed in storage unit(s) at the proper temperatures, and TVPDIP needs to be contacted in accordance with TE procedures described elsewhere in this guide. The vaccines must not be used until TVPDIP has verified that the vaccines are usable.
- Temperature logs from the mobile immunization clinic must be stored with the primary clinic logs and kept on file for three years. Temperature logs will be reviewed during a VFC Compliance Visit..

12. VFC eligibility must be screened for and status documented at the time of service.

- If eligibility cannot be documented in the EHR, eligibility may be recorded on the Patient Eligibility Screening Record, and scanned into the EHR or maintained in the paper chart.
- All eligibility information must be maintained for **three** years per VFC requirements.
- If working with a school, the school should send a permission slip/Eligibility Screening Form home with the student prior to the scheduled clinic date, and have it available on the date of service. It is not acceptable to presume all students are VFC-eligible because no eligibility screening was conducted.

13. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):

- Name of vaccine
- Date vaccine given
- Name of vaccine manufacturer
- Vaccine lot number
- Signature & title of person administering vaccine
- Address of clinic where given
- Publication date of VIS
- Date VIS given to parent/guardian

14. All immunizations must be entered in TennIIS within two weeks of administration.

15. Quality Assurance Visits will be conducted annually for the mobile clinic.

- The mobile immunization clinic will be included in the primary clinic's VFC compliance site visit. If a compliance visit is not scheduled during the upcoming year, a storage and handling visit will be performed.
- The immunization records from the mobile immunization clinic must be available for review during the annual site visit.
- Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in withdrawal of approval for use of VFC vaccines in the mobile clinic.

9. Mass Vaccinators

Mass vaccination clinics can improve access to vaccines for VFC-eligible and privately-insured children. However, these clinics require additional program oversight and vaccine accountability. Mass vaccinators must comply with all VFC Program requirements and maintain enhanced storage and handling practices. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The mass vaccinator must enroll in the VFC Program.
2. The mass vaccinator's office must pass the storage and handling site-visit; this is an initial and annual requirement.
 - Required to have a stand-alone refrigerator that meets VFC program requirements. Vaccine will need to be shipped to the office listed on the Provider Agreement. The day of the mass vaccination clinic the vaccine can be transported from the office to the clinic. The vaccine will be required to be transported in an approved portable refrigerator. The portable refrigerator will need to be able to plug into the vehicle during transport and plug into the power outlet at the clinic site.
 - Required to have a digital data logger (DDL) with a current Certificate of Calibration for the office stand-alone refrigerator. Additional DDLs will need to be purchased for each portable refrigerator.
 - If the office will not have staff available Monday – Friday to monitor the vaccine, an alarm will need to be purchased for each stand-alone refrigerator. The alarm will need to be able to send out alerts when temperatures are out-of-range.
 - Required to have private vaccine inventory (invoices must be kept for three years).
3. The mass vaccinators are required to work closely with the Regional Immunization Representative when scheduling clinics. This collaboration will prevent duplicate effort/work between the mass vaccinator and the local health department and will assist in reaching the at risk populations.
4. The mass vaccinator must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including protocols for

establishing vaccine needs (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC and private vaccine stock are transported on each clinic day.

5. Any staff participating in the mass vaccination clinics must annually complete the CDC You Call the Shots trainings.
6. The mass vaccination clinics may only be conducted within the state of Tennessee; VFC-eligible children are not required to be TN residents.
7. Complete the Mobile Immunization Clinic Log (Appendix J) that lists the clinic dates, locations and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each mass vaccination clinic.
8. The following steps are required to be completed/conducted the day of the mass vaccination clinic:
 - Portable refrigerator should be at the correct temperature prior to placing vaccine and the DDL inside the unit. It is recommended that the portable refrigerator be plugged in the night before the clinic to allow adequate time for it to acclimate. The DDL should also be placed in the stand-alone refrigerator to allow it to acclimate.
 - Only amounts of VFC vaccines that are appropriate, based on VFC need, should be transported to the clinic site.
 - Once vaccine is moved to the portable refrigeration unit, the temperatures are required to be taken hourly using the DDL. The temperatures are required to be documented on the Hourly Vaccine Temperature Log (Appendix K).
 - Upon arrival at the clinic site, staff should immediately plug the portable refrigerator into the power outlet.
 - Print the temperature data logger report at the end of the clinic day and attach it to the Hourly Vaccine Temperature Log. The Primary or Backup Vaccine Coordinator needs to review the temperature logs and sign the Hourly Vaccine Temperature Log prior to the vaccine being returned to the office's stand-alone refrigerator(s).
 - a. Vaccines exposed to temperature excursions (TEs) must be labeled "Do Not Use", placed in storage unit(s) at the proper temperatures, and TVPDIP needs to be contacted in accordance with TE procedures described elsewhere in this guide. The

vaccines must not be used until TVPDIP has verified that the vaccines are usable.

- Temperature logs from the mass vaccination clinic must be stored with the office temperature logs and kept on file for three years.
Temperature logs will be reviewed during a VFC Compliance Visit.
9. VFC eligibility must be screened for and status documented at the time of service.
- If eligibility cannot be documented in the EHR, eligibility may be recorded on the Patient Eligibility Screening Record, and scanned into the EHR or maintained in the paper chart.
 - All eligibility information must be maintained for three years per VFC requirements.
 - If working with a school, the school should send a permission slip/Eligibility Screening Form home with the student prior to the scheduled clinic date, and have it available on the date of service. The Eligibility Screening Form can be sent up to 30 days prior to the scheduled clinic date but must be in the same month. It is not acceptable to presume all students are VFC-eligible because no eligibility screening was conducted.
10. All immunizations must be entered in TennIIS within two weeks of administration.
11. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):
- Name of vaccine
 - Date vaccine given
 - Name of vaccine manufacturer
 - Vaccine lot number
 - Signature & title of person administering vaccine
 - Address of clinic where given
 - Publication date of VIS
 - Date VIS given to parent/guardian
12. A VFC Compliance visit will be conducted annually.
- The immunization records from the mass vaccination clinic must be available for review during the annual site visit.

- Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in withdrawal from the VFC Program.

Appendices

Appendix A: Resources

Resource	Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines. Website: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more. Website: http://www.cdc.gov/vaccines Phone: 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS; sign up to receive update notices via email. Website: http://www.cdc.gov/vaccines/hcp/vis/index.html
CDC: Vaccine Storage & Handling Toolkit	Information regarding best practices for vaccine storage and handling. Website: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VIS in multVDPIDle languages, "Ask the Experts", free print materials, information on vaccine-preventable diseases, and much more. Website: http://www.immunize.org
CDC "You Call the Shots" Training	Vaccine Storage and Handling (module 10) Vaccines for Children Program (module 16) Website: https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp

Appendix B: VFC Phased Re-Enrollment Schedule



2020 VFC Annual Phased Re-Enrollment Schedule



VFC providers have 60 days prior to the expiration of their current Provider Agreement (PA) to complete annual re-enrollment. Providers are encouraged to initiate re-enrollment at the *beginning* of their 2 month window. Those who do not complete re-enroll by their expiration will be dis-enrolled from the Program. Enrollment guidance documents are available in the TennIS Document Center.

Documentation for VFC Enrollment can be scanned to VFC.Enrollment@tn.gov or faxed to 615-401-6831. After submission of all required documentation and the electronic Provider Agreement in TennIS, please allow 7-10 business days for processing. For additional assistance or to report facility contact changes in the interim, please contact the **VFC Enrollment Team** at VFC.Enrollment@tn.gov or at 800-404-3006.

LOCAL HEALTH DEPARTMENTS - Agreement <i>Expires</i> on March 2nd 2020				
All local health departments (LHDs)				

EAST TN Region & KNOX Co. Metro - Agreement <i>Expires</i> on April 6th 2020				
01 - Anderson	15 - Cocke	47 - Knox - Metro	73 - Roane	
05 - Blount	29 - Grainger	53 - Loudon	76 - Scott	
07 - Campbell	32 - Hamblen	62 - Monroe	78 - Sevier	
13 - Claiborne	45 - Jefferson	65 - Morgan	87 - Union	

MID-CUMBERLAND Region - Agreement <i>Expires</i> on May 4th 2020				
11 - Cheatham	43 - Humphreys	75 - Rutherford	85 - Trousdale	
22 - Dickson	63 - Montgomery	81 - Stewart	94 - Williamson	
42 - Houston	74 - Robertson	83 - Sumner	95 - Wilson	

NORTHEAST & SOUTH CENTRAL Regions, & SULLIVAN Co. Metro - Agreement <i>Expires</i> on June 1st 2020				
02 - Bedford	30 - Greene	46 - Johnson	59 - Marshall	82 - Sullivan - Metro
10 - Carter	34 - Hancock	50 - Lawrence	60 - Maury	86 - Unicoi
16 - Coffee	37 - Hawkins	51 - Lewis	64 - Moore	90 - Washington
28 - Giles	41 - Hickman	52 - Lincoln	68 - Perry	91 - Wayne

SOUTHEAST & UPPER CUMBERLAND Regions, & HAMILTON Co. Metro - Agreement <i>Expires</i> on July 6th 2020				
04 - Bledsoe	21 - DeKalb	44 - Jackson	67 - Overton	77 - Sequatchie
06 - Bradley	25 - Fentress	54 - McMinn	69 - Pickett	80 - Smith
08 - Cannon	26 - Franklin	56 - Macon	70 - Polk	88 - Van Buren
14 - Clay	31 - Grundy	58 - Marion	71 - Putnam	89 - Warren
18 - Cumberland	33 - Hamilton - Metro	61 - Meigs	72 - Rhea	93 - White

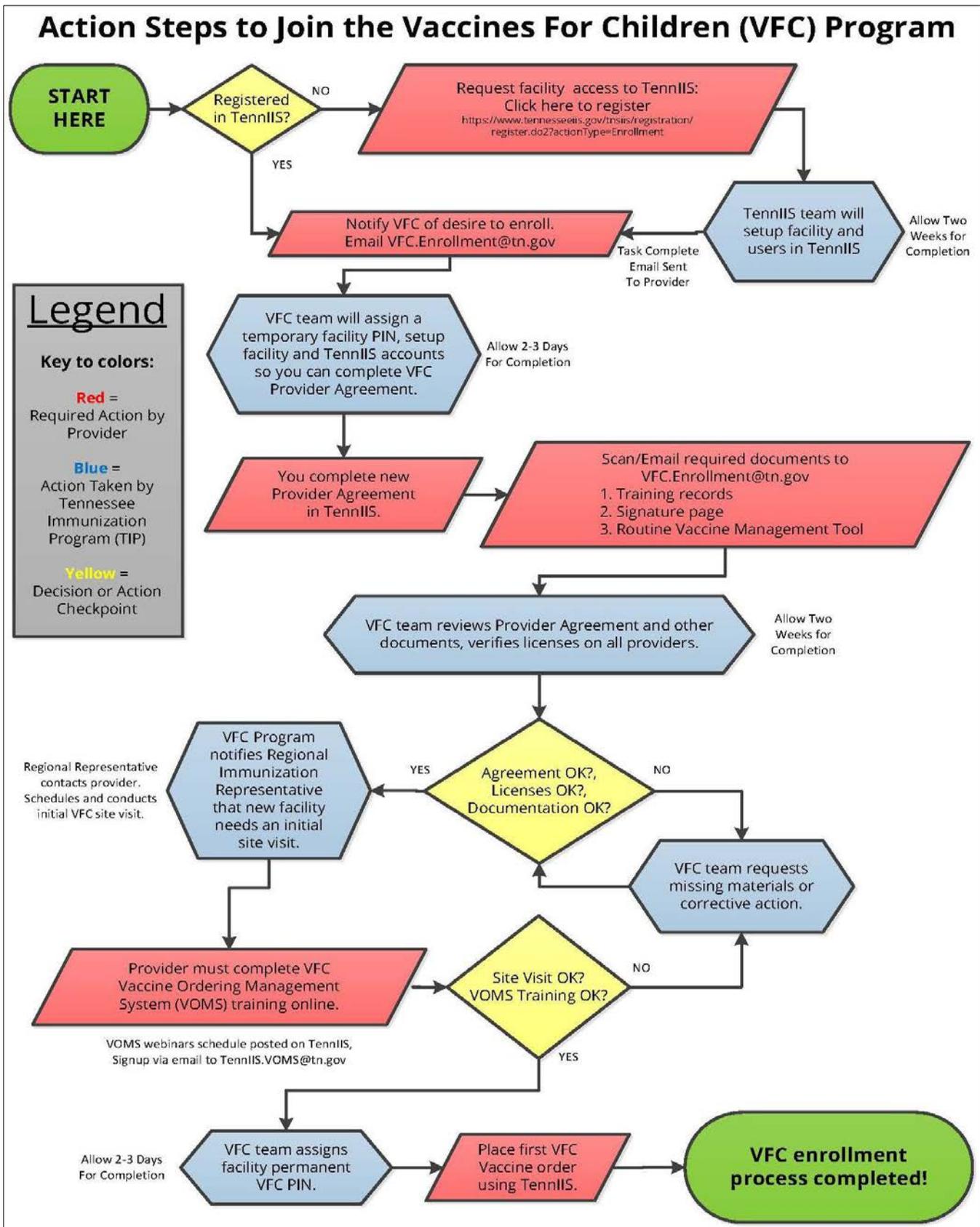
SHELBY CO. Metro - Agreement <i>Expires</i> on October 5th 2020				
79 - Shelby - Metro				

WEST TN Region & MADISON Co. Metro - Agreement <i>Expires</i> on November 2nd 2020				
03 - Benton	20 - Decatur	35 - Hardeman	40 - Henry	57 - Madison - Metro
09 - Carroll	23 - Dyer	36 - Hardin	48 - Lake	66 - Obion
12 - Chester	24 - Fayette	38 - Haywood	49 - Lauderdale	84 - Tipton
17 - Crockett	27 - Gibson	39 - Henderson	55 - McNairy	92 - Weakley

DAVIDSON CO. Metro - Agreement <i>Expires</i> on December 7th 2020				
19 - Davidson - Metro				

Tennessee Department of Health (TDH) • Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP)
 • Vaccines For Children Program (VFC)
 710 James Robertson Pkwy • AJT, 3rd Floor • Nashville, TN 37243
 Tel: 800-404-3006 • 615-741-7247 • Fax: 615-401-6831 • <https://www.tn.gov/health/cedep/immunization-program.html>

Appendix C: Flowchart for Initial VFC Enrollment



Appendix D: Examples of Insured Exceptions

INSURED EXCEPTIONS

AI/AN with Health Insurance that Covers Immunizations:

AI/AN children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC program should be made based on what is most cost beneficial to the child and family.

Insured and Medicaid as Secondary Insurance:

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

Option 1

A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.

In most healthcare situations, Medicaid is considered the “payer of last resort.” This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid, the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

Please note: If the state Medicaid agency rejects a claim for a vaccine administration fee for a child with Medicaid as secondary insurance, stating the claim must first be submitted to the primary insurer for payment, the provider should notify the awardee. The awardee should notify their CDC project officer so that CDC can work with CMS to educate the state Medicaid agency and correct the situation.

Considerations regarding this option:

- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

Option 2

A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

- If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC borrowing form.

Considerations regarding this option:

- The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- The provider should choose from the vaccine inventory that is most cost-effective for the family.
- The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Appendix F: Manual Entry Decrementing for VFC Providers



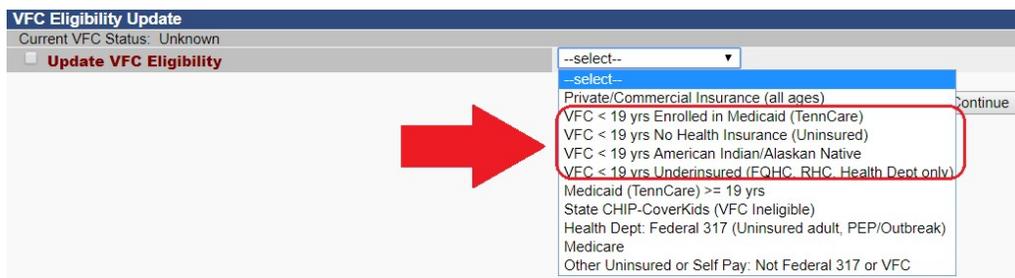
Manual Entry Decrementing for VFC Providers

What does decrementing mean and why is it important?

In order to record VFC eligible vaccinations, manual entry TennIIS users must associate a lot number to their administered vaccination. Decrementing is the process of linking VFC lot numbers directly from your facility's VOMS inventory to VFC eligible vaccinations. This is important to maintaining accurate reconciliation throughout the month and is critical to establishing dose level accountability for VFC vaccines.

How do I link a VFC eligible vaccination to a lot in my VFC inventory?

1. Find the patient and vaccination you'd like to record. To do this, you can use the [View/Add/Edit Vaccination Quick Reference Guide](#)
2. Select a VFC eligible category when recording and administered vaccination.



3. Click on the "Click to select" link in blue. A box will pop up that will ask you to select a lot number from your inventory. Select the correct lot that was used in the vaccination. After saving, you will see the lot information and the correct VFC eligibility saved on the vaccination record

Vaccination Detail Add

Vaccine 1: Hep B Ped/Adol - Preserv Free (Recombivax HB® / EngerixB®)

Date Administered: 10/29/2018

Historical: YES NO

Manufacturer: [Click to select](#)

Lot Number:

Lot Facility:

Funding Source:

Facility: DECREMENTING

Vaccinator:

Anatomical Site:

Anatomical Route:

Dose Size: Full

Volume (CC):

VFC Status: VFC < 19 yrs Enrolled in Medicaid (TennCare) **'VFC Status' will be ignored if I**

District/Region:

TennIS-Select Lot Number - Google Chrome

https://www.tennessee.gov/siistat/selectLotNumber.do?sis_vaccine_code=100...

Select Lot Number

Select	Manufacturer	Lot Number	Facility	Funding Source	Expiration Date	Doses Available
<input checked="" type="checkbox"/>	GLAXOSMITHKLINE	340525	DECREMENTING	VFC	09/20/2020	10.0

Cancel

Vaccination Detail

Vaccine: Hep B Ped/Adol - Preserv Free (Recombivax HB® / EngerixB®)

Date Administered: 10/29/2018

Historical: No

Manufacturer: GLAXOSMITHKLINE

Lot Number: 340525

Lot Facility: DECREMENTING

Funding Source: VFC

Vaccinator:

Organization (IRMS): 10262018 - DECREMENTING

Facility: DECREMENTING

Campaign:

Tier:

Anatomical Site:

Anatomical Route:

Dose Size: Full

Volume (CC):

VFC Status: VFC < 19 yrs Enrolled in Medicaid (TennCare)

Revaccination Reason:

Adverse Reaction:

District/Region:

Dates of VIS Publications:

Date VIS Form Given: 10/29/2018

Ordering Provider:

Comments:

What happens to my VOMS inventory when I decrement?

Before decrementing: there are 10 doses of the Hep B vaccine in this inventory.

After decrementing: there are now 9 doses left to reconcile from this inventory.

Reconcile Inventory

Vaccine	Lot Number	Exp Date	Quantity on Hand
Hep B Ped/Adol - Preserv Free (Recombivax HB® / EngerixB®)	340525	09/20/2020	10

Reconcile Inventory

Vaccine	Lot Number	Exp Date	Quantity on Hand
Hep B Ped/Adol - Preserv Free (Recombivax HB® / EngerixB®)	340525	09/20/2020	9

Appendix G: Vaccine Borrowing Form

Facility Name:

Pin #:

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

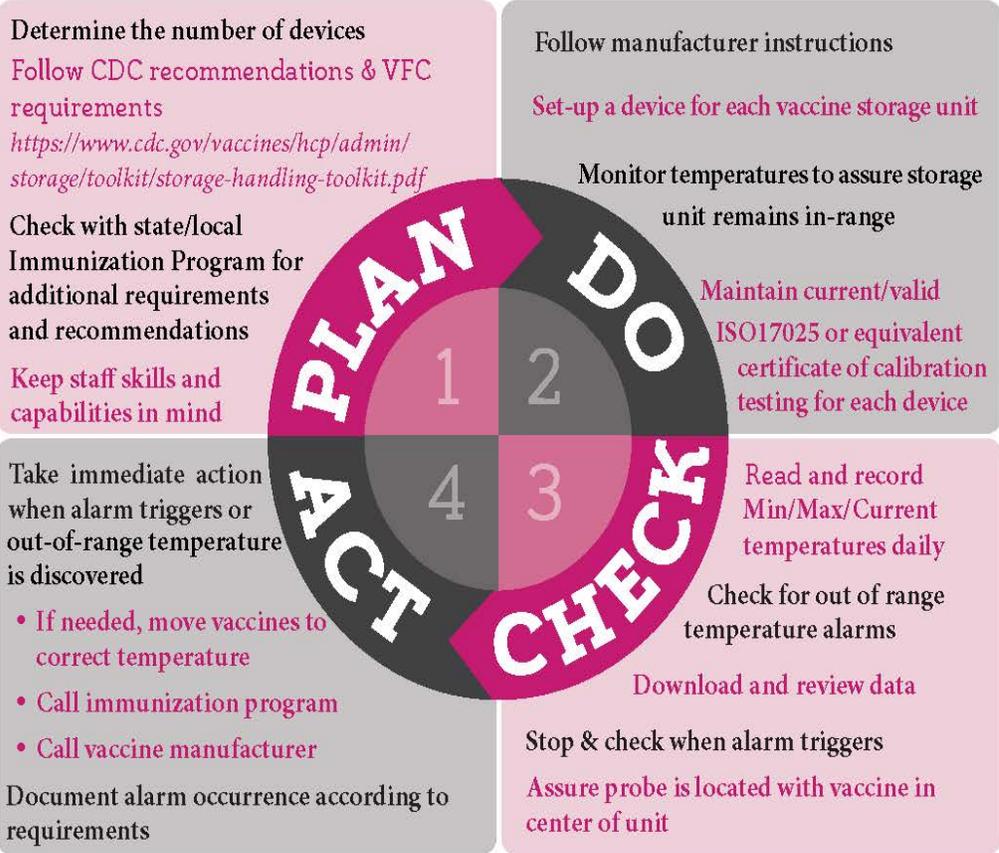
Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4	Short-dated VFC dose was exchanged with private dose	11
Accidental use of VFC dose for a private patient	5	Accidental use of a Private dose for a VFC eligible patient	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6	Other - Describe:	13Other
Other - Describe:	7Other		

WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.

A STEP-BY-STEP GUIDE TO SELECTING AND USING A DIGITAL Data LOGGER FOR VACCINE INVENTORY



For more information go to: immunizationmanagers.org/VSH

Educational resource created with support from Berlinger USA

USING A DATA LOGGER – THE DETAILS



PLAN 1

- Obtain multiple devices: one for each storage unit and one backup device with different calibration testing dates
- Ensure each device meets CDC requirements:
 - ✓ Temperature probe
 - ✓ Active temperature visibly displayed on the outside of the unit
 - ✓ Capacity for continuous temperature monitoring, recording and downloading
- Contact the Immunization Program for additional device requirements and policy/procedures for alarm notification, reporting and calibration testing
- Confirm that report shows alarms, temperature ranges (highest and lowest) and duration of excursions
- Check for Immunization Program or manufacturer training
- Consider other CDC recommendations:
 - ✓ Detachable probe in a thermal, buffered material (e.g., glycol)
 - ✓ Alarm for out-of-range temperatures: audible and visual alarms preferred
 - ✓ Current, minimum, and maximum temperature display
 - ✓ Low battery indicator
 - ✓ Memory: Minimum 4,000 readings or 39 days
 - ✓ Accuracy of +/- 1°F (0.5°C)
 - ✓ User programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

DO 2

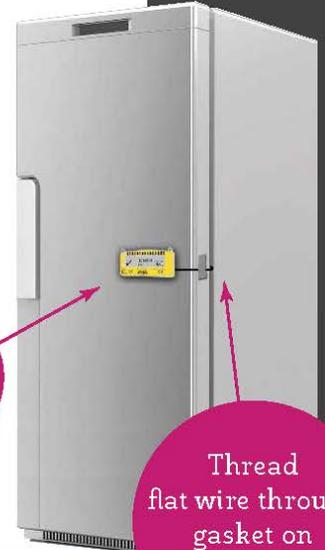
- Reference manufacturer resources for set-up and installation
- Place probe in the middle of the unit with vaccines
- Thread probe wire through door hinge side of the unit and tape in place (inside & outside the unit) or place wire in storage unit portal designed for that purpose
- Contact manufacturer and/or Immunization Program for installation trouble shooting
- Monitor temperature and replace vaccine storage unit if it does not maintain in-range temperatures
- Keep track of expiry date and ISO certificate of calibration testing for each device

CHECK 3

- Read and record temperatures at least 1x daily noting data/time/temp/initials
 - Assess at the start of clinic day and prior to vaccine administration
 - Log recording in paper or electronic format
- Download and review reports weekly
 - PDF reports simplify record keeping

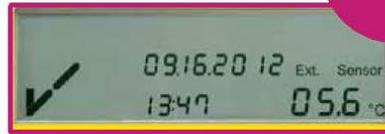
ACT 4

- Take immediate action when there is an alarm or out of range temperature
 - If needed, move vaccines to a storage unit with correct temperatures and quarantine vaccine
 - Print report and look for clues to the problem e.g. is the ave. temperature 5.0°C (41°F)?
 - If not is it too cold or too warm in the unit?
 - Document the actions taken and duration of the alarm period with the highest or lowest temp.
 - Communicate alarm information to Immunization Program and vaccine manufacturer
- Maintain reports per Immunization Program/CDC requirements



Display screen

Thread flat wire through gasket on hinged side of unit



Stabilize vial with probe on shelf



Duct tape wire to wall

For more information go to:
www.immunizationmanagers.org

Educational resource created with support from Berlinger USA

Appendix I: Packing Vaccines for Emergency Transport

Be prepared for vaccine transport. Commercially available vaccine transport options are available at a variety of price points and may be preferred. However, the protocol below is designed to safely store vaccines for hours at proper temperatures using readily available materials.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

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 $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) 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.**



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Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

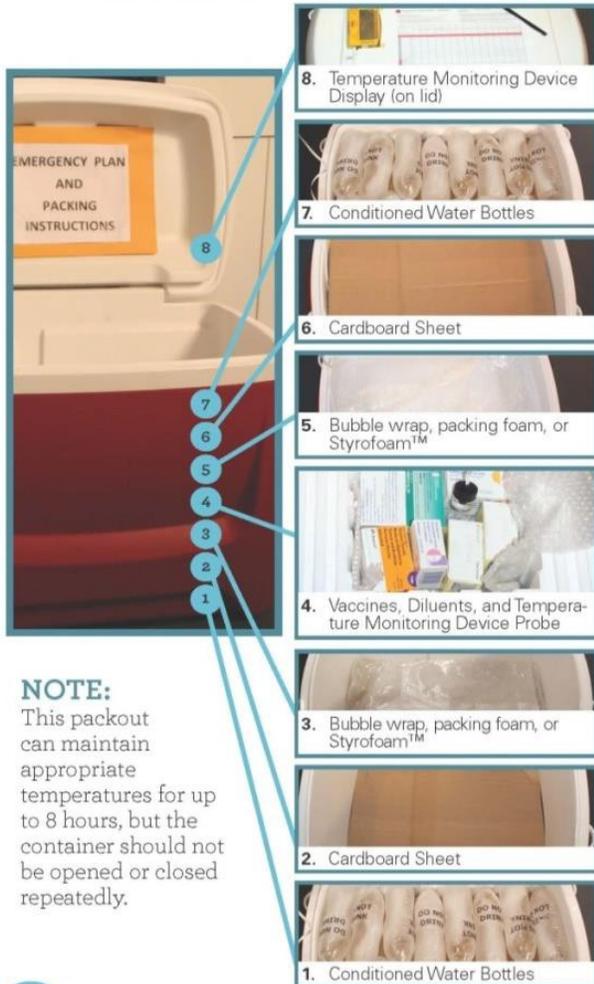
CS249275-1 August 2015

Packing Vaccines for Transport during Emergencies

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.



8. Temperature Monitoring Device Display (on lid)

7. Conditioned Water Bottles

6. Cardboard Sheet

5. Bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe

3. Bubble wrap, packing foam, or Styrofoam™

2. Cardboard Sheet

1. Conditioned Water Bottles

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.

Guide may be found on the CDC website at:

<http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>

Appendix L: Insurance Cheat Sheet

Insurance Company	TennCare/ Medicaid?	Private/Public	Covers all ACIP recommended vaccines? Justification / Other comments
Aetna (Commercial-small group carrier) *	No	Private	Yes
Allied Benefit System*	Partners with Aetna, Cigna, BCBS, and others (Employer insurance solution)		
Ambetter of Tennessee*	No	Private	Yes
Celtic – Ambetter (Commercial- Individual) *	No	Private	Yes
Celtic - Ambetter*	No	Public	Yes; Healthcare.gov (govt. marketplace)
Bright Health*	No	Public	Yes; Healthcare.gov (govt. marketplace)
Bright Health (Commercial - small group & individual) *	No	Private	Yes
Blue Cross Blue Shield-TN*	No	Public	Yes; Healthcare.gov (govt. marketplace)
BCBS (Commercial - small group & individual) *	No	Private	Yes
BlueCare (BCBS)*	Yes	Public	Yes; Medicaid plans cover children vaccines
(BCBS) TennCare Select*	Yes	Public	Yes; Medicaid plans cover children vaccines
Anthem (BCBS Co.)	Does not offer plans in Tennessee		
Amerigroup (part of Anthem) *	Yes	Public	Yes; Medicaid plans cover children vaccines
Cigna Health*	No	Public	Yes; Healthcare.gov (govt. marketplace)
Cigna Health (Commercial- Individual) *	No	Private	Yes
Farm Bureau of Tennessee	No	Private	Yes; Not an ACA compliant company, however.
Humana (Commercial- Small group) *	No	Private	Yes
Humana-Tricare	No	Public	Yes; government sponsored program
Medi-Share	Not recognized as health insurance in Tennessee – person is considered “uninsured”		
MultiPlan/PHCS (Commercial only)	Is not insurance, but a network of providers– person is considered “uninsured”		

North American Admins (Lucent Health)	Partners with Aetna, Cigna, BCBS, and others (Employer insurance solution) – person is considered “uninsured”		
Nova Net	Is not a health plan, but a provider network– person is considered “uninsured”		
Oscar Insurance Co*	No	Public	Yes; Healthcare.gov (govt. marketplace)
Oscar (Commercial- Small Group & Individual) *	No	Private	Yes
TriWest (Military)	No	Public	Yes; government sponsored program
United Health One (UHC)	No	Private	Yes; https://www.uhc.com/united-for-reform/health-reform-provisions/preventive-services
United Healthcare (Commercial- Small group) *	No	Private	Yes
United Healthcare Community Plan (UHC)*	Yes	Public	Yes; Medicaid plans cover children vaccines
ACA Compliance: All Marketplace plans are required to cover all ACIP recommended vaccines IAW ACA. All non-grandfathered private health plans are required to cover all ACIP recommended vaccines IAW ACA. Grandfathered status plans are not required to cover all of the benefits healthcare reform has deemed to be “essential,” such as certain types of testing and treatment.			
Affordable Care Act: “SEC. 2713. COVERAGE OF PREVENTIVE HEALTH SERVICES. “(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— “(1) evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force; “(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and “(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration. https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf			
Companies with Asterisk (*) verified from tn.gov website or CDC website https://www.tn.gov/commerce/insurance/consumer-resources/health-insurance-information.html https://www.tn.gov/tenncare/members-applicants/managed-care-organizations.html https://www.cdc.gov/vaccines/hcp/adults/for-practice/insurance-payment.html			