



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

2024 TVFC/ASN Provider Policy Training Sections

Introduction
Provider Eligibility and Enrollment
TVFC Patient Eligibility and Screening
Vaccine Ordering
Vaccine Distribution
Vaccine Loss
Vaccine Storage and Handling
Vaccine Transfers and Borrowing
Vaccine Reporting Requirements
Billing for Vaccine Administration
Program Evaluation
Fraud and Abuse
Documentation and Record Keeping
ASN Program
Vaccine Information Statements (VIS)



Introduction



Welcome

Upon completing this course, you will be able to describe the benefits of being a part of the TVFC/ASN program and what's required to comply with TVFC/ASN program guidelines.

Once this training has been reviewed, click on the following link to complete the mandatory quiz:

[2024 Provider Policy Training Quiz.](#)

Continuing Resources:

[Download the manual](#)

[Visit the website](#)

[New policies and memos](#)

Introduction



Upon completing this section, you will be able to identify the benefits of participating in the TVFC program.

Vaccines for Children (VFC) Program

Creation

The Vaccines for Children (VFC) program was first implemented by the CDC in 1994 to ensure that eligible children do not contract vaccine-preventable diseases because of the inability to pay for a vaccine.

VFC was created in response to a measles resurgence in the United States. The resurgence resulted in approximately 55,000 reported cases during 1989–1991¹.

The outbreak was caused, in large part, by widespread failure to vaccinate uninsured children.

How the Program Works

The VFC program is federally funded. The Centers for Disease Control and Prevention (CDC) buys vaccines at a discount from vaccine manufacturers and distributes them at no charge to private physicians' offices, public health clinics, and other health care facilities enrolled as VFC providers.

The VFC providers store and administer vaccines to eligible children at no cost for the vaccine.



**CENTERS FOR DISEASE
CONTROL AND PREVENTION**

Increasing Vaccination Coverage

For all children (both VFC-eligible and ineligible) who were born in the years since VFC began, vaccine coverage has been **near or above 90%**.

The CDC collected this data from the National Immunization Survey (NIS) and a previously published cost-benefit model to estimate illnesses, hospitalizations, and premature deaths prevented and costs saved by routine childhood vaccination.

Reducing Suffering and Disease

The CDC estimates routine childhood immunization among children born from 1994-2018 will prevent:

- 419 million illnesses,
- 8 million hospitalizations
- 936,000 deaths

In addition, vaccination has resulted in a net savings of \$406 billion in direct costs and \$1.9 trillion in total economic impact.

With support from the VFC program, immunization has been a highly effective tool for improving children's health in the U.S.

Texas Vaccines for Children Program

What is TVFC?

Texas has participated in the federal VFC program since it began in 1994. Our version is called the **Texas Vaccines for Children (TVFC) program**.

Texas leads the nation in the number of uninsured and underinsured children. Texas also has approximately 4 million children on Medicaid¹. Many of these children are not receiving the complete series of immunizations required to protect them from vaccine-preventable diseases.

Funds from the federal VFC Program are supplemented with additional state and federal funds.

By enrolling in TVFC, eligible providers can provide innumerable benefits to the families and to the people of Texas. Today, there are approximately 3,200 Texas providers enrolled in TVFC.

Responsible Entities

RE

TVFC enables more than **4.3 million Texas children** to have access to immunizations.

This is accomplished through a network of support provided by the Texas Department of State Health Services (DSHS) and with assistance from DSHS Public Health Regions (PHR) and contracted Local Health Departments (LHD).

These organizations function as **Responsible Entities (RE)** to ensure compliance with state and federal standards and the effectiveness of vaccine distribution.

As a provider, you will contact your RE for information and details about required vaccine reporting.

DSHS Immunization Section



As a part of DSHS, the Immunization Section is charged with eliminating the spread of vaccine-preventable diseases by increasing vaccine coverage for Texans, raising awareness of the diseases that vaccines prevent, and educating the public about vaccine safety.

Our Vision is to create a Texas free of vaccine-preventable diseases.

Our Mission is to provide leadership to increase vaccine coverage levels and reduce the burden of vaccine-preventable diseases for all Texas infants, children, adolescents and adults.

TVFC/ASN Provider Manual



Texas Vaccines for Children and Adult Safety Net Provider Manual 2024



Texas Department of State Health Services

Tel: (800) 252-9152 1100 West 49th Street www.ImmunizeTexas.com
Fax: (512) 776-7288 Austin, TX 78756 Immunization.Info@dshs.texas.gov

The purpose of the manual is to consolidate TVFC policies and information into one source. You may consult the manual as needed, in particular, for the handling and management of TVFC vaccines.

Throughout the year, the DSHS Immunization Section will announce new policies via the TVFC/ASN Digest (monthly e-newsletter), official letters and memorandums. Both the manual and latest updates can be found at [ImmunizeTexas.com](https://www.immunizetexas.com).

Now that you're familiar with the TVFC program let's look at provider eligibility and enrollment.

[View/download the manual](#)

Provider Eligibility and Enrollment



Provider Eligibility and Enrollment



Upon completing this section, you will be able to explain the current policies related to provider eligibility and enrollment.

Provider Eligibility Requirements

To be eligible to enroll in the TVFC program, providers must be one of the following:

- Medical Doctor (MD)
- Doctor of Osteopathy (DO)
- Nurse Practitioner (NP)
- Certified Nurse Midwife (CNM)
- Physician Assistant (PA)
- Registered Pharmacist (RPh)

Site Eligibility Requirements

The following types of organizations are eligible to participate in the TVFC program:

- Behavioral health clinic
- Birthing hospital/centers
- Community vaccinators
- Correctional facility
- DSHS public health clinics
- DSHS Public Health Department clinic as agent for FQHC/RHC-deputized
- EMS Facility
- Family planning clinic (non-health department)
- Federally Qualified Health Centers (FQHC)
- Harris Health System
- HHSC Family Planning Clinic
- Hospitals
- Juvenile detention centers
- Local Health Departments (LHD)
- Local Health Department (LHD) as agent for FQHC/RHC-deputized
- Migrant health facilities
- Mobile clinics
- Pharmacies
- Private practices
- Refugee health clinics
- Rural Health Clinics (RHC)
- School-based clinics
- Residential/Congregate Care Facility
- STD/HIV clinics
- Teen health centers
- Indian Health Service, Tribal, or Urban Clinic
- Urgent/immediate care center
- University Health System
- Women, Infants, and Children (WIC) sites

Site Eligibility Requirements

(continued)

[Texas Health and Safety Code §§161.007-161.009](#)

Texas law requires all medical providers and payors report **all immunizations** administered to clients younger than 18 years of age into the Texas Immunization Registry, ImmTrac2.

All providers that enroll in TVFC must be actively enrolled in ImmTrac2. All TVFC program providers must report doses and usage accurately and timely.

Provider Enrollment Requirements

Provider Agreement Form

The first step in becoming a TVFC provider and/or ASN provider is completing the TVFC/ASN Provider Agreement Form. You can call your RE for assistance.

The agreement must be completed and updated each year. It includes information about the facility and the provider. The TVFC/ASN program must receive and process the signed agreement before the clinic receives state and federally-funded vaccines.

The TVFC/ASN program will also check the Office of the Inspector General's (OIG) List of Excluded Individuals or Entities to ensure that a pending provider is eligible to participate in the TVFC/ASN program.

Provider Enrollment Requirements

Section of the Provider Agreement Form

Providers are required to complete the Provider Profile during initial enrollment and annual re-enrollment. The Provider Profile Section of the Provider Agreement Form asks about the provider's patient population, including a projection and identification of the number of clients that the clinic will serve in the upcoming year.

Existing providers must include accurate data from the previous 12 months and the number of insured patients. These numbers must be specific to the clinic site and not combined with other clinics' patient numbers.

Data sources must include, but are not limited to:

- IIS/Registry Data
- Benchmarking
- Number of Medicaid Claims or other billing data
- Doses administered
- Client encounter data

This data will be used to ensure that vaccine orders are in the appropriate amounts and

Provider Enrollment Requirements

Responsibilities of Primary Vaccine Coordinator/Backup Vaccine Coordinator

The TVFC/ASN programs requires that you designate a primary vaccine coordinator at your facility who will be responsible for ensuring all vaccines are stored and handled correctly. It is also required that a second staff member at the facility is appointed to serve as the backup vaccine coordinator in the absence of the primary vaccine coordinator. Each site must have a unique primary vaccine coordinator and backup vaccine coordinator. It is also required that both coordinators have unique email addresses. TVFC sites with operating hours or operating days that do not overlap may share coordinators.

The primary and backup vaccine coordinators are required to do the following to implement, oversee, and monitor the TVFC and/or ASN Program requirements:

Provider Enrollment Requirements

Responsibilities of Primary Vaccine Coordinator/Backup Vaccine Coordinator (continued)

- Ensure only eligible patients receive TVFC/ASN vaccines.
- Set up data loggers in storage units.
- Ensure staff are familiar with the operations of the data loggers including how to download the data (recommended weekly, on Mondays).
- Monitor and record the temperatures of units (refrigerator and freezer) 2 times each workday.
- Read and record the minimum and maximum temperatures at the beginning of each workday
- Reset the minimum and maximum temperatures at the end of each workday.
- Monitor the operation of storage equipment and systems.
- Maintain all documentation, such as vaccine inventory and temperature logs.
- Document TVFC/ASN vaccine inventory information.
- Place orders for additional TVFC/ASN vaccine in the Vaccine Allocation and Ordering System (VAOS).
- Report vaccine activities monthly in VAOS.
- Track and document doses administered.
- Oversee proper receipt and storage of vaccine deliveries.
- Organize vaccines to monitor expiration dates.
- Remove expired vaccine from storage units and document the loss.
- Ensure TVFC/ASN vaccine is stored and handled appropriately to safeguard vaccine viability.
- Review and analyze temperature data at least weekly to identify any shifts in temperature trends.
- Respond to out-of-range temperatures (excursions) or in the event of an emergency (unit failure, power outage, disaster).
- Oversee proper vaccine transport when necessary (i.e., during an emergency).
- Ensure other staff are trained in the proper storage and handling of vaccines.
- Notify RE of staff changes (primary or backup vaccine coordinators, or signing clinician).

Provider Enrollment Requirements

Specific Terms of Agreement

To participate in the TVFC program, each signing clinician must agree to follow all program requirements. By signing the TVFC program Agreement, the office and all practitioners associated with the medical site agree to the following:

Provider Enrollment Requirements

Specific Terms of Agreement (continued)

- To submit a profile representing populations served by the facility annually.
- To screen for and document TVFC-eligibility of all children at each immunization encounter.
- Administer TVFC vaccine to all children 18 years of age or younger who meet the established eligibility criteria.
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP).
- Maintain all records related to the TVFC program for at least five (5) years and upon request, make these records available for review.
- Immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
- Not charge an administration fee in excess of \$13.75 per vaccine dose.
- Not charge an administration fee to Medicaid or Children's Health Insurance Program (CHIP) patients.
- Not deny administration of a TVFC vaccine to an eligible child because of the inability of the child's parent or guardian to pay the administration fee.
- Not send a patient to collections or charge additional fees for non-payment of a TVFC administration fee.
- Provide a copy of the most current Vaccine Information Statements (VIS) for each vaccine at the time of administration.
- Comply with the TVFC program requirements for vaccine management, including ordering and proper storage and handling practices.
- Not be cited or terminated from Medicaid or CHIP.
- Operate within the TVFC program in a manner intended to avoid fraud and abuse.
- Participate in TVFC compliance site visits, including unannounced visits and other educational opportunities, as required.
- Acknowledge that the DSHS Immunization Section may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office and/or facility agrees to return all TVFC vaccines.

Provider Enrollment Requirements

Initial Enrollment Visit

All providers enrolling in the TVFC/ASN program must receive an enrollment visit.

When the Responsible Entity (DSHS PHR or LHD) visits the provider's office, they will complete:

- A review of all storage units in the provider's office is performed to make certain adequate and approved storage units are being used.
- A review to ensure a certified and calibrated data logger is in place in all units that will store the TVFC/ASN vaccine at this time and logged for 7 operational days before any TVFC/ASN vaccine is supplied.

The initial enrollment visit typically takes a minimum of three (3) hours. The Primary Vaccine Coordinator and Backup Vaccine Coordinator must both be available to meet with the Responsible Entity on-site for the duration of the initial enrollment visit.

Provider Enrollment Requirements

Initial Site Set-Up

Once temperature charts are logged for seven business days and temperatures are shown to be within the required range, the RE begins the clinic set-up process and performs the following activities to ensure that vaccines are stored and handled appropriately:

- Checks the equipment to include the following:
 - Placement of data loggers, probes, and calibration certificates.
 - Verifies placement of or installs plug guards.
- Trains the staff on these essential processes:
 - Vaccine choice options
 - Establishing maximum stock levels (MSLs)
 - Online vaccine management in VAOS
 - Setting up an initial order
 - Completion of a vaccine management plan
 - Completion of a temperature recording form

Provider Enrollment Requirements

Initial Site Set-Up continued

- Checks to ensure the following signage is displayed prominently within the clinic.
 - “VACCINE MANAGEMENT — Recommendations for Storage and Handling of Selected Biologicals” poster, stock no. 6-26P (if available).
 - “How to Administer Vaccinations” (Anatomic Sites for Immunizations) poster, stock no. 6-27P.
 - “Contraindications and Precautions to Vaccines for Children and Adults” poster, stock no. 6-61.
 - “Giving All the Doses” Chart, stock no. 11-12155.
 - “Refrigerator Warning Signs”, stock no. 6-180.
 - “Do Not Unplug” stickers on wall outlet and at the circuit breaker, included in the “Refrigerator Warning Signs”, stock no. 6-180.
- Provides immunization schedules, catch-up schedules, resource lists, and other materials.

Quick Review

Question

How often is the Provider Agreement Form updated?

- Every year
- Every six months
- Every two years

Quick Review

Answer

How often is the Provider Agreement Form updated?

- ✓ **Every year**
- Every six months
- Every two years

The Provider Agreement Form must be completed and updated every year.

It includes basic information about the facility and the provider. It also outlines the provider's responsibilities. The signed agreement must be received and processed by the TVFC/ASN programs before the clinic receives state and federally-funded vaccines.

Vaccine Accountability

Vaccine accountability is a cornerstone of the TVFC/ASN programs and one of the highest priorities for the DSHS Immunization Program. When a TVFC/ASN provider enrolls in the TVFC/ASN programs, they agree to the accountability requirements as a condition of participation.

All TVFC/ASN providers must ensure:

- TVFC/ASN vaccines are administered only to eligible clients.
- Vaccine loss and waste are minimized and documented.
- Fraud and abuse (as defined in the TVFC/ASN Provider Policy Manual) does not occur.
- TVFC/ASN vaccine inventory is accurately reported monthly.
- Patients are screened at all immunization encounters for TVFC/ASN eligibility.

The TVFC/ASN Provider Manual includes all the information to meet these requirements.

Provider Change of Information

Upon enrollment, the provider also agrees to maintain and update demographics, days and hours available to receive vaccine shipments and other profile information.

The RE must be contacted and information updated when there are changes to:

- Facility name
- Facility physical, mailing, or shipping address
- Facility shipping hours
- Signing clinician
- Prescribing authorities
- Patient population data change
- Primary and/or backup vaccine coordinators

Failure to properly update current clinic information may result in vaccine delays and possible negligent vaccine loss.

Provider Suspension

If a provider violates the agreements and accountability requirements that are a part of participating in TVFC/ASN programs, they may temporarily lose their ordering privileges.

Suspension is dependent upon the severity of the non-compliance issues and/or failure to complete the TVFC/ASN-required corrective action plans.

TVFC/ASN corrective action plans are set in place to correct failures in vaccine management and non-compliance issues, including, but not limited to, failure to complete re-enrollment in a timely manner; failures in vaccine management, improper storage and handling practices; and failure to complete monthly reporting requirements.

Staff at suspended sites may be required to complete additional training as part of a corrective action plan.

Provider Termination

A TVFC/ASN provider may be terminated for:

- Continued non-compliance with TVFC/ASN requirements.
- Failure to complete the re-enrollment process.
- Failure to complete required corrective actions associated with non-compliance.
- Instances of fraud and abuse, described later in this training.
- Not ordering vaccines in the past 12 months.

All providers are notified of their termination from the program via a signed letter from the Immunization Section director. Terminated providers are removed from the TVFC/ASN program for a period of one year before the provider may be considered for re-enrollment.

Re-Enrollment After Termination

If a terminated provider is approved to be re-enrolled in the TVFC/ASN program, they must complete an orientation about the TVFC/ASN program guidelines, participate in on-site education, and confirm that the problems have been resolved through a focused site review assessment.

TVFC/ASN providers terminated for instances of fraud and abuse may be considered for re-enrollment after one year. TVFC providers will only be considered for re-enrollment if actively enrolled in Medicaid at that time and has been removed from the OIG's List of Excluded Individuals and Entities (LEIE).

The Immunization Section has the authority to determine whether a provider is eligible to re-enroll in the TVFC/ASN program.

Quick Review

Question

Select all that apply.

What are the possible consequences if a provider violates TVFC/ASN program agreements and accountability requirements?

- The provider may be suspended.
- The provider may temporarily lose their ordering and administrative privileges.
- The provider may be terminated.

Quick Review

Answer

Select all that apply

What are the possible consequences if a provider violates TVFC/ASN program agreements and accountability requirements?

- ✓ The provider may be suspended.
- ✓ The provider may temporarily lose their ordering and administrative privileges.
- The provider may be terminated.

If providers violate the agreements and accountability requirements, they may be suspended and temporarily lose their ordering privileges.

Consequences are dependent upon the severity of the non-compliance issues and/or failure to complete the TVFC/ASN-required corrective action plans.

TVFC Patient Eligibility and Screening



Patient Eligibility and Screening



Upon completing this section, you will be able to identify the current policies related to patient eligibility and screening of the TVFC program.

Importance of Eligibility Screening

Screening for patient eligibility is the foundation of provider-level accountability.

Screening all children at **every** immunization encounter and documenting eligibility screening at **every visit** is the only way to ensure that TVFC vaccine is used only for TVFC-eligible children. As such, full compliance with screening for eligibility is required.

If improper screening results in the administration of TVFC vaccine to an ineligible child, providers are responsible for replacing the improperly used TVFC vaccine with private stock.

Eligibility Documentation

The screening form is completed by the parent, guardian, individual of record or by health care provider and is a self-declaration. The provider may also document eligibility through an electronic medical records system (EMR), if the EMR captures all the required eligibility elements.

Documentation must include the following :

- Date of screening
- Child's name
- Child's date of birth
- Parent/Guardian's name
- Clinic name
- Eligibility status for each visit

Patient Eligibility Screening Records must be kept on file with the patient's record for a minimum of five years after the last date of service to the patient and must be readily available.

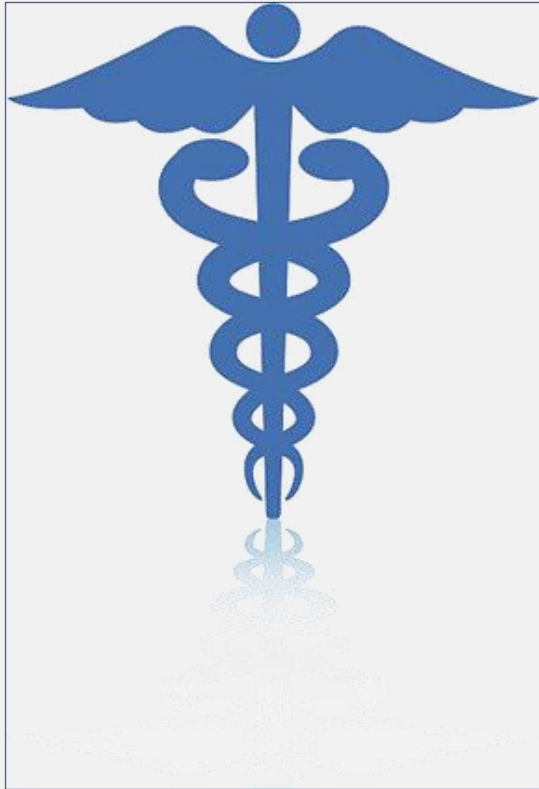
Eligibility Criteria

Children eligible to receive TVFC vaccines must be 18 years of age or younger and meet at least one of the eligibility criteria.



Eligibility Criteria

Enrolled in Medicaid or Medicaid-eligible



Insured children with Medicaid as their secondary insurance (*Medicaid-eligible*) are eligible for TVFC program and **must not** be refused vaccine administration due to their insurance status.

Eligibility Criteria

Enrolled in the Children's Health Insurance Program (CHIP)

An agreement between the DSHS Immunization Section and CHIP stipulates that vaccines for eligible CHIP enrollees are purchased through the federal contract. Each TVFC provider who administers VFC vaccines to CHIP children must be an active participating provider in CHIP. Each TVFC provider who administers VFC vaccines to CHIP children is required to bill CHIP for the vaccine administration fees.

Eligibility Criteria

Alaskan Native or American Indian

A child who is American Indian or Alaskan Native in accordance with [25 USC 1603](#) is eligible for TVFC vaccine.

Eligibility Criteria

Multiple eligibility criteria



If a child is TVFC eligible in more than one category, the provider must select and document the eligibility category requiring the least out-of-pocket expense for the parent or guardian.

Eligibility Criteria

Immigration or residency status



Immigration and/or residency status **does not** affect a child's eligibility for the TVFC program.

Quick Review

Question

If a child is TVFC-eligible in more than one eligibility category, which category should be used?

- Select any category; it won't make a difference for the provider.
- Select the category that requires the least out-of-pocket expense.
- Consider the immigration status of the child.

Quick Review

Answer

If a child is TVFC-eligible in more than one eligibility category, which category should be used?

- Select any category; it won't make a difference for the provider.
- ✓ **Select the category that requires the least out-of-pocket expense.**
- Consider the immigration status of the child.

If a child is TVFC-eligible in more than one eligibility category, the provider must select and document the eligibility category that will require the least out-of-pocket expense for the parent or guardian.

Vaccine Ordering



Texas Department of State
Health Services

2024 TVFC/ASN Provider Policy Training

Vaccine Ordering



Upon successful completion of this section, you will be able to order vaccines in the TVFC/ASN program.

TVFC-Recommended Vaccines

The TVFC program supplies all the Advisory Committee on Immunization Practices (ACIP) recommended vaccines to enrolled providers.

ACIP is a federal advisory committee designed to provide guidance to assist the U.S. Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases and increasing the safe use of vaccines and related biological products.

Providers participating in the TVFC program are required to offer all ACIP-recommended vaccines to the eligible populations they serve. House Bill 448 from the 81st Texas Legislature gives TVFC providers the opportunity to choose their preferred brands of vaccines from their available formularies.

[View ACIP recommended vaccines](#)

Approved Vaccines

All vaccines and toxoids recommended by ACIP are available from the TVFC program to enrolled clinic sites.

- Coronavirus (COVID-19)
- Diphtheria-Tetanus toxoids and acellular Pertussis (DTaP)
- Diphtheria-Tetanus toxoids and acellular Pertussis, Hepatitis B, and inactivated polio (DTaP-Hep B-IPV)
- Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, and Haemophilus influenzae type b (DTaP-IPV/Hib)
 - Diphtheria, tetanus,
 - Pertussis, Polio, *Haemophilus influenzae* type b and Hepatitis B (DTaP-IPV-Hib-Hep B)
- Diphtheria-Tetanus toxoids and acellular Pertussis and inactivated polio (DTaP-IPV)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Hepatitis A and Hepatitis B (Hep A-Hep B) combination
- Haemophilus influenzae type b (Hib)
- Human Papillomavirus (HPV)
- Influenza (Flu)
- Inactivated polio (IPV)
- Measles, Mumps, and Rubella (MMR)

Approved Vaccines

Continued

- Measles, Mumps, Rubella and Varicella (MMRV)
- Meningococcal groups C and Y and *Haemophilus influenzae* b (tetanus toxoid) (HIBMENCY)
- Meningococcal conjugate (MCV4)
- Meningococcal Serogroup B (MenB)
- Pneumococcal Conjugate (PCV)
- Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
- Rotavirus (RV)
- Respiratory syncytial Virus)
- Tetanus and Diphtheria toxoids, adsorbed (Td)
- Tetanus and Diphtheria toxoids and acellular Pertussis (Tdap)
- Varicella

[View ACIP recommended vaccines](#)

Vaccine Choice

When ordering vaccines, a provider can choose brands and presentations.

The signing clinician at TVFC/ASN-enrolled sites may choose vaccine brands and presentations. For new clinics enrolling in the TVFC program, the RE and the staff will initially select their desired vaccine brands and presentations in VAOS. Their order quantity will be based on maximum stock levels (MSL), which are calculated from the site's patient population for the first year in the program.

The site's patient population data is highly utilized in the first year of a site's enrollment in TVFC/ASN, because it is used to calculate their MSLs to establish order quantities.

Vaccine Choice

Continued

Providers will have the opportunity to choose the brand and presentation for each TVFC/ASN vaccine. They can change or adjust specific vaccine brands, presentations, and percentages within each vaccine "family" (e.g., DTaP). Providers are encouraged to review all choice selections as needed.

A provider's TVFC/ASN vaccine coordinator may complete the process; however, the provider who signed the VFC Program Provider Agreement must be consulted and agree to the vaccine choices. The vaccine choices, as well as the person making the changes, are captured electronically. TVFC/ASN providers are notified prior to the opening and closing of the vaccine choice period.

Only vaccines supplied by the CDC to the TVFC/ASN program will be available for vaccine choice.

Unavailable Vaccines



If a chosen vaccine is not available, the TVFC/ASN program has the authority to replace the unavailable vaccine with a comparable substitute.

Vaccine choices do not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or any other extraordinary law enforcement emergency.

Vaccine Inventory



The vaccine inventory plan recommends all enrolled providers to maintain a **75-day supply** of vaccine inventory.

The CDC recommends:

- Providers place orders when they have a four-week supply of vaccine available, to ensure there is enough vaccine in stock to allow for any potential delays.
- Providers order smaller, more frequent orders rather than larger orders. Smaller orders minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Providers may place additional orders.

Vaccine Inventory Plan

Providers are not required to place a vaccine order each month. They should order as needed to maintain a 75-day supply of vaccines.

While accepting an order on VAOS, providers must report "Doses Passing Inspection" and "Doses Failed Inspection." any vaccine received in error, damaged, or with questionable viability should be listed under Doses Failed Inspection.

DSHS reviews this information reported by sites daily for dissemination to the distributor, manufacturer, or RE for more action.

Maximum Stock Levels



The MLS is a calculated peak dose inventory (per vaccine type). The suggested quantity is the maximum number of doses a provider needs to maintain the 75-day inventory. Providers must consider their current inventories and unit storage capacities when placing orders to ensure adequate storage for all vaccines.

Special circumstances may allow for monthly MSL adjustments on rare occasions. The provider must request a review and obtain permission from their Responsible Entity prior to ordering more than their suggested MSL quantity.

Developing a Maximum Stock Level

MSLs are calculated based on the provider's patient population upon initial enrollment. All MSLs are monitored and revised in the ordering system.

Newly enrolled providers may have their MSL reassessed by their Responsible Entity after six months with the TVFC program.

MSLs are calculated based on patient population data during the first year, and after the first year, MSLs are calculated monthly based on doses administered data. Providers may not order vaccines above their suggested quantity without permission from their Responsible Entity.

Quick Review

Question

Providers are required to offer all ACIP-recommended _____ to eligible populations.

- immunization schedules
- dosages
- vaccines
- contraindications

Quick Review

Answer

Providers are required to offer all ACIP-recommended _____ to eligible populations.

- immunization schedules
- dosages
- vaccines
- contraindications

Providers are required to offer all ACIP-recommended vaccines to the eligible populations they serve. House Bill 448 from the 81st Texas Legislature allows TVFC/ASN providers to choose their preferred brands and presentations of vaccines from their available formularies.

Vaccine Expiration and Storage

Short-Dated Vaccines

Short-dated vaccines are those vaccines within **60 to 90 days of expiration.**

Providers can help prevent losses due to expiration by placing orders according to the established MSLs and rotating vaccines so that short-dated vaccines are used first.

Clinic staff must note vaccine expiration dates when physically counting inventory at the end of the month. The short-dated vaccine must be used first.

Having a vaccine surplus in inventory increases the risk of vaccine expiration. Vaccine surplus also increases the amount of loss in the event of refrigerator failure. Providers must have no more than the designated MSL in stock when ordering vaccines, including the order.



Notification of Expiration

Each provider must notify their Responsible Entity 60 to 90 days before the expiration of vaccines. If the provider is unable to administer the vaccine prior to expiration, the Responsible Entity may assist with moving the vaccine to another provider site, provided another provider is willing to accept the vaccine.

Vaccine diluents, the liquid mixed with a freeze-dried vaccine to reconstitute it, must be managed in the same manner as vaccines: diluents' expiration date must be checked before every reconstitution. Providers must also rotate diluent stock to use the shortest expiration date first.

If vaccines are allowed to expire, they are considered non-viable. Expired vaccines must be placed in a Vaccine Quarantine Bag clearly labeled "Do not use" and removed from storage units.

Storage Capacity



A TVFC/ASN provider must have adequate refrigeration or freezer space to accommodate a maximum order based on their MSL.

The provider must also take into consideration the space needed for their private stock.

Quick Review

Question

The suggested supply of vaccines a TVFC/ASN Provider should have on hand is a _____-day supply of vaccine inventory.

- 120
- 75
- 30

Quick Review

Answer

The suggested supply of vaccines a TVFC/ASN Provider should have on hand is a _____-day supply of vaccine inventory.

- 120
- 75
- 30

All enrolled providers should maintain a 75-day supply of vaccine inventory. The maximum stock level (MS) is a calculated peak dose inventory (per vaccine type) and is the standard number of doses a TVFC/AS provider can order each month to maintain the 75-day inventory.

Providers must consider their current inventories and unit storage capacities when placing orders to ensure adequate storage for all vaccines.

Offsite/Mass Vaccination



Pre-Book Influenza Vaccine

Pre-book is part of the provider's commitment to order doses for the upcoming flu season. Annual influenza vaccine orders are typically pre-booked by TVFC providers in the first quarter of each calendar year.

ACIP recommends routine annual influenza vaccination of all persons aged six months and older.

Flu vaccine choices will be submitted through VAOS.



Influenza Vaccine Availability

The influenza vaccine will be allocated to TVFC providers as it is made available to the state of Texas. The TVFC program completes annual influenza vaccine orders, usually pre-booked in the first quarter of each calendar year.

Once all the pre-booked orders are filled, any remaining influenza vaccine will be added to VAOS for all providers' general ordering.



The TVFC program recognizes that both TVFC-supplied and privately purchased influenza vaccines may arrive at a provider's office at different times during the influenza season. However, even if this occurs, the TVFC program does not allow TVFC providers to borrow TVFC influenza doses for administration to their ineligible clients.

Off-site/Mass Vaccination Clinics



Off-site/Mass vaccination clinics may be set up for seasonal vaccines, such as influenza, to protect a large group of patients.

Routine transport of vaccine is not recommended due to the risk of compromising the cold chain and vaccine viability. The cold chain is the monitoring of a temperature-controlled environment to maintain and distribute vaccines in optimal condition.

However, because most temporary off-site/mass clinics typically require vaccine transport on the day of the clinic, these temporary clinics (schools, local clinics) require enhanced storage and handling practices.

Off-site/Mass Vaccination Protocol

The TVFC/ASN provider must develop off-site/mass vaccination protocols to ensure outreach efforts meet all TVFC requirements, including:

- Showing the established vaccine needs (provider profile).
- A plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of TVFC/ASN stock are transported on each clinic day.
- Submit a schedule for each off-site clinic to include date, location and estimated number of vaccine doses expected to be administered.
- The type of portable storage unit being used.
- How the cold chain will be maintained from the beginning to the end of the off-site/mass vaccination clinic.
- Each site location should be documented on the Vaccine Transport Log Form.

The provider's Responsible Entity must review and approve the off-site/mass vaccination plan prior to initiation of the off-site/mass vaccination clinics.

Off-site/Mass Vaccination

Ordering and Shipping Requirements

To ensure vaccine storage and handling for off-site/mass vaccination clinics is managed properly, the following storage and handling practices are required.

All of the vaccine must be ordered and shipped directly to a location within the ordering provider's DSHS PHR. Appropriate staff must be on site and available at least one day a week other than Monday and for at least four consecutive hours during the hours of 8:00 a.m. to 5:00 p.m.

Off-site/Mass Vaccination Clinic

Proper Transportation Requirements

The vaccine must be properly transported, not shipped, to local schools or other community sites where the off-site/mass vaccination clinics will be held.

- The total time for transport alone or transport plus clinic workday must not exceed eight hours (e.g., if transport to an off-site clinic is one hour each way, the clinic may run for up to six hours).
- Only appropriate amounts of appropriate vaccines, based on TVFC/ASN need, should be transported to each scheduled clinic.
- The vaccine must be transported to and from the scheduled off-site/mass vaccination clinic at appropriate temperatures and must be monitored by a continuous monitoring data logger with a display (that can be viewed outside of the storage unit) and a probe in buffered material.

Off-site/Mass Vaccination Clinic

Proper Transportation Requirements continued

The vaccine being transported should be tracked to maintain accountability for monthly reporting.

This includes:

- Vaccine type(s) and brand names
- Quantity of each type
- NDC numbers
- Lot numbers
- Expiration dates

Off-site/Mass Vaccination Clinic

Temporary Location Proper Storage and Documentation

Upon arrival at the clinic site, the TVFC/ASN off-site/mass vaccination provider must ensure that the vaccine is stored to maintain the appropriate temperature throughout the clinic day.

- Temperature data must be reviewed and documented every hour during the day of the clinic using a continuous monitoring and recording device with a digital display and probe in buffered material. The “Temperature Recording Form”, stock no. EC-105, may be used to document hourly temperatures.
- The Vaccine Transfer Authorization Form should be used for trips that last an hour or less and the Vaccine Transport Log should be used for trips lasting more than one hour.

Off-site/Mass Vaccination

Complete Daily Inventory Requirement

After each clinic day, the provider must physically count the remaining vaccine. Assess temperatures prior to placing the vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.

Off-site/Mass Vaccination Clinic

Quarantine Vaccines Exposed to Temperature Excursion Requirements

Vaccines exposed to temperature excursions, when the temperature goes above or below its required temperature, must be separated in a vaccine quarantine bag and labeled "Do not use" until further information can be gathered from the manufacturer(s). The vaccine should be kept at appropriate temperatures until a viability determination is made.

Quick Review

Question

How often does temperature need to be logged during an off-site/mass vaccination clinic?

- Every four hours
- Twice a day
- Every hour

Quick Review

Answer

How often does temperature need to be logged during an off-site/mass vaccination clinic?

- Every 4 hours
- Twice a day
- Every hour

Temperature data must be reviewed and documented every hour during the day of the clinic. Temperature should be monitored using a continuous monitoring and recording device with a digital display and probe in buffered material resembling a vaccine.

Vaccine Distribution



TEXAS
Health and Human
Services

Texas Department of State
Health Services

2024 TVFC/ASN Provider Policy Training

Vaccine Distribution



Upon successful completion of this section, you will be able to identify the state and federal guidelines on how to receive vaccine shipments.

Receiving Vaccines

The TVFC/ASN program requires that providers always accept vaccine shipments. Providers should never refuse or return the shipments without specific instructions from the TVFC/ASN program or their Responsible Entity. The TVFC/ASN provider must ensure that the clinic address and delivery hours are up-to-date in Syntropi.

For providers to receive vaccine shipments, appropriate staff must be on-site and available at least one day a week other than Monday and for at least four consecutive hours during the hours of 8:00 a.m. – 5:00 p.m.

Establishing Availability

Each provider establishes the hours available to accept vaccine shipments when they enroll or re-enroll annually. The vaccine will be shipped so that it will arrive when the provider is available to accept the order. Provider availability times cannot be changed once an order is placed.



The TVFC/ASN provider will be held responsible for incomplete or erroneous information entered into the system. Incomplete or erroneous ordering information can result in vaccine loss.

The provider can expect their approved orders approximately two to three weeks after placing their online order in the system.

Immediate Storage

It is important to store vaccine shipments immediately to ensure vaccine viability.

Providers are required to train their staff on what a vaccine shipment looks like and have a vaccine management plan in place to ensure the vaccine is stored quickly and correctly upon arrival.



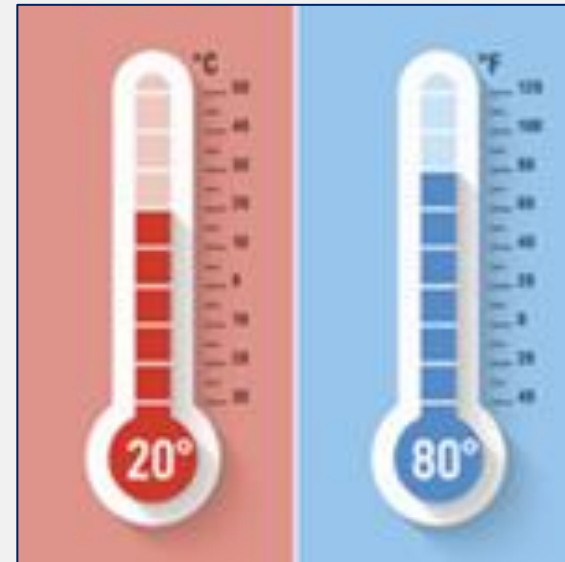
The Cold Chain

Proper receipt and storage of a vaccine delivery is important to maintain the vaccine cold chain.

The cold chain, or temperature monitoring, begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, continues through the delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of potency.

Failure in the cold chain can be costly. Should there be a failure in the cold chain, the result can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. A loss of public confidence in vaccines can lead patients to refuse revaccination and remain unprotected from serious vaccine-preventable diseases.

By maintaining the vaccine cold chain, your facility can avoid incurring the additional costs associated with loss and replacement of vaccines, as well as need to recall patients for revaccination.



Maintenance of the Cold Chain

Manufacturers and distributors pack the vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures.

Refrigerated vaccine is packed to maintain the cold chain for 72 hours. The vaccine will be shipped using high-quality cardboard boxes with Styrofoam inserts. Packages are imprinted with "Temperature sensitive product" and include red stickers reading "Refrigerate upon arrival".

MMRV and Varicella are directly shipped from Merck. Merck products are shipped frozen with a four-day pack-out. If the vaccine arrives within four days of the pack date on the invoice, then the vaccine is viable.

The provider must immediately place all vaccines in proper storage.

Vaccines Received Warm or Questionable

Vaccines must always be stored properly, even if viability is questionable. If vaccines are received warm, damaged, or in an otherwise questionable state, the provider must immediately contact their vaccine distributor, followed by their Responsible Entity. A provider's home cannot be used as storage for vaccine, even in the event of an emergency.

Questionable vaccine cannot be identified visually. They may be:

- Received with temperature indicator strip showing out of range
- Warm to the touch
- Received damaged
- Received in a cooler that does not contain ice packs
- Received in a cooler that contains ice packs that are warm



Procedure for Vaccines Received Warm or Questionable

If vaccine viability is questionable upon receipt, a provider must:

- Place the probe of the backup data logger in the questionable shipment, near the vaccine and replace the lid to gain the current temperature. Temperatures must be checked frequently to see when the temperature stabilizes.
- Separate the vaccine in a vaccine quarantine bag, and place questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.
- Contact the distributor immediately to determine if a shipping issue has occurred.
- Contact the Responsible Entity on the same day the vaccine arrived. Calls received after the day of delivery will result in the CDC's liability for vaccine replacement, regardless of the cause of the temperature excursion. This documentation must be maintained with the provider's records for a minimum of five years.
- Inform the Responsible Entity of the determination of the viability of the vaccine.
- Vaccines must be kept quarantined until instructions for replacement, reporting loss, etc., are received.

McKesson requires that vaccine returns due to shipping issues are returned within 48 hours. Merck requires that the request for replacement be received within 15 days of the original shipment.

Vaccines Received in Error

TVFC/ASN providers must call their Responsible Entity immediately upon receipt of vaccines that are received in error.

The provider may opt to keep the vaccine if they have storage capacity and will administer the doses. If vaccine was ordered by the site incorrectly, it is the site's responsibility to keep the vaccine. If the provider cannot absorb the vaccine into their stock, then their Responsible Entity may assist in redistributing the vaccine to other TVFC/ASN providers.

Quick Review

Question

Select all that apply

Results of a cold chain failure can result in _____.

- extra doses administered to patients
- increased costs for providers
- damage to public confidence in vaccines

Quick Review

Answer

Select all that apply

Results of a cold chain failure can result in _____.

- ✓ extra doses administered to patients
- ✓ increased costs for providers
- ✓ damage to public confidence in vaccines

Results of a cold chain failure can be costly. Inappropriate storage can mean extra doses administered to patients, increased costs for providers, and damage to public confidence in vaccines. More importantly, patients who refuse revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccine Loss



Vaccine Loss



Upon successful completion of this section, you will be able to explain the process of what to do if vaccine loss occurs.

Vaccines Loss

The DSHS Immunization Program requires all unopened or unused vials and syringes of expired TVFC vaccines be returned to the third-party distributor (McKesson).

Vaccine manufacturers reimburse CDC for the federal excise tax portion of the cost of the vaccine. Therefore, providers should not discard any vaccine unless specifically directed by the DSHS Immunization Section, DSHS PHR, or LHD.

Any exception to this rule will be communicated by the DSHS Immunization Program on a case-by-case basis. Providers are to immediately notify their Responsible Entity of vaccine cold chain failure events or vaccine wastage incidents involving TVFC/ASN vaccines upon discovery of the incident.



Expired or Spoiled Vaccine

Expired or spoiled vaccine is any non-viable vaccine in its original container such as a vial or syringe that can be returned for excise tax credit.

This includes expired vaccine or a vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator temperature too warm (greater than 46°F or 8°C) or too cold (less than 36°F or 2°C)
- Freezer too warm (greater than +5°F or -15°C)
- Failure to store vaccine properly upon receipt
- Vaccine spoiled in transit due to provider error
- Vaccine spoiled in transit due to shipper error, no replacement
- Mechanical failure



Ruined/Wasted Vaccine

Ruined/wasted vaccine is any non-viable vaccine that cannot be returned.

This includes:

- Vaccine drawn into the syringe but not administered
- Vaccine in an open multi-dose vial where all doses have not been administered.
 - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- Compromised vial (due to a drop causing damage to vial integrity or sterility), or broken vial
- Expired open multidose vial, unable to return
- Vaccine drawn into the syringe but refused by the patient
- Incorrect vaccine that has been prepared for patient
- Incorrect diluent drawn for or used for vaccine reconstitution



Returning Wasted Vaccine

Wasted and expired/spoiled vaccines must be removed from the storage unit, labeled "Do not use," and stored pending return to distributor.

Expired diluents do not need to be returned.

Vaccine loss must be electronically documented in Vaccine Allocation Ordering System (VAOS) no later than four days past the date of the incident(s). Spoiled and expired vaccine must be returned to the distributor within 6 months of the loss.

Procedures for Vaccine Loss

Quarantine

When a vaccine loss occurs, there are steps the provider must follow.

Remove expired/spoiled vaccine from the vaccine storage unit and place in a vaccine quarantine bag.

Procedures for Vaccine Loss

Contact RE

Contact your Responsible Entity immediately with the following information:

- Antigen
- Lot number
- Expiration date
- Reason for expiration/loss

Procedures for Vaccine Loss

Time Out of Range

If storage was compromised, provide the Responsible Entity with amount of time the product was out-of-range and the highest and lowest temperatures recorded (this information may be gathered from the data logger download).

Procedures for Vaccine Loss

Document Loss

Document the vaccine loss on the Vaccine Loss Report electronically generated in the Vaccine Allocation and Ordering System (VAOS) within four days past the date of the incident of loss. Explain the cause(s) of the loss and outline the steps taken to ensure vaccines will be protected in the future.

Procedures for Vaccine Loss

Report Loss

The Vaccine Loss Report (VLR) must be printed and signed by medical personnel with prescribing authority listed on the site's enrollment form. The report must be uploaded in the Files section of VAOS for review

The Vaccine Loss Report includes:

- Clinic demographics
- Date loss was discovered
- Type of loss
- Reason for loss
- Corrective action taken to avoid re-occurrence
- List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost

Procedures for Vaccine Loss

Return Vaccine

Providers will receive a shipping label via email for returning expired or spoiled vaccine, if applicable. The provider must wait until UPS returns for the pickup to avoid paying a fee.

Providers must:

- Ensure that all vaccines listed on the Vaccine Loss Report (VLR) are included in the box for return. Do not return broken vials or syringes with needles attached.
- Indicate on the Vaccine Loss Report the number on each box to be returned.

Only unbroken, sealed vaccine vials/syringes may be included for return. Broken vials, opened multi-dose vials, or syringes with a needle attached must never be included in the box.

Quick Review

Question

Select all that apply

Providers should discard vaccine in which of the following instances?

- Directed by their Responsible Entity (RE)
- A multi-dose was opened or accessed more than 28 days ago
- A multi-dose was opened or accessed 2 days ago

Quick Review

Answer

Select all that apply

Providers should discard vaccine in which of the following instances?

- ✓ Directed by their Responsible Entity (RE)
- ✓ A multi-dose was opened or accessed more than 28 days ago
- A multi-dose was opened or accessed 2 days ago

Providers should not discard any vaccine unless specifically directed by the DSHS Immunization Section, DSHS PHR, or LHD. Vaccine manufacturers reimburse CDC for the federal excise tax portion of the cost of the vaccine.

Any exception to this rule will be communicated by the DSHS Immunization Section on a case-by-case basis.

Revaccination After Loss



Providers who have lost vaccine as a result of improper temperature storage must assess how long the vaccines were improperly stored and how many children may have received the affected vaccines. The signing clinician determines whether or not the patient will need to be recalled and revaccinated.

The TVFC/ASN program will not provide the vaccine for recalled patients in these circumstances. The clinic will assume all financial responsibility for the cost of vaccines for recalls. Providers must contact their Responsible Entity with the determination from the signing clinician.

Negligent Vaccine Loss

TVFC/ASN providers will be held responsible for vaccine losses due to negligence. Vaccine negligence may include, but is not limited to, the following:

- Drew up dose and parent or patient refused
- Drew up wrong vaccine including:
 - Vaccine mixed with wrong diluent; or
 - Only diluent was administered
- Dropped dose resulting in:
 - Damage to vial integrity or sterility
 - Compromised vial
- Expired vaccine and the site did not notify RE 60 to 90 days before expiration
- Failure to store properly including:
 - Vaccines left out of storage; or
 - Improper monitoring of temperatures in refrigerator or freezer

Negligent Vaccine Loss (continued)

- Refrigerator temperature too cold
- Storage temperature too warm including:
 - Unit that was unplugged and a plug guard was not used
 - Unit door was left open
 - Temperatures were not documented or were monitored improperly
- Vaccine spoiled in transit due to clinic staff error including:
 - Vaccine transfers
 - Refused vaccine shipment
 - Vaccine delivered when clinic is closed, and the closure was not documented in VAOS
- Vaccine stored improperly including:
 - Vaccine left out of appropriate storage unit
 - Not stored properly upon receipt

TVFC/ASN-enrolled sites may be required to reimburse the DSHS Immunization Program for vaccine losses

Non-Negligent Vaccine Loss

Non-negligent vaccine losses include the following:

- Damaged needle or seal, particulate in the vial, discolored liquid, etc.
- Expired flu, pedi Td, or pediatric PPSV
- Expired and the clinic staff notified RE 60 to 90 days before expiration and the RE was unable to transfer
- Mechanical failure of refrigerator or freezer
- Natural disaster or power outage
- Unable to transfer open multi-dose vial
- Vaccine spoiled in shipment due to shipper error

Vaccine Disposal

- The Texas Department of State Health Services follows the Texas Commission on Environmental Quality (TCEQ) guidance on proper medical waste disposal of wasted vaccine.
- The TCEQ and DSHS define medical waste as special waste from healthcare-related facilities, which includes: treated and untreated animal waste, bulk human blood and body fluids, microbiological waste, pathological waste, and sharps.
- Following the TCEQ's guidance on disposal of medical waste, dispose of needles and associated vials in a clearly labeled sharps container, treating it as a contaminated biohazard container. Wipe down and sanitize work areas. After disposing of vaccine, take off and dispose gloves, and thoroughly wash hands with soap and water for at least 20 seconds or use an alcohol-based hand sanitizer that contains at least 60% alcohol.
- Additional information on local regulations for how to treat and dispose of medical waste in Texas can be found on TCEQ's website [LINK: https://www.tceq.texas.gov/permitting/waste_permits/msw_permits/medwaste] or by emailing info@tceq.texas.gov.

Quick Review

Question

Providers who have lost vaccine as a result of improper temperature storage must discuss the situation with the _____ to determine whether or not children will need to be recalled and revaccinated.

- Responsible Entity
- DSHS PHR
- signing clinician
- Immunization Section

Quick Review

Answer

Providers who have lost vaccine as a result of improper temperature storage must discuss the situation with the _____ to determine whether or not children will need to be recalled and revaccinated.

- Responsible Entity
- DSHS PHR
- Signing clinician
- Immunization Section

The signing clinician has the final responsibility in determining whether or not children will need to be recalled and revaccinated.

Vaccine Storage and Handling



Vaccine Storage and Handling



Upon successful completion of this section, you will be able to identify the state and federal guidelines on how to correctly store vaccines.

Importance of Vaccine Storage and Handling

There are few immunization issues more important than the appropriate storage and handling of vaccines. Vaccine-preventable disease rates have decreased in part because of proper storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can decrease their potency and reduce the effectiveness and protection they provide.

Improper storage and handling not only increases the risk presented by vaccine-preventable diseases, it results in thousands of dollars lost in wasted vaccine and revaccination. Errors can also result in the loss of patient confidence when repeat doses are required. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled.

Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built.

The following cooling materials cannot be used in units containing TVFC/ASN vaccine:

- Gel packs (thawed or frozen)
- Ice packs
- Coolant packs from vaccine shipments
- Any other coolant material that is not allowed by CDC or TVFC/ASN program.

Refrigerator and Freezer Requirements

The DSHS Immunization Section recommends the following types of units, listed in preferential order.

- Pharmaceutical/purpose-built units
- Stand-alone, single-purpose refrigerator and stand-alone single-purpose freezer
- Auto-dispensing unit
 - DSHS has approved the use of auto-dispensing or door-less units to store TVFC/ASN vaccines. This type of unit is purposely built to store vaccines. Loading vaccines in this type of unit is the only time vaccines should be kept outside of their original packaging however, providers must keep all the original vaccine packaging in the event the vaccine has to be transported outside of the unit. Servicing must be completed on auto-dispensing units as specified by the manufacturer. Monthly temperature logs must be recorded and submitted each month on the 7th. Ensure that temperature logs are posted on the unit, as with other cold storage units.
- Combination household unit
 - If a combination household unit must be used, staff are strongly encouraged to use only the refrigerator compartment to store vaccines and to use a separate stand-alone freezer to store frozen vaccines. Use of the freezer compartment of a household combination unit is discouraged.
 - The freezer can be an on-the-counter or under-the-counter type as long as appropriate temperatures are maintained. A frost-free unit with an automatic defrost cycle is preferred.
 - Combination units, if used, must have separate thermostats for the refrigerator and freezer compartments. DSHS recommends not using both the freezer and refrigerator section of a dual unit.
 - If the unit is consistently maintaining the required temperature ranges, may continue to do so. If temperature excursions occur that can't be attributed to another cause (e.g., power outage), the provider must discontinue use of one of the compartments

NOTE: Providers enrolled after July 1, 2024, will not be allowed to use the freezer compartment of a household combination unit.

Refrigerator and Freezer Requirements

(continued)

Units must be plugged directly into a wall outlet with a plug guard. Do not use any of the following for refrigerators or freezers:

- Extension cords
- Multi-outlet power strips
- Outlets that are activated by a wall switch
- Outlets with built-in circuit switches (ground fault interrupt receptacles)
- Surge protectors

NOTE: You may see vendors use terms such as "VFC-Compliant," "CDC-Compliant," or "satisfies VFC Requirements" in their marketing materials or on their websites. Should you encounter this type of language in vendor marketing materials, keep in mind that the TVFC/ASN program has not validated any product or service for compliance with TVFC/ASN program requirements or standards.

Refrigerator and Freezer Requirements

(continued)



Each refrigerator or freezer must contain a sufficient number of water bottles to help maintain proper storage temperature during peak usage of the unit. Peak usage occurs when there is frequent opening and closing of unit doors or a power failure.

Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions. Unless a pharmaceutical-grade storage unit manufacturer indicates that water bottles negatively impact the functionality of the unit, place water bottles throughout the refrigerator and freezer.

Depending on the size of the unit, the amount of vaccine stored, and the time of year, "sufficient" may differ from one clinic to the other. However, there must be adequate water bottles in each refrigerator and adequate frozen water bottles in each freezer to help maintain proper storage temperature during peak usage of the unit or until vaccines can be moved to another refrigerator or freezer.

Refrigerator Requirements (continued)



For each refrigerator, the provider must:

- Ensure the door closes completely.
- Replace crisper bins with water bottles to help maintain consistent temperature (unless used for other medical equipment or supplies).
- Place water bottles on the top shelf of the refrigerator.
- Label water bottles "Do not drink."
- Place water bottles in unit doors carefully so they cannot dislodge, and prevent the doors from closing, or weighing down the door so much that it does not seal tightly.
- Do not drink from or remove the water bottles.

Refrigerator Requirements (continued)



Do NOT store food or beverages inside a vaccine refrigerator or freezer.

- Make sure the refrigerator door is closed completely.
 - Post "Do not unplug" signs on the refrigerator, by the electrical outlet, and at the circuit breaker.
 - Do not put food or beverages in the refrigerator.
 - Do not pack a storage unit too tightly. This can restrict air circulation and impact temperature. Vaccines should be centrally stored within the unit.
 - Place vaccines with the earliest expiration dates in front to be used first.
 - Do not use the top shelf for vaccine storage.
 - Store vaccines in original packaging with lids closed until ready for administration.
-
- Never store loose vials or manufacturer-filled syringes outside of their packaging.
 - Store privately purchased vaccine on different shelves from TVFC/ASN to minimize the risk of administering TVFC/ASN vaccine to non-eligible patients. TVFC/ASN vaccines should be clearly marked to differentiate them from privately purchased vaccines.
 - Label the formulation "pediatric" or "adult," if applicable.

Refrigerator Requirements (continued)

- Store vaccines and diluents with similar packaging or names such as DTaP and Tdap or Hib and HepB, or with both pediatric and adult formulations, on different shelves to minimize the risk of administration errors.
- Do not put vaccines or diluent in the doors or on the floor of the refrigerator.
- Vaccine with diluent must be kept in the same box. The Merck diluent for MMR, MMRV and Zoster vaccines may be stored in the door of the refrigerator, but this diluent does not require refrigeration.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents should never be frozen.
- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored.



Freezer Requirements



For each freezer, the provider must:

- Make sure the freezer door is closed completely.
 - Post "Do not unplug" signs on the freezer and by the electrical outlet.
 - Do not put food in the freezer.
 - Place vaccines with the earliest expiration dates in front to be used first.
 - Store each type of vaccine in a separate container.
 - Vaccines should be centrally stored within the unit.
-
- Attach labels to shelves and containers to clearly identify each type of vaccine.
 - Store vaccines with similar packaging or names such as VAR and HZV, or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
 - Label the formulation "pediatric" or "adult," if applicable.
 - Store privately purchased vaccine in a clearly marked container separate from TVFC/ASN vaccine.
 - Always store vaccines in their original packing with lids closed until ready for use unless vaccines are stored in an auto-dispensing unit that requires vaccines to be removed from the original packing.
 - Never store loose vials or manufacturer-filled syringes outside of their packaging.
 - Diluents should never be frozen.

Freezer Requirements (continued)

- Use frozen water bottles to help maintain consistent temperature.
- Place water bottles against the walls, in the back, on the floor, and in the door racks.
- Place water bottles carefully so they cannot dislodge, preventing the door from closing securely, or weighing the door down so the seals are not tight.
- Leave 2-3 inches between all vaccines and the freezer walls.
- Do not store vaccines in the freezer doors.
- Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door.

New or Repaired Units

Read the refrigerator and freezer instructions carefully before adjusting the temperature control settings, and then verify that the temperatures did not change overnight. Some manufacturers recommend resetting the controls in the summer and winter. If so, post instructions on the refrigerator door.

Prior to using a new or newly repaired unit to store vaccines, allow 7 operational days of refrigerator or freezer temperature readings/recordings (a minimum of two times each workday) on an EC-105 form using a certified calibrated data logger.

Also record the required minimum/maximum temperatures one time at the beginning of each business day to ensure temperatures are within appropriate ranges. Submit the recordings to the Responsible Entity for review and approval, before placing vaccine in the storage unit. Minimum and maximum temperature readings must be reset at the end of each business day (if the device requires this function).



Maintaining Temperature Logs



Maintaining TVFC/ASN temperature logging requirements is mandatory for all providers:

- A Temperature Recording Form (EC-105) is required to be located on or near all units that store TVFC vaccines.
 - Freezer and refrigerator temperatures are required to be checked from a certified calibrated data logger, recorded, and initialed twice daily.
 - Minimum and maximum temperatures must be recorded on the Temperature Recording Form once at the beginning of each business day.
-
- Temperatures must be recorded manually on Temperature Recording Forms using a digital data logger.
 - Minimum and maximum temperature readings must be reset from the day before at the end of each business day.
 - Temperature Recording Forms must be maintained for five years and made readily available.
 - Data loggers must be able to be reset on site.
 - Temperature recording forms must still be completed and submitted to your RE if an auto-dispensing unit is being utilized.

Temperature Excursion

A temperature excursion is any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert.

Temperature recordings $\pm 0.1^{\circ}\text{F}$ or $\pm 0.1^{\circ}\text{C}$ from the appropriate storage unit ranges are temperature excursions and require immediate attention.

When reading data logger temperatures:

- Record the numbers on either side of the decimal point and do not round (Ex: For 46.1°F or 8.1°C , note that the numbers to the right of the decimal meet the criteria for a temperature excursion).

If any out-of-range temperature excursion is observed, the provider must document all excursions and take the following actions immediately:

- Place vaccines in a Vaccine Quarantine Bag and label vaccines as "Do not use."
- Store vaccines in a unit where they can be kept under appropriate conditions.
- Generate a report from data logger for manufacturer contact.
- Contact the manufacturer that is listed on the box to obtain documentation for the viability of the vaccine.
- Contact the Responsible Entity to report the manufacturer's vaccine viability determination and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form.

Quick Review

Question

Why do providers need to avoid packing a storage unit too tightly?

- It can make it difficult to find the correct vaccine.
- It can impact the vaccine temperature.
- It can make it hard to find short-dated vaccines.

Quick Review

Answer

Why do providers need to avoid packing a storage unit too tightly?

- It can make it difficult to find the correct vaccine.
- ✓ **It can impact the vaccine temperature.**
- It can make it hard to find short-dated vaccines.

Packing a storage unit too tightly can restrict air circulation and impact the vaccine temperature.

Quick Review

Question

Which of the following data logger temperature readings are temperature excursions?

- 46.0 F
- 47.7 F
- 35.9 F
- 38.4 F
- 46.2 F

Quick Review

Answer

Which of the following data logger temperature readings are temperature excursions?

- 46.0 F
- ✓ -47.7 F
- ✓ -35.9 F
- 38.4 F
- ✓ -46.2 F

Data Logger Requirements



DSHS requires a data logger for all units that contain TVFC/ASN vaccine, and an additional one to be kept as a backup.

Units that store TVFC/ASN vaccines must contain a centrally located data logger with a current certificate of calibration testing (also known as a Report of Calibration), set at a minimum recording interval of at least every 30 minutes.

A data logger provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed.

Using a data logger may reduce vaccine loss by providing necessary data when the vaccine would otherwise be lost.

Capabilities of Digital Data Loggers

A provider using data loggers **must still comply with twice daily temperature and once daily minimum and maximum recording requirements**. It is recommended that providers download the data from their data loggers at least once per week, on Monday, to ensure that any excursions are identified and addressed in a timely manner.

When reading the data logger, do not round the numbers up or down. Record the numbers on both sides of the decimal point and do not round (Ex: For 46.1°F or 8.1°C, note that the numbers to the right of the decimal meet the criteria for a temperature excursion). If a temperature excursion occurs, TVFC/ASN program providers must reach out to the vaccine manufacturer to obtain guidance on vaccine viability.

Capabilities of Digital Data Loggers (continued)

A digital data logger must have:

- An active temperature display that can be easily read from the outside of the unit.
- Functionality that does not require a password to access the temperature display.
- Alarm for out-of-range temperatures.
- A display that shows the current temperature, as well as minimum and maximum temperatures.
- Low battery indicator.
- Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.
- Detachable probe (kept in buffered material).

Capabilities of Digital Data Loggers (continued)

A digital data logger must have:

- An active temperature display that can be easily read from the outside of the unit.
- Functionality that does not require a password to access the temperature display.
- Alarm for out-of-range temperatures.
- A display that shows the current temperature, as well as minimum and maximum temperatures.
- Low battery indicator.
- Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.
- Detachable probe (kept in buffered material).

Capabilities of Digital Data Loggers (continued)



Probes should be placed in buffered material so that they measure temperatures that are more representative of the temperature of the vaccine in the vial rather than the air temperature of the storage unit.

Examples of buffers include:

- A vial filled with liquid, such as glycol, ethanol, or glycerin.
- A vial filled with loose media, such as sand or glass beads.
- A solid block of material, such as Teflon® or aluminum.

Disallowed Temperature Monitoring Devices

The TVFC/ASN programs do not allow the following temperature monitoring devices:

- Alcohol or mercury thermometers, even if placed in fluid-filled bio-safe liquid temperature monitoring devices
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Household mercury temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that are not calibrated
- Thermometers



These devices have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time they are read. Temperature fluctuations outside the recommended range may not be detected.

Probe Placement



The data logger probe must be placed as close to the vaccine as possible. Data logger probes must be:

- Placed in the main body of the storage unit, away from walls, ceilings, cooling vents, doors, floor, and back of the unit.
- Located in a central location of the unit near where the vaccine is stored.

The data logger probes must **not** be:

- Suspended from wire shelves in the unit
- Suspended by tape attached to the inside ceiling of the unit

In pharmaceutical or purpose-built units, the data logger is recommended to be placed in a central location; however, other placements may be suitable as these units maintain more consistent temperatures throughout the unit.

Data Logger Requirements

Providers are required to have a calibrated data logger in each unit that is either International Laboratory Accreditation Cooperation (ILAC) laboratory accredited or has a valid and up-to-date certificate issued by an ILAC laboratory.

All certificates of calibration must be sent to your RE who will submit them to DSHS Central Office for processing. Providers with expired data logger certificates of calibration will be suspended until current certificates are received. Photos of the back of data loggers will not be accepted as certificates of calibration.

Data Logger Requirements (continued)

A valid certificate of calibration matching the serial number of the data logger in use must be readily accessible and recommended to be posted on or near the refrigerator or freezer. Calibration testing should be done every 2 to 3 years or according to the manufacturer's suggested timeline. A continuous-read temperature-recording device does not replace the requirement for a certified data logger.

Certificates must contain:

- Model number
- Serial number
- Date of calibration
- Measurement results that indicate the unit passed the test and the documented uncertainty is within suitable limits (recommended uncertainty is $\pm 1^{\circ}\text{F}$ [$\pm 0.5^{\circ}\text{C}$]).
- A statement indicating that it meets International Organization for Standardization/International Electronic Commission (ISO/IEC) 17025 standards.

Back Up Data Logger

Providers must have at least one backup data logger with a valid and current certificate of calibration readily available in case a data logger in use is no longer working appropriately or calibration testing of the current equipment is required.

DSHS recommends that the backup data logger be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

The backup data logger should have a different calibration retesting date. If both data loggers have the same calibration date, they will need to be sent out for recalibration at the same time. By having different calibration dates, there will always be one data logger available for use.

Quick Review

Question

A provider using data loggers must still comply with twice daily temperature and once daily minimum and maximum recording requirements.

- True
- False

Quick Review

Answer

A provider using data loggers must still comply with twice daily temperature and once daily minimum and maximum recording requirements.

- True
- False

True. Using a data logger may reduce vaccine loss by providing necessary data when it would otherwise be lost. However, a provider using data loggers must still comply with twice-daily temperature and once daily minimum and maximum recording requirements. It is recommended that providers download the data from their data loggers at least once per week to ensure that any excursions are identified and addressed in a timely manner.

Built-in Temperature Monitoring

Refrigerators and freezers that are manufactured with built-in temperature monitoring capabilities are required to be accompanied by a certificate of calibration, and the thermostat must be capable of being adjusted by the provider as needed to maintain proper temperature. These units must meet all TVFC/ASN data logger requirements.

In addition, providers are required have a room thermometer to record the room temperature when a temperature excursion occurs in a vaccine storage unit. This is important for making vaccine viability determinations.

ICL CALIBRATION LABORATORIES, INC. 

ISO 9001:2015 CERTIFIED
METRIC TRADE AND INDUSTRIAL WEIGHT MEASUREMENT
2015 ISO 9001:2015 CERTIFIED
2015 ISO 17025:2017 CERTIFIED
2015 ISO 17025:2017 CERTIFIED

Being an ISO 17025:2017 calibration laboratory
CALIBRATION REPORT FOR THERMOMETER

Report No. ICL17025-18-0001 Page 1 of 2 Rev. 12/2016

Our instruments are calibrated and certified and tested in accordance with the requirements of the International Organization of Metrology (ISO) and the International Bureau of Weights and Measures (BIPM) and the National Institute of Standards and Technology (NIST). We are a member of the International Association of Calibration Laboratories (IAC) and the International Association of Calibration Laboratories (IAC) and the International Association of Calibration Laboratories (IAC).

CUSTOMER INFORMATION

Customer Name: [REDACTED]
Customer Address: [REDACTED]
Customer Phone: [REDACTED]
Customer Email: [REDACTED]

INSTRUMENT INFORMATION

Instrument Name: [REDACTED]
Model: [REDACTED]
Serial Number: [REDACTED]
Manufacturer: [REDACTED]

RESULTS OF PHYSICAL EXAMINATION

Visual Inspection: [REDACTED]
Functionality: [REDACTED]
Accuracy: [REDACTED]

RESULTS OF CALIBRATION

TEST TEMP	MEASURED	CORRECTION	UNCERTAINTY	DATE	OPERATOR
0 °C	0.00	0.00	±0.01	12/15/18	[REDACTED]
5 °C	5.00	0.00	±0.01	12/15/18	[REDACTED]
10 °C	10.00	0.00	±0.01	12/15/18	[REDACTED]
15 °C	15.00	0.00	±0.01	12/15/18	[REDACTED]
20 °C	20.00	0.00	±0.01	12/15/18	[REDACTED]
25 °C	25.00	0.00	±0.01	12/15/18	[REDACTED]
30 °C	30.00	0.00	±0.01	12/15/18	[REDACTED]
35 °C	35.00	0.00	±0.01	12/15/18	[REDACTED]
40 °C	40.00	0.00	±0.01	12/15/18	[REDACTED]
45 °C	45.00	0.00	±0.01	12/15/18	[REDACTED]
50 °C	50.00	0.00	±0.01	12/15/18	[REDACTED]

Special Care for Vaccines

Some vaccines are sensitive to light and their efficacy could be compromised if exposed to the light.

Providers must safeguard the following vaccines from light:

- Men B
- MMR
- HPV
- MCV4
- Hib vaccines
- Rotavirus
- **MMRV**
- **Varicella**

All of these vaccines, with the exception of **varicella** and **MMRV**, are to be stored in the refrigerator and must **never** be frozen. Varicella and MMRV must be stored in the freezer in a continuously frozen state between -58°F and <5°F (-15°C and -15°C). Measles, mumps, and rubella (MMR) vaccine may be stored properly in either a refrigerator or freezer.

Protective Equipment



To protect the power supply for units, providers must:

- Plug unit directly into a wall outlet.
- Plug only one unit into an outlet.
- Use plug guards on all units. Plug guards are effective tools in preventing the accidental unplugging of equipment.
- Post a "Do not unplug" sign on or near outlets of all units.
- Post a "Do not disconnect" sign by each circuit breaker.

Do not:

- Use extension cords.
- Use multi-outlet power strips.
- Use outlets with built in circuit switchers.
- Use power outlets that can be activated by a wall switch.
- Use surge protectors.

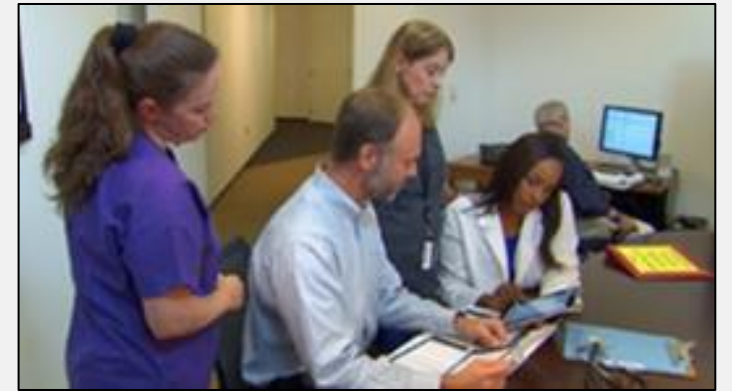
Training Personnel

Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle TVFC/ASN vaccine must be trained on proper storage, handling, and administration of vaccine.

Staff must also be familiar with the written procedures for emergency situations to assure continued viability of the vaccines.

The site is required to designate one primary and one backup vaccine coordinator to ensure that the TVFC/ASN vaccines are handled and stored properly. Both coordinators must be physically located at the clinic site and must be fully trained in routine and emergency policies and procedures. Each site must have a unique primary coordinator and backup coordinator.

All new employees that handle TVFC/ASN vaccine must be adequately trained regarding the proper storage and handling of vaccines prior to administering the TVFC/ASN vaccines.



Routine Emergency Storage and Handling Plan

Providers must have plans for routine and emergency vaccine management. The TVFC/ASN programs provide templates for the **Vaccine Management Plan** and the **Emergency Vaccine Storage and Handling Plan Checklist**. The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines.

A TVFC/ASN provider is not required to use the provided template, they may create their own based on TVFC/ASN requirements. The provided templates are valuable and available to providers if assistance is needed.

[View/download the Vaccine Storage and Handling Toolkit](#)

Emergency Storage and Handling Plan Annual Review

The Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist must be reviewed and updated annually. They must include the name of preparer, title, signature, and date the document was last reviewed.

All TVFC/ASN providers will be asked to provide a copy of their Vaccine Management Plan, Emergency Vaccine Storage and Handling Plan Checklist, and emergency transport materials at TVFC/ASN compliance site visits.

The documents must be posted on or near the refrigerator or freezer containing the TVFC/ASN vaccine. The provider must ensure all employees involved with vaccine management are aware of this plan.



Routine and Emergency Storage and Handling Plan

The following items must be addressed in the Emergency Vaccine Storage and Handling Plan.

Identify a responsible, primary person and backup person to carry out the contingency plan. Be sure to include contact information such as home, office, and cell phone numbers for both persons. Contact information must be updated annually and when changes occur.

Routine and Emergency Storage and Handling Plan

Identify an alternative location to take the TVFC/ASN vaccine for storage. A location with a power generator or other alternate source of power such as a hospital or pharmacy is preferable. Ideally, this facility must be located within a reasonable distance from the TVFC/ASN provider's clinic and can maintain the cold chain during any period when the TVFC/ASN provider's refrigerator or freezer is out of service, as well as adequate space to accommodate the largest vaccine inventory.

Temperatures for storage units are required to be monitored and recorded.

Routine and Emergency Storage and Handling Plan

Adequate supplies in amounts sufficient for packing and transporting the entire TVFC/ASN vaccine inventory must be available in case of an emergency.

Routine and Emergency Storage and Handling Plan

Be sure to contact the emergency storage location for their approval before including them as part of the plan. List the contact person(s) and phone number(s). An alternative backup location must be considered in case the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.

Vaccine Protection in the Event of an Emergency

Once the Emergency Vaccine Storage and Handling Plan Checklist is completed, it can serve as the required Emergency Vaccine Storage and Handling Plan.

All TVFC/ASN providers must review and update this plan annually or more frequently if there are any changes to the plan or changes in staff responsible for vaccine management, storage, and handling.

In the event of an emergency, a provider must contact their Responsible Entity immediately to inform them of the situation and be prepared to provide:

- The temperature of the vaccine.
- The amount of vaccine.
- Expiration dates of the vaccine.
- How long the vaccine was exposed to inappropriate temperatures.

Transporting the Vaccine in an Emergency

The TVFC/ASN provider will need to specify the following steps when transporting vaccine to the alternate location:



- Document the time of the emergency situation/power outage.
 - Document the temperature of the refrigerator and freezer before removing any vaccine for transportation.
 - Indicate which containers are being used and how the refrigerated vaccine will be packed for transportation for example, (conditioned water bottles separated from the vaccine by layered packing materials to prevent freezing and damage).
-
- If frozen vaccine is being transported, indicate whether a portable freezer or cooler will be used and what packing materials will be used.
 - Take inventory of the vaccine as it is moved into the transport container, being careful to indicate the number of doses of each vaccine and the expiration dates. Use the Vaccine Transfer Authorization Form or Vaccine Transport Log for transfers over one hour.
 - Ensure the Emergency Vaccine Storage and Handling Plan Checklist is available for documenting the process.
 - Monitor temperatures during the time the vaccine is being transported to the alternate location.

Cold Chain Management and Vaccine Transport

During emergency transport the provider must:

- Identify sufficient alternative space to store TVFC/ASN vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service.
- Ensure there are adequate supplies for packing and transporting the entire TVFC/ASN provider's vaccine supply/inventory in case of an emergency.
- Avoid prolonged temperature extremes inside vehicles, by using transport containers containing the vaccines and taking the quickest route possible.
- Do not leave vaccines unattended in vehicles.
- Do not place vaccines in the trunk of a vehicle.
- Pack refrigerated vaccines first.

Refrigerated Vaccine Transport - Assemble Packing Supplies

The following packing supplies are required for refrigerated transport.

Hard-sided coolers, Styrofoam vaccine shipping container, or other qualified container that can maintain the recommended temperature range (between 36°F [2°C] and 46°F [8°C]).

The CDC recommends transport with a portable refrigerator unit.

- Coolers should be large enough to hold the TVFC/ASN provider's typical supply of refrigerated vaccines.
- Original shipping boxes from the manufacturer can be used, if available.
- Do **not** use soft-sided collapsible coolers.
- Label the container with facility name and "Fragile vaccines – Do not freeze" and the date and time the vaccine was removed from the permanent storage unit.

Refrigerated Vaccine Transport - Assemble Packing Supplies

Conditioned frozen water bottles

- Use 16.9 oz. frozen bottles for medium/large coolers and 8 oz. bottles for small coolers.
- Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.
- **Do not** reuse coolant packs from original vaccine shipping containers as they may freeze vaccine.

Refrigerated Vaccine Transport - Assemble Packing Supplies

Insulating material – two of each layer

- Insulating cushioning material – bubble wrap, packing foam, or Styrofoam for a layer, at least 1-inch thick, above and below the vaccines. Make sure it covers the cardboard completely.
- Corrugated cardboard – two pieces cut to fit the internal dimensions of the cooler(s) and placed between the insulating cushioning material and the conditioned water bottles.
- **Do not** use packing peanuts or other loose material that may shift during transport.

Refrigerated Vaccine Transport - Assemble Packing Supplies

Temperature monitoring device – A digital data logger with a buffered probe.

- Data logger must have current and valid certificate of calibration testing.
- Data logger must be accurate within $\pm 1^{\circ}\text{F}$ [$\pm 0.5^{\circ}\text{C}$].
- The probe is buffered by pre-chilling it in the refrigerator for at least five hours prior to transport.
- The temperature monitoring device currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for remaining vaccines.

Refrigerated Vaccine Transport - Packing for Transport

1. Line the bottom of the cooler with a single layer of conditioned water bottles.
2. Place a sheet of corrugated cardboard over the water bottles.
3. Place an inch of insulating material such as bubble-wrap, packing foam, or Styrofoam over the cardboard.
4. Stack boxes of vaccines and diluents on top of insulating material.
5. When cooler is halfway full, place the buffered temperature probe in the center of the vaccines, but keep the display out of the cooler.
6. Cover vaccines with another layer of insulating material.
7. Add the second layer of corrugated cardboard.
8. Fill the remaining space in the cooler with conditioned water bottles.
9. Close the lid of the cooler securely and attach the digital data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
10. Use the Vaccine Transfer Authorization Form or Vaccine Transport Log to record the time, as well as the temperature inside of the storage unit at the time the vaccines are removed.
11. If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
12. As soon as the destination site is reached, check and record the vaccine temperature.

Refrigerated Vaccine Transport - Temperature Monitoring

In an emergency, if the vaccine temperature is between 36° F [2° C] and 46° F [8° C]; place the vaccine in the refrigerator.

If it is below 36° F or above 46° F; place the vaccine in a quarantine bag in the refrigerator and immediately contact the vaccine manufacturer to determine viability. Next, contact the Responsible Entity with the manufacturer's viability determination.

Always keep vaccine properly stored until otherwise instructed by the vaccine manufacturer or the TVFC/ASN program.

Fragile Vaccines

Varicella and MMRV vaccines are fragile and must be frozen!

The CDC and the vaccine manufacturer do not recommend transporting varicella or MMRV. If these vaccines need to be relocated in an emergency situation, the following steps must be taken.

Frozen Vaccine Transport - Assemble Packing Supplies

The following packing supplies are required for frozen vaccine transport.

Portable Freezer

The CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and $+5^{\circ}\text{F}$ [-50°C and -15°C]. Portable freezers may be available for rent.

Label the portable freezer with the facility name, "Fragile vaccines – Keep frozen" and the date and time the vaccine was removed from the permanent storage unit.

Frozen Vaccine Transport - Assemble Packing Supplies

Data Logger

Use a certified and calibrated digital data logger with a current and valid certificate of calibration testing.

Prepare the data logger by placing it in a freezer unit at least two hours before packing the vaccine.

Frozen Vaccine Transport - Assemble Packing Supplies

Cooler (if portable freezer is unavailable)

A hard-sided insulated cooler with at least 2-inch walls, Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F and $+5^{\circ}\text{F}$ [-50°C and -15°C] can be maintained.

Label the container with the facility name, and "Fragile vaccines – Keep frozen" and the date and time the vaccine was removed from the permanent storage unit.

Frozen Vaccine Transport - Assemble Packing Supplies

Frozen water bottles (if portable freezer is unavailable)

Water bottles must be frozen.

Dry ice may subject vaccine to temperatures colder than -58°F [-50°C] and is not allowed to be used, even for temporary storage or emergency transport.

Frozen Vaccine Transport - Resources

For information on proper vaccine storage and handling for transport during emergencies, when portable refrigerators and/or freezers are not available, please see the CDC document titled "**Packing Vaccines for Transport during Emergencies.**"

You may also refer to CDC's Storage and Handling webpage for links to additional resources.

[View the CDC's Storage and Handling webpage](#)

[View/download "Packing Vaccines for Transport during Emergencies"](#)

Frozen Vaccine Transport - Packing for Transport

If a portable freezer is not available and a cooler must be used:

1. Ensure that the water bottles used in the cooler are frozen.
2. Place a calibrated data logger in the container used for transport as close as possible to the vaccine.
3. Use a Vaccine Transfer Authorization Form or Vaccine Transport Log to record the time and temperature inside of the storage unit at the time the vaccines are removed. Also record the temperature of the transport container on the Vaccine Transfer Authorization Form or Vaccine Transport Log hourly.
4. Immediately upon arrival at the destination, place vaccines in a freezer at a temperature range between -58°F and +5°F [-50°C and -15°C]. Any stand-alone freezer that maintains these temperatures is acceptable.
5. Document the time the vaccine was removed from the transport container and placed in the alternate storage unit. Also document the temperature of the vaccine when it was removed from the transport container and placed in the alternate storage unit.
6. Immediately contact the manufacturer for viability data and guidance any time frozen vaccine has been exposed to a temperature above +5°F [-15°C]. Do not discard the vaccine without contacting the manufacturer. Viability determination will be made on a case-by-case basis.
7. Contact the Responsible Entity with the viability determination from the manufacturer.

Quick Review

Question

When using water bottles during transport in an emergency situation, you must condition the frozen water bottles by placing them _____ until there is a layer of water forming near the inner surface of the bottle.

- on the counter
- in a sink filled with water
- in the microwave

Quick Review

Answer

When using water bottles during transport in an emergency situation, you must condition the frozen water bottles by placing them _____ until there is a layer of water forming near the inner surface of the bottle.

- on the counter
- in a sink filled with water
- in the microwave

Before use, condition the frozen water bottles placing them in a sink filled with water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.

Vaccine Transfers and Borrowing



Vaccine Transfers and Borrowing



Upon successful completion of this section, you will be able to explain the TVFC/ASN policies on vaccine transfer and vaccine borrowing.

Vaccine Transfers

The routine re-distribution of TVFC/ASN vaccine, including the flu vaccine. Short-dated flu vaccine is not allowed. However, vaccine transfer can be allowed when necessary to avoid vaccine loss, (i.e., if a provider(s) storage unit is overstocked or if the provider withdraws from the TVFC/ASN program).

Once transfer requests are submitted in Vaccine Allocation and Ordering System (VAOS), the RE receives the transfer request and the Vaccine Transfer Authorization Form is available pre-populated with all the pertinent information for the transfer.

The DSHS PHR will approve or deny the transfer within two weeks.

The Responsible Entity can then initialize a vaccine transfer as long as they have the TVFC/ASN program PIN of where they are transferring the vaccine. The transfer information is documented and tracked in VAOS.

Procedures for Vaccine Transfer

Required Reasons

To conduct a vaccine transfer, the TVFC/ASN provider, who is transferring the vaccine, must complete the following requirements.

Ensure that the vaccine transfer is occurring for one of the following reasons:

- Short-dated vaccine
- Withdrawal, suspension, or termination of a TVFC/ASN provider from the TVFC/ASN programs
- Other (emergency situation)

Procedures for Vaccine Transfer

Transfer Authorization Form

Complete and sign the Vaccine Transfer Authorization Form.

Each vaccine to be transferred must be listed on a separate row and include:

- Vaccine type
- National Drug Code (NDC)
- Lot number
- Expiration date
- Number of doses that are being transferred

Send the completed Vaccine Transfer Authorization Form to the Responsible Entity or upload to VAOS. For emergency situations, providers must call prior to submitting or faxing the form.

Procedures for Vaccine Transfer

Transfer Approval

Once the provider's Responsible Entity receives the form, the DSHS PHR will approve or deny the transfer if applicable within two weeks. If approved, a signed copy of the form will be sent to the TVFC/ASN provider requesting the transfer and the LHD (if applicable). Once the provider receives the approval, they may conduct the transfer in VAOS.

Procedures for Vaccine Transfer

Pack Using Proper Cold Chain Management

The Responsible Entity will ensure that the vaccine is packaged using proper cold chain management.

Procedures for Vaccine Transfer

Vaccine Transfer Form

Include a copy of the Vaccine Transfer Authorization Form in the transfer package. The Vaccine Transfer Authorization Form is printed after the transfer is conducted in VAOS.

The TVFC/ASN provider taking possession of the vaccine must keep the Vaccine Transfer Authorization Form on file for a minimum of five years. The form must be readily available.

Procedures for Vaccine Transfer

Temperature Recording Form

Include a Vaccine Transfer Authorization Form to document temperatures before, during, and upon conclusion of the vaccine transfer.

The TVFC/ASN provider taking possession of the vaccine will document the transfer on the Vaccine Transfer Authorization Form.

Vaccine Borrowing

Vaccine Borrowing is the utilization of TVFC/ASN vaccines as a replacement system for filling the vaccine needs of non-TVFC/ASN patients.

The CDC requires that state immunization programs enhance oversight of all vaccine borrowing within TVFC/ASN provider sites. As such, the TVFC/ASN programs are enforcing its policy of not allowing vaccine borrowing between TVFC/ASN and non-TVFC/ASN patients.

All TVFC/ASN providers are expected to maintain an adequate inventory of vaccine for both their TVFC/ASN-eligible and privately insured patients. Vaccines supplied by the TVFC/ASN programs cannot be provided to a non-TVFC/ASN-eligible patient.

Undocumented borrowing and administering of TVFC/ASN vaccines to a non-TVFC/ASN patient is considered fraud. No provider may use TVFC/ASN vaccines as a replacement system for filling the vaccine needs of a non-TVFC/ASN privately insured patient.

Procedure for Vaccine Borrowing

If a TVFC/ASN dose(s) is accidentally administered to a non-TVFC/ASN eligible client, the TVFC or ASN provider must complete the following steps.

Document

Document the incident by completing the Vaccine Borrowing Form (EF11-14171).

Each vaccine that was administered to a non-TVFC/ASN-eligible client must be listed on a separate row on the form.

[View/download the form](#)

Procedure for Vaccine Borrowing

Document

If a TVFC/ASN dose(s) is accidentally administered to a non-TVFC/ASN eligible client, the TVFC or ASN provider must complete the following steps.

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Document the incident by completing the Vaccine Borrowing Form (EF11-14171).

Each vaccine that was administered to a non-TVFC/ASN-eligible client must be listed on a separate row on the form.

[View/download the form](#)

Procedure for Vaccine Borrowing

Report

Report the incident by submitting a copy of the Vaccine Borrowing Form to their Responsible Entity **within 24 hours**. Adherence to HIPAA guidelines is mandatory when submitting this form.

The Vaccine Borrowing Form must be kept as part of the TVFC/ASN program records for a **minimum of five years** and be made readily available.

Procedure for Vaccine Borrowing

Replace

Replace the vaccine immediately with privately purchased vaccine and account for the replacement in VAOS.

Educating Staff

It is the responsibility of the provider to ensure that all staff members are familiar with TVFC/ASN programs requirements:

- Adequate vaccine supply must be maintained in accordance with the clinic's patient population (TVFC/ASN and private patients).
- The TVFC/ASN vaccine and private vaccine must be kept separately and clearly labeled as such.
- All providers must track vaccine usage and account for all doses of TVFC/ASN vaccine.
- Continued non-compliance with TVFC/ASN policies and procedures may be considered fraud and abuse. A non-compliant TVFC/ASN provider may be referred to CMS Medicaid Integrity Program (MIP) Field Office.



Quick Review

Question

Vaccine transfer can be allowed between TVFC/ASN providers when necessary to avoid _____.

- provider suspension
- staff training
- vaccine loss

Quick Review

Answer

Vaccine transfer can be allowed between TVFC/ASN providers when necessary to avoid _____.

- provider suspension
- staff training
- ✓ **vaccine loss**

Vaccine transfer can be allowed between TVFC/ASN providers when necessary to avoid vaccine loss.

If a transfer must occur, TVFC/ASN providers are required to submit a Vaccine Transfer Authorization Form (EC-67) to their Responsible Entity and receive pre-approval prior to conducting vaccine transfers.

Vaccine Reporting Requirements



Vaccine Reporting Requirements



Upon successful completion of this section, you will be able to explain the reporting requirements in the TVFC/ASN programs.

Reporting Requirements



The TVFC/ASN programs require providers to monitor the temperatures of all refrigerators and freezers containing TVFC/ASN vaccines and to submit reports to their Responsible Entity utilizing TVFC/ASN programs forms documenting vaccine inventory and usage.

All reports should be submitted in VAOS. If internet access is not available, contact your RE and coordinate report submission.

All records related to the TVFC/ASN programs are required to be maintained for five years and made readily accessible.

Vaccine Ordering for Sites without Internet Access

TVFC/ASN-enrolled sites without access to the internet must contact their Responsible Entity. The Responsible Entity will enter the TVFC/ASN vaccine order in VAOS. The TVFC/ASN-enrolled site must submit the following paper forms to their Responsible Entity to place a vaccine order.

- Monthly Biological Report (stock no. C-33)
- Pediatric or Adult Biological Order Form (stock no. EC-68-1 or EC-68-2)
- Temperature Recording Forms (stock no. EC-105)

The monthly biological report is reviewed by the Responsible Entity to ensure that the beginning inventory matches the last month's ending inventory.

Calculations must be correct, and all corrections will be reported to the staff at the TVFC/ASN-enrolled site, so the records can be corrected prior to ordering.

Monthly Reports

Between the 1st and the 7th of each month, the following reports must be completed in VAOS:

- Temperature Logs
- Receipt of vaccine shipments (if applicable)
- Vaccine transfers (if applicable)
- Doses Administered
- Physical Inventory
- Vaccine loss (if applicable)

[View forms on the TVFC/ASN website](#)

Monthly Biological Report (C-33)

Monthly Biological Report (C-33)

The image shows a screenshot of the 'Monthly Biological Report (C-33)' form. It is a complex spreadsheet with multiple columns and rows. The columns are organized into sections: 'Inventory' (including Vaccine, Lot, Expiration, and Quantity), 'Administration' (including Date, Time, and Site), and 'Physical Count' (including Date, Time, and Count). The rows list various vaccine types and their corresponding data points.

The **Monthly Biological Report** is now documented in VAOS and includes vaccine received, doses administered, vaccine transferred, vaccine loss, and physical count. The Tally and Physical Count report may be used to help document vaccine management.

Qualified TVFC providers who participate in the ASN Program are required to distinguish between their adult and pediatric vaccines and order and report adult vaccines separately from TVFC pediatric vaccines. The Combined Tally and Inventory Sheet is an optional form that may assist in tracking pediatric doses versus adult doses administered.

Temperature Recording Form (EC-105)

A Temperature Recording Form is to be maintained on all refrigerators and freezers that store TVFC/ASN vaccine (including temporary day storage units). Providers may choose to use Fahrenheit (Stock C-105RF and C-105FF) or Celsius (Stock C-105RC and C-105FC) forms. Temperatures must not be converted from Fahrenheit to Celsius or Celsius to Fahrenheit.

Providers must record refrigerator and freezer temperatures twice daily and record the minimum and maximum temperatures since the last reading, at least once daily. Results of each check must be documented on the Temperature Recording Form and the form must be initialed by the staff member conducting the check. Instructions for completing the Temperature Recording Form are listed on the top of the form.

Completed Temperature Recording Forms for the previous month are submitted to VAOS or the Responsible Entity.



Temperature Recording Form (EC-105)

[continued]

The image shows a form titled "Vaccine Storage Troubleshooting Record" with sub-headers for "Refrigerator" and "Freezer". The form is divided into several sections with headings: "Event Description", "Storage Unit Temperature", "Room Temperature", "Name of Person Completing the Report", "Description of the Event", "Action Taken, including the instructions and procedures given by the Responsible Entity and the individual spoken to", and "Results". Each section has a corresponding text area for recording information. The form is presented as a grayscale thumbnail.

In case of an excursion providers must notify their Responsible Entity right away and include the following information on the Troubleshooting Record (found on the last page of the EC-105):

- Date and time of event
- Storage unit temperature
- Room temperature
- Name of person completing the report
- Description of the event
- Action taken, including the instructions and procedures given by the Responsible Entity and the individual spoken to
- Results

All documentation regarding temperature deviations must be retained for review during the TVFC Compliance Visits and any unannounced storage and handling visits.

Temperature Recording Form (EC-105)

[continued]

The image shows a 'Vaccine Storage Troubleshooting Record' form. The form is titled 'Vaccine Storage Troubleshooting Record' and has sub-headers for 'Refrigerator' and 'Freezer'. It contains several sections for data entry, including fields for 'Date and Time of Event', 'Storage Unit Temperature', 'Room Temperature', 'Name of Person Completing the Report', 'Description of the Event', 'Action Taken', and 'Results'. The form is designed to be filled out in a structured manner to document any temperature deviations.

In case of an excursion providers must notify their Responsible Entity right away and include the following information on the Troubleshooting Record (found on the last page of the EC-105):

- Date and time of event
- Storage unit temperature
- Room temperature
- Name of person completing the report
- Description of the event
- Action taken, including the instructions and procedures given by the Responsible Entity and the individual spoken to
- Results

All documentation regarding temperature deviations must be retained for review during the TVFC Compliance Visits and any unannounced storage and handling visits.

Quick Review

Question

Required monthly reports must be submitted between the _____ and the _____ each month or any time an order is placed.

- 1st and the 15th
- 2nd and the 4th
- 1st and the 7th
- 28th and the 30th

Quick Review

Answer

Required monthly reports must be submitted between the _____ and the _____ each month or any time an order is placed.

- 1st and the 15th
- 2nd and the 4th
- 1st and the 7th
- 28th and the 30th

Required monthly reports must be submitted between the 1st and the 7th of each month. The following documents must be completed and submitted to **VAOS**.

These records include (but are not limited to):

- Temperature Logs
- Receipt of vaccine shipments (if applicable)
- Vaccine transfers (if applicable)
- Doses Administered
- Physical Inventory
- Vaccine loss (if applicable)

Billing for Vaccine Administration



Billing for Vaccine Administration



Billing for Vaccine Administration

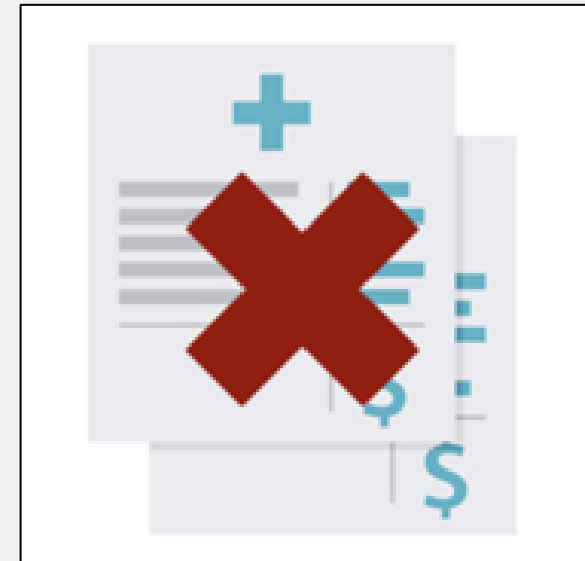
Upon successful completion of this section, you will be able to identify the charge that providers are allowed for administration of a vaccine in the TVFC/ASN program.

Billing for Vaccine

Providers who are enrolled in the TVFC/ASN programs are prohibited from charging any TVFC/ASN-eligible patient for the cost of vaccines. TVFC/ASN vaccines are provided at no cost to the provider in order to vaccinate eligible patients.

Charging for the cost of vaccines supplied by the TVFC/ASN programs constitutes fraudulent behavior. Fraud in the TVFC/ASN programs will be handled in the same manner as Medicaid fraud.

If a private provider has already accepted that patient into the practice as their patient, they may not refer a TVFC/ASN-eligible patient to another health care provider for TVFC/ASN vaccines, unless directed by DSHS.



Administration Fee

Providers are required to obtain vaccines at no cost in order to vaccinate TVFC-eligible children, including Medicaid and CHIP children.

The TVFC provider may charge an administration fee for administering vaccine to TVFC-eligible children. The maximum administration fee for TVFC vaccine is \$13.75 per dose.

TVFC sites that choose to bill a vaccine administration fee to non-Medicaid patients after the date of service must issue only a single bill to the patient within 90 days of the administration of the vaccine. Sites can still continue to bill for other charges such as office visits or labs. As usual, unpaid administration fees may not be sent to collections and the sites must not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

Medicaid Patients

For Medicaid VFC-eligible children, the provider must accept the reimbursement for immunization administration fee set by the state Medicaid agency or the contracted Medicaid health plans. Providers are reimbursed the lesser of the billed amount or the maximum allowable fee.

As stated in the CDC Vaccines for Children Operations Guide, the state Medicaid agency may have the discretion to pay an administration fee up to the regional maximum amount.

Children who are enrolled in Medicaid as their **secondary** insurance are also eligible to receive TVFC vaccines.

As stated in the Texas Medicaid Provider Procedures Manual (TMPPM), providers should bill their usual and customary fee except for vaccines obtained from the TVFC program.

For more information on Medicaid reimbursement, view the [Texas Medicaid Provider Manual](#).



CHIP Patients

Children (0-18 years of age) who are enrolled in CHIP are eligible to receive TVFC vaccines; however, TVFC providers must bill CHIP for the administration of a vaccine to a CHIP-enrolled child.

For more information on CHIP reimbursement, view the [CHIP Provider Manual](#)

Required Vaccinations



Vaccines are required to be available to all TVFC/ASN-eligible patients. Services cannot be denied due to the inability to pay the administration fee. A TVFC/ASN provider may not send a patient or parent/guardian to collections due to inability to pay. Penalties for the inability to pay administration fees must not be charged.

Quick Review

Question

Charging for the cost of vaccines supplied by the TVFC/ASN programs _____.

- can be gauged appropriately by locality
- is allowed under certain circumstances
- constitutes fraudulent behavior

Quick Review

Answer

Charging for the cost of vaccines supplied by the TVFC/ASN programs _____.

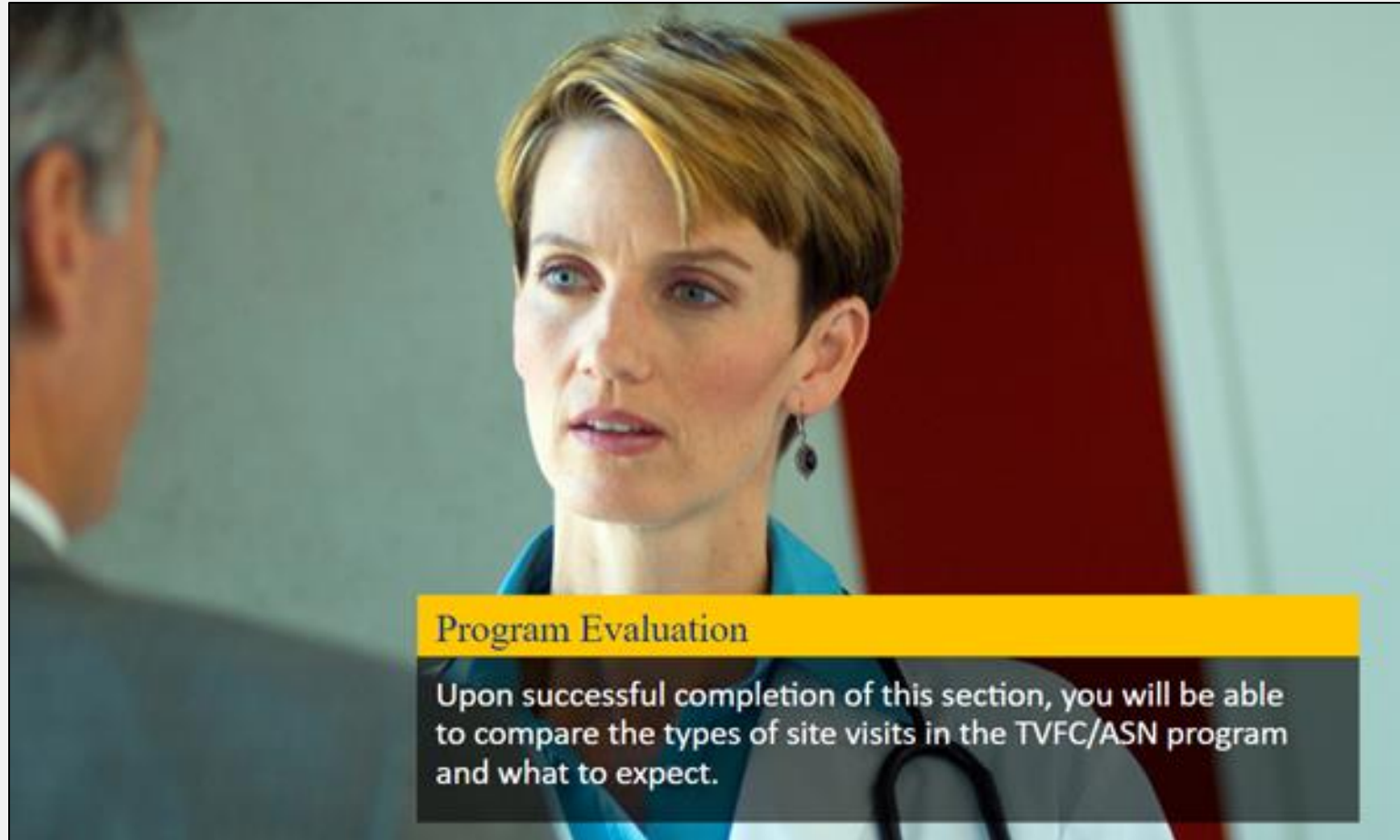
- can be gauged appropriately by locality
- is allowed under certain circumstances
- ✓ **constitutes fraudulent behavior**

Charging for the cost of vaccines supplied by the TVFC/ASN programs constitutes fraudulent behavior. Fraud in the TVFC/ASN programs may be handled in the same manner as Medicaid fraud.

Program Evaluation



Program Evaluation



Program Evaluation

Upon successful completion of this section, you will be able to compare the types of site visits in the TVFC/ASN program and what to expect.

Compliance Site Visits



By signing the Program Provider Agreement, the provider agrees to allow a DSHS or DSHS-contracted entity to conduct a Compliance Site Visit at least every other year at their site.

Newly enrolled providers should receive a Compliance Site Visit between 6-12 months of enrollment.

Data-Driven Site Visits

Compliance Site Visits are driven by data, not dates, to ensure that providers with the most needs are seen first.

The purpose of the compliance visit is to assess, support, and educate the site regarding TVFC/ASN policies and procedures. If areas of concern are identified, the Responsible Entity will provide a follow-up call or visit to assist the clinic with any changes or questions.

Providers will be contacted prior to the scheduled Compliance Site Visit and will receive a confirmation letter, email, or fax that includes the date, time, materials needed, and summary of the site visit process.

How to Prepare

During a Compliance Site Visit, the reviewer will need access to the following:

- A space to work.
- A power source.
- Access to patient records.
- Any temperature logs or data for the last three months, or longer if deficiencies are found.
- Any vaccine borrowing forms (EF11-14171) for the previous 12 months.
- The circuit breaker.
- Admitting and billing personnel to clarify eligibility screening and billing processes.
- All vaccine storage units where TVFC/ASN vaccine is stored.

Immunization Quality Improvement for Providers (IQIP)

The Immunization Quality Improvement for Providers (IQIP) visit will assess vaccination coverage rates based on the immunization records reported into Texas' Immunization Registry, ImmTrac2. Texas law requires all medical providers to report all immunizations administered to clients who are younger than 18 years of age to the immunization registry. The IQIP Program will determine how successful your site is at meeting this requirement, while at the same time assessing your vaccination coverage.

During an IQIP site visit, you will be evaluated on the successful reporting of immunization records to the Texas' Immunization Registry and also on the clinic's efforts to increase coverage rates at your site.

After the initial IQIP site visit, follow-ups will be scheduled at 2-months, 6-months and 12-months. After the 12-month follow-up is completed, your IQIP visit will be finished for the year.

Follow-Up Activities

Upon completion of the Compliance Site Visit, the reviewer will discuss the outcomes of the visit with the TVFC/ASN primary or backup vaccine coordinator. The discussion will include a review of the site visit findings and a formal follow-up plan with a timeline that addresses any issues of non-compliance and opportunities for improvement.

The signing clinician, primary, or backup vaccine coordinator are required to attend the Compliance Site Visit. At the end of the visit, the staff that was present at the site visit must sign the Acknowledgment of Receipt. The Acknowledgement of Receipt is the document that attests to the fact that a Compliance Site Visit was completed, the provider received the results of the visit, and that both the reviewer and the primary or backup vaccine coordinator understands all non-compliance issues identified and the actions necessary to address them.

DSHS Quality Assurance and Improvement (QAI) team will conduct all required follow-up activities. The purpose of follow-up activities is to ensure that areas for improvement identified are understood by site's provider/staff and corrective actions have been identified and implemented.

Follow-Up Activities (continued)

Follow-up activities are conducted as necessary to address any issues and are dependent upon the severity of the non-compliance issues and the follow-up action plan.

Follow-up activities can include, but are not limited to:

- Visiting the clinic to observe corrective actions.
- Calling the primary or backup vaccine coordinator at the clinic.
- Sending a letter to address the deficient items identified during the site visit.
- Determining the provider's compliance with the corrective action plans, if applicable.

The Responsible Entity works with providers on non-compliance issues by providing education and guidance regarding corrective actions, including monitoring.

If a provider exhibits habitual non-compliance and does not follow corrective actions in response to education, the provider may be put on probation and their ability to order vaccine may be suspended. If non-compliance continues, the provider may be terminated from the program.

Unannounced Storage and Handling Visit



Unannounced storage and handling visits may be conducted to serve as "spot checks." Unannounced visits focus on vaccine storage and handling.

Vaccine storage and handling issues are identified and addressed immediately during unannounced visits. The provider is expected to make onsite corrections to safeguard the vaccine.

The provider's Responsible Entity will prioritize sites for unannounced visits based on the following criteria:

- Vaccine loss
- Improper storage
- Improper documentation of temperature logs
- Vaccine orders inconsistent with population profile data
- Newly enrolled sites
- Determination of compliance with corrective actions

Annual TVFC/ASN Provider Satisfaction Survey

In addition, the TVFC/ASN program will conduct an annual TVFC/ASN Provider Satisfaction Survey to help identify areas of the TVFC/ASN program that are working well and those that need improvement.

The survey will be sent electronically to all providers and the final results will be collected and submitted to program staff for review.

Questions in the survey will address provider satisfaction with the current vaccine ordering and shipping practices; TVFC/ASN policies and procedures; reporting requirements; customer service provided by TVFC/ASN state, regional, and local staff; and communication methods of the TVFC/ASN program.

The survey will also ask TVFC/ASN providers about their use of the Texas Immunization Registry (ImmTrac2) as part of their daily practice.

Quick Review

Question

Select all that apply

The main purpose of a compliance site visit is to_____.

- reprimand
- assess
- support
- critique
- educate
- scrutinize

Quick Review

Answer

Select all that apply

The main purpose of a compliance site visit is to_____.

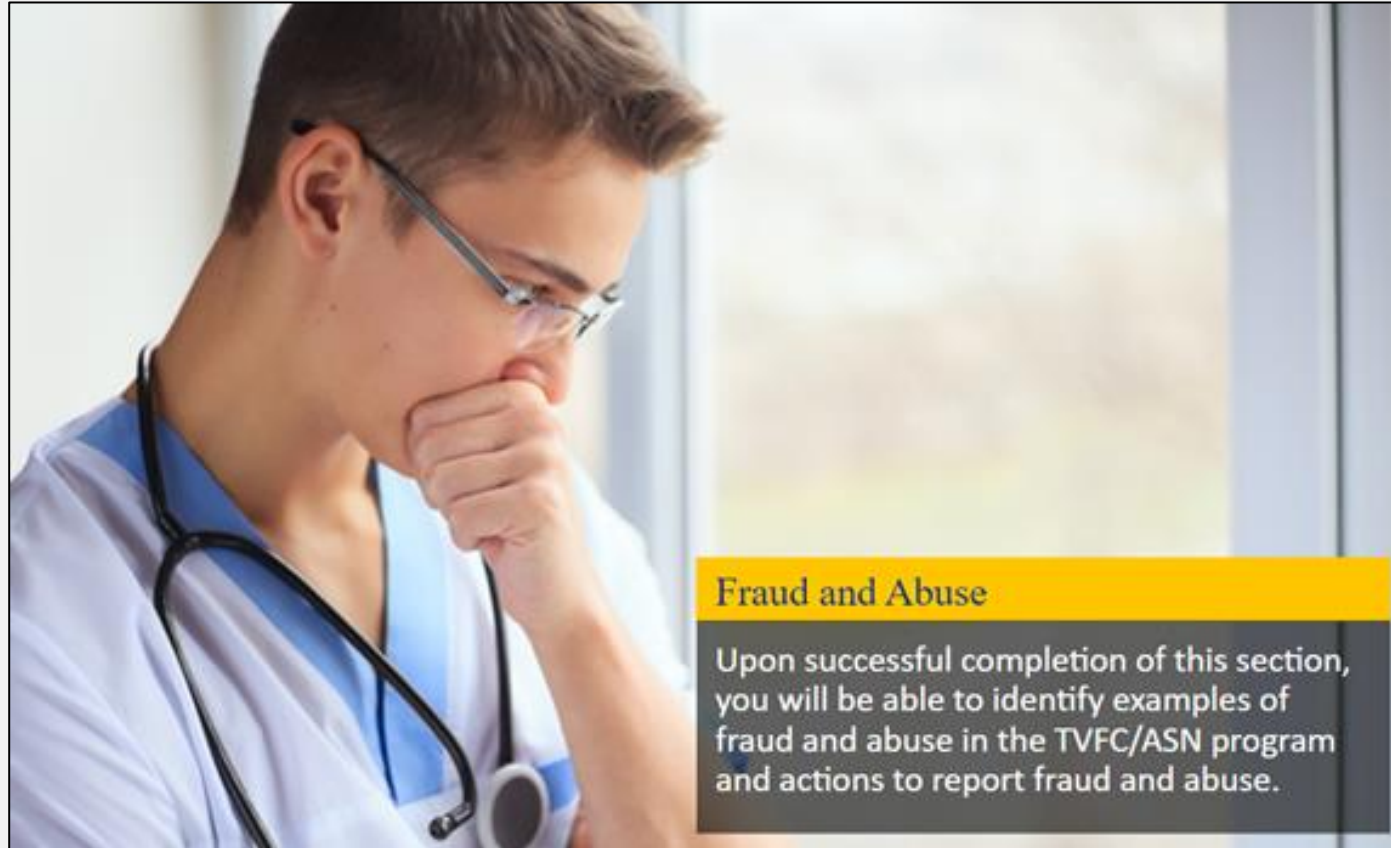
- reprimand
- assess
- support
- critique
- educate
- scrutinize

The purpose of the visit is to assess, support, and educate the clinic regarding TVFC/ASN policies and procedures. If areas of need are identified, the Responsible Entity will provide a follow-up call or visit to assist the clinic with any changes or questions.

Fraud and Abuse



Fraud and Abuse



Fraud and Abuse

Upon successful completion of this section, you will be able to identify examples of fraud and abuse in the TVFC/ASN program and actions to report fraud and abuse.

Fraud and Abuse

As the complexity of immunizations and immunization-related programs grow, TVFC/ASN providers may become more vulnerable to unintentionally committing acts that could be construed as fraud or abuse.

Fraud and abuse, whether intentional or not, is subject to all federal fraud and abuse laws.

Fraud and Abuse Definitions

Fraud

A working understanding of what constitutes fraud and abuse is critical for all persons in the TVFC/ASN program. The following are definitions of terms related to fraud and abuse.

Fraud

An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in an unauthorized benefit to himself or another person.

It includes any act that constitutes fraud under applicable federal or state laws.

Fraud and Abuse Definitions

Abuse

Abuse

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 TVFC program, a health insurance company, or a patient) or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary costs to the Medicaid Program.

Fraud and Abuse Definitions

Oversight

Oversight

The act of training, monitoring, and providing assistance to providers on TVFC/ASN program policies and procedures.

Fraud and Abuse Definitions

Enforcement

Enforcement

Identifying rules and policy violations and ensuring corrective action is taken.

Fraud and Abuse Definitions

Termination

Termination

Action taken when a provider is no longer eligible for the TVFC/ASN program due to fraud, abuse, or non-compliance.

Fraud and Abuse Definitions

Waste

Waste

The careless, inefficient, or unnecessary use of TVFC/ASN program resources.

Examples of Fraud and Abuse

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier to prevent or detect than others. All TVFC/ASN providers should familiarize themselves with the examples below, as they illustrate common practice errors that could result in fraud or abuse allegations. **This list provides examples only and should not be considered an exhaustive list of situations that would constitute fraud or abuse.**

- Provide TVFC/ASN vaccine to non-TVFC/ASN-eligible patients.
- Sell or otherwise misdirect TVFC/ASN vaccine.
- Bill a patient or third party for TVFC/ASN vaccine (other than administration fees).
- Charge more than \$13.75 for administration of a TVFC vaccine to an eligible child
- Failure to meet licensure requirements for enrolled providers.
- Deny TVFC/ASN-eligible patients TVFC/ASN vaccine because of the inability to pay the administration fee.

Examples of Fraud and Abuse

(continued)

- Send a parent or guardian to collections or charge additional fees for non-payment of the administration fee.
- Fail to implement provider enrollment requirements of the TVFC/ASN program.
- Fail to screen for and document TVFC/ASN eligibility at every visit.
- Fail to maintain TVFC/ASN records for five years.
- Fail to fully account for TVFC/ASN vaccine.
- Fail to properly store and handle TVFC/ASN vaccine.
- Order TVFC/ASN vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of TVFC/ASN doses.
- Loss of TVFC/ASN vaccine due to negligent waste.

Failure to Comply with TVFC/ASN Requirements



When providers enroll in the TVFC/ASN program, they agree to comply with all the requirements of the program.

Lack of adherence to the TVFC/ASN program requirements by an enrolled provider could lead to fraud and abuse of the TVFC/ASN program by that provider.

Non-compliance may occur due to an unintentional lack of understanding of the requirements. Behavior may also be intentional.

If the non-compliance appears intentional and the clinic staff or signing authority has received financial benefits from the behavior, the situation will result in immediate referral for investigation to the Medicaid Fraud Waste and Abuse Section (FWA) or the Texas Office of Inspector General (OIG) by the DSHS Immunization Section.

Fraud and Abuse Prevention



The TVFC/ASN program actively works with enrolled providers to help prevent fraud and abuse in the TVFC/ASN program. The best methods to prevent fraud and abuse are strong educational components discussed during the provider enrollment process and during the TVFC/ASN Compliance Visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse.

Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to DSHS or the Responsible Entity via email, telephone, fax, or letter.

Newspaper articles and internet pages that promote potential fraudulent situations are also investigated.

The Responsible Entity and DSHS quality assurance (QA) contractors must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Section in any form that merit further investigation will be referred to the Centers for Medicare and Medicaid Services, Medicaid Integrity Group Field Office.

The state Medicaid agency will conduct preliminary investigations and as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at [42 CFR section 455.15](#) and [42 CFR section 455.23](#).

Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to DSHS or the Responsible Entity via email, telephone, fax, or letter.

Newspaper articles and internet pages that promote potential fraudulent situations are also investigated.

The Responsible Entity and DSHS quality assurance (QA) contractors must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Section in any form that merit further investigation will be referred to the Centers for Medicare and Medicaid Services, Medicaid Integrity Group Field Office.

The state Medicaid agency will conduct preliminary investigations and as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at [42 CFR section 455.15](#) and [42 CFR section 455.23](#).

Quick Review

Question

Some types of fraud and abuse are easier to prevent or detect than others.

- True
- False

Quick Review

Answer

Some types of fraud and abuse are easier to prevent or detect than others.

- True
- False

Fraud or abuse can occur in many ways and some types of fraud and abuse are easier to prevent or detect than others.

Documentation and Record Keeping



Documentation and Record Keeping



Vaccine Record Keeping Requirements

The 1986 National Childhood Vaccine Injury and Compensation Act requires providers nationwide to record specific information in the medical record each time a vaccine is administered. The following information is required:

- Name of vaccine administered.
- Date administered (month, day, year).
- Date vaccine information statement (VIS) was given.
- Publication date on VIS.
- Name of vaccine manufacturer.
- Vaccine lot number.
- Name and title of health care professional administering the vaccine.
- Address of the clinic where the vaccine was administered.

Immunization cards are designed to capture all information required when vaccines are administered. Immunization cards can be ordered free of charge from the Immunization Section.

[Order Immunization Unit Cards for Provider \(C-100\)](#)

TVFC/ASN Best Practices

The TVFC/ASN program recommends the following best practices:

- Designate an immunization staff member to answer questions from patients and parents.
- Keep the immunization record and patient eligibility forms together.
- Place immunization records at the front of each patient chart.
- Encourage patients and parents to provide immunization records to show history.
- If a patient has no records, check ImmTrac2 or call previous providers.
- Empower staff to assess immunization status at every visit.
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered.

The Texas Immunization Registry (ImmTrac2)



TVFC-enrolled sites must enroll in and report to the [Texas Immunization Registry \(ImmTrac2\)](#). ImmTrac2 is operated by the DSHS Immunization Section and is an important component of Texas's strategy to improve immunization coverage rates. Texas Law requires medical providers to report all immunizations administered to children are younger than 18 years of age to ImmTrac2 within 30 days of administering the vaccine.

ImmTrac2 is designed to consolidate immunization records from multiple sources throughout the state, including clinics, pharmacies, and health care providers. The registry allows authorized organizations easy access to immunization histories of participating clients, as well as "reminder" and "recall" capabilities.

The Texas Immunization Registry

(ImmTrac2)



Adults can consent to ImmTrac2, which stores their immunization information for a lifetime. Individuals who turn 18 years old, and were participating in ImmTrac2 as a minor, must sign an adult consent form by their 26th birthday to keep their immunization information in ImmTrac2.

With access as a registered user of ImmTrac2, providers can confirm whether a patient is in ImmTrac2 and can consent individuals in ImmTrac2 who desire to participate.

TVFC program providers must register as an authorized organization with ImmTrac2 by completing a site registration in Syntropi. For information about ImmTrac2 or to register, call the ImmTrac2 Customer Support Line (800) 348-9158 or visit the ImmTrac2 webpage.

[Visit the Immtrac2 webpage](#)

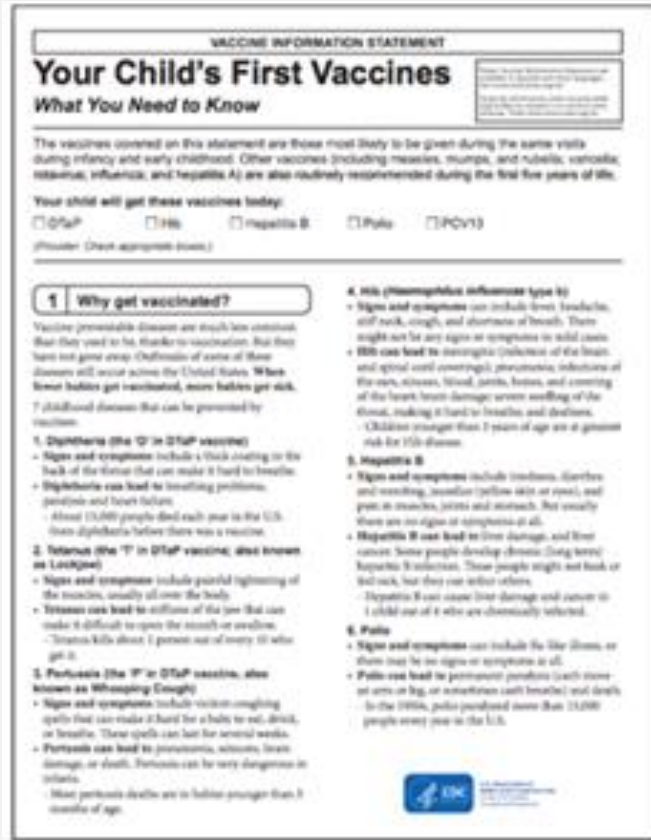
Addressing Vaccine Hesitancy



Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in disease outbreaks. While the majority of parents believe in the benefits of immunizations and have their children vaccinated, some have concerns about the safety of vaccines. Concerns about vaccine safety are preventing some parents from having their children immunized.

Overcoming barriers requires both knowledge and interpersonal skills on the part of the provider. Providers should have an understanding of vaccines, up-to-date recommendations, and reliable resources to direct parents and patients to in order to find accurate information. Also, the providers will need to have the skills necessary to deal with fears and misconceptions about vaccines, and the ability to provide a supportive and encouraging environment for patients.

Providing Information



[View Vaccine Information Statements](#)

When a parent or patient initiates a discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The Vaccine Information Statement (VIS) provides an outline for discussing vaccine benefits and risks. Providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school and child care entry, which might require unimmunized children to stay home from school during outbreaks.

Documentation of these discussions in the patient's record might reduce potential liability if a vaccine-preventable disease occurs in the unimmunized patient.

Vaccine Adverse Events

The logo for the Vaccine Adverse Event Reporting System (VAERS) features the letters "VAERS" in a bold, blue, sans-serif font. The letters are contained within a thin blue rectangular border.

Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC. The purpose of VAERS is to detect possible signs of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of U.S. licensed vaccines.

Reports of adverse events are welcome from all concerned individuals, including, but not limited to:

- Patients
- Parents
- Healthcare providers
- Pharmacists
- Vaccine manufacturers

Vaccine Adverse Events (continued)

You should use the [VAERS Reporting Website](#) to report all adverse events after vaccination, even if it is unclear whether the vaccine caused the event. Be prepared with all information needed for the VAERS reporting form including patient and provider details, adverse event description and outcome, and vaccine details such as manufacturer, lot number, and injection site.

For a serious adverse event (one that causes life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability, or death), please also provide a copy of the VAERS report submitted to CDC to your RE. This can be done most easily by using the "pdf upload" option on the VAERS website and then sending a copy of that PDF to your RE.

Quick Review

Question

One tool to help when addressing vaccine hesitancy with a concerned parent is to show them factual information on the _____.

- VIS
- VAERS website
- Biological Report

Quick Review

Answer

One tool to help when addressing vaccine hesitancy with a concerned parent is to show them factual information on the _____.

- ✓ **VIS**
- VAERS website
- Biological Report

The Vaccine Information Statement (VIS) provides an outline for discussing vaccine benefits and risks. Providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children.

Adult Safety Net Program

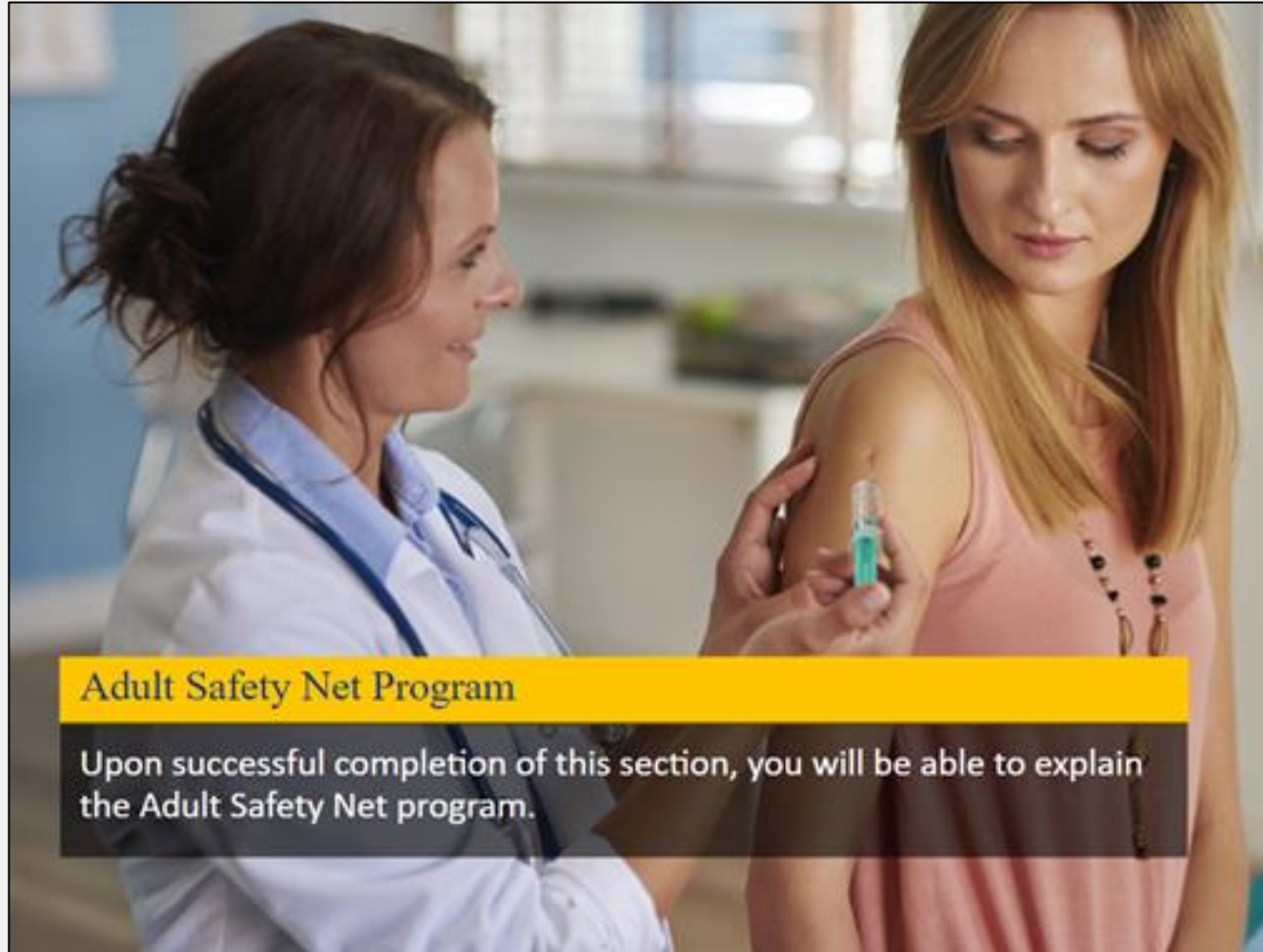


TEXAS
Health and Human
Services

Texas Department of State
Health Services

2024 TVFC/ASN Provider Policy Training

Documentation and Record Keeping



Adult Safety Net Program

Upon successful completion of this section, you will be able to explain the Adult Safety Net program.

Adult Safety Net (ASN) Program

The DSHS Adult Safety Net (ASN) program was developed to ensure uninsured adults can access the recommended adult vaccines.

Texas has a significant number of adults who have not received the recommended vaccinations and are at an increased risk of contracting vaccine-preventable diseases.

The ASN Program helps to address this public health issue by providing adult vaccines at no cost to enrolled providers.

Eligible ASN Provider Types

Provider types that may enroll in the ASN Program include, but are not limited to, clinics that are formally recognized as one of the following:

- DSHS Public Health Regions (PHR)
- Local Health Departments (LHDs)
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)
- Federally Recognized Indian Tribes

As a requirement, all providers who are enrolled in the ASN Program must be actively enrolled in the Texas Immunization Registry, ImmTrac2. Although ASN providers are not required to report to ImmTrac2, it is imperative for ASN providers to actively consent adult patients and report vaccine doses to ImmTrac2. All ASN providers are required to report adult vaccine doses administered in a timely and accurate manner into VAOS.

ASN Eligibility



Only adults aged 19 years and older who are uninsured are eligible to receive ASN vaccines.

Those with medical insurance, including Medicare or Medicaid, are not eligible for the ASN Program. In addition, those who are underinsured (who have insurance that does not cover immunizations) are not eligible for the ASN Program.

Patients who are 19 years of age and who previously initiated a vaccination series under the TVFC program, but have not completed the series, may complete the series using vaccines provided through the ASN Program. This provision only applies to patients that have not yet reached their 20th birthday.

A "series" in this case is specific to two (2) doses of Hepatitis A (HepA); three (3) doses of Hepatitis B (HepB); two (2) doses of (Meningococcal Conjugate (MCV4); two (2) doses of Measles, Mumps, and Rubella (MMR); and three (3) Tetanus, Diphtheria/Tetanus, Diphtheria, Pertussis (Td/Tdap).

This policy does not apply to Men B, Polio, HIB or Flu vaccines.

ASN Vaccine Formulary

The ASN Program supplies the following ACIP recommended vaccines and toxoids to enrolled sites:

- Coronavirus (COVID-19)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Hepatitis A and Hepatitis B (Hep A-Hep B) combination
- Measles, Mumps, and Rubella (MMR)
- Meningococcal conjugate (MCV4)
- Tetanus and Diphtheria toxoids (Td)
- Tetanus and Diphtheria toxoids and acellular Pertussis (Tdap)

It may be necessary for the DSHS Immunization Program to make changes to the ASN vaccine listed based on available funding. Official information will be distributed to all ASN-enrolled sites if changes to the vaccine formulary are necessary. The COVID-19 vaccine will remain available to enrolled ASN providers on a temporary basis, and updates will be provided as they are made available.

ASN Records

All ASN providers are required to maintain a record of the eligibility status of adults receiving the vaccines. When administering any ASN vaccine, eligibility status must be screened for and documented on the Adult Eligibility Screening Record.

Records must be maintained by the clinic providing the service. Information must be stored in the medical record either on paper, or in an EMR. All ASN providers are required to screen for eligibility each time a patient is present for a vaccine.

The Adult Eligibility Screening Record determines and records eligibility for the ASN Program. Copies must be maintained for five years and made available on request by the TVFC/ASN program, the Responsible Entity, or DSHS quality assurance contractor.

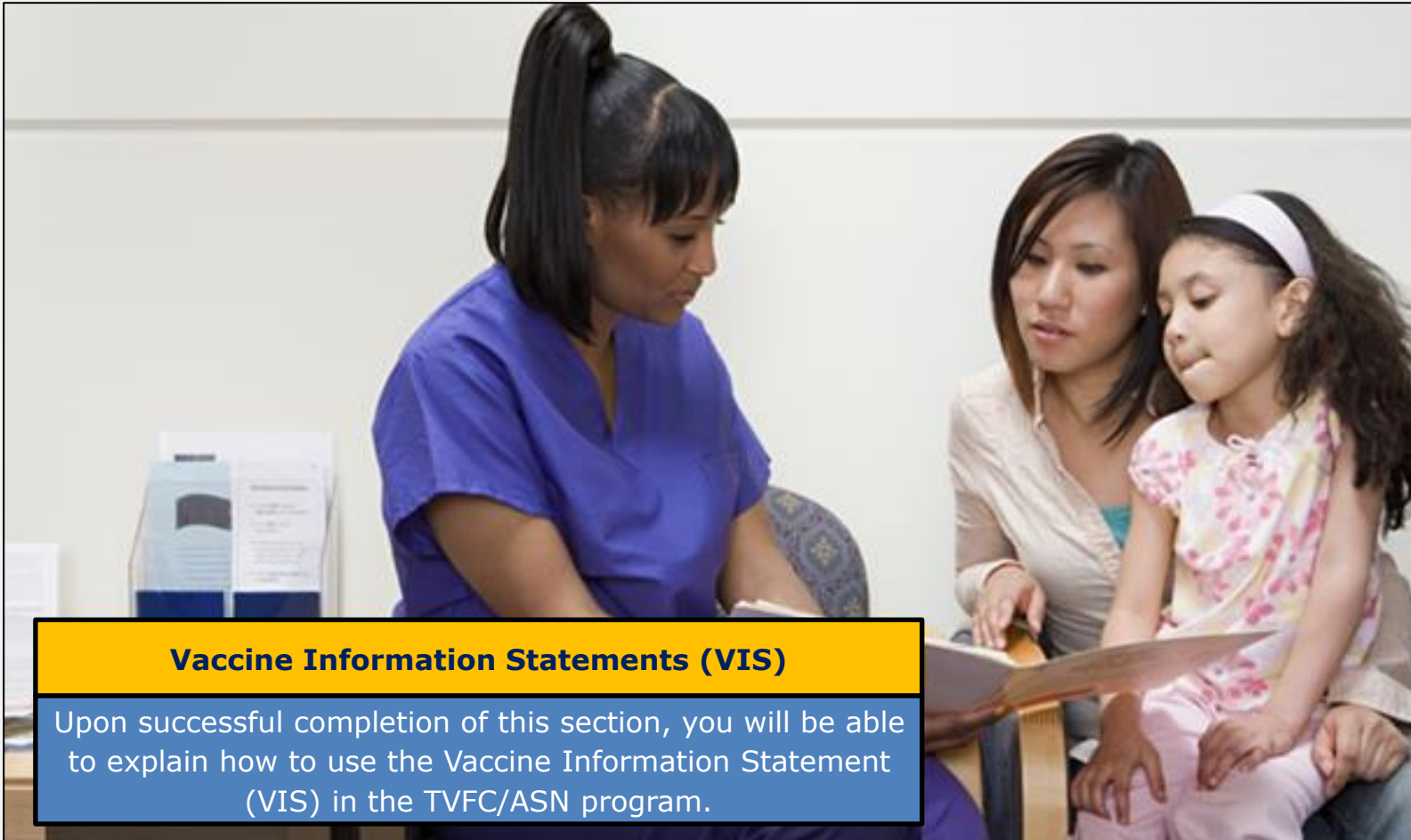
ASN Administration Fee

ASN sites may charge an administration fee for administering ASN vaccine to ASN-eligible adults. The maximum administration fee that may be charged is \$25.00 per dose. Services must not be denied due to the patient's inability to pay the administration fees. ASN sites that choose to bill a vaccine administration fee after the date of service must issue only a single bill to the patient within 90 days of the administration of the vaccine. ASN patients must not be sent to collections or charge penalties for the inability to pay administration fees.

Vaccine Information Statements (VIS)



Documentation and Record Keeping



Vaccine Information Statements (VIS)

Upon successful completion of this section, you will be able to explain how to use the Vaccine Information Statement (VIS) in the TVFC/ASN program.

Vaccine Information Statements (VIS)



[Vaccine Information Statements - VISs - CDC information sheets for patients](#)

All immunization providers (regardless of whether they are enrolled in the TVFC program) are required by the National Vaccine Childhood Injury Act ([NCVIA-42 U.S.C. § 300ss-26](#)) to provide a patient, parent, guardian, or other responsible adult a current Vaccine Information Statement (VIS).

The appropriate VIS must be given prior to vaccination and must be given prior to each dose of a multi-dose series.

The VIS informs the client and their parent, guardian, or other responsible adult about the benefits and risks of the vaccine the child/patient is receiving. Providers must ensure they are using the most current version of each VIS. A list of current VISs for vaccine can be found on the [Immunization Action Coalition \(IAC\) website](#).

Providing a VIS

Providers may provide the VIS as a **paper copy or in the following ways:**

- A permanent, laminated, office copy of each VIS, which must be read prior to vaccination.
- A computer monitor or video display where the VIS can be reviewed.
- As a downloadable document that can be accessed via a smartphone or other electronic device by the client, parent, guardian, or other responsible adult to a smartphone or other electronic device.

The parent/patient must still be offered a copy in one of the formats mentioned above to be read during the immunization visit, as a reminder.

Foreign Language VIS

Providers must take reasonable steps to provide information in the appropriate languages in order to ensure patients with limited English proficiency are effectively informed. All VIS are available in more than 20 languages and can be downloaded from the [IAC website](#).

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Quick Review

Question

Select all that apply.

Sites may provide the VIS in the following ways:

- A paper copy
- A permanent, laminated, office copy of each VIS, which may be read prior to vaccination
- Reviewed on a computer monitor or video display
- Downloaded by the client, parent, guardian, or other responsible adult to a smartphone or other electronic device

Quick Review

Answer

Select all that apply.

Sites may provide the VIS in the following ways:

- ✓ A paper copy
- ✓ A permanent, laminated, office copy of each VIS, which may be read prior to vaccination
- ✓ Reviewed on a computer monitor or video display
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Course Complete



Course Complete

Exit the course and complete the assessment to obtain credit. For additional information view the course resources.

Thank You!



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