2026-2027

VFC Provider Handbook

Tennessee Vaccine- Preventable Diseases and Immunization Program

Vaccines for Children (VFC) Program

TN Department of Health

Contents

Introduction

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

Our Mission: To prevent, detect, treat, and respond to communicable and environmental diseases and public health emergencies.

Our Vision: A better prepared, more resilient, and healthier Tennessee

Core Values:

- Equity
- Integrity
- Compassion
- Service
- Innovation

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. VPDIP provides federally purchased vaccine to eligible healthcare providers enrolled in the VFC Program in Tennessee. 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". Vaccines and Immunizations | CDC

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)
VPDIP	Vaccine Preventable Diseases and Immunization Program
VAERS	Vaccine Adverse Event Reporting System
VFA	Vaccines for Adults Program
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System (module within TennIIS)

TN VFC Program Contact List

- **VFC Enrollment Team**
  - Contact for general VFC enrollment questions, to report a facility change, or to update the Primary or Back-Up VFC Contacts.
  - VFC.Enrollment@tn.gov OR 800-342-1813 option 5, then 2
  - Complete this Vaccine Operations Enrollment Hub REDCap survey to:
    - Enroll your facility in a new immunization program
    - Complete annual re-enrollment
    - Dis-Enroll from a program
    - Update a coordinator's information for your facility
    - Update your facility's address
    - Request a merge with another facility
    - Report an update to your vaccine storage unit
- **Vaccine Ordering Management System (VOMS)**
  - Contact for VFC vaccine ordering, inventory, or returns questions
  - TennIIS.VOMS@tn.gov OR 800-342-1813 option 2
  - Complete this Vaccine Borrowing Report Form to report vaccine borrowing
- **VFC Quality Assurance Team**
  - Contact for questions regarding VFC vaccine storage and handling, temperature excursions, DDL or vaccine storage equipment.
  - Temperature.Health@tn.gov OR 800-342-1813 option 5, then 1
  - Complete this Vaccine Storage Unit Changes REDCap survey to report a new unit and request approval for vaccine storage
  - Complete this Temperature Excursion REDCap survey to report vaccine manufacturer viability recommendations to VPDIP for vaccines involved in a temperature excursion.

- **VFC Team**
  - Contact for general questions or concerns
  - VFC.Help@tn.gov OR 800-342-1813 option 5, then 3
- **VFC Fraud and Abuse Prevention**
  - Contact to report concerns with VFC Fraud and Abuse
  - VFC-Fraud.health@tn.gov OR 800-342-1813, option 5, then 3
  - Online reporting tool: Suspected Fraud and Abuse Reporting Tool
- **TennIIS Help Desk**
  - Contact for general TennIIS assistance
  - TennIIS.Help@tn.gov OR 800-342-1813
- **TennIIS Facility Registration and User Management**
  - Contact for TennIIS password resets
  - TennIIS.Registration@tn.gov OR 800-342-1813 option 3
  - Complete this Portal Registration REDCap survey to:
    - Start a new organization/facility enrollment application
    - Add a new facility to an existing organization
    - Add, reset, or deactivate users in an existing organization/facility
    - Update organization/facility Point of Contact (POC)
    - Update organization/facility address
    - Your facility name has changed
    - Your active organization has acquired a new facility
- **TennIIS Training**
  - Contact for questions regarding School Immunization Requirements, Immunization Recommendations and Clinical Questions TennIIS.Training@tn.gov OR 800-342-1813
- **TennIIS Interoperability Team**
  - Contact for assistance with electronic data exchange, Electronic Health Record (EHR)-TennIIS connection issues
  - TennIIS.MU@tn.gov OR 800-342-1813

VFC Program Resources for VFC Providers

- **TDH VPDIP Website: Immunization Program**
  - Documents and forms referenced in the VFC Provider Handbook can be found in the VPDIP For Providers section.
- **TennIIS Document Center**
  - Important VFC communications are sent to all VFC contacts and are posted in the Document Center. These recordings, communications, and QRG documents are accessible once the user is logged into TennIIS.
- **TennIIS Homepage: TennIIS-Web Main Page**
  - The TennIIS homepage has links to TennIIS training guides, videos, webinars, and other helpful resources.

VFC Program

1.1 Who May Enroll

To participate in the Tennessee VFC Program, a healthcare provider must have an active, unencumbered medical, pharmacy, or advanced nursing practice license in the state of Tennessee. In addition to providing practice information, Advance Nurse Practitioners, Physician Assistants and Pharmacies (if working under a collaborative practice agreement), must also submit their supervising physician's (MD, DO) full name, medical license number, and NPI number on the online Provider Agreement in TennIIS. For pharmacies not working under a collaborative practice agreement, provide prescribing pharmacists full name, license number, and NPI number.

Providers enrolling in the VFC Program agree to **all conditions** contained in the Provider Agreement in this handbook.

1.2 Initial Enrollment Process

A facility may join the VFC Program at any time. All enrolling providers must first register their facility and staff with TennIIS and request a TennIIS user account here. Once logged into TennIIS, click on the Document Center and refer to the Enrollment Walkthrough Guide for detailed instructions on completing the enrollment process.

1. Complete the online Redcap Facility Registration Application to register a new facility and add user accounts
    A. To register a new facility in TennIIS, complete the TennIIS facility registration application on the public TennIIS homepage at Portal Registration (tn.gov)
    B. 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
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:
    A. **TennIIS** – Additional resources and program information are available on the TennIIS homepage under the TennIIS Training and Education tab. All staff who will be using TennIIS are encouraged to review the online training materials.
    B. **Vaccine Ordering Management Training (VOMS)** – The link can be found under VFC Training > Training Videos. This video shows how to order VFC vaccine and manage your VFC vaccine inventory. It is intended for at least two people at each location responsible for VFC vaccine ordering (usually the Primary and Back- up Vaccine Coordinators).
    C. **CDC's *You Call the Shots*** – The Primary and Back-up VFC Contacts must complete these modules annually. The Agreement Signatory must complete these initially and are encouraged to complete annually: Vaccine Storage and Handling (module 10) and Vaccines for Children (module 16). These must also be completed for all new enrollees and signatories and may be completed for annual education. A Certificate of Completion must be submitted to VPDIP for full credit. The modules can be accessed at CDC Train. Please note, the refresher training courses and audit only versions are not accepted.
4. Complete a Routine and Emergency Vaccine Management Plan (REVMP).
5. Complete the online Provider Agreement in TennIIS.
    A. **Contact Details** – VPDIP 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.
    B. **Provider Profile** – VPDIP 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 after six (6) months and 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 documents:
    A. CDC You Call the Shots Training certificates of completion for the Agreement Signatory and Primary and Back-up coordinators.
    B. Print and sign 3-page Provider Agreement
    C. Routine and Emergency Vaccine Management Plan (REVMP)
    D. Agreement Signatory must sign the Delegated Authority (DA)
    E. Upload two days of DDL temperature readings for each vaccine storage unit
    F. Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit current Notice of Award from the US Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates FQHC status.
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.
    A. 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 VPDIP.

1.4 Provider Profile

The Provider/Practice Profile is a section within the Provider Agreement in TennIIS. 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 recertification, 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 TennIIS. 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. While digital records can be maintained, it is also recommended to keep physical records to prevent losing records due to staffing changes, computer failure, etc. These records include:

- Enrollment documentation
- VFC patient screening and eligibility documentation
- Billing
- Medical records of immunizations
- Vaccine ordering records
- Vaccine purchase and accountability records
- Temperature logs/DDL reports

1.6 Changes in Staff/Facility Status

Providers are required to contact the VFC Program by email (VFC.Enrollment@tn.gov) within the time frame 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 VPDIP **within 48 business hours**. A valid Provider Agreement is required to continue participation in the VFC Program; non-compliance may result in VFC vaccine retrieval.
   - Any new Certifying Provider, Primary Point of Contact, or Backup Point of Contact is required to complete the CDC You Call the Shots training modules Vaccine Storage

and Handling (module 10) and Vaccines for Children (module 16). 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**.
   - ❖ Vaccine Coordinator must complete the CDC You Call the Shots training modules Vaccine Storage and Handling (module 10) and Vaccines for Children (module 16) 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.
   - ❖ The Primary Vaccine Coordinator is required to train the Back-Up Vaccine Coordinator
3. Changes in listed healthcare providers, **report within 10 days**
4. Changes in mailing/shipping address, **report within 10 days**
5. Changes in 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 VPDIP 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 the facility is located. Providers must complete annual re-enrollment **60 days** prior to the expiration of their current Provider Agreement. The Phased Enrollment Schedule is in the TennIIS Document Center.

1. The Primary Vaccine Coordinator will receive an annual re-enrollment reminder email and alert message in TennIIS 60 days prior to expiration of the current agreement.
2. If a Provider Agreement expires without renewal, VFC vaccine ordering is suspended. The facility will be unable to order vaccines until the Provider Agreement is approved.

Steps to complete Annual Re-enrollment

Annual Re-enrollment is the same as the initial enrollment process with minor exceptions.

1. Add and complete a new online Provider Agreement in TennIIS. 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 Visit, including both the Primary and Backup Coordinators, or Education Site Visit, OR
   - ❖ Complete the CDC *You Call the Shots* training modules (Vaccine Storage and Handling and Vaccines for Children) for the current enrollment year.
3. Complete and sign pages 2, 15, 16, and page 18 of the REVMP.
4. Upload the required documentation to the VFC Enrollment Redcap:
   A. Training records for the VFC Primary and Back-up Coordinators
   B. Print and sign 3-page Provider Agreement
   C. Routine and Emergency Vaccine Management Plan (REVMP)
   D. Agreement Signatory must sign the Delegated Authority (DA)
   E. Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit current Notice of Award from the US Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates FQHC status.
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 / Termination from the VFC Program

Either VPDIP or the provider may terminate the VFC Provider Agreement and Delegated Authority at any time.

Facility Request	A facility closed or withdrawals from the VFC program must provide VPDIP at least 10 business day notice written notice to allow time for VFC Vaccine to be retrieved by the RIR. Notice may be emailed to VFC.enrollment@tn.gov.
Failure to comply with the program	A facility that fails to comply with the VFC program requirements or that fails to implement appropriate and timely corrective action risks being suspended by the program
Failure to complete annual re-enrollment	A facility who allows their current Provider Agreement to expire without being renewed will be unable to order VFC vaccines until it is approved.
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 reapply.

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

1.9 Backup Power Systems

1. VFC Providers must have an alternate VFC Provider as an emergency backup facility. The emergency backup facility MUST be a VFC Provider. This location cannot be in another state.
    A. If you cannot find a VFC Provider to be your emergency backup location
        i. Ask your RIR to assist
        ii. Your backup location may be a Store Only Facility with approval
2. The VFC Program will approve portable generators with the following information provided on Page 15 of the REVMP:
    A. Generators MUST be self-powered (gas or battery powered)
    B. A detailed plan is submitted on how you will monitor the generator and vaccine storage units during emergencies, conduct quarterly tests, and service annually (submit annually with VFC Enrollment)
    C. Must include the specifications of the portable generator.
    D. Must include the model of the portable generator.
3. If you have an approved generator or back up battery power source, pages 15 & 16 of the REVMP MUST be filled out and signed, documenting quarterly testing and annual service.

1.10 Store Only Backup Locations

1. Store only backup locations are not routinely allowed. Under extenuating circumstances, if a store only backup location is desired, the Vaccine Operations Team must be consulted.
2. All Store- Only Backup locations must enroll as a VFC Store- Only Provider via the Redcap Link: VFC Store Only Backup Facility Enrollment (tn.gov)
3. Once approved, this facility will have a site visit.
4. Store Only locations must have an Agreement Signatory, Primary Vaccine Coordinator, and a Backup Coordinator. The Agreement Signatory, Primary Vaccine Coordinator, and Backup Coordinator must complete the You Call the Shots Modules Vaccine Storage and Handling (module 10) and Vaccines for Children (module 16).
5. Submit required documentation at: VFC Store Only Backup Facility Enrollment (tn.gov)

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.

Fraud and Abuse Examples:

- Failure 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 fee for administration of VFC vaccine
- Over-ordering VFC vaccine (e.g., quantities or patterns do not match the provider profile)
- Waste of VFC vaccine
- Denying VFC eligible children VFC- funded vaccine due to parents' inability to pay for administration fee
- Failing to screen for and document eligibility status at each visit
- Failure to maintain VFC records for a minimum of three years
- Failing to fully account for VFC-funded vaccines
- Failure to properly store and handle VFC vaccine

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

Any person may contact VPDIP 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 use the VFC Fraud and Abuse Reporting Tool.pdf (tn.gov). 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 Vaccine-Preventable Diseases and Immunization Program (VPDIP) (Attn: VFC Program Manager), 710 James Robertson Parkway, AJT 3rd Floor, Nashville, TN 37243
2. **Telephone report** – Call (800)-342-1813 and request to speak to the VFC Program Manager
3. **Online report**– Go to the online reporting tool at Suspected Fraud and Abuse Reporting Tool (tn.gov) 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..

Vaccine Eligibility and Documentation

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 factors considered when screening for VFC eligibility is age and if 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 vaccines (see Insured Exceptions table below).

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

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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*** - Underinsured children may receive VFC vaccine only at an FQHC, RHC, or LHD.
    - ❖ 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 does not provide first dollar coverage (which includes copays, coinsurance, or deductibles) for ACIP recommended vaccines. This means that copays, coinsurance, or deductibles will not apply for the administration of any ACIP-recommended vaccines purchased using

VFC funding. This applies only to the cost of the vaccine not to any administration fee or office visit fee (which may have a separate co-pay or co-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 because of the cost of all the services provided at the visit, VFC vaccine may be used.

Reminder: *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 insurance status.

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.
2. **CoverKids** – The state child health insurance plan is not part of Medicaid, even though CoverKids may be managed by a TennCare MCO, CoverKids children are NOT eligible for VFC.

Insured exceptions include

American Indian/Alaska Native with health insurance that covers immunizations	AI/AN 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 on what is most cost beneficial to the child and family
	A child may have private health insurance and Medicaid as secondary insurance. The

Insured, with Medicaid as secondary insurance	child is VFC-eligible if they are enrolled in Medicaid. However, the parent is not required to participate in the VFC Program. There are two options: 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 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 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)

Requirement for Manual Entry Providers:

Providers adding VFC-eligible vaccinations in TennIIS **manually,** must associate a VFC lot number from their inventory for VFC eligibility to be recorded correctly in TennIIS. Accurate VFC eligibility documentation in TennIIS is directly tied to the process of manually decrementing vaccine from a provider's inventory. At the time of entering the administered

vaccination into TennIIS, 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. Refer to the TennIIS Document Center for a Manual Entry Decrementing for VFC Providers Quick Reference Guide.

Automatic decrementing is enabled for HL7 providers; a message is sent from the EHR to TennIIS and removes a dose from inventory each time a vaccine administration data is documented.

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. The provider may bill one time for the administration fee **within 90 days of service**.
4. Providers may charge an office visit fee, in addition to the administration fee if other services were provided in addition to vaccinations.
5. Nirsevimab (Beyfortus)/Clesrovimab (Enflonsia):
   Vaccination describes the act of receiving an antigen to induce immunity through production of antibodies against a specific disease. Immunization describes the process of becoming immune, either through vaccination (described in last sentence) or through the passive receipt of antibodies, such as with monoclonal antibodies. While vaccines are considered immunizations, not all immunizations are vaccines. Nirsevimab (Beyfortus)/ Clesrovimab (Enflonsia) is considered an immunization rather than a vaccine because as a monoclonal antibody, it passively provides immunity against RSV. Nirsevimab (Beyfortus)/ Clesrovimab (Enflonsia) is part of the Vaccines for Children Program. All the CDC and VPDIP vaccine rules also apply to Nirsevimab (Beyfortus)/ Clesrovimab (Enflonsia).

3.4 Vaccine Administration Documentation

In accordance with 42 U.S.C. § 300aa–25, all VFC providers must maintain immunization records that include ALL 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 administered the vaccine
8. Address of clinic where vaccine was administered

3.5 Vaccine Information System (VIS), Vaccine Adverse Event

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.

Before administering VFC monoclonal antibody immunizing products (e.g. nirsevimab/clesrovimab), providers should provide an Immunization Information Statement. Providers should not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not yet have a VIS or Immunization Information Statement available, a provider may use the manufacturer's package insert, written FAQs, or any other document to inform patients about the benefits and risks of that vaccine. Providers may also produce their own information materials for patients. Once a VIS is available, providers should use it. If the vaccine is under an Emergency Use Authorization (EUA), providers should make the EUA Fact Sheet for Recipients available for patients.

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. Each VIS may be reviewed on a computer monitor (or any video display).

3. Each VIS 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. Each VIS may be made available to be read before the immunization visit 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.
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 CDC News & Updates | CDC.

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 Vaccine Adverse Event Reporting System (VAERS) (hhs.gov). Deaths or severe reactions possibly associated with immunization should also be reported to VPDIP by phone.

Vaccine Ordering 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 Quick Reference Guide for Receiving and Placing Orders is also available in the TennIIS Document Center 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 routinely recommended vaccines for the VFC-eligible population 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. VPDIP recommends providers maintain a four- to-six-week supply of vaccine to allow for any potential shipping delays.

1. With respect to the VFC program, if a VFC provider serves and plans to vaccinate privately insured (non-VFC-eligible) populations, they should stock a separate vaccine supply for the specific vaccines they plan to offer non-VFC-eligible patients. CDC is not

requiring VFC providers to maintain a full stock of all ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance includes, but is not limited to, RSV monoclonal antibody products. If a VFC provider does not carry privately purchased stock, they are not permitted to use VFC stock on non-VFC-eligible patients. If a VFC provider does have privately purchased vaccines in addition to public vaccines, they must clearly separate these two stocks of vaccines. Vaccine inventories do NOT have to be stored in separate units however the vaccines must be clearly labeled and separated as **VFC** vaccines and **Private/Commercial vaccines.**

2. Providers are required to reconcile their VFC inventory every month, **even if a vaccine order is not placed**.
3. Any provider who repeatedly fails to reconcile their VFC inventory monthly 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. You will automatically be taken to the reconciliation page when trying to place an order if it has been over 30 days since your last reconciliation.
5. Providers should review the Inventory Reconciliation Quick Reference Guide in the TennIIS Document Center.
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. **McKesson now requires that you report any shipping concerns with product that comes from their distribution facility direct via this phone number: 1-877-836-7123. If you receive a shipment and you are concerned about viability, please call this number immediately, and email the VOMS team at TennIIS.VOMS@tn.gov to notify us that you have made a call into McKesson directly.**
    A. Please note this does NOT include product that comes from the MERCK Distribution facility- only Mckesson. The Merck distributed products process will remain the same where you will simply email the VOMS inbox with the packing slip, photos of the inside/outside of shipping container, including any DDL photos if applicable from the shipper. This has to be reported as soon as possible (must be the same day or they will not send out a replacement) and we will contact Merck on your behalf. You will know if a shipment has come from McKesson by looking at the top left corner of your packing slip received with the 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 monthly for any orders that were not correctly received into provider inventory. Any provider who failed to accept an order into their inventory will be contacted by VPDIP. Repeated failure to accept orders into inventory will result in mandatory VOMS training and risk of suspension from the VFC program.

4.4 Vaccine Ordering and 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. A packing slip and shipping label will be emailed to the primary email on file for vaccines to be shipped back to the supplier. Expired vaccine must be returned within 30 days of expiration. To review steps for this process, reference the Submit a Return Quick Reference Guide available in the TennIIS Document Center.

4.5 Vaccine Borrowing

VFC enrolled providers are recommended to maintain a minimum of four weeks' worth of 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 VPDIP and due to extraordinary circumstances. For situations where borrowing is needed, contact VPDIP at (800) 342-1813 or TennIIS.VOMS@tn.gov to request approval.

If approved, borrowing must be documented "dose-by-dose" for each patient in the Vaccine Borrowing Redcap link. Doses borrowed from VFC inventory must be replaced within 30 days. Replacement must be documented in the borrowing form redcap link and submitted to VPDIP every month.
****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 VPDIP.**

4.6 Vaccine Transfers

It is important to report to VPDIP any VFC vaccine with short expiration dates (vaccines expiring within three months) that are unlikely to be used before they expire. This allows VPDIP 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 VPDIP. You may utilize the Vaccine Advertisement function in TennIIS under the **Orders/Transfers** to share short-dated vaccines. Please include all the requested information including vaccine details.

4.7 Vaccine Schedule

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:
Vaccines and Immunizations | CDC
The CDC Vaccine Schedule app is available on iOS and Android devices.

4.8 Vaccine Advertisement

Vaccine Advertisement page is located under the **Orders/Transfer** tab in TennIIS. This page can be used to list any excess vaccines you have that will not be used or any on hand vaccines that will expire within three months or less that may not get used by your facility. Any excess and expiring vaccine should be posted to this page. The regional RIR should also be notified. The RIR and VOMS will work to try to find a new home for the vaccines to avoid wastage. The doses will also remain in your inventory and can still be used by your facility until moved to a new location. Once a new home for the vaccine has been found, VOMS will transfer the doses out of your inventory and remove them from the Advertisement page.

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 are valued at more than $10,000; most practices have far larger inventories. Vaccines must be stored appropriately to maintain efficacy. Failure to store and manage 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 are 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 vaccines and 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. Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines).

3. A stand-alone household frost-free refrigerator (a self-contained unit that only refrigerates).
4. A stand-alone automatic defrost freezer.
5. 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: Manual Defrost Freezer Units.pdf (tn.gov)
6. A pharmaceutical grade combination unit

VPDIP 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 VPDIP for review and approval prior to vaccine being placed in the unit(s). In addition, any time a vaccine storage unit is moved (i.e., to a different outlet, room, or location) two days of digital data logger temperature readings must be sent to temperature.health@tn.gov for review prior to VFC vaccine storage in that unit.

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 the vaccine at a high risk of freezing
3. Household refrigerator/freezer units that may be **converted** to a refrigerator or freezer

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 **Do Not Unplug** warning labels on both the plug and circuit breaker for each storage unit. **Do Not Use** 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

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

5.3 Temperature Monitoring Devices

VFC providers are required to use a digital data logger (DDL) with continuous temperature monitoring capability and a current / valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing VFC vaccines. DDLs must be used during on-site vaccine storage, vaccine transport, and mass vaccination clinics. A DDL is required to always be with the vaccine! 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
    - Ultracold freezer low alarm (too cold) set to trigger after 15 consecutive minutes below -90°C
    - Ultracold freezer high alarm (too warm) set to trigger after 60 consecutive minutes above -60°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) set to 5-minute increments with a maximum interval of 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.

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 are performed twice each day. A back-up DDL must be readily available in case a DDL in use is no longer working, calibration testing of the current DDL is required, or emergency vaccine transport 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 the VFC Vaccine Storage Unit & DDL Guidance document for more details.

DDL reports MUST be printed, reviewed, and signed by the Primary or Backup Coordinator EVERY week. They should be kept for three years for documentation per the CDC.

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 evaluated 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 VPDIP or a 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 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 and recorded for each vaccine storage unit manually twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are also reviewed and recorded 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 **twice daily** temperature readings on the Vaccine

Storage Unit Digital Data Logger Sign-off Sheet so that the identity of the person checking the temperatures is recorded. If the DDL report can document the initials of the person completing the twice a day reading, the sign- off sheet does not need to be completed.

Refrigerators should always maintain temperatures between 2°C and 8°C. 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. Vaccine that is stored in an ultra-cold freezer should be stored between -80°C and -60°C.

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 or ultracold freezer is outside the -60 C to -90 C range **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. Ultracold freezer temperature is below -90°C for > 15 consecutive minutes.
5. Ultracold freezer temperature is above -60°C for > 60 consecutive minutes.

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 VPDIP for any planned or unplanned power outages as soon as possible.

5.8 Reporting a Temperature Excursion (TE)

Beginning July 2025, temperature excursions must be reported by clinic staff to the vaccine manufacturers directly for viability evaluation. Once evaluated, VFC and VFA (317) providers are then required to report the viability recommendations from the manufacturer to Tennessee Department of Health through the Temperature Excursion Evaluation and Reporting Form REDCap survey. Please see the TennIIS Document Center for additional resources on this process:

5.9 Unreported Temperature Excursion

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:

- Provider will need to submit **weekly** temperature logs to their RIR for **four weeks** and then **monthly for the next five months**.
- RIR will conduct an Education Visit for the Certifying Provider (Agreement Signatory) and Primary and Back-up Vaccine Coordinators.
- Provider may be required to service or purchase a new unit. If so, vaccine orders will be placed on hold. The invoice and two days of temperatures will need to be sent to Temperature Health at Temperature.Health@tn.gov for approval before approval is given to store VFC vaccine in unit.
- If there was vaccine loss, the provider may receive an Unannounced Storage and Handling Visit during the six-month period.

- ❖ 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 VPDIP will notify TennCare.

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 managed 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 (Agreement Signatory) listed on the Provider Agreement should not be designated as the Primary or Back-up VFC Contact because the provider normally does not conduct 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:

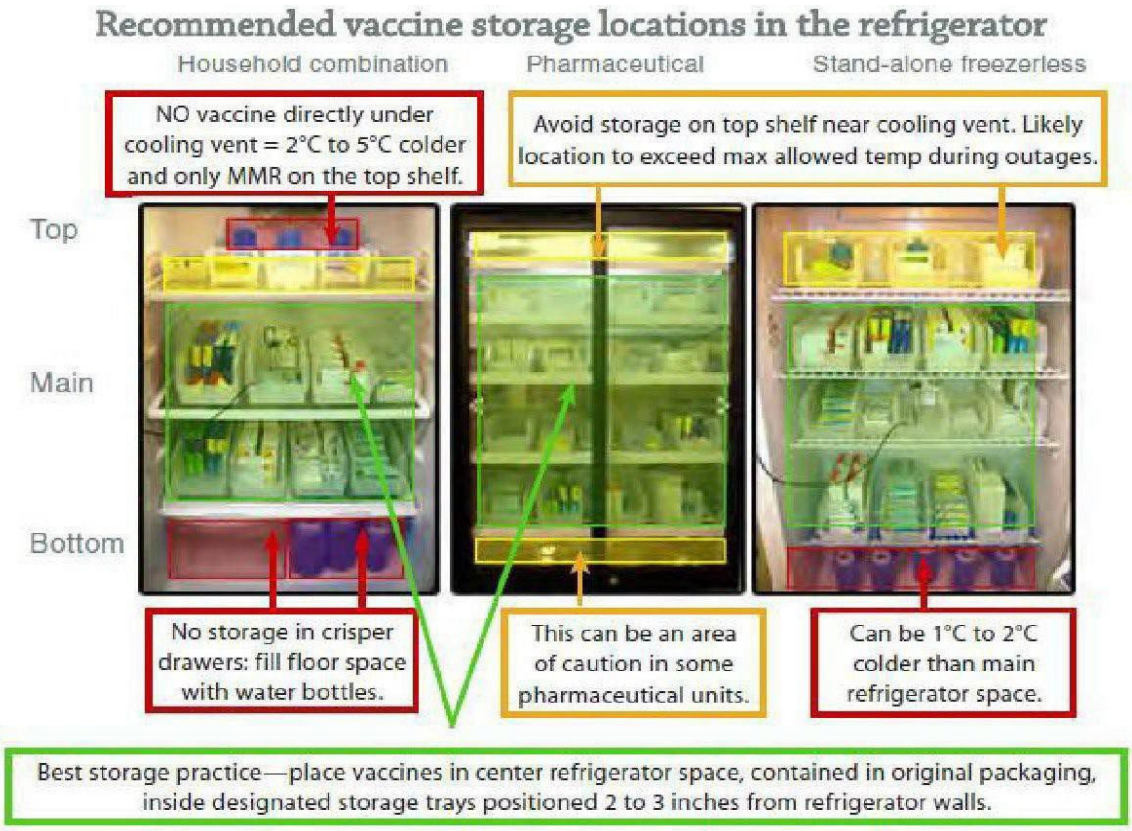
1. Ordering vaccines
2. Overseeing proper receipt and storage of vaccine deliveries
3. Documenting vaccine inventory information
4. Organizing vaccines within storage units
5. Setting up temperature monitoring devices
6. Reading and recording storage unit temperatures a minimum of two times (morning 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 datalogger report** foreach 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 Routine and Emergency Vaccine Management Plan (REVMP)

VFC providers are required to develop, maintain, and implement a Routine and Emergency Vaccine Management Plan (REVMP). 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
3. Temperature monitoring
    - ❖ Vaccine storage
    - ❖ Vaccine shipment receiving procedures: **Facilities must provide one day of four consecutive hours for shipping times for any day but Monday**
4. Vaccine ordering procedures
5. Inventory control (e.g., stock rotation)
6. Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
7. Manual Defrost Plan for providers that don’t have an automatic defrost freezer.
8. For providers that do not have the non-routine ACIP recommended vaccines in their inventory, a referral plan needs to be added, for patients who require these vaccines.
9. For providers that do not serve privately insured patients, a referral plan needs to be available if a patient’s insurance status changes.
10. Documentation of staff training on all plan elements
11. Recorded review date within the last 12 months
12. 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. In addition, if medications and biologicals are stored in the same storage unit; they should be marked and stored **below** the vaccines (blood, urine due to risk of contamination from drips, leaks, or spills.
5. Place water bottles throughout refrigerator and freezer storage units (not required for pharmaceutical grade units) to:
    - ❖ Stabilize and 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/back up battery power source) and a security system to alert personnel in the event of a power outage.
13. If applicable, test back-up generators/back up battery power source quarterly and service at least annually (check manufacturer specifications for test procedures and maintenance schedules). Document the quarterly tests and annual service on pages 15 & 16 of the REVMP.
14. Vaccines should be prepared immediately prior to administration. CDC and VPDIP 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

- **Contacts at alternate or back-up storage locations must be contacted annually and agree to accept vaccines during an emergency.**
- **All emergency backup locations must be VFC providers.**

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 2 to 8ºC, for refrigerated vaccines, for a specified number of hours or the use of the CDC emergency transport vaccine qualified pack-out). A DDL must always remain with the vaccine, including during transport. Vaccine Transport Logs should be completed.

The Routine and Emergency Vaccine Management Plan template may be found here: REVMP.pdf (tn.gov)

Quality Assurance Visit

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

7.1 Enrollment Visit

Enrollment Visits are required for newly enrolling providers. 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 Visit

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 all 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 annual education. This requirement may be met by participating in a VFC Compliance or Education Visit with both primary and back up contacts in attendance in the previous 12 months, or by completing the current version of the CDC's online CDC *You Call the Shots* training modules annually Vaccine Storage and Handling (module 10) and Vaccines for Children (module 16) (updated in January of each year).

7.5 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 strategies designed to increase on-time immunization among children 0-18 years of age in adherence to the Advisory Committee on Immunization Practices' (ACIP) -recommended immunization schedule.

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 the childhood series. 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 immunization coverage assessments of at least two cohorts- birth, childhood, adolescent, or older teen cohorts. Coverage rates are shared with the provider and staff during the initial IQIP site visit. The RIR and provider then discuss four core strategies to improve immunization service and raise coverage rates for children and adolescents.

These four core strategies include:

1. Facilitate return for immunization
2. Leveraging IIS, HER, or Electronic Systems to improve immunization practice
3. Give a strong immunization recommendation (emphasize HPV vaccine if provider has adolescent patients)
4. Strengthen Immunization Communications to Address Vaccine Hesitancy

During the 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, one of which must be either Give a Strong Immunization Recommendation or Strengthen Immunization Communications to Address Vaccine Hesitancy.

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 TennIIS 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 TennIIS. A Manage Patient Population Quick Reference Guide is available in the Document Center of TennIIS and provides step-by-step guidance on how to inactivate patients in bulk. Practices with an electronic connection to TennIIS may upload historical immunizations from their EHR. Email the TennIIS team at TennIIS.MU@tn.gov with a subject line of "VFC Backloading" for details.

Temporary, Mobile, Off-Site, or Satellite Clinics

Under the conditions outlined below, VFC providers may conduct temporary, mobile, off-site, or satellite clinics. The VFC Program may also collaborate with community vaccinators. These opportunities can improve access and vaccination coverage. Interested VFC providers should reach out to their RIR regarding submitting a plan for the clinic and/or submit a plan during annual VFC re-enrollment. The plan must cover all the requirements listed in the section below.

This 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 clinic must comply with all VFC Program requirements, including screening and documenting VFC eligibility. They also must maintain enhanced practices for storage and handling, which include:

1. The immunization records from the clinic must be available for review during site visits.
2. Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement. Vaccines may only be transferred to the mobile unit on the day of the clinic.
3. Clinics may only be conducted within the state of Tennessee; VFC-eligible children are not required to be TN residents.
4. Providers should base the number of VFC vaccines transported to a temporary, mobile, off-site, or satellite clinic on the expected anticipated number of VFC-eligible children who will be served.
5. The provider must complete the Vaccine Transport Log 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.
6. The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours unless guidance from the manufacturer differs (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
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 8°C; freezer temperature consistently colder than minus (-15°C). 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.

- ❖ 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.

8. Only staff that have completed VFC training may transfer vaccines between the provider's practice and the mobile unit.
9. Upon arrival at the clinic site, the mobile clinic staff must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:
    - ❖ Staff should immediately plug the portable refrigerator into the power outlet.
    - ❖ Since the vaccine is at a temporary location, temperature data must be reviewed and documented **every hour** during the clinic using a DDL.
    - ❖ The Vaccine Transport Log is required to be completed at the beginning and the end of the transport. During transport the temperatures are required to be documented on the hourly Vaccine Temperature Log.
10. 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 Temperate 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 VPDIP needs to be contacted in accordance with TE procedures described elsewhere in this guide.
    - ❖ Temperature logs from the mobile immunization clinic must be stored with the primary clinic logs and kept on file for three years.
11. 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 collaborating 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.

12. VFC Providers that conduct 1-9 offsite clinics per year will be required to submit Vaccine Transport Logs and Hourly Temp Logs from all clinics conducted within the last year during annual re-enrollment. VFC Providers that conduct 10 or more offsite clinics per year will be required to participate in annual VFC Compliance Visits. This documentation will be reviewed during the visit.

Best practices for vaccine handling during a temporary, mobile, off-site, or satellite clinic include the following:

- Not drawing up vaccines before arriving at the clinic site
- Not pre-drawing doses at the clinic site before they are needed
- Using manufacturer-filled syringes, if possible, instead of pre-drawing vaccines
- Pre-drawing at the clinic no more than one multidose vial (MDV) at one time
- Monitoring patient flow to avoid drawing up unnecessary doses
- Discarding any remaining vaccine in pre-drawn syringes at the end of the workday

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