

2023-2024

VFC Provider Handbook

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



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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.





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

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:

Protect, Promote, and Improve the Health and Prosperity of People in Tennessee

Our Vision:

Healthy People, Healthy Communities, Healthy Tennessee

Core Values:

- Collaboration
- Equity
- Excellence
- Compassion
- Integrity
- Respect

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

VPDIP Contact Information

VFC Enrollment and Operations		
Contact for general VFC	Phone: (800)342-1813	
enrollm ent questions, to	Fax: (615)401-6831	
report a facility change, or	Email: <u>VFC.Enrollment@TN.gov</u>	
update the Primary and		
Back-up VFC Contacts		
VFC Quality Assuranc e Tea	am Phone: (000)342-1013	
Contact for VFC vaccine	Fax: (615)401-6829	
storage and handling issues,		
VFC compliance questions or	Email: <u>VFC.Help@TN.gov</u> (VFC Questions)	
Concerns, VFC report Card and training webinars.		
Temperature Excursions	Email: <u>Temperature.Health@TN.gov</u> (TEs)	
Vaccine Ordering Mana	agement System (VOMS)	
Contact for vaccine ordering,	Phone: (615) 532-8511 (Public Health	
inventory, reconciliation,	Departments) (800-342-1813)(All other	
returns, supply issues, VOMS	VFC Providers)	
training and VOMS user	Email: <u>TennIIS.VOMS@TN.gov</u>	
permissions.		
TennIIS Help Desk		
Contact for general TennIIS	Phone: (800)342-1813	
assistance.	Email: <u>TennIIS.Help@TN.gov</u>	
TennIIS Facility Registratio	n and User Manageme nt	
Contact to register a facility	Phone: (800) 342-1813	
in TennIIS, to add or	Email: TennIIS.Registration@TN.gov	
inactivate users, or to apply	Website: https://www.tennesseeiis.gov	
TennIIS user permissions.	Redcap Link: Portal Registration (tn.gov)	
TennIIS Training		
Contact for information and	Phone: (800)342-1813	
training opportunities for	Email: <u>TennIIS.Training@TN.gov</u>	
TennIIS patient		
management, clinical and		
immunization questions.		

TennIIS Interoperability Team	
Contact about establishing	Phone: (800)342-1813
an interface between your	Email: TennIIS.MU@TN.gov
Electronic Health Record	
(EHR) and TennIIS.	
VFC Fraud and Abuse Prevention	
	Phone: (800)342-1813
Contact VPDIP to report concerns about misuse or mishandling of VFC vaccines. Reports may be anonymous; all are confidential.	Fax: (615)253-3279
	Email: <u>VFC-Fraud.Health@TN.gov</u>
	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

VFC Program Resources for VFC Providers

TDH VPDIP website	Documents and forms referenced in the VFC Provider Handbook can be found under VFC Guidance & Toolkits on the VPDIP 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
TennIIS Registration Portal	PortalRegistration (tn.gov)
VFC Enrollment Portal	https://redcap.link/vfcenrollment

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, Physician Assistants Providers enrolling in the VFC Program agree<u>to all</u> <u>conditions</u>

containedin the Provider Agreement andthis handbook.

and Pharmacies, 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, provide prescribers full name, medical license number, and NPI number along with a

copy of the Cooperative Agreement.

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 <u>TennIIS</u>; 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 <u>link</u> and refer to the Enrollment Walkthrough Guide for detailed instructions on completing the enrollment process.

- 1. Complete the online Redcap Facility Registration Application Portal Registration (tn.gov) to register new facility and add user account: <u>https://redcap.link/vfcenrollment</u>
 - a. To register a new facility in TennIIS, complete the TennIIS Facility
 -Registration application on the public TennIIS homepage at
 <u>Portal Registration (tn.gov)</u>
 - 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 <u>TennIIS.Registration@tn.gov to</u> request one.
- 2. Complete the online RedCap VFC Enrollment Portal <u>https://redcap.link/vfcenrollment.</u>
- 3. Email the VFC Enrollment team at <u>VFC.Enrollment@tn.gov</u> with your facility information and your intent to enroll in the VFC Program.

- 4. Training requirements for all new VFC clinics:
 - a. 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.
 - b. 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).
 - 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: <u>Vaccine Storage and</u> <u>Handling</u> and <u>Vaccines for Children</u>. Must be completed for all new enrollees and signatories and may be completed for annual education. A Certificate of Completion must be submitted to VPDIP as proof. The modules can be accessed at: <u>Welcome to TCEO (cdc.qov)</u>
- 5. Complete a Routine and Emergency Vaccine Management Plan (REVMP).
- 6. Complete the online Provider Agreement in TennIIS.
 - 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 on e 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.

- 7. **Submit required documentation** Upload in the VFC Enrollment Redcap Survey here <u>https://redcap.link/vfcenrollment</u>
- 1. CDC You Call the Shots Training certificates of completion for the Agreement Signatory and Primary and Back-up coordinators
- 2. Print and sign 3-page Provider Agreement Signature
- *3. Routine and Emergency Vaccine Management Plan(REVMP)*
- 4. Upload <u>two</u> days of DDL temperature readings for each vaccine storage unit to <u>Temperature.Health@tn.gov</u> for review and approval.

5. 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

- 8. 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.
- 9. 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.
- 10. 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 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 numbersannually.**

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. These records include:

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



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.

EOCS

1.6 Changes in Staff/Facility Status

Providers are required to contact the VFC Program by email (<u>VFC.Enrollment@TN.gov</u>) or fax (615-401-6831) 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 <u>within 48 business hours</u>. A valid Provider Agreement is required to continue participation in the

VFC Program; non-compliance will result in VFC vaccine retrieval.

- New vaccine coordinators must complete the CDC You Call the Shots training modules (Vaccines for Children and Vaccine Storage and Handling) 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 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 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 <u>30 days</u> of the departure of the former Coordinator
 - The Primary Vaccine Coordinator is required to train the Back-Up Vaccine Coordinator
- 3. Listed medical providers, report within 10days
- 4. Mailing/shipping address, report within 10days
- 5. Vaccine delivery hours, report within 10days
- 6. Facility status (e.g., closure, merge, moving)

• Changes to the facility status must be reported at least **<u>10 business days</u>** 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 a facility is located.

Providers must complete re-enrollment within <u>60 days</u> prior to the expiration of their current Provider Agreement. The Phased Enrollment Schedule is in the Document Center in TennIIS and <u>Appendix B</u>.

- 1. The Primary Vaccine Coordinator will receive an annual reenrollment reminder email and alert message in TennIIS 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 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, including both the Primary and Backup Coordinators, or Education Site Visit, OR
 - Complete both CDC You Call the Shots training modules

 (Vaccine Storageand Handling and Vaccinesfor Children) for
 the current enrollment year. The modules can be accessed
 at: <u>https://www.cdc.gov/vaccines/ed/voucalltheshots.html</u>
- 3. Complete and sign pages 2, 13, 14 and page 17 of the REVMP.

- 4. Upload the required documentation to the VFC Enrollment Redcap <u>https://redcap.link/vfcenrollment</u>.
- 1. Training records for the Primaryand Back-up VFC Coordinators (either Certificates or Completion for the CDC <u>You Call the Shots</u> training modules or verification of participating in a VFCCompliance Visit or VFC Education Visit n the past 12 months),
- 2 Routine and Emergency Vaccine Management Plan (REVMP)
- 3. 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
- 4. Three-page signed Provider Agreement
- 5 If a Pharmacy, must provide a cooperative agreement

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

Facility Request	A facility closed or withdrawals from the VFC program must provide VPDIPat least 10 business day notice written notice to allow time for VFC Vaccine to be retrieved by the RIR. Notice may be emailed to <u>VFC.enrollment@tn.gov</u> or faxed to (615)401-6831
Failure to comply with program	A facility that falls 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 removed from the program and required tore- 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.

VPDIP 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.

1.9 Generators

- If you do not have a generator, you will need <u>two</u> VFC providers for your emergency backup locations.
- 2. If you do have a generator, you will need 1 emergency backup location.
 - a. The emergency backup facility MUST be a VFC Provider
 - b. For facilities who have two emergency backup locations, please read Section 1.10
- 3. The VFC Program will approve <u>portable generators</u> with the following information provided on Page 14 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
- 4. If you have an approved generator, page 14of the REVMP MUST be filled out and signed, documenting quarterly testing and annual service.
 - 1. If your facility has two emergency backup locations, the first backup facility

MUST be a VFC Provider.

• This location cannot be in another state.

2. If you cannot find a VFC Provider to be your second emergency backup location

- Ask your RIR to assist
- Your second location may be a Store Only Facility with approval

1.10 Store Only Backup Locations

- 1. All Store- Only Backup locations must enroll as a VFC Store- Only Provider via the Redcap Link: <u>https://redcap.link/vfcenrollment</u>
 - Click on Enroll as a Store Only Facility
 - 2 Once approved, this facility will have asitevisit.
- 3 Store Only locations must have an Agreement Signatory, Primary Vaccine Coordinator, and a Backup Coordinator

a. Both Agreement Signatory, Primary Vaccine Coordinator and Backup Coordinator must complete the You Call the Shots Modules 10 & 16 along with the appropriate Covid Modules if necessary.

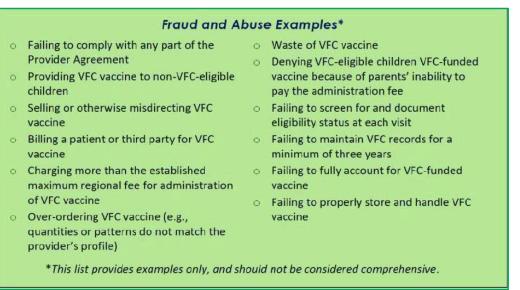
- 4 Submit required documentation via: <u>https://redcap.link/vfcenrollment</u>
 - 1. Training records for the Primary and Back-up VFC Coordinators (either Certificates or Completion for the CDC <u>You Call the Shots</u> training modules or verification of participating in a VFC Compliance Visit in the past 12 months),
 - 2. Routineand Emergency Vaccine Management Plan(REVMP)
 - 3. Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit current Notice of Award from the USDepartment of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates
 - 4. Three-Page signedProvider Agreement
 - 5. If a Pharmacy, must provide a cooperative agreement

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.



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

- Written report Print and complete the <u>VFC Provider Fraud Report form</u> (<u>PH-</u> <u>4130</u>). Submit the completed form (PH-4130) to the Tennessee Immunization Program by fax, e-mail, or mail.
 - Fax: (615)253-3279
 - E-mail: <u>VFC-Fraud.Health@tn.gov</u>
 - 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.
- 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 <u>Office of the</u> Inspector General (OIG) Exclusions Program webpage.

3. 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:

 Medicaid-eligible – For the purposes of the VFC Program, the terms "Medicaideligible" 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 (Al/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 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 underinsurance status. Please refer to our insurance "Cheat Sheet" in AppendixL.

*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 ACIPrecommended 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, even though CoverKids may be managed by a TennCare MCO, the CoverKids children are NOT eligible for VFC.

Insured exceptions include (<u>Appendix C</u>):

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

Insured, with Medicaid as secondary insurance A child may have private health insurance and Medicaid as secondary insurance. The 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.

32 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 <u>Patient</u> <u>Eligibility Screening Record</u> (Appendix D), 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 <u>Appendix E</u> for a Manual Entry Decrementing for VFC Providers Quick Reference Guide.

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

33. 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.
- 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 <u>90 days</u> of service.
- 4. Providers may charge an office visit fee, in addition to the administration fee.

34. 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
- Name and title of person who administered the vaccine.
- 8. Address of clinic where vaccine was administered.

This requirement is only applicable to Direct Data Entry providers. Automatic decrementing is enabled for HL7 providers; a message is sent from their EHR to TennIIS and removes a dose from the inventory each time vaccine administration data is documented.

35. 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 provide 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 <u>https://www.cdc.gov/vaccines/hcp/vis</u>.

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 <u>http://www.vaers.hhs.gov</u>. Deaths or severe reactions possibly associated with immunization should also be reported to VPDIP 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 <u>TennIIS homepage</u> under the TennIIS Training tab. A <u>Create, Submit and Receive Vaccine Orders</u> Quick Reference Guide is also available to assist in the process. Questions regarding this process may be sent to the VOMS team at <u>TennIIS.VOMS@TN.gov</u>.

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. VPDIP 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 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 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 by the due date 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.

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 VPDIP immediately (within 2 hours) at (800) 342-1813. It is critical that VPDIP contact McKesson the same day the vaccine arrived at the provider 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 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.

4.4VFC 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. 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 60 days. To review steps for this process, reference the <u>Returning Vaccines</u> Quick Reference Guide available on the TennIIS homepage.

Influenza vaccine orders are entered into the provider's inventory as doses arrive. The lot numbers are then available to reconcile as expired and returned as with all VFC vaccines. UPS will email a return label within 72 hours.

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 VPDIP and due to

extraordinary circumstances. For situations where borrowing is needed,

contact VPDIP at (800) 342-1813 to request approval.

If approved, borrowing must be documented "dose-by-dose" for each patient on the <u>Vaccine Borrowing Form</u> (Appendix F). Doses borrowed from VFC inventory must be replaced within 30 days. Replacement must be documented on the borrowing form 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 contact details.

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 <u>the CDC website at</u>: <u>https://www.cdc.gov/vaccines/index.html</u> 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 3 months or less that may not get used by your facility. You will post excess vaccine to this page and notify your RIR. Then 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.

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 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 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
- 5. 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 send DDL reports to <u>temperature.health@tn.gov</u> or fax 615-401-6829.

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. 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 onsite 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:

- 6. A detachable, buffered probe (or digitally buffered device that mimics a buffered probe)
- 7. 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) 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 <u>smaller</u> 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 dependable as a DDL in monitoring vaccine temperature. Providers with these type units must have a back-up data logger if emergency vaccine transport is required.
- Contact VPDIP to determine if such a unit is capable of meeting VFC

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, 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 <u>Appendix G</u> for a guide for selecting a DDL.

54 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:

- 8. 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)
 - An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been evaluated correctly according to

international standards. 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)
- 9. An entity that provides documentation demonstrating the calibration testing performed meets ISO/ IEC 17025 international standards for calibration testing and traceability. Certificate mustinclude 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 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 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 **twice daily** temperature readings on the <u>Vaccine Storage Unit Digital Data Logger Sign-off Sheet</u> (Appendix Q) 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.

DDL reports MUST be printed, reviewed, and signed by the Primary or Backup Coordinator EVERY week

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 -90°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 \geq 15 consecutive minutes.
 - Temperatures below 0°Cquickly damages vaccine. Quick action may save vaccine.
- 2. Refrigerator above 8° C for ≥ 60 consecutive minutes.
- 3. Freezer above- 15° Cfor ≥ 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.
- 6. TE is part of a pattern of frequent excursions, regardless of duration.
- 7. There is concernabout 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 VPDIP for any planned or unplanned power outages as soon as possible.

5.8 Reporting a Temperature Excursion (TE)

When a TE is identified, VPDIP 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.

1. Attempt to return vaccine to proper storage conditions: 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 the vaccine; label "Do Not Use until Notified by VPDIP" (Appendix H) • Do not administer vaccine untilapproved by VPDIP! Immediately call VPDIP(if during business hours) 4. If instructed by VPDIP, 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)

- 1. Troubleshoot can you identify why it went out of range?
- 2. Quarantine the vaccine; label "Do Not Use until Notified by
- 3. VPDIP." Do not use any vaccine until approved by VPDIP!
- 4. Immediately call VPDIP, 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 <u>Temperature.Health@tn.gov</u>

1. ľ	f the unit is out-of-range and it cannot be returned to proper temperature,
t	ransfer the vaccine to the designated backup location listed in your REVMP.
•	For packing instructions, see <u>Appendix I</u> . A DDL must always be with the
	vaccine during transport and at the backup location and checked every hour
	that the vaccine remains in the transport cooler.
2. ľ	f the unit is back in-range:
•	Quarantine the vaccine; label "Do Not Use Until Notified by VPDIP"
3. 0	Contact Temperature Health the next business morning to report
t	he Temperature Excursion (TE).
•	If the vaccine needs to be used before the next business day do one of the
	following (still required to call Temperature Health, the next business
	morning):
	i. Contact vaccine manufacture's customer service lines directly to report
	the problem to obtain guidance.

5.9 Unreported Temperature Excursions:

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

- Provider will need to submit weekly temperature logs to their RIR for <u>four weeks</u> and then <u>monthly for the next five-</u> <u>months.</u>
- 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 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 Temperature Health at <u>Temperature.Health@tn.gov</u> or faxed to 615-401-6829 for approval before approval is given to store VFC vaccine in unit.
- If there was vaccine loss, the provider will 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.

6.Vaccine Management

61. 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** for each vaccine storage unit
- 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
- Primary VFC Contact is responsible for providing training to the Back-up Contact

62 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.
 - Facilities must provide <u>two days</u> of <u>four consecutive hours</u> for shipping times, excluding Fridays.
- 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)

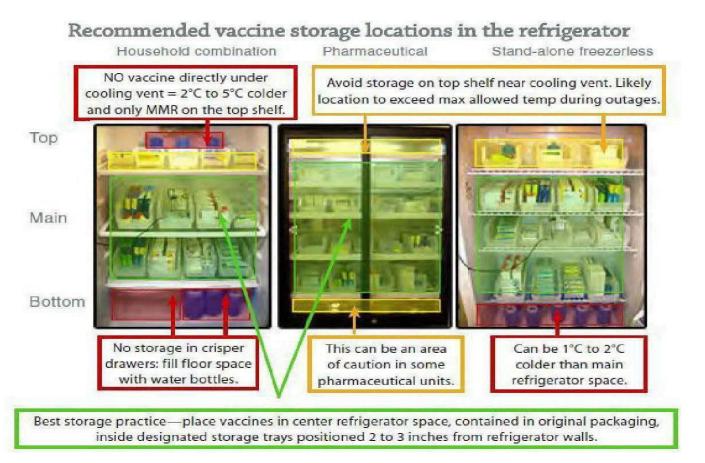
6. Manual Defrost Plan for providers that don't have an

automatic defrost freezer.

- 7. For providers that do not have the non-routine ACIP recommended vaccines (i.e., P n e u m o v a x 2 3 [PPV23] and Meningococcal B [MENB]) in their inventory, a referral plan needs to be added, for patients who require these vaccines. Single doses of these vaccines may be ordered through VOMS.
- 8. For providers that do not serve privately insured patients, a prior approved 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



63 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:

- 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 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 NOTUSE."
- 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 servicing on page14 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.

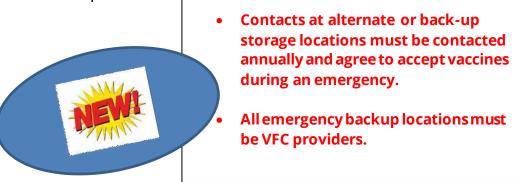
64 Emergency Vaccine Storage and Handling Plan

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 8°C, for refrigerated vaccines, for a specified number of hours or the use of the <u>CDC emergency</u> transport vaccine qualified pack-out (<u>Appendix I</u>). A DDL must always remain with the vaccine, including during transport. <u>Vaccine Transport Logs</u> (<u>Appendix M</u>) should be

completed.



Routine and Emergency Vaccine Management Plan template may be.

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

7. Quality Assurance Visits

Federal and state requirements mandate that VPDIP 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 <u>all</u> 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: <u>Vaccine Storage and Handling</u> and <u>Vaccines for Children</u> (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 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 knowledgably 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-year-old adolescents, using immunization data from the provider's active patients in TennIIS. Children are assessed based on their completeness of the 4:3:1:3:3:1:4 series(4 DTAp, 3 Polio, 1 MMR, 3 Hib. 3 Hep B, 1 Varicella, 4 PCV), 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 sit 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 vaccination.
- 2. Leveraging TennIIS functionality to improve immunization practice
- 3. Give a strong vaccine recommendation (emphasize HPV vaccine if provider has adolescent patients)

4. Strengthen vaccination communications

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:

- **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.

7.6 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 VPDIP 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, and in the future the RIR contacts the VFC Primary Contact via telephone if opportunities for data quality improvement have been Identified(This has not yet been set a Go-Live date). VPDIP 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. <u>All</u> <u>staff listed on the Provider Agreement will receive the quarterly report card.</u> 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. Interested VFC providers should reach out to their RIR regarding submitting a plan for the mobile clinic. The plan must cover all the requirements listed in the section below.

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 initial storage and handling site-visit.
 - Any staff participating in the mobile immunization clinics must pass an *Initial and annual* VFC Compliance Visit
 - 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 <u>Mobile Immunization Clinic Log</u> (<u>Appendix J</u>) 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 8°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 (<u>Appendix K</u>).
- 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 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. The vaccines must not be used until VPDIP 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 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.

All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42US 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 vaccine was administered.
- Publication date of VIS
- Date VIS given to parent/guardian.
- **13.** All immunizations must beentered in TennIIS within <u>two weeks</u>

of administration.

- 14. 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.
- 15. 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 mayresult in withdrawal of approval for use of VFC vaccines in the mobile clinic.

9.0 Community Vaccination Clinic

Community vaccination clinics can improve access to vaccines for VFC-eligible and privately insured children. However, these clinics require additional program oversight and vaccine accountability. Interested VFC Providers should reach out to their RIR regarding submitting a plan for the community vaccinator clinic. The plan must cover all the requirements listed in the section below. Community vaccination Clinics 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 Community vaccination Clinic must enroll in the VFC Program.
- 2. The Community vaccination Clinic's office must pass an initial and annual VFC Compliance Visit.
 - 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 community 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 Community vaccination Clinics 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 Community vaccination Clinic 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 Community vaccination Clinic must annually complete the CDC You Call the Shots trainings.
- 6. The Community vaccination Clinic 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 (<u>Appendix J</u>) that lists the clinic dates, locations, and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each community vaccination clinic.
- 8. The following steps are required to be completed/conducted the day of the community 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 Vaccine Transport Log (<u>Appendix M</u>) 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. (<u>Appendix K</u>).
 - 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 Temperate Log prior to the vaccine being returned to the office's stand-alone refrigerator(s).

• 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. The vaccines must not be used until VPDIP has verified that the vaccines are usable.

- Temperature logs from the Community 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 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. The Eligibility Screening Form can be sent up to 30 days prior to the scheduled clinic date but <u>must be in the same month</u>. 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 vaccine was administered
 - 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: <u>http://www.cdc.gov/vaccines</u> 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/storag e- handling-toolkit.pdf
Immunize.org	Evidence-based vaccine information, VIS in multiple languages, "Ask the Experts", free print materials, information on vaccine-prevent able diseases, and much more. Website: <u>http://www.immunize.org</u>
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



2024 VFC Annual Phased Re-Enrollment Schedule



VFC providers have 60 days prior to the expiration of their current Provider Agreement (PA) to complete annual reenrollment. 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 TennIIS Document Center.

Documentation for VFC Enrollment can be scanned to <u>VFC.Enrollment@tn.gov</u> or faxed to 615-401-6831. After submission of all required documentation and the electronic Provider Agreement in TennIIS, 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 <u>VFC.Enrollment@tn.gov</u> or at 800-342-1813.

LOCAL HEALTHDEPARTMENTS- Agreement <u>Expires</u> on March 4th 2024 All local health departments (LHDs)

EAST TN Region & KNOXCo. Metro – Agreement Expires on April 1st 2024						
01 - Anderson	15 – Cocke	47 – Knox – <u>Metro</u>	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-CUMBERLANDRegion – Agreement Expires on May6th 2024						
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& SOUTHCENTRALRegions, & SULLIVANCo. Metro- Agreement Expires on June 3rd 2024						
02 – Bedford	30 – Greene	46 – Johnson	59 – Marshall	82 – Sullivan – <u>Metro</u>		
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 & UPPERCUMBERLANDRegions, & HAMILTONCo. Metro – Agreement Expires on July1st 2024						
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 – <u>Metro</u>	61 – Meigs	72 – Rhea	93 – White		

	SHELBYCO. Metr	o – Agreement <u>Expires</u>	on October 7 th 2024	
79 – Shelby – Metro				

WEST TN Region & MADISONCo.Metro – Agreement Expires on November4 th 2024					
03 – Benton	20 – Decatur	35 – Hardeman	40 – Henry	57– Madison – <u>Metro</u>	
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. Metr	o – Agreement <u>Expires</u>	on December 2nd 202 4	t i
deen	Motro				

19 – Davidson – <u>Metro</u>

Tennessee Department of Health (TDH) • TennesseeVaccine-Preventable Diseases and Immunization Program (VPDIP) • VaccinesForChildrenProgram(VFC)

710 James Robertson Pkwy • AJT, 3rd Floor • Nashville, TN 37243

Appendix C: Examples of Insured Exceptions

INSURED EXCEPTIONS

Al/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 <u>full immunization benefits</u> 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 D: Patient Eligibility Screening Record

longer depending VFC eligibility scre status has not cha	on state law. The r eening and docume inged. While verific	ecord may be com entation of eligibility ation of responses	pleted by the pa y status must tak s is not required,	ations must be kep rent, guardian, indiv e place with each in it is neœssary to re st capture all reporti	idual of record, nmunization vis tain this or a sin	or by the health ca it to ensure the chi nilar record for eac	are provider Id's eligibilit
					ig contentente		
2. Child's Date of	Last Name of Birth:/	,	First I	lame		MI	
	ian/Individual of Re	ecord:					_
4. Primary Provi	der's Name:	Last Name		First Name		MI	
4. Thinkiy 1100	Last Na	ame	First	Name		М	
ine tr e preg	A		VFC Vaccine C	ible for federal VFC	-	eligible for VFC	Vaccine G
Date	Medicaid Enrolled	No Health Insurance	American Indian or Alaskan Native	*Underinsured served by FQHC, RHC or deputized provider	Has health insurance that covers vaccines	**Other underinsured	***Enroll CHII (Cover
							2
covered by insurance. Clinic (RHC) or under program in order to va ** Other underinsured	In addition, to receive an approved deputized coinate underinsured o are children that are un	VFC vaccine, underins I provider. The deputiz hildren. nderinsured but are no	sured children must l red provider must ha t eligible to receive fi	only covers specific vac be vaccinated through a ve a written agreement ederal vaccine through t s are provided by the sta	Federally Qualified with an FQHC/RHC he VFC program b	I Health Center (FQHC C and the state/local/te ecause the provider of	:) or Rural Hea mitorial immur facility is not :
covered by insurance. Clinic (RHC) or under program in order to va "" Other underinsured FQHC/RHC or a depu """Children enrolled in	In addition, to receive an approved deputized coinate underinsured of are children that are un tized provider. Howeve separate state Childre	VFC vaccine, underins I provider. The deputiz hildren. Inderinsured but are no er, these children may m's Heatth Insurance F	sured children must h zed provider must ha t eligible to receive f be served if vaccine Program (CHIP). The	e vaccinated through a ve a written agreement ederal vaccine through t	Federally Qualified with an FQHC/RHC he VFC program b ate program to cove red insured and an	I Health Center (FQHC Cand the state/local/te ecause the provider of er these non-VFC eligi e not eligible for vaccin) or Rural Hea mitorial immun r facility is not a ble children.

https://www.tn.gov/health/cedep/immunization-program/ip/vfc/vfc-provider-guidance.html

Tennessee Vaccine-Preventable-Diseases and Immunization Program



Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

Description of this guide:

This guide includes instructions for automatic decrementing for providers who submit data via Direct Data Entry (DDE) to the TennIIS IWeb Portal. A description of the changes to current TennIIS processes, troubleshooting tips, and the addition of Correct Lot Decrementing are also included.

Included in this guide:

- <u>Current Processes</u>
- <u>Automatic Decrementing via DDE</u>
- <u>Correct Lot Decrementing</u>
 - o <u>Common Decrementing Errors</u>
 - o <u>Correct Decrementing Module</u>
- Patient Detail Report
- Updates to Inventory Reconciliation
- Contact Information



Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

Current Processes

Providers with vaccine inventory in TennIIS are currently responsible for:

- Creating, Submitting, and Receiving vaccine orders (Order Management QRG)
- Reporting administered doses directly to TennIIS via DDE with automatic decrementing capabilities (Medical Office User QRG, Pg. 10)
- Inventory reconciliation every 30 days for VFC lots and on a daily basis for COVID-19 lots (Reconciliation QRG)

What's New!

Providers are now able to troubleshoot automatic decrementing of doses from their virtual inventory using Correct Lot Decrementing. This functionality will now be required prior to reconciliation and ordering for all providers who manage an inventory in TennIIS.

The following process walks through this new functionality from start to finish:

- 1. Patient is given a vaccine.
- 2. Administered vaccine information is entered directly into TennIIS and includes all fields required for automatic decrementing.
- 3. TennIIS will compare the vaccine information to the virtual inventory.
- 4. If a match is found, 1 dose will be removed from the virtual inventory. The patient's vaccination record will be updated.
- 5. If a match is not found, the virtual inventory will not be updated, and the administered vaccine will go to the Correct Decrementing queue. The patient's vaccination record will be updated.
- 6. The TennIIS inventory manager for the facility will check and correct vaccines in the Correct Decrementing queue prior to reconciliation and before a new order can be placed.

Automatic Decrementing via DDE

Automatic decrementing is the method of decrementing the number of vaccine doses in a provider organization's inventory in TennIIS when the organization reports a vaccination event through DDE into TennIIS. For a lot to decrement from the virtual inventory, the administered vaccine information entered in the Vaccination Detail page must match the vaccine information associated with a lot in the facility's virtual inventory.

The data elements required for automatic decrementing to occur when an administered dose is entered into TennIIS are shown below, where Historical must be "No" for administered doses, and Date Administered should not be after the vaccine expiration date.



Quick Reference Guide

Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

Vaccine 1:	DTaP (Infanrix®)
Date Administered:	mm/dd/yyyy
Historical:	○ YES ● NO
Manufacturer:	Click to select
Lot Number:	
Lot Facility:	
Funding Source:	
Provider Noted on Record:	
Lot Noted on Record:	
Manufacturer Noted on Record:	
Facility:	Select
Vaccinator:	Select
Anatomical Site:	Select
Anatomical Route:	Select
Dose Size:	Full
Volume (CC):	
VFC Status:	Patient is not VFC Eligible.
District/Region:	
VIS Publications Dates:	1. 2. 3. 4.
Date VIS Form Given:	10/28/2021
Ordering Provider:	Select
Comments:	

A dose will decrement if the Manufacturer, Lot Number, Lot Facility, and Funding Source can be selected ("Click to Select") from the facility's inventory for an administered vaccine. The VFC status of the patient must be consistent with the lot's funding source for automatic decrementing to occur.

If these fields are not available in the inventory for the administered vaccination, such as for privately funded doses, the Lot and Manufacturer "Noted on Record" fields should be populated instead. In this case, the administered dose will not decrement from the provider's virtual inventory. If you feel a pandemic or publicly funded lot is missing from your inventory, please contact <u>TennIIS.VOMS@tn.gov</u> for assistance in correcting the inventory to avoid a recurring issue with this lot number.

Please note that privately funded vaccinations will not be added to TennIIS inventories and will not follow the automatic decrementing process.

For more information on entering vaccinations into TennIIS using DDE, please go to the <u>TennIIS home page</u> and find our "Manual Entry Into TennIIS" training video under the "Training and Education: FAQs, Training Guides/Videos/Webinars, and Workarounds" tab.

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Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

Correct Lot Decrementing

If TennIIS is unable to match the administered vaccine information entered on the Vaccination Detail page to an existing lot in the facility's TennIIS inventory, the administered vaccine will go to the Correct Decrementing queue to await resolution. The vaccine information will populate the patient's record but will not decrement a dose from the virtual inventory.

The Correct Decrementing module in TennIIS allows inventory managers to review and correct administered vaccines that did not match a lot in the facility's TennIIS inventory. This function will update the vaccine information on a patient's record as well as correctly decrement the virtual inventory.

4

This process should be done prior to reconciliation.

Common Decrementing Errors

Most vaccinations that end up in the Correct Decrementing queue are due to one of the following issues, usually from data entry error:

- Incorrect or missing lot number
- Incorrect or missing manufacturer
- Dose not linked to the correct TennIIS facility
- Funding source not appropriate for dose given
 - o Ex. Private funding source for a publicly funded vaccine
- Mismatched patient eligibility and funding source
 - Ex. Non-VFC patient receiving a publicly funded vaccine

Correct Decrementing Module

- 1) Login to TennIIS.
 - Open the "Lot Numbers" menu and select the "Correct Decrementing" option.

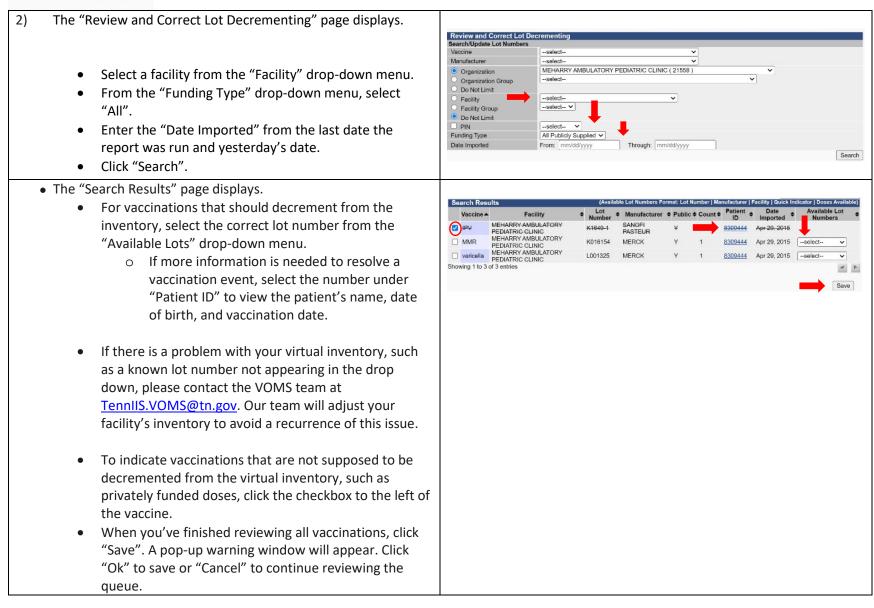
Lot Numbers
Reconciliation
Aggregate Vaccine
Counts
Search/Add
Search Results
Detail
Correct Decrementing
5

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TN Department of Health

Quick Reference Guide

Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users





Quick Reference Guide

Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

Patient Detail Report								
The Patient Detail Report will show providers more information on which vaccines are not decrementing from the virtual inventory.								
1)	 Login to TennIIS. Open the "Reports" menu and select the "Report Module" option. 	✓ Reports Patient Record Report Module State Reports Mgmt Reports School Reports						
2)	Click "Patient Detail Report" under the "Patients" section.	Patients Daily Patient Immunization List Patient Detail Schedule Patient Totals Recall for Inactivation Updated Patients Labels Clinical Notes Contraindication Report Aggregate Contraindication Report						
3)	 Select the report parameters: Select the "By Service" radio button. Enter a "Vaccination Date Range" that matches the doses administered report date range. If you are a pharmacy or a health department, update "Inactive Status at the Organization Level" to "Active and Inactive Patients". Select "Non-Decremented Doses Only" in the "Doses Decremented" drop-down menu. Click "Create Report". 	Patient Detail Report Run By By Ownership By Service Limit Report By Vaccination Date Range From: mm/dd/yyyy Through: mm/dd/yyyy Birth Date Range From: Birth Date Range From: Modelance Section Ne ItBace Down Dearanted Through: Down Dearanted Through: <						

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Quick Reference Guide

Automatic and Correct Lot Decrementing for Direct Data Entry via TennIIS Portal Users

	Total Patients Having Vaccines: 11 Total Patients With All Vaccines Deleted: 0 Deleted vaccinations are shown with a line through them.
"N" for vaccinations that did not decrement.	Patient ID First Name Middle Name Last Name Bitthday Guardian F.N. Phone Number VFC Eligible Facility B774/2 MARQUISE UURNLEY 06/02/072 KANESHA (42/)224-4075 NO MEHARRY ANDULATORY PEDATRIC CLINIC
	Vaccine Vacc. Dose Mfg. Lot Funding VFC HistoricalDetrementedVaccinator Pacility Date VIS Publication Reporting Date State Code Eligible DISP 6 certasts 04/21/2010 Full PRVT NO N N MEMARY 04/21/2010 C012 C012 C012 C012 C012 C012 C012
	antigena PEDIATRUC OLINIC
	Patient ID First Name Middle Name Last Name Birthday Guardian F.N. Phone Number VFC Eligible Facility 7769595 MONDARTUS C COX 01/15/2015 HARRETTE (815)5/33-4063 YES
	Vescine Vesc. Dose Mig. Lot Funding VFC HistoricalDecrementedVescinator Facility Date ViS Form ViS Publication Reporting Data & Siza Code Eligible Hos 8. acclescent or 01/15/2015 Full PRVT NO Y N MEMARYAMBULATORY East Printy
	redshakalinini kunishunisi nuni miku i nuni nuni nuni nuni nuni nuni nuni
Updates to Inventory Reconciliation	
Before a new order can be placed, the provider's virtual inventory mus	t be reconciled even if doses are being automatically decremented. If
reconciliation is not done before ordering, a redirection back to the Re	o ,
econciliation is not done before ordening, a redirection back to the he	concination page prior to placing an order will occur.
-	
	e reconciliation Category "Administered" and Reason of "Administered
but not linked to a vaccine" should no longer be used unless a vaccine [•]	that ended up in Correct Decrementing could not be resolved.
Ideally, if automatic decrementing and Correct Decrementing are being	gused together, the "Quantity on Hand" and the "Physical Inventory"
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS	
inventory.	or Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS	or Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS inventory. Reconciliation categories of Correction, Expired, Recall, Spoiled, Transf	or Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS inventory. Reconciliation categories of Correction, Expired, Recall, Spoiled, Transf	or Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS inventory. Reconciliation categories of Correction, Expired, Recall, Spoiled, Transf Contacts	or Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS er, and Wasted are still fine to use if applicable.
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS inventory. Reconciliation categories of Correction, Expired, Recall, Spoiled, Transf Contacts For questions regarding Inventory, Correct Decrementing, or Reconcilia	bor Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS Fer, and Wasted are still fine to use if applicable. ation, please contact the TennIIS VOMS team at <u>VOMS@tn.gov</u> .
listed on the Reconciliation page should match, meaning no Category of If you notice your inventory numbers are off, please email the VOMS inventory. Reconciliation categories of Correction, Expired, Recall, Spoiled, Transf	bor Reason are required to be selected. team BEFORE making any adjustments or corrections to your TennIIS Fer, and Wasted are still fine to use if applicable. ation, please contact the TennIIS VOMS team at <u>VOMS@tn.gov</u> .

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Appendix F: VaccineBorrowing 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 (70ther or 130ther) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose			Reason for Borrowing Private Dose					
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1		VFC vaccineshipment 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)			Ran out of VFC vaccine between orders (not due to shipping delays)					
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			Accidental use of a Private dose for a VFC eligible patient					
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6		Other – Describe:	13Other				
Other – Describe:	70ther							
WHAT TO DO WITH THIS FORM:								
Completed forms must be sent to VPDIP every month, they can be emailed to Tenniis.VOMS@tn.gov and also need to be kept on file for 3 years.								

1

Date Range of V	accine Reporting	(date of first	dose horrowed	to date of last	dose horrowed).	/	/	to /	1	
Date mange of v	accine neporting	Juan or mor	dost bollowed	to date of fast v	dost bollowed).		_/		/.	

VACCINE BORROWING REPORT TABLE										
A Vaccine Type Borrowed (please include lot# and expiration date)	B Stock Used (VFC or Private)	C Patient Name		D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate Stock was not U (Use legend code on page one reason for each dose	sed 1 to mark	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)		
I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.										
Provider Name: Provider Signature: Date:										

2

Form may be found on the Tennessee Vaccine-Preventable Diseases and Immunization Program website at:

https://www.tn.gov/health/cedep/immunization-program/ip/vfc/vfc-provider-guidance.html

Appendix G: Guide to Selecting a Digital Data Logger

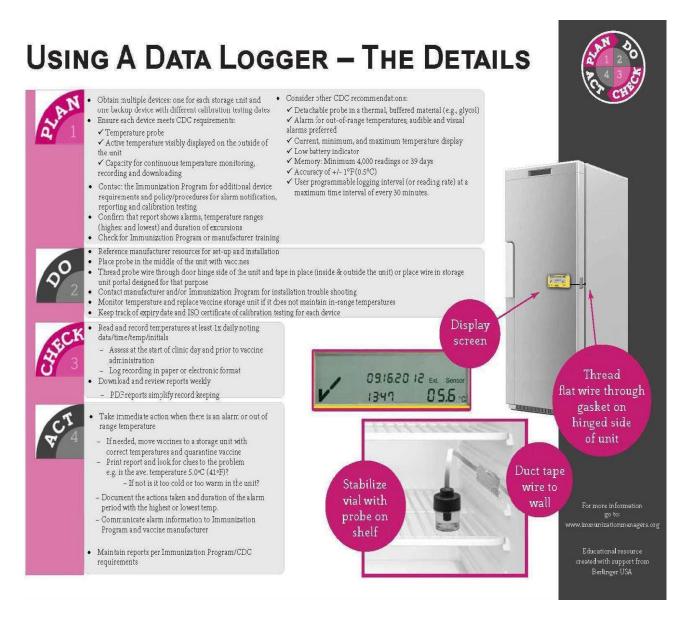


For more information go to: immunizationmanagers.org/VSH

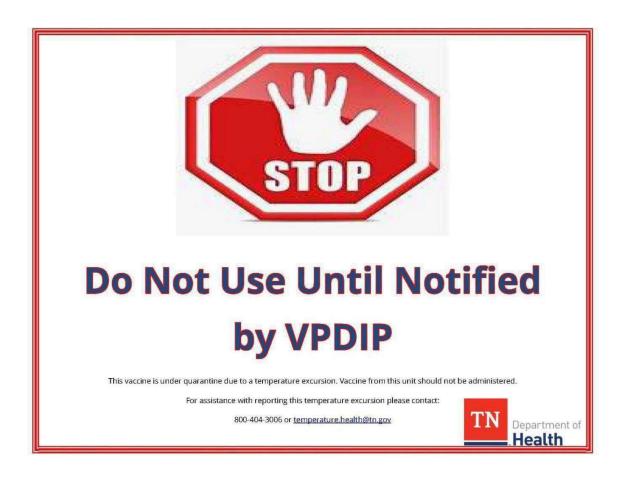
Educational resource created with support from Berlinger USA

A STEP-BY-STEP GUIDE TO Selecting and Using a Digital Data Logger for Vaccine Inventory

Determine the number of devices Follow manufacturer instructions Follow CDC recommendations & VFC requirements Set-up a device for each vaccine storage unit https://www.cdc.gov/vaccines/hcp/admin/ Monitor temperatures to assure storage storage/toolkit/storage-handling-toolkit.pdf unit remains in-range Check with state/local Immunization Program for Maintain current/valid additional requirements and recommendations ISO17025 or equivalent certificate of calibration Keep staff skills and testing for each device capabilities in mind Take immediate action Read and record when alarm triggers or Min/Max/Current out-of-range temperature temperatures daily is discovered Check for out of range • If needed, move vaccines t temperature alarms correct temperature Download and review data • Call immunization program Stop & check when alarm triggers • Call vaccine manufacturer Assure probe is located with vaccine in Document alarm occurrence according to center of unit requirements



Appendix H: Vaccine Quarantine Sign

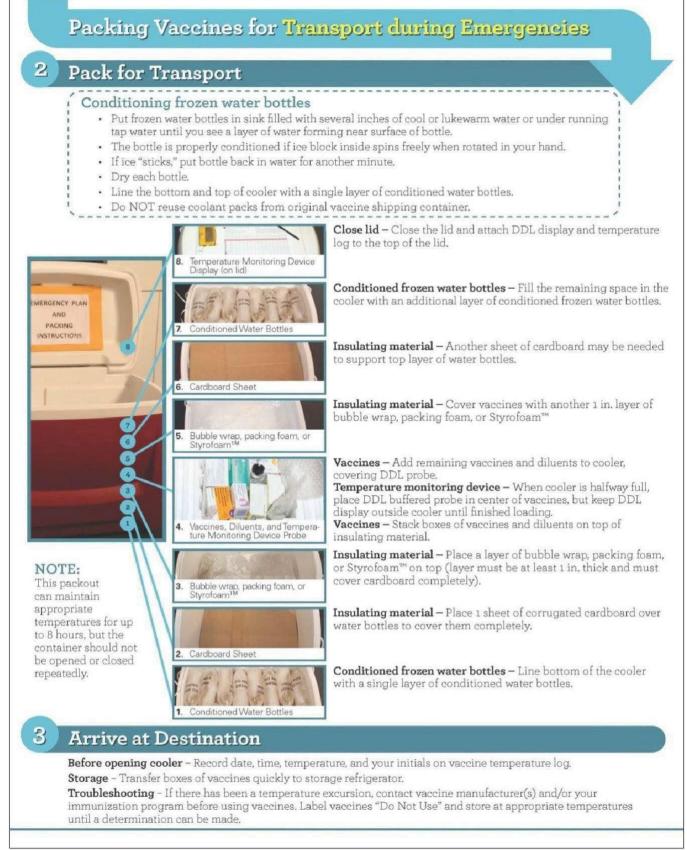


Appendix I: Packing Vaccines for Emergency Transport

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.

Refrigerated Vaccine Transport Instructions:





Guide may be found on the CDC website at:

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

TRANSPORTING FROZEN VACCINE

GUIDELINES FOR EMERGENCY VACCINE TRANSPORT

CDC discourages any vaccine transport. Vaccines should only be transported when absolutely necessary. Call the vaccine manufacturer if you have concerns.

ASSEMBLE PACKING SUPPLIES AND DOCUMENTS

Hard-sided cooler

Frozen cold packs

NEVER USE DRY ICE. Keep enough frozen cold packs in your vaccine freezer to make two layers in the transport cooler.

Data logger

Retrieve your backup device's buffered probe and its digital display.

4

2

E

Insulating cushioning material

Use 2-inch layers of bubble wrap to prevent vaccines from shifting. Do NOT use packing peanuts or other loose material that might shift during transport.

Transport Log Print a copy of the VFC "Frozen Vaccine Transport Log" (IMM-1116).

Vaccine management plan

Find the alternate vaccine storage location in your practice's vaccine management plan.

PREPARE FOR TRANSPORT

If transferring vaccines to another VFC provider, complete the transfer form at MyVFCvaccines.org. (Refer to Provider Operations Manual for details.)

- 1 Verify that the alternate vaccine storage location can store all of your vaccines.
 - Complete the top portion of the transport log.
 - Record the "Time" and "Temperature of vaccines in freezer before transfer" on the bottom of the transport log.
 - Remove vaccines from the freezer.
 - Complete the "Vaccine Inventory Information" on the transport log before proceeding.

alifornia Department	of Public Health	Immunization Branch	Vaccines for C	hildren Program •	F717 org



VACCINE FOR ON FICELAR VALUE AND	LOBEN (VEC) PROG Isport Log	RAH		nu _88/A	non V
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Continued on next page

IMM-1130 Page 1 (8/18)

TRANSPORTING FROZEN VACCINES (CONTINUED)



Out of range, above 5.0°F (-15.0°C): label the vaccines "Do Not Use" and store them in the vaccine freezer; alert your supervisor; immediately report the excursion to SHOTS at MyVFCvaccines.org.

California Department of Public Health, Immunization Branch, Vaccines for Children Program • EZIZ.org

3. Record the "Time" and "Temperature of cooler upon

arrival" on the transport log before removing

log.

vaccines.

IMM-1130 Page 2 (8/18)

	Mobile Immunization Clinic Log									
Clinic Date	Clinic Location	VFC Vaccine Type	VFC Vaccine Amount	Private Vaccine Type	Private Vaccine Amount					
			+ +							
			+ +							

Appendix J: Mobile Immunization Clinic Log

Form may be found on the Tennessee Vaccine-Preventable Diseases and Immunization Program website at:

https://www.tn.gov/health/cedep/immunization-program/ip/vfc/vfc-provider-guidance.html

Appendix K: Hourly Temp Logs

TN Vaccine-Preventable Diseases and Immunization Program (VPDIP)

Hourly Vaccine Temperature Log - Celsius Refrigerated

Refrigerated vaccines must be maintained between 2°C and 8°C.

Contact VPDIP immediately if vaccine is exposed to temperature below 2°C for more than 15 minutes or above 8°C for more than 60 minutes. Take the below actions:

- 1. Label vaccine "do not use"
- 2. Store vaccine under proper conditions as quickly as possible

3. Notify VPDIP at 1-800-342-1813 or temperature.health@tn.gov

Date:

Location:

Time Vaccine Placed into Unit: ______ Temperature: _____

Time Vaccine Removed from Unit: ______ Temperature: _____

Time	AM/PM	Temperature	Initials

Date:

Time:_____

VFC Coordinator Signature: _____

Prior to the vaccine being returned to the clinic, the VFC Coordinator must review temperature logs to verify vaccine cold chain has been maintained; attach this log to the data logger report.

TN Vaccine-Preventable Diseases & Immunization Program 1-800-342-1813

TN Vaccine-Preventable Diseases and Immunization Program (VPDIP)

Hourly Vaccine Temperature Log - Celsius Freezer

Frozen vaccine must be maintained between -50°C and -15°C.

Call VPDIP immediately if vaccine is exposed to temperature above -15°C for more than 60 minutes. Take the below actions:

- 1. Label vaccine "do not use"
- 2. Store vaccine under proper conditions as quickly as possible
- 3. Notify VPDIP at 1-800-342-1813 or temperature.health@tn.gov

Date:_____

Location:

Time Vaccine Placed into Unit: ______ Temperature: _____

Time Vaccine Removed from Unit: ______ Temperature: _____

Time	AM/PM	Temperature	Initials

Date:_____ Time:_____

VFC Coordinator Signature: _____

Prior to the vaccine being returned to the clinic, the VFC Coordinator must review temperature logs to verify vaccine cold chain has been maintained; attach this log to the data logger report.

TN Vaccine-Preventable Diseases & Immunization Program710 James Robertson Parkway Nashville, TN 372431-800-342-1813

 Tennessee Vaccine-Preventable-Diseases and Immunization Program
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Appendix L: Insurance Cheat Sheet

Medicaid?	Insurance Type	Covers all ACIP recommended vaccines? Justification / Other comments		
No	Private	Yes		
Partners with Aetna, Cigna, BCBS, and others (Employer insurance solution)				
No	Private	Yes		
No	Private	Yes		
No	Public	Yes; Healthcare.gov (govt. marketplace)		
No	Public	Yes; Healthcare.gov (govt. marketplace)		
No	Private	Yes		
No	Public	Yes; Healthcare.gov (govt. marketplace)		
No	Private	Yes		
Yes	Public	Yes; Medicaid plans cover children vaccines		
Yes	Public	Yes; Medicaid plans cover children vaccines		
Does not offer plans in Tennessee				
Yes	Public	Yes; Medicaid plans cover children vaccines		
No	Public	Yes; Healthcare.gov (govt. marketplace)		
No	Private	Yes		
No	Private	Yes; Not an ACA compliant company, however.		
No	Private	Yes		
No	Public	Yes; government sponsored program		
Not recognize	ed as health insuran	ce in Tennessee – person is considered "uninsured"		
and the second second second		5, and others (Employer insurance solution) – person is		
ls not a health	h plan, but a provid	er network– person is considered "uninsured"		
No	Public	Yes; Healthcare.gov (govt. marketplace)		
No	Private	Yes		
No	Public	Yes; government sponsored program		
No	Private	Yes; https://www.uhc.com/united-for-reform/health-reform- provisions/preventive-services		
No	Private	Yes		
Yes	Public	Yes; Medicaid plans cover children vaccines		
	Partners with No No No No No No No Ves Ves Ves Ves Does not offer Yes No Ves No No No No No No No No No No No No No	Partners with Aetna, Cigna, BCBSNoPrivateNoPrivateNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicYesPublicYesPublicDoes not offer plans in TennesseYesPublicNoPrivateNoPrivateNoPrivateNoPrivateNoPrivateNoPrivateNoPrivateNoPublicNoPublicNoPrivateNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPublicNoPrivateNoPublicNoPrivateNoPublicNoPrivateNoPrivate		

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. <u>https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf</u>

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

Appendix M: Vaccine Transport Logs

Vaccines for Children (VFC) Program Refrigerated Vaccine Transport Log									
Instructions:	Instructions: Complete this log when transporting vaccines to an alternate or back-up refrigerator. Date:								
Provider Nam	ne:				VFC PIN:				
Transferred T	o:				VFC PIN:				
Vaccines Trar	nsferred Due To: 🗆 P	ower Outage 🛛 Excess Suppl	y 🗆 Short Dated 🔲 (Unit Malfunction 🛛 Bu	ilding Maintenance 🛛 Other: _				
Vaccine II	nventory Inforn	nation – may also atta	ach most recent re	conciliation repo	ort from TennIIS.				
Vaccine	Lot Number	Number of Doses	Expiration Date	Vaccine Previously	Transported? (Yes/No)	Comments			
Temperat	ture Monitoring	g Information							
Temperature	of vaccine in refrigera	itor prior to transfer:	(Celsius/Fahrenheit:	Time:				
Temperature	of vaccine in cooler b	efore departure:		Celsius/Fahrenheit:	Time:				
Temperature	remperature of vaccine in cooler upon arrival:				Time:				
Temperature	Temperature of back-up refrigerator: Celsius/Fahrenheit: Time:								
Contact the V	FC Program (800-404	-3006) if temperatures during	transport exceed recomm	ended ranges.	Total Transport Time:	Min/Hr			

Form may be found on the Tennessee Vaccine-Preventable Diseases and Immunization Program website at:

Refrigerated Vaccine Transport Log - Final.pdf (tn.gov)

		or Children (VFC er Vaccine Transpo				TN Department of		
Instructions: Complete this log when transporting vaccines to an alternate or back-up freezer. Date:								
Provider Nam	ie:				VFC PIN:			
Transferred T	o:				VFC PIN:			
Vaccines Tran	nsferred Due To: 🗆 P	ower Outage 🛛 Excess Supp	ly 🗆 Short Dated 🗖 U	nit Malfunction 🛛 Buildin	ng Maintenance 🛛 Other: _			
Vaccine Ir	wentory Inforn	nation — may also att	ach most recent re	conciliation report	from TennIIS.			
Vaccine	Lot Number	Number of Doses	Expiration Date	Vaccine Previously Tra	nsported? (Yes/No)	Comments		
Temperat	ure Monitoring	g Information						
Temperature	of vaccine in freezer p	prior to transfer:	c	elsius/Fahrenheit:	Time:			
Temperature	of vaccine in cooler b	efore departure:	c	elsius/Fahrenheit:	Time:			
Temperature	Temperature of vaccine in cooler upon arrival: Celsius/Fahrenheit: Time:							
Temperature of back-up freezer: Time: Time:								
Contact the V	FC Program (800-404	-3006) if temperatures during	transport exceed recomme	ended ranges.	Total Transport Time:	Min/Hr		

Form may be found on the Tennessee Vaccine-Preventable Diseases and Immunization Program website at:

Freezer_Vaccine_Transport_Log - Final.pdf (tn.gov)



VFC Enrollment Quick Reference Guide



vfc.enrollment@tn.gov

VFC PIN #_

RIR:___

AGREEMENTSIGNATORY CHANGE

- NOTIFIEDWITHIN 48 HOURS
- MUST SUBMIT ANEW PAIN TENNIIS
- SUBMITA NEW THREE-PAGE PA SIGNED
- YCTS COMPLETED WITHIN 30 DAYS

Contact Changes

Primary and Backup Coordinator Changes**MUST** be reported within <u>10 business</u> days to both the RIR and VFC Enrollment

My Emergency Backup Facilities are:

- 1. PIN#:
- 2. PIN#:

Vaccine Storage & Handling



Unit Guidelines

- Large enough to store the year's largest inventory without crowding (i.e. flu season, back to school inventory)
- Wire shelving recommended
- Must have digital or dial thermostat-No units with three settings
- Frost Free/ Auto defrost freezers preferred
- Manualdefrost units must have a defrost plan in the REVMP with a secondary back-up unit for use
- No glass doors unless double paned pharmaceutical grade unit

Temperature Excursions

<u>A Temperature Excursion (TE)</u> occurs when a vaccine is stored at a temperature outside it's recommended range as defined by the manufacturer's package insert.

Refrigerator	Freezer	Ultra Cold Freezer
Above 8C for 60 consecutive minutes	Above -15C for 60 consecutive minutes	Above -60C for 60 consecutive minutes
Below 2C for 15 consecutive minutes	Below -50C for 15 consecutive minutes	Below -90 for 15 consecutive minutes

When you hear an alarm?

DO NOT USE THE VACCINE

CALL VPDIP IMMEDIATELY during business hours(8:00AM – 4:30PM Central Time) 800-342-1813

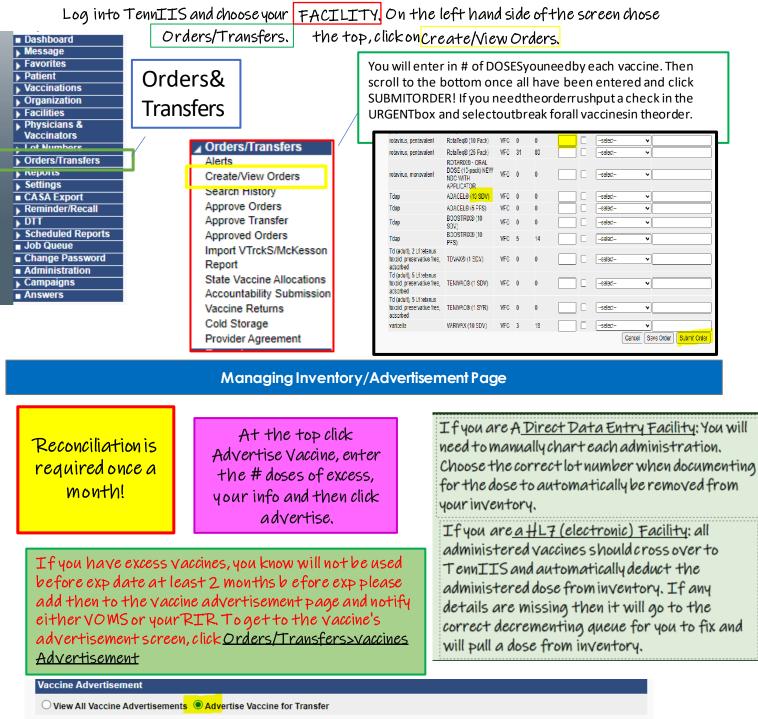
Email or fax data logger reportto: temperature.health@tn.gov or 615-401-6829



VFC Enrollment Quick Reference Guide



Vaccine Ordering & Management: How to Order?



Vaccine	Lot #	Exp Date	Doses on Hand	Advertise Qty	Contact First Name	Contact Last Name	Phone Number	Phone Ext	Email	Comments	
Hib (PRP-T)	L75AZ	04/18/2024	84.0	25	Kristen	Adkins					Advertise
DTaP-IPV	F5492	10/27/2024	20.0								Advertise
Hep B											



VFC Enrollment Quick ReferenceGuide



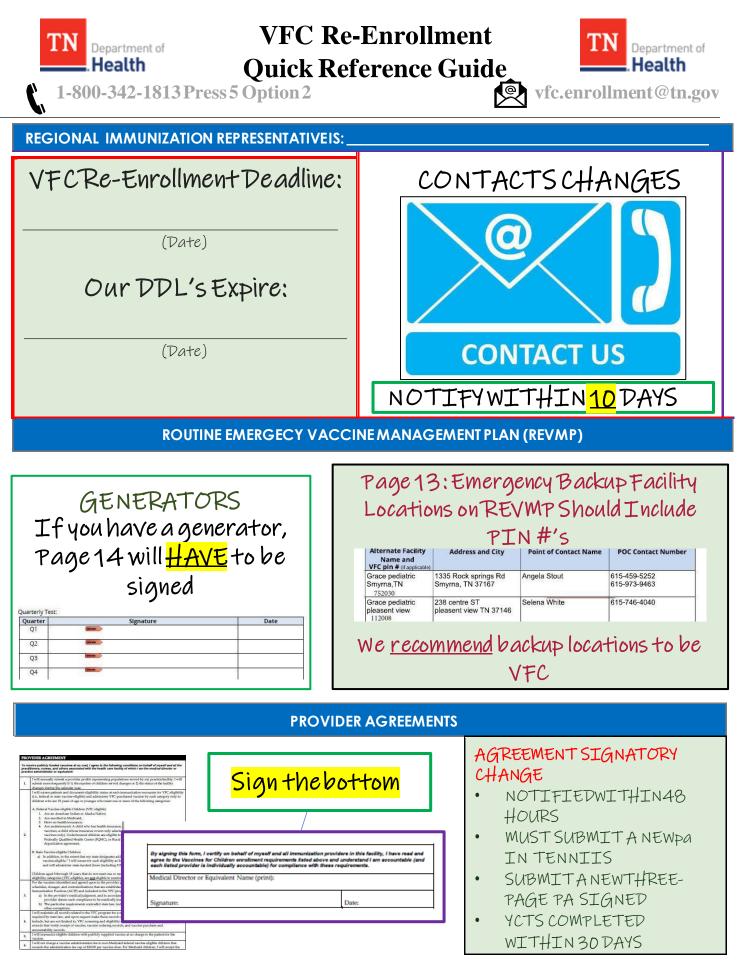
Decrementing Report

If your counts are NOT reflecting in TennIIS correctly, <u>always</u> reach out to VOMS before trying to fix so your overall numbers are not thrown off.

Review and Correct Lot Decrementin Search/Update Lot Numbe If you have administered Maccine --select-Manufacturer -select-¥ doses not deducting from your **BAPTIST MEMORIAL HEALTHCARE CORPORATION (10248** ¥ Organization -select-Lot totals in TennIIS, then Organization Group Do Not Limit they could be sitting in the BMMG - ATOKA PEDIATRI ¥ Eacility --select-- 🗸 Facility Group decrementing correction que, Do Not Limit PIN --select-- 🗸 waiting for you to manually A Funding Type From: 04/22/2023 Date imported Through: 05/22/2023 move them over. (Search LOT NUMBERS TAB>Correct decrementing) Email<u>TennIIS.Voms@tn.gov</u>forany Run the report from the date of last recon till the questions or corrections current dayand make all the selections below are marked Once the report is ran if you see any listed for the Lots that have counts off, then you will need to click the drop down and select the lot # then scroll to the bottom and click save. This will deduct a doses from the lot in tenniis If you ever have a negative count on your inventory list, you will have to email VOMS at tenniis.VOMS@tn.gov so they can fix this count for you. This happens when vaccines are crossing over from EHR but someone is also manually reconciling them as administered as well. **Returning Expired Vaccines** The day after a vaccine expires, it will turn RED in TennIIS. Then you can reconcile all remaining on hand doses out as Expired, expired. Then located beside the create order button is the vaccine return button, click it. Then enter the doses in and click Submit & <u>Print Return.</u> The packing slip will pop up for you to print and insert into the packing with the vaccines. Vaccine Return

Sending C	organization	ganization EAST TN PUBLIC HEALTH REGION, ALL CLINICS		Contact First Name:		GAIL			
Sending F	acility	00101 - ANDERSON CO. H.D. (WAS CLINTON)	C	Contact Last Name: Phone Number:		BAIRD			
			F			(865)425-8800			
Shipping L	abel Metho	d: OMail OPick-up OEmail	E	Email:		GAIL BAIRD@TN.GOV		/	
Return Quantity	Wasted Quantity	Vaccine	Funding Source	Lot Number	Usable Quantity Available	Expiration Date	Return Reason	Wastage Cost	Option
		Vaccine Td (adult), 2 Lf tetanus toxoid, preservative			Quantity				Option
	9	free, adsorbed (Massachusetts Biologic	VEC	A134A	0	05/14/2023		\$166.58	Remove

If the packing slip doesn't pop up, you can email VOMS for a copy. One the return has been submitted, UPS will email the Label directly to you.

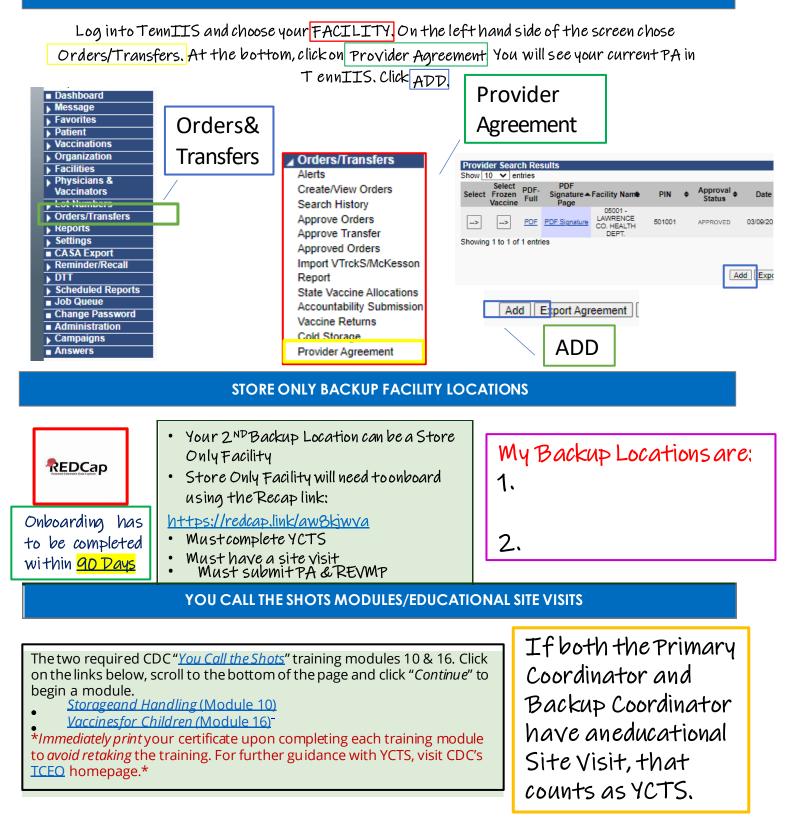




VFC Re-Enrollment Quick Reference Guide



HOW TO CREATE A PROVIDER AGREEMENT IN TENNIIS





VFC Re-EnrollmentChecklist

Use this Checklist below for Annual Re-Enrollment

Mark Your Calendar for Deadlines: First 2 weeks

- Email your providers he deadline for re-enrollment
- □ Include the following paperwork:
 - REVMP-newest version
 - Three-page ProviderAgreement
 - You Call the Shots Instructions for Modules 10 & 16
 - You Call the Shots Printing Guide
 - VFC Re-Enrollment Walkthrough Guide PPT
 - VFC Handbook

□ VFC Enrollment Team will provide a list of Providers whoneed additional assistance in 2 weeks

Mark Your Calendar for Deadlines: Second 2 weeks

- Site Reviewerswill be given Providerswhoneedadditional hands-on assistance and plan a route
- Site Reviewerswill provide hands on assistance to complete Annual Re-Enrollment by deadline
- Site Reviewers can check on DDL's and can provide DDL's if oneswill expire soon **Note:** Site Reviewers will include RIR's in correspondence

Provider Reminders:

Contact Changes

- Primary and Backupchanges <u>MUST</u> be reported within <u>10 days</u>
- Agreement Signatory changes <u>MUST</u> be reported within <u>48 hours</u> and must submit the following documents:
 - Three-page signed Provider Agreement
 - You Call the Shots Modules 10 & 16
 - Add a New Provider Agreement in TennIIS
- Emergency Backup Facility Locations= REVMP Page 13
 - Generator= 1 VFC Backup Facility Location= Page 14 needs to be signed
 - Must be a VFCProvider
 - No Generator= 2 VFC Backup Facility Locations
 - 1st location <u>MUST</u> be a VFCProvider
 - 2nd location should be a VFC Provider, however if you have a provider who is not than they can become a Store Only Backup Facility with approval from VFC Enrollment Team.
 - CDC Guidelines recommend bothbackup locations be VFC Providers
 - Store Only Backup Facility will need to onboard with Redcap Link: <u>https://redcap.link/efnqflng</u>

VFC Re-EnrollmentChecklist

- □ Make sure they are ordering Private Vaccines
- **D** Remind them of the VFC Report Card
- □ VFC Enrollment Te-am is always here to help!
- ☐ You can call us at 1-800-342-1813 Press 5, Option 2
- □ You can email us at VFC.Enrollment@tn.gov



VPDIP Phone Tree

When you contact the TennIIS Help Desk at (800) 342-1813 Monday through Friday, 7AM to 4:30PM CST, we have implemented a Phone Tree to best route your inquiry.

Please Press 1 to Request Immunization Records or for Help with TennIIS Records or email <u>TennIIS.Records@tn.gov</u>

Please Press 2 for Assistance with (VOMS) vaccine ordering, inventory, or returns or email <u>TennIIS.VOMS@tn.gov</u>

Please Press 3 for TennIIS Password Resets or email <u>TennIIS.Registration@tn.gov</u>

Please Press 4 for Questions Regarding School Immunization Requirements, Immunization Recommendations and Clinical Questions or email <u>TennIIS.Training@tn.gov</u>

Please Press 5 for Temperatures Excursions & Vaccines for Children (VFC) Program or email <u>Temperature.Health@tn.gov</u>

- Option 1: To report a temperature excursion please leave a message and someone will call you back or email Temperature.Health@tn.gov
- Option 2: For questions about the Vaccines for Children (VFC) program including VFC provider enrollment or email <u>VFC.Help@tn.gov</u>
- Option 3: For all other VFC questions including VFC Fraud Reporting or email <u>VFC-</u> <u>Fraud.Health@tn.gov</u>

Please Press 6 TennIIS Organization/Facility/User Registration or email <u>TennIIS.Registration@tn.gov</u>

Please Press 7 For assistance with electronic data exchange, Interoperability, EHR-TennIIS connection issues or email <u>TennIIS.MU@tn.gov</u>

Please Press 8 for information about becoming a COVID-19 Vaccine Provider or email <u>Vaccine.Onboarding@tn.gov</u>

Please Press 9 for information regarding the Kindergarten Survey Report, Program Effectiveness and Vaccine Coverage Rates or email <u>TIP.Quality@tn.gov</u>

Please press 0 for all other questions or email <u>TennIIS.Help@tn.gov</u>

It is required that temperatures are reviewed within each vaccine storage unit twice a dayand the minimum and maximum temperatures are reviewed each morning. Document time temperatures were takeneach day the clinic is open. Follow appropriate procedures to evaluate a new alarm and document follow-up on the data logger print out; clear the alarm on the datalogger.

Unit Type (circle): Fridge	Freezer	UC Freezer
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Month/Year

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Alarm Date	Tin		Category				
	DAM	ШРМ	□Non-Reportable	□Reportable			
	DAM	ПЬ	□Non-Reportable	□Reportable			
	DAM	ШРМ	□Non-Reportable	□Reportable			
	DAM	ПЬ	□Non-Reportable	□Reportable			
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	DAM	ПЬ	□Non-Reportable	□Reportable			
	DAM	ШРМ	□Non-Reportable	□Reportable			

If an alarm is noted on the front page, please indicate the category of the event below.

The first time a new alarm is noted, download the data logger report, quarantine the product with a "do not use until notified by TVPDIP" sign, and Call 800-342-1813 or email <u>Temperature.Health@tn.gov</u> to report the temperature excursion. Please include your PIN number, a good contact phone number, the reason for submitting the report, and a list of the inventory affected if you choose to email the excursion information. The inventory listed must include brand Name, LOT numbers, expiration dates, and the quantity of doses affected.

Please note, the temperature excursion business hoursare 8:00 AM to 4:30 PM Monday through Friday. We are closed on all Tennessee state holidays. You must report all excursions within 1 business day.

If you have a non-reportable alarm, please document this with your weekly printouts of your DDL and notate the reason the alarm was unreportable IE no vaccine in unit due to defrost, alarm parameters set incorrectly, etc. If vaccine was not in the unit, you must document the date and time vaccine was removed and returned (if applicable) to the unit.

Tennessee Vaccine-Preventable Diseases and Immunization Program at 800-404-3006 or 615-741-7247